



# The Effectiveness of Family-based Weight Loss Treatment Implemented in Primary Care: A Randomized Control Trial

## Study Protocol

Protocol Identifying Number: U01 HL131552  
Principal Investigator: Leonard H. Epstein, PhD  
IND/IDE Sponsor: National Heart, Lung and Blood  
Institutes (NHLBI)  
Funded by: NIH  
Draft or Version Number: v.0.

2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22

23	I. <b>Contents</b>	
24	II. 6	
25	III. 8	
26	IV. 9	
27	Background Information	9
28	Study Summary	9
29	Scientific Rationale	10
30	V. 10	
31	Description of Study Design	10
32	Outcome and Objectives	11
33	Study Organization and Roles and Responsibilities	11
34	1. 12	
35	2. 12	
36	3. 13	
37	4. 13	
38	5. 13	
39	6. 13	
40	Additional Committees	14
41	1. 14	
42	2. 14	
43	3. 14	
44	4. 14	
45	5. 14	
46	6. 15	
47	Study Timeline	15
48	II. 15	
49	Recruitment	16
50	1. 16	
51	Inclusion Criteria	16
52	Exclusion Criteria	17
53	2. 18	
54	Screening	20
55	Consenting Process	21
56	1. 22	
57	2. 22	

58	3.	23	
59		Randomization	23
60		Assessments	24
61		Participant Timeline	25
62	1.	25	
63	2.	26	
64	3.	26	
65	4.	26	
66	5.	26	
67	6.	26	
68	II.	28	
69		Usual Care (UC)	28
70		Family-based Behavioral Weight Loss Treatment (FBT)	28
71	1.	28	
72	2.	28	
73		Dietary Goals	28
74		Physical Activity Goals	28
75		Behavior Change Tools	29
76		Delay of Gratification	29
77		Social Facilitation Approaches	29
78		Educational Tools	29
79	3.	30	
80	4.	34	
81		Session Structure	34
82		Session Content	35
83	5.	35	
84	III.	36	
85		General Training in Study Procedures	35
86		PLAN Coach Training and Fidelity	36
87	1.	36	
88	2.	37	
89	3.	37	
90	4.	37	
91	5.	37	
92	6.	37	

93	7.	37	
94	8.	38	
95	Assessment Training and Fidelity		38
96	1.	39	
97	2.	39	
98	II.	39	
99	Practice Retention		39
100	1.	39	
101	2.	39	
102	Participant Retention		40
103	1.	40	
104	2.	40	
105	3.	40	
106	Intervention Participation		41
107	Assessment Participation		41
108	4.	41	
109	5.	41	
110	Risks to Human Subjects		42
111	1.	42	
112	2.	43	
113	3.	43	
114	Potential Benefits to Human Subjects and Others		44
115	II.	44	
116	Safety Oversight		44
117	1.	45	
118	Specification of Safety Parameters		47
119	1.	48	
120	2.	48	
121	3.	48	
122	Classification of Adverse Events		47
123	1.	48	
124	2.	48	
125	3.	48	
126	Adverse Event Assessment and Tracking		49
127	Adverse Event Reporting Procedures		50

128	Study Halting Rules for Participant Safety	52
129	II. 54	
130	REDCap	53
131	Testing the Data Management System	53
132	Data Security and Confidentiality	54
133	Forms and Datasets Manual	54
134	Archiving Data	54
135	Quality Control	54
136	1. 56	
137	2. 57	
138	3. 57	
139	4. 57	
140	5. 58	
141	III. 58	
142	Measures to Minimize Bias	67
143	1. 69	
144	2. 69	
145	3. 69	
146	Masking of Assessment Staff	68
147	Reducing Bias in Unmasked Groups	69
148	II. 71	
149	Study Website	69
150	Conflicts of Interest	70
151	Publications and Presentations Policy	70
152	Protocol Amendments	70
153	Protocol Deviations	70
154	III. 73	
155	IV. 77	
156	A. 77	
157	Addendum: Assessment Protocol in Response to Coronavirus Pandemic (COVID-19)	186
158	C. 190	
159	Assessment Measures	236
160	Remote assessments Protocol	239
161	FAMILY NUTRITION & PHYSICAL ACTIVITY (FNPA)	255
162	D. Additional Forms	300

163  
164

165  
166

## II. List of Abbreviations

AAP	American Academy of Pediatrics
AE	Adverse Event
ANCOVA	Analysis of Covariance
BMI	Body Mass Index
BOV	Percent over weight
CCC	Clinical Coordinating Center
CFR	Code of Federal Regulations
CITI	Collaborative Institutional Training Initiative
COI	Conflict of Interest
CME	Continuing Medical Education
CMP	Clinical Monitoring Plan
CRO	Clinical Research Office
CTSI	Clinical Translational Science Institute
DCC	Data Coordinating Center
DD	Delay Discounting
DSMB	Data Safety Monitoring Board
DSMP	Data Safety and Monitoring Plan
UC	Usual Care
EMR	Electronic Medical Records
FBT	Family-Based Treatment
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FRG	Food Reference Guide
FWA	Federalwide Assurances
GCP	Good Clinical Practice
GR-PBRN	Greater Rochester Practice Based Research Network
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
MOC	Maintenance of Certification
MOP	Manual of Procedures
NCH	Nationwide Children’s Hospital
NIH	National Institutes of Health
NPP	Non-participating parent
NHLBI	National Heart, Lung and Blood Institutes
OHRP	Office for Human Research Protections
PBRN	Practice Based Research Network
PC	Project Coordinator
PCN	Primary Care Network
PCP	Primary Care Provider
PLAN	Primary Care Pediatrics, Learning, Activity, Nutrition
PHI	Private Health Information
PI	Principal Investigator

REDCap	Research Electronic Data Capture
RGH	Rochester General Hospital
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SEC	Study Executive Committee
SMC	Safety Monitoring Committee
SMH	Strong Memorial Hospital
TFC	Training and Fidelity Core
UB	University at Buffalo
UBIRB	University at Buffalo Institutional Review Board
UP	Unanticipated Problem
URMC	University at Rochester Medical Center
US	United States
USPSTF	United States Preventive Services Task Force
WU	Washington University in St. Louis

167

168



169 **III. Statement of Compliance**

170

171 PLAN with Families will be conducted according to the study protocol developed to follow the Good  
172 Clinical Practice guidelines (GCP) set by the United States (US) Code of Federal Regulations (CFR)  
173 regarding clinical trials with the approval of the University at Buffalo Internal Review Board (UBIRB). All  
174 personnel responsible for conducting this trial will be trained through the Collaborative Institutional  
175 Training Initiative (CITI). The Principal Investigators agree that no deviation from, or changes to the  
176 protocol will take place without prior agreement from the sponsor and documented approval from the  
177 UBIRB, except where necessary to eliminate an immediate hazard(s) to the trial participants

178

179 We agree to ensure that all staff members involved in the conduct of this study are informed about their  
180 obligations in meeting the above requirements.

181

182

183

184 Principal Investigator: \_\_\_\_\_  
185 Print/Type Name

186

187 Signature: \_\_\_\_\_ Date: \_\_\_\_\_

188

189

190

191

192 Principal Investigator: \_\_\_\_\_  
193 Print/Type Name

194

195 Signature: \_\_\_\_\_ Date: \_\_\_\_\_

196

197 **IV. Introduction and Study Rationale**

198

199 **Background Information**

200 Childhood obesity is associated with a risk for the development of adult obesity, with children with  
201 obesity at all ages at increased risk of becoming adults with obesity.<sup>1,2</sup> In addition to the risk of  
202 becoming an adult with obesity, obesity during childhood is associated with cardio-metabolic  
203 changes including increases in blood pressure, cholesterol and triglyceride levels, and insulin  
204 resistance that initiate a trajectory of cardiovascular and metabolic disease as an adult.<sup>3</sup> Childhood  
205 obesity is also associated with psychological and behavioral changes that negatively impact the  
206 child's quality of life.<sup>4,5</sup> Obesity is a familial disorder. The most reliable risk factor for childhood  
207 obesity is parental obesity.<sup>2</sup> Beginning in infancy,<sup>6</sup> and extending through adolescence,<sup>2</sup> parents with  
208 obesity increase the risk of the child or adolescent experiencing obesity. Parents with obesity may  
209 also suffer from cardio-metabolic disease, initiating a cycle of both obesity and cardiovascular and  
210 metabolic disease that impacts both generations. Parental behaviors, such as modeling and support  
211 of child unhealthy behaviors, are associated with childhood obesity.<sup>7-10</sup> Given the relationship  
212 between child and parental obesity and that parents arrange family eating and exercise  
213 environments, model behaviors for their children, and reinforce healthy or unhealthy behavior  
214 patterns, it is logical that targeting both the parent and child can have a positive impact on  
215 childhood weight control.

216

217 Family-based childhood obesity treatment (FBT) was developed over 30 years ago and has proven  
218 effective in decreasing child and parent weight.<sup>11</sup> FBT targets changes in eating and physical activity  
219 through child and parent behavior change. One implication of FBT is that it may be more cost-  
220 effective than separate treatments of the child with obesity by his or her pediatrician and the parent  
221 with obesity by his or her primary care doctor. To test this, we randomized families to FBT or  
222 separate and simultaneous treatment for the parent and child with obesity. Results at 12 months  
223 showed FBT was associated with superior child and parent weight loss than separate treatment and  
224 was significantly more cost-effective per pound of weight loss.<sup>12</sup> Family-based weight loss programs  
225 also convey additional health benefits beyond weight loss, such as improvements in cardio-  
226 metabolic risk factors<sup>13</sup> and health related quality of life.<sup>14,15</sup>

227

228 **Study Summary**

229 Family-based treatment (FBT) is a behavioral weight control intervention that targets children with  
230 overweight/obesity and their parents,<sup>16-18</sup> and has the capacity to improve the weight status of non-  
231 targeted family members such as siblings.<sup>19</sup> FBT has significant positive effects on body weight in  
232 children for up to 10-years of follow-up,<sup>20,21</sup> and a robust relationship is observed between child and  
233 parent outcomes.<sup>22,23</sup> FBT's concurrent care of two generations of obesity in the family is more  
234 efficacious and cost-effective than if parents and children are treated separately.<sup>12</sup> Despite its  
235 recognized efficacy, FBT is mainly available in specialty clinics<sup>13,16,24</sup> and many children fail to receive  
236 this evidence-based level of treatment,<sup>25-28</sup> as recommended by the U.S. Preventive Services Task  
237 Force.<sup>25-28</sup> Primary care offers an optimal setting for delivery of FBT by capitalizing on the  
238 established relationship between primary care providers and families.<sup>29</sup> Using behavioral  
239 interventionists co-located within the primary care setting overcomes barriers posed by  
240 fragmentation of care, and lack of provider time and training. One of the challenges to integrating  
241 childhood obesity treatment into primary care is optimizing limited health care resources. In  
242 behavioral weight loss programs, some individuals learn diet, physical activity, and behavior change  
243 information quickly, while others learn more slowly. Individuals also differ in their ability to  
244 implement treatment recommendations due to individual differences, such as problems with

245 delaying gratification. FBT accommodates these individual differences by using a personalized  
246 system of instruction, or a mastery model, in which the content and dose of treatment is calibrated  
247 to the needs of the family, ensuring that treatment effort is consistent with need. This multi-site,  
248 clinical trial aims to evaluate over a two-year period the effectiveness of FBT delivered by a trained  
249 behavioral interventionist co-located within primary care compared to usual care alone (UC).  
250 Participants will be a representative sample of 528 families with a 6-12-year-old child with  
251 overweight/obesity and a participating parent with overweight/obesity. Weight changes in  
252 approximately 228 siblings with overweight/obesity and between 2-18 years of age will also be  
253 studied. Additionally, this study provides the opportunity to explore factors important to successful  
254 implementation of FBT in a primary care setting. Provider attitudes, such as those related to  
255 evidence-based practices in general<sup>30</sup> as well as their specific perceptions of FBT,<sup>31</sup> may predict their  
256 intended use of co-located FBT,<sup>31</sup> as intentions are reliable predictors for future behavior.<sup>32,33</sup>

## 257 **Scientific Rationale**

259 Obesity in youth has tripled in the last 30 years, a trend that is particularly disturbing because the  
260 majority of youth with obesity remain obese as adults. Because childhood obesity is associated with  
261 increased risk of adult cardiovascular diseases such as hypertension, hyperlipidemia, and type 2  
262 diabetes, improved access to evidence-based treatments is vital. Many organizations are responding  
263 to the demand for services by implementing programs for childhood obesity. However, obesity care  
264 is currently dominated by high-intensity behavioral treatment implemented in specialty clinics or by  
265 less effective, low-intensity treatments implemented in primary care. Effective family-based  
266 treatment delivered within primary care, matching national recommendations, has never been  
267 evaluated in a randomized, controlled trial. If we can demonstrate effectiveness in this setting, we  
268 will be establishing for the first time that childhood obesity can be addressed by trained behavioral  
269 interventionists in a setting that provides routine access to large numbers of children with obesity  
270 without requiring the intense environment of a specialty clinic. Moreover, by studying  
271 approximately 228 siblings with obesity in our initial secondary aim, we are asking a seminal  
272 question about whether the “family” component of FBT translates into benefits for family members  
273 not directly participating in the program. Affirmative evidence regarding this question will suggest  
274 multiple avenues of future research that have the potential to reorder our thinking about how best  
275 to implement cost-effective family-based obesity programs. The proposed study continues our  
276 efforts to translate FBT for widespread implementation and dissemination for treatment of children  
277 with overweight or obesity and families into primary care settings. It aims to shift current research  
278 and clinical practice paradigms by demonstrating the effectiveness of delivering FBT within primary  
279 care using a behavioral health provider who is co-located in a primary care setting.

## 280 **V. Study Design**

### 281 **Description of Study Design**

282 *The study is an individually randomized group treatment (IRGT)<sup>34</sup> trial such that the individual, in this*  
283 *case the family, is the unit of randomization. It differs from a classic individually randomized trial in that*  
284 *the intervention is either a group intervention or conducted by an agent responsible for implementing*  
285 *the intervention in a defined set of individuals. The PLAN study will evaluate the effectiveness of family*  
286 *based treatment (FBT) delivered by a coach versus usual care (UC) treatment delivered by primary care*  
287 *providers. Both FBT and UC will be delivered in pediatric offices. In PLAN, participants are randomized at*  
288 *the family level and only one eligible child (the index child) is included in the primary outcome analysis.*  
289 *The trial will enroll up to 1284 subjects from 528 randomized families at four sites, each having at least*  
290 *one overweight/obese participating child age 6-12 and at least one participating parent. Since the study*

293 *has four sites with three coaches per site, the analysis plan involves a nesting of the coach within the site.*  
294 *Some sites have backup and floating coaches that are involved in delivering FBT to study participants,*  
295 *which will also be accounted for when outcome data is analyzed (**This change was made on 12.4.18***  
296 ***prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.18.19**). While this*  
297 *nesting suggests a classic cluster randomized trial, an IRGT trial is different because the nesting applies*  
298 *only to the intervention group. Since the UC group has no nesting factor in this IRGT trial, a proper*  
299 *analysis must reflect the fact that the FBT group and the UC group must use different covariance*  
300 *structures. In addition to one participating child and parent from each family, the sample will also*  
301 *include up to 228 overweight/obese siblings and non-participating parents who will not be direct*  
302 *recipients of the intervention. There will be two years of follow-up with comprehensive assessments at*  
303 *baseline, 6, 12, 18 and 24 months. The primary outcome is percent over BMI at 24 months in the child.*  
304 *Our primary hypothesis is that the FBT intervention will be superior to UC alone in the participating child*  
305 ***(DSMB approved protocol addenda, 11.2.18).***

306

### 307 **Outcome and Objectives**

308 *This study will test between-group differences in child (**Primary Specific Aim 1**) weight change, as well as*  
309 *weight change in parents (**Secondary Aim 1**), siblings with overweight/obesity (**Secondary Aim 2**),*  
310 *changes in parent and child delay of gratification and how changes in delay of gratification are related to*  
311 *parent and child weight changes (**Secondary Aim 3**), participant level predictors of treatment success*  
312 *(**Secondary Aim 4**), and how provider attitudes toward evidence-based treatment and perceptions of FBT*  
313 *may relate to their intention to use co-located FBT in their practices in the future (**Exploratory Aim 1**).*  
314 *Establishing that FBT can be effectively implemented within real world settings is crucial to creating a*  
315 *system by which children and their families who suffer from obesity can be treated in a centralized*  
316 *primary care setting (**DSMB approved protocol addenda, 11.2.18**). To investigate the discussions*  
317 *between PLAN FBT coaches and their PLAN FBT families regarding perception of food cost and food*  
318 *choices PRE and POST COVID. (**Exploratory Aim 2**) (**DSMB requested protocol addenda, 9.22.20**).*

319

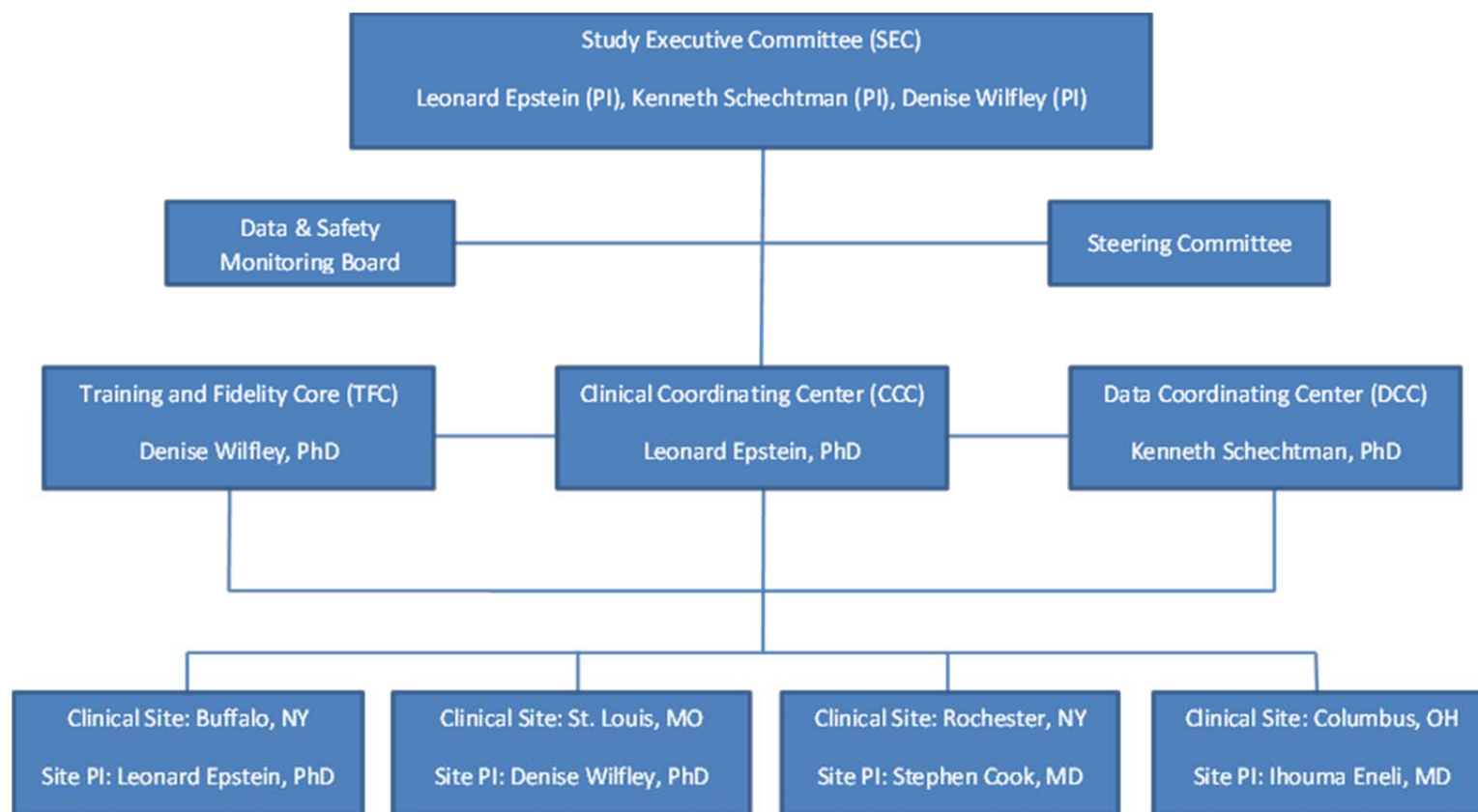
320

### 321 **Study Organization and Roles and Responsibilities**

322 *This project continues long-standing collaborations between study PIs: Drs. Epstein, Wilfley, and*  
323 *Schechtman, and an enhanced partnership from prior professional associations with Drs. Cook and*  
324 *Eneli. The organizational structure includes a Clinical Coordinating Center, a Data Coordinating*  
325 *Center, and four clinical sites (see **Figure 1** below).*

326

327 **FIGURE 1. Study Organization Chart**



328

329

**1. Study Executive Committee (SEC)**

330

Members of the SEC will include Drs. Epstein, Schechtman, and Wilfley. The three PIs will alternate responsibility for the development of SEC meeting agendas and will co-lead regular meetings throughout the study. The SEC will be responsible for decision-making related to the overall scientific conduct of the study and monitoring the overall progress of the study to ensure timely study completion. In addition, the SEC will be responsible for final approval of the study protocol and for any changes to the developed protocol, all of which will be documented in writing as part of the SEC minutes. Throughout the study, the PIs will communicate weekly by teleconference to make decisions on the scientific direction of the grant (e.g., data collection, data analysis) and guidance regarding study procedures. Daily decisions about the project will be made by email and phone as needed.

339

340

**2. Steering Committee**

341

The PIs and Co-Is will form a Steering Committee (Drs. Epstein, Wilfley, Schechtman, Cook, Eneli, and Quattrin) that will manage the oversight and coordination of project management, research administration, publications and data sharing, and integration of all resources needed for the project. The University at Buffalo will subdivide the award funds and each PI will be responsible for their own budget. The Steering Committee will oversee decisions on minor changes in research direction and have the authority to reallocate funds and resources among PIs. Dr. Epstein will be first to serve as Chair of the Steering Committee and be responsible for communication among PIs and Co-Is, including meeting schedules and agendas. The position of Chair will rotate among the PIs on a yearly basis. Dr. Epstein will be designated the contact PI

349

350

351 and be responsible for submitting all necessary documents to NIH, including IRB approvals and  
352 annual progress reports. The Steering Committee will meet as needed and at least on a  
353 quarterly basis by phone to discuss study-related decisions and to evaluate the overall scientific  
354 conduct of the study.

355  
356 **3. Clinical Coordinating Center (CCC)**

357 Located within the University at Buffalo and directed by Dr. Epstein, PI, with Dr. Teresa Quattrin,  
358 Co-I, the CCC will be responsible for study oversight, including developing the treatment and  
359 assessment protocol, study website development, and coordination and monitoring of study  
360 procedures and progress across sites. Dr. Quattrin is experienced in overweight assessment and  
361 treatment in the primary care setting and will provide general medical guidance to the study as  
362 well as oversee the evaluation and adjudication of adverse event reports.

363  
364 **4. Training and Fidelity Core (TFC)**

365 The TFC will be housed at Washington University in St. Louis. Dr. Wilfley will serve as PI for the  
366 TFC. Dr. Wilfley will provide leadership to the TFC and will be responsible for the content and  
367 integrity of behavioral interventionist training activities and implementation of the intervention  
368 across all clinical sites. The TFC will conduct the trainings and will supervise the interventionists  
369 to ensure adherence to the treatment protocol during the training and active treatment phases  
370 of the study.

371  
372 **5. Data Coordinating Center (DCC)**

373 The DCC will also be housed at Washington University in St. Louis under the direction of Dr.  
374 Schechtman as PI. The DCC will provide scientific, organizational, statistical, quality control, and  
375 operational leadership in support of the present study. Dr. Schechtman has directed many NIH-  
376 funded DCCs and has served as head of the DCC for a weight loss maintenance study for which  
377 Dr. Wilfley was PI and Dr. Epstein was Co-I.

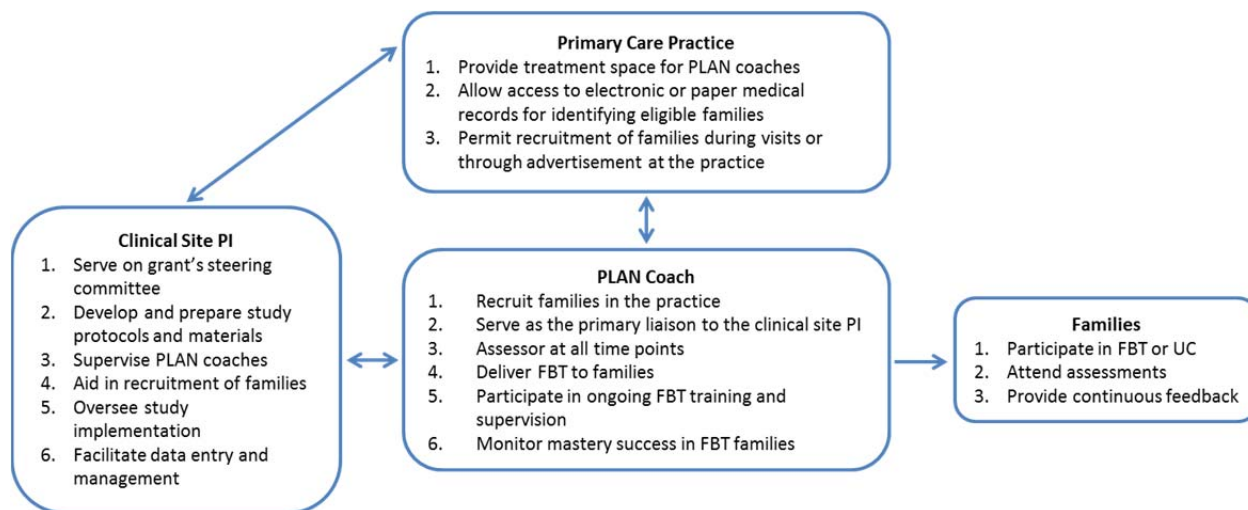
378  
379 **6. Clinical Sites**

380 Dr. Wilfley will serve as PI for the St. Louis, Missouri clinical site. Dr. Epstein, will serve as the PI  
381 for the Buffalo, New York clinical site with Dr. Teresa Quattrin serving as Co-I. Dr. Quattrin is  
382 experienced in overweight assessment and treatment in the primary care setting and will  
383 provide general medical guidance to the study team. She will also evaluate adverse event  
384 reports to determine appropriate disposition. Two additional clinical sites in Rochester, New  
385 York and Columbus, Ohio will be directed by Drs. Stephen Cook and Ihuoma Eneli, respectively.  
386 Drs. Cook and Eneli will serve as PIs for their clinical sites and will be primarily responsible for  
387 recruitment of practices and oversight of study-related processes within these practices (see  
388 **Figure 2** below).

393  
394  
395  
396  
397  
398  
399

**Additional  
Committees**

**FIGURE 2. Clinical Site Organization**



400  
401  
402  
403  
404  
405  
406  
407  
408  
409  
410  
411  
412  
413  
414  
415  
416  
417  
418  
419  
420  
421  
422  
423  
424  
425  
426  
427  
428  
429  
430  
431

**1. Safety Monitoring Committee**

The Safety and Monitoring Committee (SMC), chaired by Dr. Teresa Quattrin, will oversee the assessment and reporting of adverse events (AE), serious adverse events (SAE), and unanticipated problems (UP). The SMC will be responsible for evaluating adverse event reports from the DCC and determining appropriate disposition. Additional members include: Drs. Ihuoma Eneli and Rebecca Campo.

**2. Interventionist Committee**

The Interventionist Committee, co-chaired by Dr. Leonard Epstein and Colleen Kilanowski, will meet on a monthly basis to discuss participant progress in the intervention and to trouble-shoot areas of concern (e.g., non-compliance to treatment). Each clinical site will be represented by a lead interventionist who will summarize site progress with the project coordinators and chairs of the Interventionist Committee. Additional members include: Dr. Rebecca Campo, Gracie Matychak, Megan Dahlman, Andrea Goard, and Sarah Kruger.

**3. Recruitment and Retention Committee**

The Recruitment and Retention Committee, chaired by Dr. Ihuoma Eneli, will oversee accrual milestones related to the recruitment and retention of families in the study. The Committee will monitor and communicate recruitment and retention strategies across sites and will make site-specific recommendations based on recruitment reports from the DCC. Additional members include: Drs. Charlotte Pratt and R. Robert Welch.

**4. Quality Control and Measurement Committee**

The Quality Control Committee, chaired by Dr. Denise Wilfley, will oversee the accuracy and completeness of computerized data, the common administration of protocols across sites, adherence to protocol requirements, and training and certification of study staff in assessment procedures and data collection. Additional members include: Nasreen Moursi, and Peter Dore.

**5. Ancillary Study Committee**

The Ancillary Study Committee, chaired by Dr. Stephen Cook, will oversee the submission process for ancillary study proposals and will evaluate the feasibility of these proposals in regard to their cost, impact on IRB protocols, and burden to participants. The Committee will meet

432 monthly to review proposals and will provide recommendations to the Steering Committee.  
 433 Additional members include: Drs. Charlotte Pratt and Rebecca Campo.

434  
 435 **6. Publication and Presentations Committee**

436 The Publication and Presentation Committee, chaired by Dr. Kenneth Schechtman, will be  
 437 responsible for defining publication policies, prioritizing if multiple papers and abstracts challenge  
 438 resources, and encouraging the involvement of junior investigators in the dissemination of study  
 439 results. This Committee will oversee the creation of a publications and presentations database that  
 440 will facilitate the tracking of completed publications and the notification of abstract due dates and  
 441 pending timelines for preparing material for publications and presentations. Additional members  
 442 include: Doctors Leonard Epstein, Denise Wilfley, Stephen Cook, Ihuoma Eneli, and Nancy Geller. All  
 443 proposed publications will be disseminated to the Publication and Presentation Committee, and  
 444 forwarded to Colleen Kilanowski and Alexandria Phipps for proper filing of documents.  
 445

446 **Study Timeline**

447 The first 12 months of the study will be devoted to study organization and training of staff in their  
 448 research and clinical functions (see **Table 1**). Website development will occur in order to facilitate  
 449 training and initiate recruitment and study implementation. Behavioral interventionists called PLAN  
 450 coaches and study support staff will be hired and fully trained in their roles. PLAN coaches will  
 451 attend a live training at WU led by the TFC and will also utilize online and printed materials.  
 452 Recruitment of study participants utilizing the research match design will also begin, as it entails  
 453 passive collection of information from families interested in participating in studies aimed at weight  
 454 loss. Active recruitment will begin in month 16 and will continue through month 30. It is expected  
 455 that all 528 families across all of the practices will be enrolled during this time period. Treatment  
 456 initiation will also begin in month 17, as recruitment allows, and will continue through month 54.  
 457 This will allow all participants recruited by month 31 to finish two years of treatment and final  
 458 assessments. Months 55-60 will be used for study closeout and data analysis.  
 459

460 **TABLE 1. Study Timeline**

Study Activity	Study Months									
	Year 1		Year 2		Year 3		Year 4		Year 5	
	1-6	7-12	13-18	19-24	25-30	31-36	37-42	43-48	49-54	55-60
<b>Planning &amp; Data Base Development</b>	X									
<b>Web Development</b>	X	X								
<b>Interventionist Hiring &amp; Training</b>	X	X								
<b>Piloting &amp; Participant Recruitment</b>			X	X	X					
<b>Treatment Delivery</b>			X	X	X	X	X	X	X	
<b>Data Monitoring Reports</b>				X	X	X	X	X	X	X
<b>Data Analysis</b>									X	X
<b>Study Closeout</b>										X

461  
 462 **II. Study Procedures and Schedule**

463 Study procedures will be carried out within primary care practices. The general roles and responsibilities  
 464 of: 1) the PIs at the four clinical sites; 2) the administrators and providers at participating practices; 3)  
 465 the PLAN coaches; and 4) the families randomized to the two conditions are summarized in the sections  
 466 that follow. An overview of study flow is provided in following sections as well as in **Figure 1** in **Appendix**  
 467 **D**.



468  
469 **Recruitment**

471 **1. Participants**

472 Families will be recruited from pediatric practices in our Practice-based Research Networks  
473 (PBRNs) in several ways. Each practice will have children who meet age, height, and weight  
474 criteria flagged in their charts, and we will use multiple approaches to recruit families. First, we  
475 will establish a ResearchMatch approach to recruiting in each PBRN. ResearchMatch, an online  
476 recruitment tool, will accrue families in one of two ways. At intake for a well- or sick-child visit,  
477 forms designed to acquaint families with the study will be introduced by PLAN coaches, and  
478 families can sign up for additional information about this study. Their information will be  
479 entered into a database by the PLAN coaches, and they will be contacted if they meet criteria. In  
480 addition, we will set up a website that they will be directed to in a flyer, and they can sign up to  
481 participate from the website. Since the pediatrician generally will not have information on  
482 parental health, this will need to be collected prior to deciding study eligibility, and the family  
483 database will assist in this endeavor by including information about all family members after a  
484 phone screen is conducted by the PLAN coaches with the participating parent. Second, PBRN  
485 practices post study advertisement at offices for interested families to visit the study website to  
486 complete questionnaires to ensure they meet eligibility criteria. If the families meet eligibility  
487 criteria, a PLAN coach will follow up with the families to schedule their first appointment at their  
488 earliest convenience. At this appointment, the PLAN coach will confirm the families’ interest to  
489 participate and eligibility prior to participation. Third, Plan coaches will meet with families  
490 during well-child visits to introduce the study, assess their interest, and explain next steps. Each  
491 of these methods in collecting their information regarding interest and eligibility will be  
492 preceded by getting their verbal consent over the phone or a check box indicated on the web  
493 pages.

494  
495 During recruitment, PLAN coaches will explain that there is a 50/50 possibility of getting one  
496 treatment over the other treatment. This will be like a flip of the coin and no one can just pick  
497 one treatment or the other. This study is testing if the FBT is as good as the care provided by  
498 their doctors normally given or better. Randomization will occur after the first appointment.  
499

501 **Inclusion Criteria**

502 The PLAN study inclusion criteria and methods for assessing these criteria are summarized in  
503 **Table 2**. The screening surveys and measures may be found in **Appendix B**.

504  
505 **TABLE 2. PARTICIPANT INCLUSION CRITERIA**

Participant	Inclusion Criteria	Measurement
Targeted Child	Between the ages of 6 and 12 years <sup>1</sup>	Initial Eligibility Survey <sup>2</sup>
	BMI above the 85 <sup>th</sup> percentile for age and sex	Initial Eligibility Survey <sup>3</sup>
	At least one parent with overweight or obesity (BMI>25) who is willing to participate	Initial Eligibility Survey
	Able to speak and comprehend English at a first grade level	Eligibility Phone Screen ( <i>This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved</i> )

		<i>protocol addenda on 11.2.18)</i>
	Resides with targeted parent at least 50% of the time <sup>4</sup>	Eligibility Phone Screen
	Supplemental evaluation of eligibility as needed	PCP Medical Clearance Form
<b>Targeted Parent</b>	<i>(DSMB approved protocol addenda, 11.2.18)</i>	<del>Initial Eligibility Survey</del> <sup>5</sup> <i>(DSMB approved protocol addenda, 11.2.18)</i>
	Agrees to attend all treatment meetings	Eligibility Phone Screen
	Able to speak and comprehend English at a first grade level	Eligibility Phone Screen, <del>WRAT</del> <i>(This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18)</i>
	Must be targeted child's biological or adoptive parent or legal guardian	Eligibility Phone Screen
	Supplemental evaluation of eligibility as needed	PCP Medical Clearance Form
<b>Sibling (if applicable)</b>	Between the ages of 2 and 18 years <sup>6</sup>	Eligibility Phone Screen <sup>2</sup>
	BMI above the 85 <sup>th</sup> percentile for age and sex	Eligibility Phone Screen <sup>3</sup>
	Must reside with targeted child and parent	Eligibility Phone Screen

506 *(This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol*  
507 *addenda on 11.2.18)* <sup>1</sup>If family has two children between the ages of 6 and 12 years, it will be encouraged that  
508 the older sibling be the primary participant, as it is more likely the older sibling will serve as a role-model for the  
509 younger sibling; <sup>2</sup>Calculate age using screen date and birth date; <sup>3</sup>BMI Percentile Calculator:  
510 <https://nccd.cdc.gov/dnpabmi/calculator.aspx>; <sup>4</sup>If 50/50 split, it will be encouraged that non-targeted parent sign  
511 an agreement to be supportive of study goals and to allow contact from study team; <sup>5</sup>BMI:  
512 [https://www.cdc.gov/healthyweight/assessing/bmi/adult\\_bmi/english\\_bmi\\_calculator/bmi\\_calculator.html](https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi_calculator.html); <sup>6</sup>In  
513 families where more than one eligible sibling is available, we will enroll the sibling whose age is closest to that of  
514 the study child.

### 516 Exclusion Criteria

517 The PLAN study exclusion criteria and methods for assessing these criteria are summarized  
518 in **Table 3**. The screening surveys and measures, including a table of exclusionary  
519 medications, may be found in **Appendix B**.

521 **TABLE 3. PARTICIPANT EXCLUSION CRITERIA**

Participant	Exclusion Criteria	Measurement
<b>Targeted Child and/or Parent</b>	Concussion in the last 3 months <sup>1</sup>	Initial Eligibility Survey
	Planning to move away from the area within the next 2 years	Initial Eligibility Survey
	Pregnant or is planning on becoming pregnant during the two-year study period	Eligibility Phone Screen
	Participation to any degree in weight-management/weight-loss program <sup>2</sup>	Eligibility Phone Screen

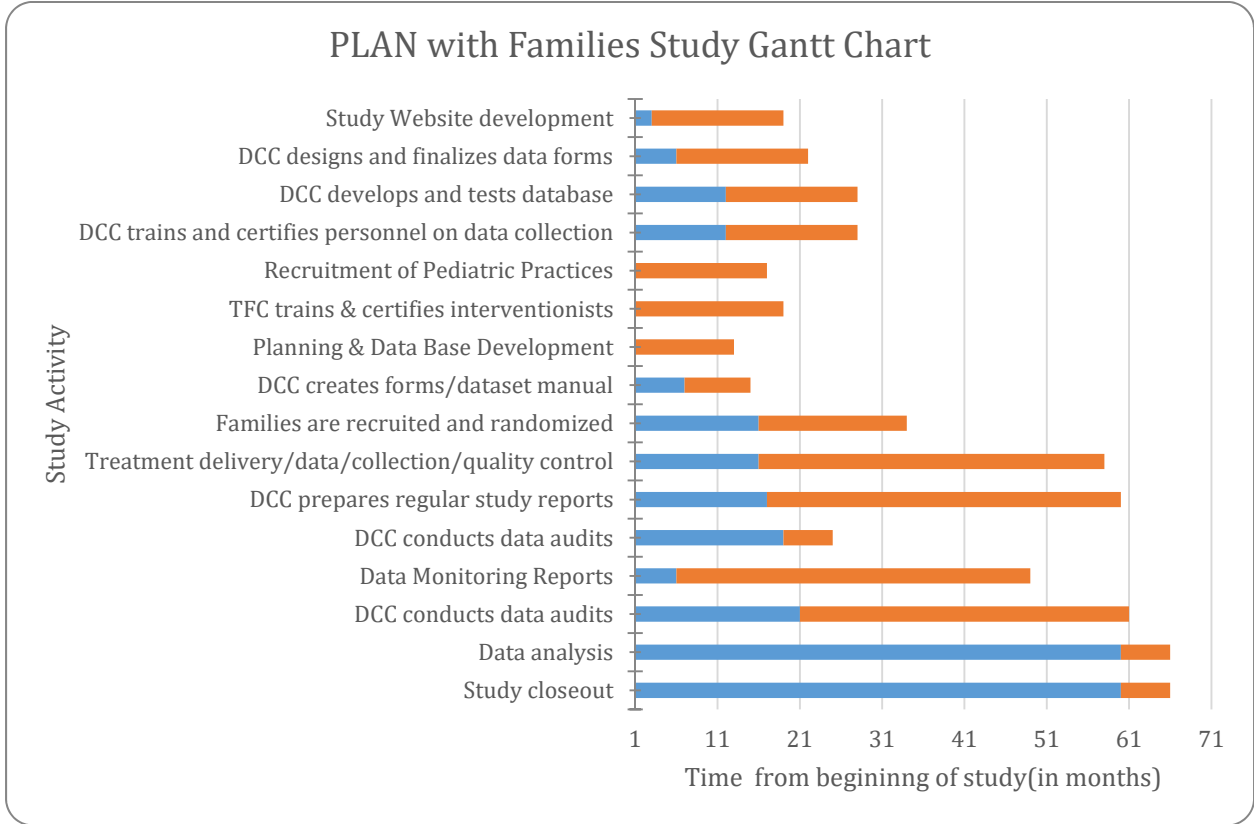
Weight-related surgeries (e.g., gastric bypass) <i>within the last two years. (DSMB approved protocol addenda, 11.2.18)</i>	Eligibility Phone Screen
Weight-affecting medications known to cause weight gain or loss if at current dose for < 6 months	Eligibility Phone Screen
Medications affecting growth (e.g., systemic corticosteroids 2+ weeks in the past year, insulin, oral hypoglycemics, thyroid hormone, growth hormone)	Eligibility Phone Screen
Medical condition altering nutritional status or intestinal absorption (e.g., inflammatory bowel disease, diabetes and taking insulin)	Eligibility Phone Screen
Medical condition that affects growth (i.e., genetic or metabolic disease/syndrome associated with obesity)	Eligibility Phone Screen
Chronic medical conditions, including: Type 1 diabetes, heart disease or heart failure, HIV or AIDS, muscular dystrophy, renal diseases, hypothyroidism (if untreated or if treated with medication for <6 months)	Eligibility Phone Screen
Severe restriction of diet that would inhibit family from reasonably following the Traffic Light Eating Plan	Eligibility Phone Screen
Significant developmental delays, intellectual disabilities, or Autism Spectrum Disorder	Eligibility Phone Screen
Unmanaged/active psychiatric conditions (e.g., binge eating disorder or schizophrenia) meeting full DSM-5 criteria or impairing clinical symptoms (e.g., suicidality)	Child: PSC, QEWP-5 (Child Self-Report & Parent Report of Child), KSADS if warranted Parent: PHQ, SCID if warranted
Disability that prevents performance of physical activity at the level of a brisk walk	PCP Medical Clearance Form

522 PSC=Pediatric Symptom Checklist; QEWP-5=Questionnaire on Eating and Weight Patterns; KSADS=Kiddie Schedule  
523 for Affective Disorders and Schizophrenia; PHQ=Patient Health Questionnaire; SCID=Structured Clinical Interview  
524 for DSM Disorders; <sup>1</sup>Eligible once 3 months since concussion passes; <sup>2</sup>Eligible if willing to stop program.  
525

## 526 2. Primary Care Pediatric Practices

527 Practice recruitment will begin during the planning stage of the study (see Table 4. PLAN with families  
528 Study Gantt Chart). Each clinical site is responsible for recruiting appropriate numbers of practices to  
529 ensure participant recruitment goals can be met. Given differing practice and caseload sizes across sites,  
530 the number of practices recruited may vary across each site. As a minimum benchmark, by July 1 2017,  
531 all sites must have identified sufficient pediatric practices to give them access to a minimum of 3303  
532 children with overweight or obesity, or a minimum of 9714 total children study-wide (assuming a 34%  
533 prevalence rate of overweight/obesity). This number was identified assuming 57.1% of children with  
534 overweight/obesity will have a parent with overweight/obesity based upon 1286 families with an age-  
535 eligible overweight/obese child in a screening database maintained by Dr. Epstein in Buffalo, in which  
536 734 (57.1%) had at least one obese parent. It is estimated that 10% of these families will express  
537 willingness to participate in the study. This estimate is based on previous experience of the former study  
538 Co-I Dr. Jane Garbutt as she ran a recent trial assessing an asthma intervention for families recruited  
539 from a primary care setting. Dr. Garbutt's study was low intensity and she described a 20% uptake rate.  
540 Given the intensity of our intervention, a more conservative 10% is estimated. Additionally, after

541 agreeing to be screened, it is estimated that only 70% of willing families will meet eligibility criteria  
 542 and/or will decide they are interested in participating. This estimate is based on the recent COMPASS  
 543 trial conducted by Dr. Wilfley, which found that approximately 66% of families that attended a study  
 544 orientation meeting entered the study. It is believed our rate will be slightly higher, as participation in  
 545 the study will begin soon after study orientation, whereas families in the COMPASS trial generally did  
 546 not initiate treatment right away due to the cohort nature of the study.



547  
 548 *Gantt Chart Updated, (DSMB approved protocol addenda, 11.2.18).*

549  
 550 Additionally, given the recruitment goal for minority families, all sites must have access to a minimum of  
 551 826 (30%) minority children with overweight or obesity, or 2,429 total minority children must be  
 552 available study-wide. (Table 5. DCVS Accrual Milestones below).

553  
 554  
 555  
 556

## DCVS Accrual Milestones: QUARTERLY Reporting

PI: DR. LEONARD EPSTEIN

Grant # / Project: HL131552-01

Title: Effectiveness of Family-based Weight Loss Treatment Implemented in Primary Care

Program Director: Charlotte Pratt

**Total Target Pop.: 528**  
**Target Minorities. %: 29.2%**  
**Target Women %: 50.2%**

Start Date Recruitment: November 1, 2017

End Date Recruitment: May 31, 2019

End Date Grant: \* May 31, 2021

Calendar Year	1 <sup>st</sup> Quarter Jan - Mar	2 <sup>nd</sup> Quarter Apr - June	3 <sup>rd</sup> Quarter July - Sep	4 <sup>th</sup> Quarter Oct - Dec	Total
2016	0	0	0	0	0
2017	0	0	0	56	56
2018	84	84	84	84	336
2019	82	54	0	0	136
2020	0	0	0	0	0
2021	0	0	0	0	0
2022	0	0	0	0	0
<b>Total</b>	<b>166</b>	<b>138</b>	<b>84</b>	<b>140</b>	<b>528</b>

\* Number yrs of funding: 5

Signature of Authorized Representative:

Date Signed

557  
 558 *MAP Updated, (DSMB approved protocol addenda, 11.2.18).*  
 559

560 **Screening**

561 At the initiation of the screening process, the participating parent will complete the Initial Eligibility  
 562 Survey in person, over the phone, or online via REDCap (Research Electronic Data Capture) with the  
 563 assistance of the PLAN coach or Research Support Specialist. The survey will gather preliminary  
 564 eligibility criteria including height, weight, and age. If eligible based on this survey, a PLAN coach will  
 565 contact the parent to discuss the study in further detail and to answer any questions the parent may  
 566 have. The PLAN coach will obtain the parent's verbal consent to continue with the screening process  
 567 and will then complete the Eligibility Phone Screen, which gathers additional information on medical  
 568 and psychiatric history for both parent and child. For families found to meet eligibility criteria on  
 569 both the Initial Eligibility Survey and the Eligibility Phone Screen, an orientation appointment will be  
 570 scheduled following the Phone Screen, to complete the process of determining eligibility to  
 571 participate in the study.  
 572

573 Prior to the orientation appointment, the parent and child will complete survey questionnaires via  
574 REDCap, including the Patient Health Questionnaire (PHQ), Pediatric Symptom Checklist (PSC), and  
575 Questionnaire on Eating and Weight Patterns Parent Report of Child (QEWP-5). These  
576 questionnaires assess for symptoms of eating disorders and other psychiatric disorders (e.g.,  
577 depression, anxiety, and substance abuse). If the respondent's scores are above clinical cut-offs on  
578 these questionnaires, they will be flagged in REDCap and a PLAN coach will follow-up with the  
579 parent over the phone prior to the orientation appointment to further assess for the presence of  
580 eating disorders or other psychopathology by administering the relevant modules of the Structured  
581 Clinical Interview for DSM Disorders (SCID) and Kiddie Schedule for Affective Disorders and  
582 Schizophrenia (KSADS). A score of "Yes, present" for any of the psychiatric conditions assessed by  
583 these semi-structured clinical interviews will prompt the PLAN coach to inquire about any current or  
584 past treatment to gauge impairment level. This information will be entered into the Eligibility  
585 Tracking Form.

587 Each week, the clinical site PI, with guidance from the doctoral-level psychologists on the study  
588 team as needed, will review participants flagged in this way and will make all final decisions  
589 regarding eligibility. If the parent or child only exhibits subthreshold symptoms of a disorder, the  
590 family will be eligible to participate assuming there are no impairing symptoms present (e.g.,  
591 suicidality). If the parent or child meets full DSM-5 criteria for any psychiatric disorder, the family is  
592 ineligible to participate, and the PLAN coach will provide a referral for treatment to the family. Once  
593 the parent or child has been symptom-free for six months, the family is eligible to re-screen for  
594 enrollment into the study. The Eligibility Tracking Form (see **Appendix B**) will be completed to  
595 document the process by which each participant's eligibility or ineligibility is determined  
596

597 *(This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved*  
598 *protocol addenda on 11.2.18).* The pediatrician or parent's physician will be contacted if information  
599 about the family meeting inclusion or exclusion criteria is needed. Families will be asked to provide a  
600 standard form requesting information about the patient's current specified medical condition, and  
601 to forward or have the PCP send the form to site clinical PI.

### 603 **Consenting Process**

604  
605 All participants will meet with a trained study staff member and will be consented following the Manual  
606 of Procedures of the University at Buffalo Institutional Review Board (UBIRB), the IRB of Record for the  
607 study. Coaches will file the paper consent forms in the following order:

- 608 1. *Child Assent*
- 609 2. *Parental Permission for Child*
- 610 3. *Parent Consent*
- 611 4. *Sibling Assent 7-13*
- 612 5. *Sibling Assent 14-17*
- 613 6. *Adult Sibling Consent*
- 614 7. *Parental Permission for Sibling*
- 615 8. *Non-Participating Parent Consent*
- 616 9. *Targeted Child – 7-13 Re-assent*
- 617 10. *Targeted Child – 14-17 Re-assent*
- 618 11. *Sibling – 7-13 Re-assent*
- 619 12. *Sibling – 14-17 Re-assent*
- 620 13. *Sibling – Adult – Re-consent*

621 14. *Coronavirus Addendum*

- 622
- 623 a. Example consent/assent templates for all study participants are included in **Appendix A**.
- 624

625 **1. Family Consent**

626 Families who are eligible for the study will meet with a trained study staff member and will be  
627 given written and verbal information about the study. Full disclosure of the purpose of the  
628 study, the benefits and risks to individuals who participate, and the confidential nature of  
629 information obtained during the study will be explained to participants. Families will be aware  
630 from the outset that they will be randomly assigned to an active treatment condition (FBT) or a  
631 usual care control condition (UC) following baseline assessment completion. They will also be  
632 aware that their expected participation will be 2 years and may require anywhere from 26 to 96  
633 sessions of FBT. Families will be informed of alternative lifestyle change resources available to  
634 them, such as physical activity programs or sports teams for youth at the YMCA or other  
635 organizations, other commercially available child fitness or weight loss programs, or pediatric  
636 dietitians or fitness trainers, and if so desired, referrals will be made. Potential participants will  
637 also be informed that they may drop out at any time during the study and that their withdrawal  
638 from the study will in no way impact their ability to receive medical care through their primary  
639 care practice. The staff member will answer any questions the family has about the study, and  
640 then participants will be consented according to the policies and procedures of the UBIRB

641

642 Each capable parent 18-years or older will sign the consent form for himself/herself and will also  
643 sign the parent permission form, which provides consent for his/her child age 6-12 to  
644 participate. In addition, the parent will sign a separate permission form that provides consent  
645 for participating siblings (i.e., a sibling who is overweight/obese) age 2-17 to participate. Older  
646 siblings will sign assent forms, which will be written and explained at a reading level appropriate  
647 for the child population. Non-participating parents and siblings who are 18 years of age will sign  
648 their own consent form. A copy of the signed consent, permission, and assent forms and study  
649 staff contact information will be given to the potential participants, and all original forms will be  
650 kept in the participant's confidential research record. Participants will also be asked to give  
651 written consent for the PLAN coach to audio record their treatment sessions so the study team  
652 can assess adherence to the treatment protocol; however, participants will not be excluded  
653 from the study if they refuse audio recording. In our experience, less than 1% of participants  
654 refuse audio recording.

655

656 Since the children involved directly (as targeted children) and indirectly (as siblings) will mature  
657 throughout the course of their time in the PLAN program, a PLAN Coach or Measurement Coach  
658 will re-assent and re-consent impacted children using assent and consent forms that explain  
659 their participation using age appropriate language. The re-assenting and consenting processes  
660 will take place at the next assessment appointment after they age into a new category. Example  
661 consent/re-assent templates for impacted children are included in **Appendix A** (*This change was  
662 made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda,  
663 10.25.19*).

664

665

666 **2. Primary Care Provider Consent**

667 Since we are interested in primary care *providers'* knowledge of evidence-based treatments as  
668 well as their attitudes toward and their satisfaction with the treatment conditions implemented

669 within their practices, we plan to collect basic demographic data (e.g., age, years in practice,  
670 highest degree obtained) and responses to self-report questionnaires from the physicians  
671 providing UC to the participating families. Primary care *providers* willing to participate in this  
672 research will sign a consent form that outlines the purpose of their participation in providing  
673 research data, the benefits and risks to individuals who participate, and the confidential nature  
674 of information obtained. Participation in the research portion is completely optional and a  
675 decision not to participate will in no way affect their role as a care *provider* on the study nor  
676 their current job status, which will be clearly outlined in the consent form. A trained study staff  
677 member will answer any questions the primary care *provider* has about his or her participation  
678 in the study (*This change was made on 2.27.18 prior to review and approval by the DSMB, DSMB*  
679 *approved protocol addenda on 11.2.18*).

### 681 3. PLAN Coach Consent

682 PLAN coaches will also be asked to participate in research designed to assess the delivery and  
683 implementation of FBT in the primary care setting through reporting of demographic data and  
684 responses to self-report questionnaires. As with the primary care providers, if they are willing  
685 participants, they will be asked to sign a consent form that outlines the purpose of their  
686 participation in providing research data, the benefits and risks to individuals who participate,  
687 and the confidential nature of information obtained. Additionally, a separate section of the  
688 consent form will allow researchers access to FBT session recordings for analysis and reporting  
689 in future publications. While the monitoring of audio-recordings for training and quality control  
690 purposes will be part of the expected duties of the PLAN coaches, participation in the research  
691 portion (e.g., providing demographic information, and the use of audio recordings for data  
692 analysis and scientific publication purposes) is completely optional, and a decision not to  
693 participate will in no way affect their role as a PLAN coach on the study, which will be clearly  
694 outlined in the consent form. This consent form will be administered by a trained study staff  
695 member who will answer any questions the PLAN coach has about his or her participation in the  
696 study prior to the on-site training seminar.

697 Additionally, PLAN coaches will be asked to participate in an audio-recorded semi-structured  
698 interview; interested coaches will provide consent over the phone and will be asked a series of  
699 questions by a trained post-doctoral researcher on the study. The questions are based on the  
700 coaches' discussions with FBT families pre-COVID and amid-COVID regarding food cost,  
701 perception, and behaviors. The telephone interviews are voluntary and will be completed based  
702 on the coaches' availability. (*This change was made 7.13.20, pending DSMB approval*)

703

704

705

### 706 Randomization

707 The DCC will use the REDCap randomization module to create an online password protected  
708 randomization system that will facilitate the random assignment of families. When the website is  
709 entered, the user will provide information that establishes the eligibility of the family. Group  
710 assignments will be revealed only if all eligibility criteria are satisfied. To avoid temporal bias,  
711 randomization will be blocked within clinic using random block sizes in order to preclude the  
712 possibility that investigators might know in advance the assignment of the last family in a particular  
713 block.



714  
715 Families who enroll in the study will be scheduled for a baseline assessment to gather preliminary  
716 study data. Following this visit, the family will be randomized and then informed of the treatment  
717 condition to which they have been assigned. *A PLAN coach will follow up with families randomized*  
718 *to FBT to schedule the first FBT visit (Session 0; This change was made on 9.18.17 prior to review and*  
719 *approval by the DSMB, DSMB approved protocol addenda on 11.2.18). Ideally, all treatment sessions*  
720 *will take place in the pediatric practices. If there are issues with space at the pediatric practices, FBT*  
721 *families can be seen at alternate locations (i.e., satellite office, university setting, etc.) for their*  
722 *weekly and assessment sessions. Usual care assessments can also be conducted at an alternate*  
723 *setting. (This change was made on 10.17.18 prior to review and approval by the DSMB, DSMB*  
724 *approved protocol addenda on 11.2.18)*

725  
726 Participant randomization will begin November 2017 *(This change was made on 11.9.2017 prior to*  
727 *review and approval by the DSMB, DSMB approved protocol addenda, 11.2.18) and will go through*  
728 *August 15<sup>th</sup>, 2019 (This change was made on 6.6.19 prior to review and approval by the DSMB,*  
729 *DSMB approved protocol addenda on 9.29.19).*

730  
731 36 families will be randomized each month of this period (9 families per site) with the last three  
732 months (Sept. 2018-Nov. 2018) decreasing to 32 families each month (8 families per site) in order to  
733 reach 528 families (132 families per site). It is estimated that 43.2% of randomized families will have  
734 an age- and weight-eligible sibling; however, sibling recruitment goals will not be included in  
735 randomization benchmarks. This estimate is based upon unpublished data in which 163 of the 377  
736 screened families for a similar weight control program (43.2%) had at least one age and weight-  
737 eligible sibling.

738  
739 Randomization benchmarks will be overseen by the Recruitment and Retention Committee. The DCC  
740 will prepare a recruitment report for review by the Recruitment and Retention Committee each  
741 month indicating the number of randomized total families and randomized minority families. If a  
742 clinical site is not meeting randomization benchmarks, the committee will make recommendations  
743 on how to improve their recruitment strategies such as identification of alternative sources of  
744 participants at the sites, the possible need for increased recruitment resources, more efficient use of  
745 existing resources, or the addition of new clinics at one or more site. An official review of  
746 randomization benchmarks will be conducted by the Study Executive Committee (SEC) and will occur  
747 quarterly at 20%, 40%, 60%, 80%, and 100% of the accrual period. At these time points, if sites are  
748 not at 100% or more of their randomization targets, despite remediation efforts, recommendations  
749 to redistribute funds across sites may be made at the discretion of the Study Executive Committee  
750 to ensure study recruitment milestones are met.

751  
752 **Assessments**

753  
754 Participating parent and child weight will be measured at each major assessment (at baseline and every  
755 6 months), and weight will be assessed throughout FBT as part of a goal setting and reinforcement  
756 system by the blind assessors. *Child height will also be measured at each major assessment or as needed*  
757 *to determine progress (This change was made on 11.9.17 prior to review and approval by the DSMB,*  
758 *DSMB approved protocol addenda on 11.2.18). Weight will be measured using a wireless, portable scale*  
759 *(SR Scales, Tonawanda NY), calibration certified. Two weights for each participant will be taken*  
760 *according to a uniform protocol and will be written on hard copy measurement sheets. The handwritten*  
761 *weights will be manually entered into the REDCap database by a blinded measurement coach, which will*

762 eliminate potential measurement bias and minimize errors in data entry (*DSMB approved change,*  
763 *11.18.19*). Height will be measured using the portable stadiometer HM200P PortStad by the Charder  
764 manufacturing company within the pediatric practices (*This change was made on 4.6.17 prior to review*  
765 *and approval by the DSMB, DSMB approved protocol addenda on 11.2.18*). Hard copy height and weight  
766 measurement forms will be uploaded to the secure REDCap database to allow the CCC, DCC and TFC to  
767 check for transcription and/or unit of measurement errors. All assessors will be provided with the height  
768 and weight protocol (see Height and Weight Measurement in **Appendix C**) in order to ensure that  
769 participants are being measured accurately and consistently and we will retain the written record of  
770 participant height and weight, as well. On the basis of height and weight, BMI is calculated according to  
771 the following formula: BMI = kg/m<sup>2</sup>. Children will be considered overweight at or above the 85th BMI  
772 percentile for their age and sex.<sup>35</sup> Parents will be considered overweight if their BMI is greater than or  
773 equal to 25 kg/m<sup>2</sup>, and obese if their BMI is greater than or equal to 30.<sup>36</sup>

774  
775 In line with Secondary Aim 1, overweight sibling height and weight will also be assessed at each  
776 major assessment time point in the same manner described above. *Alternatively, parents also have*  
777 *the option to give consent for assessors to review the non-participating sibling(s)'s medical records*  
778 *to access height and weight data (DSMB approved protocol addenda, 11.2.18)*. Additionally, non-  
779 participating parent and other sibling heights and weights will be assessed at each major assessment  
780 time point if feasible.

781  
782 Delay discounting will be assessed at baseline and again at 12 and 24 months through use of a brief  
783 computer task administered via REDCap on a laptop. Additionally, baseline predictors of treatment  
784 outcome will be assessed, specifically, parental inconsistency in rewards and environmental  
785 enrichment of the home. Data will be collected using self-report questionnaires designed to assess  
786 these constructs administered on-line via REDCap (see **Appendix C**). Finally, for the FBT group,  
787 treatment adherence will be measured throughout the study by treatment session attendance and  
788 completion of diet and physical activity self-monitoring in habit books or specialized mobile  
789 applications.

## 790 791 **Participant Timeline**

### 792 793 **1. Enrollment/Baseline**

794 Families who are eligible for the study will meet with a trained study staff member and will be  
795 given written and verbal information about the study. Full disclosure of the purpose of the  
796 study, the benefits and risks to individuals who participate, and the confidential nature of  
797 information obtained during the study will be explained to participants. Families will be aware  
798 from the onset that they will be randomly assigned to an active treatment condition (FBT) or a  
799 Usual Care (UC) control condition following baseline questionnaire completion. They will also be  
800 aware that their expected participation will be 2 years and may require anywhere from 26  
801 sessions to 96 sessions of FBT if randomized to that condition. The study staff member will  
802 answer any questions the family has about the study, and then participants will be consented  
803 according to the policies and procedures of the University at Buffalo Institutional Review Board  
804 (IRB), the IRB of Record for the study. Study staff will follow-up with families by phone to inform  
805 them of their randomization status and will schedule the first FBT visit for those families  
806 randomized to FBT. PLAN coaches will also send reminders for FBT visits to their families  
807 throughout the study to decrease missed appointments.

808

809 **2. Follow-up**  
 810 Following baseline, families will be assessed at months 6, 12, 18, and 24. Links to brief self-  
 811 report questionnaires via REDCap will be sent by study staff to all randomized families to  
 812 complete prior to their assessment time point and families will be scheduled for assessment  
 813 visits to collect height and weight measures and to complete the delay discounting task (DD; at  
 814 12 and 24 months only). Families will be greeted by the blinded PLAN coach or assessor at the  
 815 practices to complete the DD computer task and collect heights and weights according to the  
 816 protocols. Families will also have the opportunity to complete the REDCap questionnaires if they  
 817 were unable to do so prior to the in-person assessment. Blinded PLAN coaches and assessors  
 818 will complete all necessary forms and submit them into REDCap following this appointment.  
 819 Families will be reminded of their next assessment in the series until it is the final visit. Home  
 820 visits can be arranged for assessment appointments if necessary, and will be attended by two  
 821 PLAN staff members.

822 **3. Final Study Visit**  
 823 The final study visit will be conducted similarly to the previous measurement appointments,  
 824 although families will not be scheduled for any additional appointments.

825 **4. Early Termination Visit**  
 826 Families that are terminated early will be notified by phone or an in-person meeting to relay the  
 827 reason(s) for the termination and provide any resources that would be available and  
 828 appropriate. The families' access to the website and data links will be eliminated.

829 **5. Unscheduled Visit**  
 830 PLAN coaches will be available to meet with families at the practices for scheduled  
 831 appointments. Should a family arrive at the practice without an appointment, the office staff  
 832 will be instructed to encourage the family to notify their PLAN coach or assessor. The PLAN  
 833 coach or assessor will follow up with the family by phone, email or text to confirm their next  
 834 appointment or to schedule an alternate visit time and will then record the contact in the  
 835 participant tracking form in REDCap.

836 **6. Schedule of Events**  
 837 See **Table 4** below for an outline of events for study participants.

838 **7. Remote Assessments**  
 839 Due to the serious nature of Covid-19 and instructed social distancing, in person assessments  
 840 and sessions are halted. Assessments and sessions will be held through University and Hospital  
 841 approved platforms such as Zoom, Webex, and Skype for business. An instructional video will be  
 842 sent to all PLAN participating families to show how to correctly measure height and weight at  
 843 home with supplies sent from PLAN. Supplies will include a foldable yard stick, a scale and  
 844 carpenter's edge if the families do not have access to one. Remote assessment protocol and  
 845 scripts have been included in Appendices on page 239.

850 **Table 4. Measurement Timeline**

Measures	Method	Time (min)	Examinee	Time point				
				0	6	12	18	24
Primary and Secondary Aim 1 Outcomes								

Weight <sup>1</sup> & Height	Scale and stadiometer	5	P,C,S, NPP	X	X	X	X	X
<b>Delay Discounting (Secondary Aim 2)</b>								
Delay of Gratification	Computer Task	20	P,C	X		X		X
<b>Participant Level Predictors (Secondary Aim 3)</b>								
Parental Survey	Questionnaire	2	C	X				
Environmental Enrichment	Questionnaire	10	P	X				
SAE/AE Survey	Questionnaire	5	P,C		X	X	X	X
<b>Provider Level Predictors (Exploratory Aim)</b>								
Attitudes towards Evidence-Based Treatments	Questionnaire	5	PCP	X				
Attributes of FBT <sup>2</sup>	Survey Questions	5	PCP			X		
Intended Adoption <sup>3</sup>	Questionnaire	1	PCP					X
<b>Participant and Provider Level Descriptors</b>								
Family Demographics	Questionnaire	10	P, P <sub>c</sub>	X				
Family Nutrition and Physical Activity ( <i>DSMB approved protocol addenda, 9.29.19</i> ).	Questionnaire	10	P	X		X		X
Participant Adherence to FBT	Session Attendance <sup>1</sup>	NA	P,C	X	X	X	X	X
Participant Acceptability	Client Satisfaction Questionnaire	5	P,C					X
24 Month Survey ( <i>DSMB approved protocol addenda, 9.29.19</i> ).	Questionnaire	15	P,C					X
Provider Demographics	Questionnaire	10	PCP	X				
Provider Usual Care Survey	Questionnaire	10	PCP	X				X
Chart review of UC compliance	Questionnaire	--	Plan Coach					X
Coach Demographics ( <i>This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19</i> ).	Questionnaire	5	PLAN Coach					X
Coach Treatment Knowledge ( <i>This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19</i> ).	Questionnaire	10	PLAN Coach					X
Coach Attitudes Toward Evidence Based Treatment ( <i>This change was made on</i>	Questionnaire	10	PLAN Coach					X

7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).								
Coach Attributes of FBT (This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).	Questionnaire	5	PLAN Coach					X
<b>Total Time for Each Group</b>								
<b>Child</b>				12	5	10	5	10
<b>Parent</b>				55	5	10	5	15
<b>Provider</b>				25	0	5	0	11
<b>PLAN Coach</b> (This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).				0	0	0	0	30

853  
854  
855  
856  
857  
858  
859  
860  
861  
862  
863  
864  
865  
866  
867  
868  
869  
870  
871  
872  
873  
874  
875  
876  
877  
878  
879  
880  
881  
882  
883

**II. Treatments**

**Usual Care (UC)**

The usual care control group will consist of the care typically delivered by the family’s pediatrician for children with overweight or obesity. (This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18). The implementation of UC may vary between physicians but typically include an assessment of the child’s weight, help removing barriers to weight loss, and introduction of goals for better weight management.

**Family-based Behavioral Weight Loss Treatment (FBT)**

**1. Introduction**

Each PLAN coach will provide FBT to families randomized to FBT. FBT utilizes behavior change techniques to target family-wide changes in diet and physical activity habits with the goal of promoting weight loss and subsequently healthy weight maintenance in both the participating child and his or her parent. Preliminary evidence demonstrates effects may even extend to other family members not enrolled in the program. Due to social distancing as a result of Covid-19, all participating families will be shown an instructional video intended to aid in gathering reliable height measurements.

**2. Conceptual Components**

**Dietary Goals**

Consume 1200-1800 kcal/day (This change was made on 4.6.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18). Increase fruit and vegetable consumption and decrease consumption of high energy dense and/or low nutrition density foods and beverages to help shape food preferences. Calories will be adjusted according to weight change without reducing calories below 1000 to ensure essential calories are being met for a healthy diet (<http://health.gov/dietaryguidelines/2015/guidelines/appendix-2/>).

884  
885  
886  
887  
888  
889  
890  
891  
892  
893  
894  
895  
896  
897  
898  
899  
900  
901  
902  
903  
904  
905  
906  
907  
908  
909  
910  
911  
912  
913  
914  
915  
916  
917  
918  
919  
920  
921  
922  
923  
924  
925  
926  
927  
928  
929  
930  
931

**Physical Activity Goals**

90 minutes of moderate to vigorous physical activity each day for children and 60 minutes of moderate to vigorous physical activity 5 days per week for adults. Decrease time spent engaging in sedentary activities such as watching TV and playing computer games to two hours or less per day (This change was made on 4.7.2017 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18). Information on achieving a healthy number of sleep hours each night will also be given. Moderate to vigorous physical activity goals will be shaped and mastered at different increments.

**Behavior Change Tools**

Self-monitoring, goal setting, problem solving, stimulus control, positive parenting techniques such as the provision of incentives for behavior change, assistance in reducing the need for immediate gratification using episodic future thinking (EFT) – a method for improving impulse control, and finding behavioral substitutes for highly reinforcing food. Families will have access to traditional paper and pencil self-monitoring, and after self-monitoring skill is acquired, families can choose to use traditional or technology-based self-monitoring systems such as use of a FitBit or MyFitnessPal.

**Delay of Gratification**

The ability to delay gratification can be quantified by delay discounting (DD), or the tendency to discount large future rewards for smaller, immediate rewards.<sup>37</sup> Research suggests that children with obesity are more likely to choose a small immediate food reward over a larger delayed food reward.<sup>38-40</sup> Inconsistent parenting and less enriched environments also have a negative impact on ability to delay gratification. Thus, we use FBT to improve parental consistency to reduce DD, alter the shared family environment to reduce DD, and provide individual skills in parents and children to reduce DD.

**Social Facilitation Approaches**

Social facilitation approaches are designed to help families engage in social events and activities as alternate reinforcers to unhealthy eating and activity behaviors. Participants are taught assertion and communication skills to improve their social interactions within their existing social networks and participants are encouraged to form new relationships that serve to support and reinforce healthy behaviors. Additionally, children are coached on their abilities to deal with teasing to reduce negative social interactions.

**Educational Tools**

The Traffic Light Eating Plan and Food Reference Guide, which utilizes GREEN, YELLOW, and RED labels for food to guide families toward the goal of consuming low energy-dense, high nutrient-dense foods will be used. Foods are assigned a traffic light color based on the average calories to obtain basic nutrients for each food group in the Food Guide Pyramid. For example, if a serving of a vegetable is less than 60 kcals/serving it is a GREEN food, if it is between 60-80 kcals/serving it is a YELLOW food, and if the vegetable is greater than 80 kcals/serving it is a RED food. Foods in the other food group categories are designated YELLOW or RED based on how many calories it takes to provide nutrients for foods in that food group (vegetables are the only food group with GREEN food designations)

932 The Traffic Light Activity Program and Activity Reference Guide also utilize GREEN,  
933 YELLOW, and RED labels for different levels of caloric expenditure to guide families  
934 toward increasing physical activity and reducing sedentary behaviors. Sedentary  
935 activities, those that are 1.9 3 METS (Metabolic Equivalent) or less, are considered RED  
936 activities, and the goal is to reduce them, particularly, screen time. YELLOW activities  
937 are 2.0 to 2.9 METS, equivalent to the lower end of MVPA (moderate to vigorous  
938 physical activity). Activities that are 3.0 METS or greater are considered GREEN  
939 activities. The goal is for child participants to obtain 90 minutes of MVPA per day and for  
940 parents to obtain 60 minutes of MVPA at least 5 days per week. Activities can include  
941 lifestyle behaviors (e.g., walking to school, biking with friends), or participating in  
942 organized sports, but must be engaged in for bouts of at least 10 minutes.

### 944 **3. Mastery-Based FBT Level System<sup>41,42</sup>**

945 FBT will be implemented on an individual basis to adapt the dose of treatment to the individual  
946 participant needs. While adaptable, FBT “dose” will be consistent with the USPSTF  
947 recommendation of 26 or more hours of individualized, intensive intervention.<sup>13,43</sup> The minimal  
948 FBT dose includes 8 weekly visits, 8 two times per month visits, and 6 monthly visits for the first  
949 year, and 4 quarterly visits for the second year of intervention. A mastery system will be used to  
950 ensure parent and child are reading and understanding the program materials. Families are  
951 encouraged to initiate behavior change at their pace, and are rewarded for incremental  
952 changes. The goal for all families is for children to show a reduction of percent over BMI of at  
953 least 10 percent.

954  
955 Mastery of program information recognizes that not everyone learns at the same rate. Master  
956 of program content includes five areas: 1) changes in individual diet and activity; 2) changes in  
957 the family; 3) changes in peer networks; 4) changes in community; and 5) relapse prevention.  
958 Instruction on parenting will be given throughout each section. Progression through treatment  
959 topics will be based on mastery of treatment knowledge as demonstrated by scores of at least  
960 80% on quizzes related to the content of each unit. If scores of 80% are not achieved at the end  
961 of each unit, areas for remediation will be targeted and corrective feedback will be given until  
962 scores of 80% are obtained (multiple versions of unit quizzes will exist for this purpose).

963  
964 Changes in eating, activity and parenting are rewarded using a point system. Children and  
965 parents work independently toward their goals at their own pace. They will focus on the  
966 behavioral goals in the areas in diet, physical activity and parent/child interactions as part of the  
967 reinforcement system. The other supporting behaviors skills are encouraged through program  
968 materials, interactions with coaches, and parental praise. Participants move toward the  
969 ultimate behavioral goals of FBT independently of each of the specific goals or other participant  
970 in the family (children and parents move at their own independent pace). The behavioral skills  
971 we are emphasizing have demonstrated success over traditional FBT through 1-year follow-up.<sup>42</sup>  
972 These behavioral skills have demonstrated associations with weight loss and weight loss  
973 maintenance (e.g., changes in diet, monitoring, sleep<sup>44</sup>; episodic future thinking<sup>45-48</sup>; skills related  
974 to the family/home and social environment<sup>49</sup>; relapse prevention skills<sup>50,51</sup>). **Table 5**, displays the  
975 behavioral goals, and the frequency of sessions based on the families weight loss success. The  
976 bolded behaviors will be reinforced with points, all others will be reinforced by praise.

977  
978

## MASTERY-BASED FBT BEHAVIORAL SKILLS LEVEL SYSTEM

### Session Frequency

*Session frequency will be determined solely by weight change<sup>1</sup>, as measured in each treatment session. In order to reduce session frequency, both parent and child must meet weight loss goals for 2 consecutive weeks. Any subsequent weight gain will result in an increase in session frequency until pattern of loss has been restored.*

Weight		Weekly	Bi-Weekly	Monthly	Quarterly
	<b>Reduction in Percent Over BMI (C)</b>	15%	Weight loss ≥20%	Maintain weight loss ≥20%	Maintain weight loss ≥20%

979

<b>Reduction in Percent of Total Body Weight (P)</b>	10%	Maintain weight loss ≥10%	Maintain weight loss ≥10%	Maintain weight loss ≥10%
--	-----	---------------------------	---------------------------	---------------------------

### Mastery Behaviors

*Mastery behaviors to be assigned by PLAN coach according to treatment protocol; families must demonstrate mastery (meeting goal 5 of 7 days) for 2 consecutive sessions in order to progress to next mastery level. Behaviors will be tracked via P & C Habit Books.*

<b>Nutrition</b>	<b>Calorie Range total per day</b>	1200-1800 <sup>2</sup> (This change was made on 4.6.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).			Adjusted <sup>3</sup>
	<b>GREEN Foods/Drinks total per day</b>	2	3	4	≥5
	<b>RED Foods/Drinks total per day</b>	≤10	≤7	≤4	≤2
<b>Physical Activity (PA)</b>	<b>GREEN PA (C)</b> <i>minutes X days per week (DSMB approved protocol addenda, 11.2.18).</i>	30x3	45x4	60x5	90x5
	<b>GREEN PA (P)</b> <i>minutes X days per week (DSMB approved protocol addenda, 11.2.18).</i>	20x3	30x4	45x4	60x5

### Driving Behaviors

*Driving behaviors to be assigned by PLAN coach according to treatment protocol and individual needs. Targets listed reflect overall PLAN goals to be achieved through shaping; session goals will be assigned to progress from baseline to target.*

<b>Parenting</b> <i>(This change was made on 10.17.18 prior to</i>	<b>Praise times per day</b>	1	2	3	4
	<b>Stimulus Control times per week</b>	1	2	3	4
	<b>Daily Check In days per week</b>	4	5	6	7



<i>review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18)</i>	<b>Meal Planning</b> <i>days per week</i>	2	3	4	5
<b>Weight Graph*</b>	<b>Graphing Weight (C)</b>	2 days per week			
	<b>Graphing Weight (P)</b>	7 days per week			
<b>Nutrition</b>	Dinner Prepared at Home	≥3 days per week			
<b>Routines</b>	EFT Practice (P)	≥5 times per week			
	Recreational Screen Time	≤2 hours per day or ≤15 hours per week (This change was made on 4.7.2017 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18)			

980

	<b>Healthy Sleep Routines (C)</b>	<b>9-11 hours per night</b>
	Healthy Sleep Routines (P)	7-9 hours per night
<b>Social</b>	Engaging in PA with Family	≥3 times per week
	Engaging in Healthy Eating & PA with Friends	≥3 times per week
	Accessing Healthful Community Eating & PA Resources	≥3 times per week

981

**NOTES ON MASTERY-BASED FBT BEHAVIORAL SKILLS LEVEL SYSTEM:**

- C = child; P = parent; PA = physical activity; EFT = episodic future thinking
- Weight percentages are a guide
  - Weight loss will be individualized based on initial participant weight and subsequent weight loss
  - <sup>1</sup>Weight change will be assessed in reference to lowest measured weight (e.g., if loss in week 3 and gain in week 4, loss can only occur in week 5 if weight is below week 3 measurement)
- Bolded behaviors will be reinforced by the point system
- Calorie ranges individually assigned based on weight loss
- <sup>2</sup>Calories for weight loss will range from 1200-1800 to promote 0.5 lb. loss for children and 1 lb. loss for parents each week
- <sup>3</sup>*Adjusted* refers to adjustment of caloric intake (as monitored by coach) designed to maintain body weight in a healthier weight range
- *\*Completing the weight graph involves having families weigh at home. If families do not have access to a home scale, the coach will lend them a commercial-grade scale for the duration of the study (This change was made on 10.17.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).*
- *Specific and timely praise statements*
  - Verbal praise statements
  - Physical gestures such as hugs

- *Stimulus control*
  - Arranging the environment so triggers are less impactful (i.e., reducing cues for less healthy behaviors and increasing cues for healthy behaviors)
  - Number of stimulus control changes in the environment that were operating that week
- *Episodic future thinking practice*
  - Practicing simulating future events when making decisions about small immediate rewards vs. larger delayed rewards

982  
983  
984  
985  
986  
987  
988  
989  
990  
991  
992  
993  
994  
995  
996  
997  
998  
999  
1000  
1001  
1002  
1003  
1004  
1005  
1006  
1007  
1008  
1009  
1010  
1011  
1012  
1013

Meeting behavioral goals is assessed by the FBT PLAN coach during sessions by reviewing parent and child daily habit books and a self-report FBT monitoring checklist completed by the parent that tracks behavioral goal progress over the previous week. Weight loss is conjointly required, in addition to self-reported habit changes, to increase assurance in the accuracy of self-reported behavior changes. Since weight loss is related to these self-reported behavioral changes, we do not want to reinforce participants who report making the changes but who are not losing weight. In this way, participants who report behavioral changes are not moved to the next phase of session frequency unless they show expected weight loss. Likewise, participants who show weight loss but who do not report behavioral change will remain at the same session frequency until behavioral change meets mastery criteria. This is to ensure that behavioral skills that are known to promote weight loss and weight maintenance are acquired and maintained over time. Weight loss goals were selected based on literature demonstrating a 5-10% loss in body weight yields clinically significant changes<sup>52,53</sup>; however, they may be individualized based on initial participant weight and subsequent weight loss. Participants will be moved from weekly sessions to biweekly sessions to monthly sessions to quarterly sessions when they have met the specified behavioral goals for at least 2 weeks and when they have met the weight loss criterion. Weight loss criteria for weekly, biweekly, and monthly sessions were designed for weight loss, and quarterly sessions for weight maintenance.

Dosage will be based on mastery of program material, progress in behavior change, and weight change. Sessions will be weekly for at least 8 weeks and until at least a decrease of 10% percent over BMI is observed. Sessions will go to 2 times per month and will continue for at least 8 weeks or until a new weight loss goal is attained. Treatment will transition to maintenance goals and less frequent meetings. If a family is able to reach the weight maintenance after 6 months, they will switch to quarterly meetings until the end of the study. If participants are unable to maintain behavioral goals or weight loss/maintenance goals of any level at any point, they will be returned to intensive weekly sessions to prevent relapse. This will occur until participants are able to maintain their weight loss for 2 weeks at the given level at which point they will continue to progress through the dosing schedule. See **Table 6** for examples of different “dosing” based on rates of progress through the program.

1014 **TABLE 6. FBT Sessions Over 24 Months Based on Differential Rates of Mastery of FBT**

	Maximum Dose	Moderate Dose	Minimum Dose
Number of Weekly Sessions	48	24	8
Number of Biweekly Sessions	24	12	8
Number of Monthly Session		12	6
Number of Quarterly Sessions			4
<b>Total Number of Contacts Over 24 Months</b>			
	72*	48	26
<p><i>Note:</i> *With the mastery model, it is possible that a family could be seen weekly for the duration of the study</p> <p>a. (approximately 96 visits over the course of the entire study). However, we have chosen to illustrate a more typical visit frequency for families slow to master behavioral skills of 72 sessions over the course of the study. If a family is showing signs of becoming a retention risk, then we will adjust the frequency of FBT sessions to a treatment schedule that is acceptable to the family (<i>This change was made on 3.18.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19</i>).</p>			

1015  
1016 **4. Family Sessions**

1017  
1018 **Session Structure**

1019 Each treatment session will be structured as follows: parents and children are first weighed  
1020 and then have a 30-60-minute individual family meeting with their PLAN coach, during  
1021 which time the family: 1) reviews habit books and self-report checklists with their PLAN  
1022 coach; 2) receives feedback on behavioral skill acquisition, weight goals, and progression  
1023 through the levels of FBT; 3) receives education on diet and physical activity (See **Table 7** for  
1024 a list of education topics); 4) is taught behavior change techniques; 5) sets behavioral goals  
1025 for the week; and 6) reviews and addresses any barriers to goal attainment or to adherence  
1026 with the weight loss behaviors.

1027  
1028 **Table 7. Overview of FBT Education Topics**

Unit	Chapter	Topics
1	1	Introduction to PLAN; Pediatric Care Practice, Learning, Activity and Nutrition
2	2	Traffic Light Eating Plan
3	3	Monitoring Food; Recording Daily Intake
	4	Monitoring Red Foods
4	5	Measuring Foods; Portions
5	6	Recognizing Hunger and Satiety Cues
6	7	Reading and Understanding Food Labels
7	8	Pre-Planning
8	9	Positive Parenting and Praise
	10	Being a Good Model for Your Child
	11	Encouragement; Daily Meetings
9	12	Goal Setting; Cutting Calories
10	13	Traffic Light Activity Program
11	14	Energy Balance

12	15	Stimulus Control
13	16	Healthy Shopping and Budgeting
14	17	Healthy Routines: Behavior Chains; Meal Regulations
	18	Healthy Routines: Sleep; Self-Weighing
15	19	Reviewing Traffic Light Eating Plan Concepts
16	20	Reinforcement and Rewards
17	21	Prospection
18	22	Problem Solving Skills
19	23	High Risk Situations: Restaurants, Parties, Holidays and Vacations
20	24	Recipes and Healthy Cooking
21	25	Decreasing Red Activity
22	26	Social Support and Making Social Networks Even Healthier
	27	Planning Physically Active Social Gatherings
23	28	Taking on Teasing
	29	Stigma and Body
24	30	Emotional Eating
25	31	Focusing on Health at School, Work and Neighborhood
26	32	Consolidating Healthy Living Skills
	33	Maintaining Motivation and Relapse Prevention
	34	Long-Term Maintenance

1029

1030

**Session Content**

1031

1032

1033

1034

1035

1036

1037

1038

1039

1040

1041

1042

1043

1044

1045

1046

1047

**5. Technological Support**

1048

1049

1050

1051

1052

1053

1054

FBT focuses on parents as the gatekeepers of health-related behaviors by improving parenting skills for the modification of child eating and activity behaviors as well as general child-parent interactions. Parents will be trained in general parenting methods to foster positive behavior change, such as learning to praise their child and implementing a parent-delivered reinforcement system. Reinforcers, such as additional time spent with a parent engaging in a favorite activity or a sleepover with a friend can be earned for meeting dietary and activity goals. Parents will be provided with strategies to modify the shared home environment in order to facilitate the behaviors that are targeted. Children and their parents will be taught problem solving and preplanning to deal with challenging situations, as well as techniques for coping with teasing. A unique aspect of FBT is the emphasis on creating an ecology that supports long-term change, which includes modifying the family environment, reshaping peer group networks, and ensuring that there are community resources available to the family to maintain behavior change. In this way, barriers to weight loss and maintenance of the loss are addressed across contexts, reinforcing healthy lifestyle changes and making them more readily sustainable.

A study website will provide information to families about FBT, provide downloadable versions of the Traffic Light Eating Plan and Food Reference Guide and the Traffic Light Activity Program and Activity Reference Guide, and provide links to handouts with information on healthy cooking and recipes, getting more physical activity, and positive parenting tips. All quizzes to assess mastery of educational materials will also be accessible via the study website, with multiple versions of quizzes on each topic available, recognizing that some participants will acquire mastery of the required behavior change information more slowly than others.

1055  
1056  
1057  
1058  
1059  
1060  
1061  
1062  
1063  
1064  
1065  
1066  
1067  
1068  
1069  
1070  
1071  
1072  
1073  
1074  
1075  
1076  
1077  
1078  
1079  
1080  
1081  
1082  
1083  
1084  
1085  
1086  
1087  
1088  
1089  
1090  
1091  
1092  
1093  
1094  
1095  
1096  
1097  
1098  
1099  
1100  
1101  
1102

### III. Training and Fidelity Monitoring

#### General Training in Study Procedures

The DCC will work closely with clinic investigators to ensure the training and certification of all staff that perform study procedures. These efforts will focus on ensuring that (1) investigators, coordinators, and designated backups have appropriate familiarity with the details of the protocol; (2) all evaluations are carried out by individuals certified as being knowledgeable about and experienced with relevant study procedures; and (3) relevant staff are comfortable with data entry and management procedures. To accomplish these goals, the following procedures will be carried out.

- a. During the multisite FBT training at WU, the DCC will facilitate a meeting to discuss the details of the protocol and the standardization of data collection and to provide hands on experience with data collection procedures. During that meeting, staff will be certified to perform the task to which they are assigned by demonstrating the appropriate competencies and knowledge.
- b. Certification of data entry personnel will require that they establish familiarity with the system by entering data on at least four test subjects.
- c. At least two individuals will be certified to perform every task to ensure that backup is always available.
- d. ID numbers of individuals performing assessments will be included on data forms and will be computerized. Using a DCC maintained list of certified personnel, it will be routinely confirmed that assessments have been performed by certified individuals.
- e. Modified data on forms will be initialed and dated by the person making the change.
- f. When new personnel are hired during the study, individual clinics will be empowered to certify the new person as an alternative to less efficient centralized efforts.

#### PLAN Coach Training and Fidelity

FBT PLAN coaches will be hired by the clinical site PI. Clinical site PIs will be encouraged to hire individuals with at least a bachelor's degree, and who possess, or are pursuing, an advanced degree in a related field of study such as dietetics, social work, or clinical psychology. Basic demographic information will be gathered regarding PLAN coach age, gender, educational background, race/ethnicity, prior experience with families or behavioral health interventions, etc. to help tailor training to their level of experience and to identify any PLAN coach level descriptors associated with ease of acquiring fidelity and competency in intervention delivery. These PLAN coaches will be trained using a combination of education, interactive role-playing, simulations, and treatment practice with pilot patients.

<https://buffalo.zoom.us/j/2320132211?pwd=VUJHMGRVSIU1NzYwUHZVMjh3MUUYrdz09>

##### 1. Multisite FBT Training

PLAN coaches will attend a multisite FBT training at Washington University in St. Louis during the week of April 24-28, 2017 and at the University at Buffalo on July 11-12, 2017. All PLAN coaches will complete the on-site training workshops and must earn an 80% or above on the post-training assessment at the end of these trainings in order to be certified to initiate recruitment. If any coaches do not achieve this score, remedial instruction will occur and they may repeat the quiz.

1103  
1104  
1105  
1106  
1107  
1108  
1109  
1110  
1111  
1112  
1113  
1114  
1115  
1116  
1117  
1118  
1119  
1120  
1121  
1122  
1123  
1124  
1125  
1126  
1127  
1128  
1129  
1130  
1131  
1132  
1133  
1134  
1135  
1136  
1137  
1138  
1139  
1140  
1141  
1142  
1143  
1144  
1145  
1146  
1147  
1148  
1149  
1150

**2. Educational Materials**

The study website will include articles on FBT for the PLAN coaches to read, and it will also provide a thorough training manual to teach behavioral, diet, and exercise principles used in the study, as well as other relevant readings. The website will also include web-based pre- and post-assessments of FBT knowledge. PLAN coaches will need to demonstrate mastery of the material prior to working with families.

**3. Interactive Role Playing and Simulation**

Live and Skype training sessions will provide the opportunity to role play important behavioral skills. Training will conclude with a treatment session simulation, during which PLAN coaches will be rated on their utilization of FBT components to ensure competency. If the written and simulated assessments demonstrate lack of knowledge and skills, FBT concepts will be retaught until mastery is achieved.

**4. Pilot Patients**

PLAN coaches will practice delivering FBT to two families (at least 12 sessions each) not randomized to the study. They must demonstrate competency on at least four consecutive FBT sessions for each family, as determined by ratings of their audio- recorded treatment sessions, before they may begin treatment with a randomized family.

**5. Post-Training**

Training acceptability will be assessed using a 6-item self-report questionnaire adapted from Lyons and colleagues. PLAN coaches will receive supervision throughout their delivery of FBT. Manuals and checklists will be used during FBT treatment sessions, and each FBT session will be audio recorded. Supervision will be provided for all PLAN coaches by study staff experienced in FBT from the Training and Fidelity Core (TFC). Treatment fidelity will be evaluated by random audits of audio recordings using integrity checklists. Audits will be conducted by trained TFC raters who were not involved in training the PLAN coaches. The text below provides a summary of the PLAN coach training and quality control process for the present study.

**6. Alternate Training**

As some turnover in PLAN coach staffing is inevitable following the initial training workshop and piloting of families, an alternative method for training and certifying PLAN coaches has been developed. Within the first two weeks of hiring, new PLAN coaches must complete HIPAA and CITI training, watch the video recordings of the first training and pass the post-training quiz with a score of 80%. They will then role play four mock sessions with their fellow PLAN coaches, which will be audio recorded. FBT supervisors will review these sessions and provide feedback. The coaches will then schedule four simulations with the Training and Fidelity Core. After completing these simulations, the coach will begin seeing families randomized to FBT. All sessions will be audio recorded, reviewed by supervisors and feedback will be provided in writing and over the phone until 8 consecutive sessions have been rated 'competent'. Once the replacement coach receives satisfactory ratings on at least eight consecutive sessions, they will be certified to work with randomized families (*DSMB approved protocol addenda, 3.18.19*).

**7. Summary of FBT Training Process:**

- a. Complete HIPAA/CITI training as required by IRB of Record and/or participating clinical sites
- b. Read and become familiar with:

- 1151 i. Study Protocol
- 1152 ii. General Articles Describing FBT
- 1153 iii. Treatment Manuals
- 1154 iv. Traffic Light Eating Plan and Food Reference Guide
- 1155 v. Traffic Light Activity Program and Activity Reference Guide
- 1156 c. Participate in on-site training workshops to be held prior to the randomization of the
- 1157 first participant
- 1158 d. Earn a score of 80% or greater on post-training assessment
- 1159 e. Engage in role plays *and simulations* with a TFC FBT expert to practice key behavioral
- 1160 intervention strategies (*This change was made on 11.9.17 prior to review and approval*
- 1161 *by the DSMB, DSMB approved protocol addenda on 11.2.18*).
- 1162 f. Conduct at least 12 treatment sessions with two pilot families
- 1163 g. Participate in regularly scheduled teleconference Clinical Case Review Groups for
- 1164 supervision with a TFC FBT expert and other PLAN coaches
- 1165 h. Provide audio recordings of the first four sessions with each pilot family and then two
- 1166 audio recordings from randomly selected visits with pilot patients for rating by the TFC
- 1167 FBT expert; if audits of any of these recordings result in competency ratings by the TFC
- 1168 FBT expert of less than “competent,” the PLAN coach will receive written and verbal
- 1169 corrective feedback and must submit audio recordings of all subsequent pilot sessions
- 1170 until two consecutive sessions (for each family) are rated as “competent” before
- 1171 working with families randomized to FBT
- 1172 i. “Certification of Interventionist” form signed by TFC FBT expert and returned to DCC
- 1173 prior to starting intervention with participants which confirms that:
- 1174 i. Appropriate human subjects training has been completed
- 1175 ii. Readings have been done and understood
- 1176 iii. Pilot training has been successfully completed
- 1177 iv. The PLAN coach agrees to uphold the highest ethical and professional standards
- 1178 while working with participants in the study

#### 1179 **8. Booster Training**

- 1181 a. Booster training workshops will occur every 6 months; PLAN coaches must score 80% or
- 1182 greater on quizzes given after workshops.
- 1183 b. Two intervention session recordings will be randomly selected by the TFC FBT expert
- 1184 every 6 months to ensure PLAN coach adherence to the treatment protocol
- 1185 c. Recordings must receive a competency rating of “competent.” If rated “not competent,”
- 1186 corrective feedback is provided to the PLAN coach and session audio recording reviews
- 1187 will be repeated until two randomly selected recordings are rated as competent.

#### 1188 **Assessment Training and Fidelity**

1190 Assessments will be performed only by trained and certified staff members. Details of the  
1191 assessment protocol and the standardization of data collection procedures will be presented at the  
1192 FBT training. Additionally, assessment staff will gain hands on experience with the relevant data  
1193 collection procedures and will be certified to perform these tasks during the training. At least two  
1194 individuals at each site will be certified to perform each task to ensure that backup is always  
1195 available. The DCC will maintain lists of certified personnel. Individual clinics will be empowered to  
1196 certify new personnel as an alternative to the initial centralized training session. Video-recordings of  
1197 skilled assessors conducting the assessment procedures will be available following the training  
1198 workshop to aid in standardization of training across sites.

1199  
1200  
1201  
1202  
1203  
1204  
1205  
1206  
1207  
1208  
1209  
1210  
1211  
1212  
1213  
1214  
1215  
1216  
1217  
1218  
1219  
1220  
1221  
1222  
1223  
1224  
1225  
1226  
1227  
1228  
1229  
1230  
1231  
1232  
1233  
1234  
1235  
1236  
1237  
1238  
1239  
1240  
1241  
1242  
1243  
1244  
1245  
1246

**1. Initial Training**

All PLAN coaches and assessors will complete assessment training at the WU FBT training during the week of April 24-28, 2017 and the UB FBT training on July 11-12, 2017. During these trainings, staff will learn standardized procedures for collecting height and weight, (*This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18*), and collecting data via REDCap (including family surveys). Staff will have the opportunity to pilot these procedures on volunteer staff and study team members throughout the training. Additionally, all sites will be provided with the necessary educational materials to ensure adherence to assessment procedures following the training.

Study tasks will be performed only by staff that are trained and certified to perform their assigned task. At the in-person trainings or video-taped instructional trainings, the standardization of data collection procedures will be discussed. Additionally, staff will gain hands on experience with the relevant data collection procedures and will be certified to perform these tasks. The DCC will maintain lists of certified personnel, and individual sites will be empowered to certify new personnel as an alternative to the initial centralized training session. During the initial session, staff will be rigorously trained to certify new personnel that may be added during the implementation of the study via procedures detailed by the DCC. The DCC assessor training will be recorded, and video-recordings of skilled assessors conducting the assessment procedures will be available following the training workshop to aid in standardization of training across sites.

**2. Certification**

All PLAN coaches and assessors will be required to reach reliability *for height and weight measurements* (3mm for height, .25 lbs for weight, *this change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18*). Coaches will complete 10 different measurements according to the height procedures. If the reliable staff member and new staff member do not meet acceptable reliability criteria, additional participants should be measured by both staff members until adequate reliability is established. Additionally, they must prove competent in administering REDCap surveys as assessed by the clinical site project coordinator (*This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18*). When PLAN coaches and assessors reach reliability or competency for each of these measures, they will receive a “Certification of Assessment.”

**II. Research Procedures and Approach**

**Practice Retention**

**1. Expectations**

- a. Create realistic expectations *prior* to recruitment.
- b. Provide practice with information regarding the study (e.g., recruitment, treatment, space considerations).
- c. Explain to practices how this study may impact their workflow.
- d. Keep clear and timely communication with the practices.

**2. Ongoing Strategies**

- a. Prepare and post/distribute recruitment materials for practices.



- 1247 b. Remain friendly and open to answer any questions or concerns.
- 1248 c. Lend solutions to any issues that may arise in the practice concerning the study.
- 1249 d. *Pay out incentive money*
- 1250 e. *Update progress of study and recruitment goals (This change was made on 3.23.18 prior to*
- 1251 *review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).*
- 1252

**Participant Retention**

1254 Each of the sites has experience in subject retention, and both the University at Buffalo and  
 1255 Washington University have experience in retention in FBT. We will use a 3-step evidence-based  
 1256 approach to retention.<sup>54-56</sup> First, we will gather names, addresses and phone numbers of at least two  
 1257 family members or friends who have regular contact with the participating families. Second, we will  
 1258 send greeting cards for birthdays and holidays to the participant over the course of the study. Third,  
 1259 we will provide personal and telephone contacts with the same staff over time whenever possible to  
 1260 facilitate familiarity and rapport. We will also provide continued emphasis on the importance of  
 1261 their contribution to their community and the legitimacy of the project.

**1. Expectations**

- 1263 a. Emphasize up front the common challenges families face.
- 1264 i. Big time commitment
- 1265 ii. Family emergencies
- 1266 iii. Changes in routine
- 1267 iv. Resistance from family members
- 1268 v. Some difficulty reaching goals
- 1269 b. Discuss how the study is a big commitment.
- 1270 c. Discuss why participation in the study is worth it.
- 1271 i. State-of-the-art program that teaches the child and parent how to lose weight and
- 1272 maintain the loss
- 1273 ii. Decreased risk for health problems for the child and parent now and in the future
- 1274 iii. Prevention of heart disease and type 2 diabetes
- 1275 iv. Increased energy, better sleep, and better overall fitness from regular exercise
- 1276 v. Improvement in mood and sense of accomplishment from completing the program
- 1277 vi. Mastering skills earlier in life to reduce the social stigma of obesity
- 1278 d. Discuss commonality of resistance from child and how to handle it.
- 1279 e. Emphasize the expertise of the staff and their ability to help with this problem.
- 1280

**2. Ongoing Strategies**

- 1281 a. Always have a positive attitude and treat all participants in a caring, person-centered
- 1282 manner.
- 1283 b. Thank the families for coming and praise efforts from week to week.
- 1284 c. Treat each participant as an individual and demonstrate respect for cultural practices.
- 1285 d. Emphasize the potential importance of the study in conversations.
- 1286 e. Respect the family's and school's schedule and demonstrate appreciation for their efforts to
- 1287 attend.
- 1288 f. Show consideration for the family's schedule by starting and ending on time.
- 1289

**3. Participation and Retention Benchmarks**

1291

1294  
1295  
1296  
1297  
1298  
1299  
1300  
1301  
1302  
1303  
1304  
1305  
1306  
1307  
1308  
1309  
1310  
1311  
1312  
1313  
1314  
1315  
1316  
1317  
1318  
1319  
1320  
1321  
1322  
1323  
1324  
1325  
1326  
1327  
1328  
1329  
1330  
1331  
1332  
1333  
1334  
1335  
1336  
1337  
1338  
1339  
1340  
1341

**Intervention Participation**

Participants are expected to attend at least 70% or more of their prescribed FBT meetings, as indicated by their level of mastery of program knowledge and skills. The study staff will use a “case management approach” to ensure that each participant’s active involvement is cultivated and tracked, which will include opportunities for make-up sessions, telephone sessions, and home visits to maintain participation.

Families randomized into the UC group will attend medical appointments at the discretion of the physician according to their usual practices and availability, as well as the preferences of the participating family. As such, no benchmarks for usual care visits are specified.

**Assessment Participation**

Retention guidelines indicate that at least 80% of participants who are randomized will be retained at the 24-month assessment. It is estimated that drop-out rates will be higher in the first six months, as a steeper dropout rate was observed in the first four months of the recently completed, NIH funded COMPASS trial, than in the following 20 months. In order to maintain participation in assessment time points, we will offer flexible scheduling, make-up audio sessions, and home visits.

**4. Participant Tracking**

Participants will be tracked in REDCap in order to maximize retention in the study and, as necessary, to capture any drop-outs or withdrawals that occur during the study period. PLAN coaches can verify the status of their FBT families by accessing the REDCap Record Status Dashboard, which will list all existing records/responses and their status (i.e., incomplete or complete) for every data collection instrument in the study. PLAN coaches can verify that FBT families and UC families at their site have completed assessment time points as well as the family members that participated in these assessments. Additionally, PLAN coaches can utilize the REDCap calendar to manage participants and appointments, and they will complete Tracking Forms each week to document session attendance or absence of their FBT families. In order to ensure that families in both arms are captured at all necessary time points, the DCC will send regular reports to indicate participant status and subsequent required actions on behalf of the study team.

**5. Participant Withdrawal or Termination**

Children and parents can withdraw from the research at any time, and siblings and non-participating parents can withdraw or be withdrawn without any consequences to the other family members’ status in the study. If participants withdraw, they will be debriefed about the nature of the study, asked permission to obtain data collection through medical records or brief appointments, and, if terminated, provided with the reason for their removal as well as a referral if deemed appropriate. Any information that had been provided may be retained by the researcher and analyzed. This includes permission to collect body composition information from their physicians at determined measurement time points (if not revoked upon their withdrawal).

Participants who exhibit unhealthy weight loss, clinically concerning symptoms of disordered eating, or develop an illness or condition that would bias the data may be withdrawn from research analyses, as determined by the SEC, SMC, and the Data Safety and Monitoring board (see **section IX**) and referred to an appropriate professional (*This change was made on 3.23.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18*).

1342  
1343  
1344  
1345  
1346  
1347  
1348  
1349  
1350  
1351  
1352  
1353  
1354  
1355  
1356  
1357  
1358  
1359  
1360  
1361  
1362  
  
1363  
1364  
1365  
1366  
1367  
1368  
1369  
1370  
1371  
1372  
1373  
1374  
1375  
1376  
1377  
1378  
1379  
1380

*Lost to Follow-Up for FBT Families (DSMB approved protocol addenda, 9.29.19):* A designation of Lost to Follow-Up (LTF) is applied to intervention families that we have not had contact with for 3 months (90 Days).

- a. During the 3 months after last contact the Coach should:
  - i. Attempt all retention strategies outlined by the retention algorithm (Appendix Z of Manual of Procedures).
    - 1. For instance, handwritten note, text, call (day, evening, and weekend), email, etc.
  - ii. Note: Families going on a scheduled hiatus are NOT LTF.
- b. Once the family is labeled lost to follow up, Coaches will attempt contact them monthly
- c. A family can come back to the study after being marked LTF.
  - i. When an LTF family comes back, re-engagement will include:
    - 1. Review of contact info, alt. contacts, and best methods of contact and time of day.
    - 2. Review of initial motivation for study and link it to why they want to continue.
    - 3. Problem solving barriers to attendance and make plan for future
      - a. Attempt to rebuild momentum.
    - 4. Review weight change during break.

## **Risks to Human Subjects**

### **1. Potential Risks**

Safety of human participants is of utmost concern especially in a trial involving children. Efforts will be made to limit the use and disclosure of participants' personal information, including research study and medical or education records, to people who have a need to review this information. We will collect information on changes in height and weight from medical records as needed if a family discontinues study participation or is unable to provide data at the 24-month time point. The assessment process may carry potential risks. For example, some of the questions may be upsetting to participants, and some participants might feel uncomfortable having their height and weight measured. Other risks associated with participation in the intervention include possibly feeling hungry when dieting or sore after exercising. In addition, in select children, excessive attention paid to dieting may lead to an eating disorder or to growth problems. There are also several potential risks to family members in the course of therapy. First, there is a degree of inconvenience for family members who may miss work, school activities, meetings, etc. Second, there is the risk, as there is in any therapy, of a stress reaction occurring. Third, there may be some family disagreements during the implementation of the intervention as issues of family functioning, communication, and discipline may be discussed.

1381 Finally, there is the risk of a breach of confidentiality. Coach interviews are expected to be no or  
1382 minimal risk of asking the interview questions.

1383

1384 **2. Adequacy of Protection Against Risks**

1385 All key personnel involved in the design or conduct of research involving human subjects will  
1386 receive the required education on the protection of human research participants prior to the  
1387 start of the study. The PLAN coaches will collect and manage data collected from these  
1388 participants and will not engage the pediatricians in the research. If required by a site's  
1389 individual IRB, PLAN coaches will complete Business Associate Agreements prior to their work  
1390 within the practices.

1391

1392 Individuals administering assessments will be made aware of the possibility of a participant's  
1393 discomfort about answering questions or having height and weight measured. Participants will  
1394 be informed that they do not have to answer any questions that make them uncomfortable, and  
1395 height and weight will be measured in private to minimize embarrassment. Participants will be  
1396 advised of the possibility of hunger with dieting or soreness after exercise. In order to reduce  
1397 the risk of exercise-related injury, all participants will be encouraged to follow their primary care  
1398 physician's instructions regarding exercise.

1399

1400 On an ongoing basis, the family meetings will serve as the primary venue to detect and address  
1401 any eating disturbance, and study PLAN coaches will be trained to monitor, recognize, and  
1402 intervene if symptoms of disordered eating behaviors or attitudes emerge. If a PLAN coach  
1403 notices that a participant is consuming a nutritionally inappropriate quantity or quality of foods,  
1404 he or she will assist the participant in achieving appropriate intake. Should a participant show  
1405 symptoms consistent with an eating disorder during treatment, the PLAN coach, in consultation  
1406 with the treatment supervisor at the Training and Fidelity Core, will decide whether to  
1407 recommend that the family be withdrawn from treatment and/or refer them for treatment  
1408 elsewhere. This will be stated in the consent form.

1409

1410 To the extent possible, flexibility in scheduling treatment sessions and assessments will help  
1411 minimize the inconvenience of missing work, school activities, or meetings due to treatment  
1412 obligations. Having expert and well-supervised PLAN coaches conduct treatments will mitigate  
1413 the risk of a stress reaction occurring. The PLAN coaches will be aware of how to recognize such  
1414 stress responses in their early form, and will conduct sessions in such a way as to reduce such  
1415 responses. PLAN coaches will also be trained to deal with potential family disagreements. If any  
1416 participant appears to be in crisis, appropriate action will be taken based on established suicide  
1417 and crisis assessment protocols, and any adverse event will be reported promptly to NIMH and  
1418 to the IRB of Record.

1419

1420 **3. Confidentiality**

1421 Patient confidentiality will be maintained in compliance with HIPAA regulations. Any identifying  
1422 information will be kept confidential, and patient records will be kept in locked files protected  
1423 by two locks and accessible only by those directly involved with the implementation of the  
1424 study. The locked files will be housed in the clinical site PI's office at each site, and no data, files,  
1425 or any other study participant information will leave these offices. Treatment session audio  
1426 recordings will be securely stored at each center, and will be labeled by study ID, date and  
1427 session number, without further identifiers. These recordings will be stored in locked cabinets  
1428 with restricted access and will be destroyed three years after the end of the study, depending

1429 on the policy set by the Study Executive Committee and the IRB of record. Copies of selected  
1430 session audio recordings, labeled as above, will be sent to the Training and Fidelity Center at WU  
1431 for auditing.

1432 All coach interview audio files will be stored in a double password protected computer and a de-  
1433 identified file name. The audio files will be transcribed using Amazon Transcribe, once this is  
1434 completed the audio files will be destroyed. The transcription file will be de-identified and also  
1435 stored in a double password protected computer.

1436  
1437 All materials, discussions, and proceedings of the Data and Safety Monitoring Board (DSMB) are  
1438 completely confidential, and members and other participants in DSMB meetings are expected to  
1439 maintain confidentiality. All employees of the study with access to protected health information  
1440 are required to complete HIPAA and CITI training and comply with the privacy procedures in  
1441 place at their institutions.  
1442

### 1443 **Potential Benefits to Human Subjects and Others**

1444 The prevalence of overweight in both children and adults has been increasing at an alarming rate.  
1445 Effective treatments for childhood obesity have the potential to provide substantial health benefits  
1446 and to decrease the number of children tracking obesity into adulthood. Although we do not  
1447 guarantee any benefits from this study, the intervention, if successful and if it replicates our  
1448 previously completed studies, has several potential benefits. Potential benefits to participants  
1449 include improved physical health, improvements in the quality of nutritional intake, increases in  
1450 physical activity, reduction in body weight, and long-term maintenance of this reduced body weight.  
1451 The treatment may also reduce the stress on the family posed by the burden of obesity. In addition,  
1452 it is possible that skills to solve ongoing problems that perpetuate obesity may improve. The  
1453 growing prevalence of obesity and its health-related consequences highlight the need to examine  
1454 potential treatments that may help children to lose weight and sustain weight loss over time, and to  
1455 investigate the effectiveness of providing these treatments within primary care settings. Therefore,  
1456 the potential risks that are associated with this study are reasonable when considering the many  
1457 health-related benefits that the participants and their families may gain. Coach interviews has no  
1458 benefits to the coaches. Potential benefits to researchers include: detailed accounts of discussions  
1459 of food cost and perception between PLAN FBT coaches and families, direct discussions with  
1460 coaches (implementers of the treatment intervention), and a deeper understanding of  
1461 when/how/why coaches tailor pieces of the treatment.  
1462  
1463

## 1464 **II. Data Safety and Monitoring Plan**

### 1465 **Safety Oversight**

1466 An independent panel of experts with experience in clinical trials, health services research,  
1467 biostatistics, and pediatric and adult obesity, consisting of at least three members who are not  
1468 affiliated with the study – including a clinician with expertise in childhood obesity, an  
1469 epidemiologist, and a patient advocate – will be appointed to constitute a DSMB. Members  
1470 named include study staff and a representative of NIH. In addition, the study PIs, Drs. Leonard  
1471 Epstein and Denise Wilfley, the director of the DCC, Dr. Ken Schechtman, and designated staff  
1472 will attend the DSMB meetings (as non-voting participants) and will be responsible for preparing  
1473  
1474

1475 and presenting data reports from the study. The DSMB will provide oversight and ongoing  
1476 monitoring of participant safety, recruitment and retention rates, quality of data collection, and  
1477 integrity of the study and will convene during the first 3 months of the study to allow for a full  
1478 review of the study protocol. The study data will be reviewed by the DSMB every 6 months via  
1479 teleconference or more frequently if preferred by the DSMB. The DSMB will receive a report  
1480 from the study DCC approximately 4 weeks before each review date. These reports will include  
1481 the major variables necessary for monitoring safety and quality of data collection and integrity  
1482 of the study and will include otherwise blinded outcome data. Because study protocol and  
1483 consent forms are relevant to the safety and quality of data, the DSMB will also review these  
1484 documents before the onset of the study. Based on this review, the DSMB will possess the  
1485 authority to prevent the study from starting or to recommend that the study be stopped after it  
1486 has begun. The DSMB will prepare a report based on the material received from the DCC, which  
1487 will be forwarded to the PIs to review at study executive committee meetings and also to be  
1488 forwarded to the IRB of Record, as well as project officer, by Dr. Epstein.  
1489

1490 **1. Safety Monitoring Committee**

1491 First, we have established an internal Safety and Monitoring Committee (SMC) to oversee the  
1492 assessment and reporting of adverse events (AE), serious adverse events (SAE), and  
1493 unanticipated problems (UP). This committee, which will be chaired by Dr. Teresa Quattrin, will  
1494 regularly review reports of AEs, SAEs, and unanticipated problems in collaboration with the  
1495 DSMB. Additional members include Rebecca Campo, PhD.  
1496

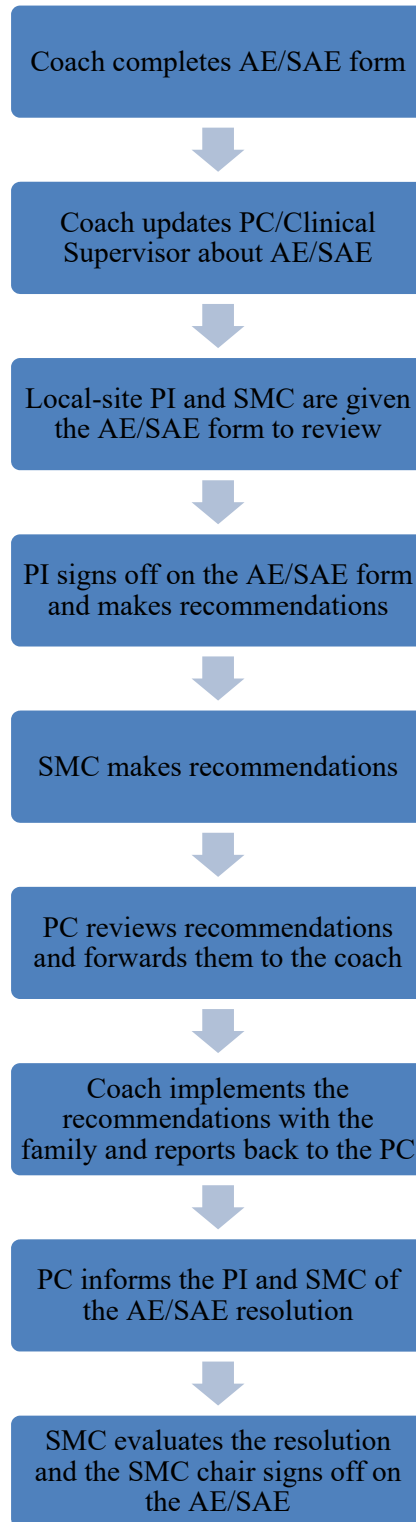
1497 Should a member of the study staff become aware of a possible AE, SAE, or UP (see section IX.D  
1498 in the study protocol), s/he will notify the clinical site PI, local site PI, and PC with a detailed  
1499 email summarizing the event (*This change was made on 3.23.18 prior to review and approval by*  
1500 *the DSMB, DSMB approved protocol addenda on 11.2.18*), complete an Adverse Event Form or  
1501 Serious Adverse Event Form, and as recommended by the site PI and PC contacts the SMC. The  
1502 local site PI will sign off on the AE/SAE and will forward this and a recommendation for action to  
1503 the Safety Monitoring Committee (SMC). Each site PI will make sure that the AE/SAE is reported  
1504 to the IRB within the allotted time frame (*DSMB approved protocol addenda, 3.18.19*). The SMC  
1505 will then evaluate the severity of the event and determine the necessity for immediate action on  
1506 behalf of the study group. If immediate action is necessary, the SMC will consult with the  
1507 Steering Committee to recommend a course of action. If immediate action is not necessary, the  
1508 event will be documented in the study database and discussed at the next scheduled DSMB  
1509 meeting. The PC will review any recommendations from the SMC and/or local-site PI and  
1510 forward them to the coach. The Coach will implement the recommendations with the family and  
1511 report the outcome back to their site PC. The PC then informs the PI and SMC of the AE  
1512 resolution. After the AE/SAE and event resolution is reviewed, the chair of the SMC will sign off  
1513 on all AEs/SAEs (see Figure 1; *DSMB approved protocol addenda, 9.29.19*). Additionally, the DCC  
1514 will prepare monthly reports that summarize adverse events and assess whether there is  
1515 evidence of a between group difference in AE and SAE rates.  
1516

1517 All serious adverse events will follow an expedited reporting timeline, which includes  
1518 immediately notifying all participating IRBs through the designated PIs in accordance with OHRP  
1519 guidance.  
1520

1521 Lastly, all AEs, SAEs, UPs, and study withdrawals will be forwarded to the DSMB accompanied by  
1522 a detailed explanation according to the timeline in Table 10 of the study protocol. The DSMB will

1523 ensure that all corrective and/or preventative action plans have been appropriately  
1524 implemented.  
1525  
1526

**Figure 1. Internal AE/SAE Reporting Procedures** (*DSMB approved protocol addenda, 9.29.19*)





1531  
1532  
1533  
1534  
1535  
1536  
1537  
1538  
1539  
1540  
1541  
1542  
1543  
1544  
1545  
1546  
1547  
1548  
1549  
1550  
1551  
1552  
1553  
1554  
1555  
1556  
1557  
1558  
1559  
1560  
1561  
1562  
1563  
1564  
1565  
1566  
1567  
1568  
1569  
1570  
1571  
1572

**Specification of Safety Parameters**

**1. Adverse Events**

For the purpose of this study, an adverse event (AE) will be defined as any untoward or unfavorable occurrence (e.g., symptom, sign, or disease) that is temporally associated with a subject’s participation in the study, whether or not it is related to participation.

**2. Serious Adverse Events**

For the purpose of this study, a serious adverse event (SAE) will be defined as any untoward occurrence that results in death, is life threatening, requires hospitalization or prolongs existing hospitalization, or creates persistent and significant disability.

**3. Unanticipated Problems**

For the purpose of this study, an unanticipated problem (UP) will be defined as any event that is unexpected, is related or possibly related to participation in the research study, and suggests the research places participants or others at a greater risk of harm than was previously known or recognized.

**Classification of Adverse Events**

**1. Severity**

AEs will be assessed for severity and can thereby be classified as mild, moderate, or severe in nature. Mild AEs require minimal or no treatment and do not interfere with the participant’s daily activities. Moderate AEs result in a low level of inconvenience or concern with the therapeutic measures and may cause some interference with functioning. Severe AEs interrupt a participant’s usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.

**2. Relatedness**

AEs will be assessed for their relatedness to the procedures involved in the research study and can thereby be classified as: (1) definitely related, (2) possibly related, or (3) not related (see Table 8 and 9; *DSMB approved protocol addenda, 9.29.19*).

**3. Expectedness**

Expectedness will be assessed in terms of the event’s nature, severity, and frequency. Events are considered unexpected when they are not listed in the protocol and consent forms *or* are not listed at the specificity or severity that has been observed (see Table 8 and 9; *DSMB approved protocol addenda, 9.29.19*).

1573  
1574

**TABLE 8. Adverse Events Determination Table** (DSMB approved protocol addenda, 9.29.19).

<b>Classification</b>	<b>Adverse Events</b>	<i>Expected</i>	<b>Relatedness*</b>
Physical Activity	Broken Bones/Fractures	X	(Possibly) Related
	Bruising	X	(Possibly) Related
	Concussion	X	(Possibly) Related
	Cuts	X	(Possibly) Related
	Joint Swelling/Pain/Sprain	X	(Possibly) Related
	Muscle Pulls	X	(Possibly) Related
	Tendonitis	X	(Possibly) Related
	Shin Splints	X	(Possibly) Related
	Sprains	X	(Possibly) Related
	Strains	X	(Possibly) Related
	Soreness	X	(Possibly) Related
	Asthma Exacerbated during PA	X	(Possibly) Related
Mental Health	Eating Disorders: Not present before study enrollment	X	(Possibly) Related
	Loss of Control: Due to external causes		Not Related
	Loss of Control: No external causes mentioned	X	(Possibly) Related
	Emotional outbursts during sessions	X	(Possibly) Related
	General anxiety or depression due to external causes		Not Related
	Anxiety or Depression with any mention of the study	X	(Possibly) Related
	Extreme depression or suicidal idealization		(Possibly) Related

1575  
1576

1577 **TABLE 9. Very Common Pediatric Events Table** (DSMB approved protocol addenda, 9.29.19).  
 1578

Very Common Pediatric Events	Expected	Relatedness
Abdominal pain and/or vomiting and/or diarrhea for ≤48 hours	X	Not Related
Allergic/seasonal rhinitis	X	Not Related
Cold or URI	X	Not Related
Ear infection	X	Not Related
Influenza and flu-like symptoms	X	Not Related
Pharyngitis/tonsillitis	X	Not Related
Worsening of asthma symptoms <b>not</b> related to physical activity in patient with known asthma or reactive airway Disease (RAD) <b>and</b> NOT requiring pediatrician or ED visit	X	Not Related
Note: The SMC created a list of very common pediatric events to account for AEs that typically occur within the target population regardless of study participation.		

1579  
 1580  
 1581  
 1582  
 1583  
 1584  
 1585  
 1586  
 1587  
 1588  
 1589  
 1590

**Adverse Event Assessment and Tracking**

The occurrence of an adverse event (AE), serious adverse event (SAE), or unanticipated problem (UP) may come to the attention of research staff during treatment sessions, assessment visits, or other participant contact (e.g., scheduling phone call or e-mail). PLAN coaches and assessors will be made aware of possible expected events, including: adverse emotional experiences (e.g., discomfort, embarrassment), or stress, hunger with dieting, soreness after exercise, and emergence of potential eating disordered attitudes or behaviors. As outlined in Adequacy of Protection Against Risks (VIII.C.2), measures will be in place to reduce the likelihood of these events occurring.

To account for differences in the frequency of participant contact between the two study groups, blinded measurement staff will systematically assess for AEs in both the intervention and control groups through use of a standardized questionnaire (see MOP) that is administered at each major assessment time point. If any items are endorsed on the questionnaire, the blinded measurement staff will gather additional information and, if necessary, follow the steps for recording and reporting adverse events outlined below and in section IX.E. AEs uncovered in the course of treatment will also be subject to the procedures below. Combining between visit and at visit AEs will result in an alternative count that the DSMB requested. This alternative count will be comprised of all AEs, whether reported at or between visits. Blinded coaches will be unaware if an AE was reported between visits, and any duplicates will be removed by an unblinded reviewer (*Pending DSMB Approval*)

All AEs, including those not meeting the criteria for SAEs, will be captured on an Adverse Event Form or Serious Adverse Event Form (see **Appendix D**), which must be approved of and signed by the clinical site PI. Information to be collected includes event description, time of onset (and offset if applicable), assessment of severity, relationship to study treatment, expectedness, actions taken,

1607 and outcome of the event. Additionally, all SAEs will require categorization (e.g., death,  
1608 hospitalization, permanent impairment, etc.) and documentation of any interventions implemented  
1609 in response to the event.

1610  
1611 All AEs occurring during a participant’s study participation must be documented appropriately  
1612 regardless of relationship. All AEs will be followed by the DSMB to adequate resolution and will be  
1613 recorded in the data collection system. Any medical condition that is present at the time that the  
1614 participant is screened will be considered as baseline and not reported as an AE. However, if the  
1615 study participant’s condition deteriorates at any time during the study, it will be recorded as an AE.  
1616 Changes in the severity of an AE will be documented to allow for an assessment of the duration of  
1617 the event at each level of severity. AEs characterized as intermittent require documentation of  
1618 onset and duration of each episode.

1619  
1620 The clinical site PIs will record all reportable events with start dates occurring any time after  
1621 informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of  
1622 study participation. Events will be followed by the DSMB for outcome information until resolution or  
1623 stabilization.

1624  
1625 It is important to note that in previous similar clinical trials in the PIs’ respective laboratories, the  
1626 procedures outlined above have been used to protect against and minimize potential risks to  
1627 participants, and they have proved effective in preventing emotional and physical complaints as well  
1628 as adverse events.

1629  
1630 Due to the fluid situation of COVID-19, 3 additional questions have been added to the AE  
1631 questionnaire. Asking these questions could give us data on the effects of the pandemic and could  
1632 help explain changes in FBT attendance and assessment retention.

- 1633  
1634 i. Do you have a positive COVID-19 test?  
1635 ii. Did you have exposure to someone with a known positive COVID-19 test?  
1636 iii. Did you need to get tested for COVID-19?

1637  
1638 (Pending DSMB approval)

1639  
1640  
1641 **Adverse Event Reporting Procedures**

1642 Upon initial receipt of information, all fatal or life-threatening suspected serious adverse events will  
1643 be immediately reported to the IRB of Record, internal IRBs, NHLBI, SMC, and DCC via Dr. Epstein  
1644 and the clinical site PIs. All non-fatal, non-life-threatening suspected SAEs will be reported within 15  
1645 calendar days to the IRB of Record, internal IRBs, NHLBI, SMC, and DCC via Dr. Epstein and the  
1646 clinical site PIs. Any unanticipated problems that do not classify as SAEs will be reported within 14  
1647 days of the investigator becoming aware of the problem to the IRB of Record, internal IRBs, NHLBI,  
1648 SMC, and DCC via Dr. Epstein and the clinical site PIs. All UPs will also be reported within 30 days of  
1649 the IRB’s receipt of information to the Office for Human Research Protection via the IRB. Non-  
1650 serious adverse events will be documented in the study database following their occurrence and will  
1651 be reported annually to the IRB of Record and internal IRBs via Dr. Epstein and the clinical site PIs.  
1652 See Table 6 for a detailed outline of reporting timelines.

1653

1654 Adverse event questionnaires and reporting forms are included in Appendix D of the study protocol.  
1655 Once a site’s research staff becomes aware of an adverse event’s occurrence, that staff (i.e., PLAN  
1656 coach or assessor) will consult with the clinical site PI or project coordinator to complete the  
1657 appropriate event form and notify the SMC. Adverse event questionnaires will only be administered  
1658 after assessment measurement by blinded measurement staff, who will correspondingly complete  
1659 an adverse event log (10.12.20; pending DSMB approval). The SMC will then evaluate the severity of  
1660 the event and determine the necessity for immediate action on behalf of the study group. If  
1661 immediate action is necessary, the SMC will consult with the Steering Committee to recommend a  
1662 course of action (e.g., discontinuation of treatment, referral to higher level care). If immediate  
1663 action is not necessary, the event will be documented in the study database and discussed at the  
1664 next scheduled DSMB meeting. Additionally, the DCC will prepare monthly reports that summarize  
1665 adverse events and assess whether there is evidence of a between group difference in AE and SAE  
1666 rates.

1667  
1668 All adverse events and study withdrawals, together with a detailed explanation of the event and  
1669 withdrawal, will be forwarded to the DCC and the DSMB. In addition, at its regular meeting, the  
1670 DSMB will summarize all adverse events of any severity, to be forwarded to the IRB via the  
1671 designated PI. All serious adverse events will be immediately recorded by the clinical site PI and  
1672 reported to the IRB and DCC, via the designated PI; information (i.e., event, actions, and implications  
1673 for study) will then be distributed to the other clinical sites. Any SAEs and AEs that are judged to be  
1674 possibly or probably related to participation in the study and/or change their assessment of risk of  
1675 participation will be immediately reported to the DSMB. The remaining SAE/AEs will be sent to the  
1676 DSMB with the 6 month reports (**DSMB approved protocol addenda, 3.18.19**). If any participant  
1677 appears to be in crisis but the event is not classified as an SAE, appropriate action will be taken  
1678 based on established suicide and crisis protocols, and any adverse event will be reported promptly  
1679 to the DSMB and IRB.

1680  
1681 In addition to the existing procedures referenced above, the SMC recommends that as soon as child  
1682 mental health SAEs are reported, to a coach or a PLAN staff designee verbally informs the  
1683 participants’ primary care provider and/or pediatric office staff designee with the description of the  
1684 SAE, date, and referral so that they may follow-up according to their office procedure. Specifically, if  
1685 a child enrolled in the study reports self-injury, a suicide attempt, or harm to others, then this will be  
1686 addressed as a SAE and reported verbally to the pediatrician. The event will be reported by the  
1687 individual with the most amount of information within 24 business hours of learning about the  
1688 event. If a medical, behavioral, or mental health intervention is deemed necessary to address this  
1689 event, it is the pediatrician’s responsibility to follow up with their patient to ensure appropriate care  
1690 is provided. Before this procedure goes into effect, the PLAN coach will communicate this plan with  
1691 each pediatric practice to develop a practice-specific protocol with who to contact and how. In the  
1692 event that a coach is unsure about the severity of the child mental health AE, they will collaborate  
1693 with the local-site PI to determine the severity of the event and whether or not it should be  
1694 reported to the pediatric office. All other mental health AEs will not be reported to the pediatrician,  
1695 but will be reported to the IRB and DSMB as part of normal reporting procedures (**DSMB approved**  
1696 **protocol addenda, 11.18.19**).

1697  
1698 If a parent becomes pregnant, the PLAN coach will notify the clinical site PI and all weight loss  
1699 treatments will be stopped. The family’s continuation in the study will be limited to the child,  
1700 siblings and non-participating parent if enrolled. The DCC, DSMB, and IRBs will be notified through

1701 AE reports and a standard form for excluding participants from further data collection and  
 1702 treatment. Please see **Table 10** below for further details regarding AE reporting.

1703  
 1704  
 1705

**TABLE 10. Adverse Event Reporting Guidelines**

What Event is Reported	When is Event Reported	By Whom	To Whom
Fatal or life-threatening unexpected, suspected serious adverse event	Immediately upon initial receipt of information	Contact PI	<ul style="list-style-type: none"> <li>• IRB of Record</li> <li>• NHLBI</li> <li>• SMC</li> <li>• DCC</li> <li>• All PIs and Co-Is</li> </ul>
		Clinical Site PIs	<ul style="list-style-type: none"> <li>• Internal IRBs</li> </ul>
Non-fatal, non-life-threatening unexpected, suspected serious adverse event	Within <b>15 calendar days</b> of initial receipt of information	Contact PI	<ul style="list-style-type: none"> <li>• IRB of Record</li> <li>• NHLBI</li> <li>• SMC</li> <li>• DCC</li> <li>• All PIs and Co-Is</li> </ul>
		Clinical Site PIs	<ul style="list-style-type: none"> <li>• Internal IRBs</li> </ul>
Unanticipated problem that is not an SAE	Within <b>14 days</b> of the investigator becoming aware of the problem	Contact PI	<ul style="list-style-type: none"> <li>• IRB of Record</li> <li>• NHLBI</li> <li>• SMC</li> <li>• DCC</li> <li>• All PIs and Co-Is</li> </ul>
		Clinical Site PIs	<ul style="list-style-type: none"> <li>• Internal IRBs</li> </ul>
All unanticipated problems	Within <b>30 days</b> of the IRB's receipt of the report of the UP from the investigator.	IRB	<ul style="list-style-type: none"> <li>• OHRP</li> </ul>
		Contact PI	<ul style="list-style-type: none"> <li>• IRB of Record</li> </ul>
		Clinical Site PIs	<ul style="list-style-type: none"> <li>• Internal IRBs</li> </ul>
All non-serious AEs that are not UPs	Documented in study database and reported annually	Contact PI	<ul style="list-style-type: none"> <li>• IRB of Record</li> </ul>
		Clinical Site PIs	<ul style="list-style-type: none"> <li>• Internal IRBs</li> </ul>

1706 **Study Halting Rules for Participant Safety**

1707  
 1708  
 1709  
 1710  
 1711  
 1712  
 1713  
 1714  
 1715  
 1716  
 1717  
 1718

There are few risks to family-based behavioral interventions. The intervention focuses on improving child and parent health behaviors through behavioral strategies and improved parenting and parent/child relations. The main risks are development of disordered eating or psychopathology and risks due to a sedentary person beginning to exercise. We will be carefully monitoring participants for excess weight loss, psychopathology, and activity-induced injuries. Although we expect that there will be very few serious adverse events, we will employ the following stopping guideline based on the number of SAEs in the intervention group. The guideline is summarized in **Table 11**, which provides data for maximum acceptable SAE rates of 2%, 4%, 6%, 8%, and 10% and for observed numbers of SAEs of 2, 3, 4, and 5. **Table 11** is calculated using 1-sided 95% binomial confidence intervals and can be interpreted as presenting the maximum total sample size N that is required in order to conclude that the toxicity level of the intervention may be excessive for a given number of

1719 observed SAEs and a given defined acceptable SAE rate. For example, suppose we define 2% as the  
 1720 maximum acceptable SAE rate. Then **Table 11** indicates that if the third SAE occurs in fewer than 41  
 1721 intervention group subjects, then the guideline will have been exceeded because the SAE rate is  
 1722 greater than the acceptable 2% value with 95% certainty.

1723  
 1724 **TABLE 11. MAXIMUM ACCEPTABLE SAE RATES**

Number of Observed SAEs	Maximum Acceptable SAE Rate				
	2%	4%	6%	8%	10%
2	18	9	6	4	3
3	41	21	14	10	8
4	69	34	23	17	14
5	99	50	33	25	20

1726  
 1727 Several points about the above discussion are worth mentioning. First, we have used the term  
 1728 “guideline” instead of “rule” because we view the decision making process as one in which the  
 1729 guideline triggers a multifaceted discussion with the DSMB of whether the study should be stopped  
 1730 or modified because of the observed SAE rate. We do not view reaching the stopping boundary as a  
 1731 rule that should automatically lead to the termination of the study. Second, the rule will be applied  
 1732 both to parents and children separately. Third, we propose setting 2% as the maximum acceptable  
 1733 SAE rate because of the low anticipated SAE rate in this study.

1734  
 1735 At each DSMB meeting, recruitment and retention data will be presented to the DSMB. If  
 1736 recruitment is less than 90% of the target or if retention is less than 80% among randomized  
 1737 subjects, study investigators will present proposals for improvements in each of these two domains.  
 1738 Note that we use an 80% figure for retention because the original power computations had  
 1739 assumed a 20% dropout rate. Thus, an 80% retention rate is not an indication of reduced statistical  
 1740 power. If under performance by these definitions in either of these domains is present, the DCC will  
 1741 perform conditional power computations based on various scenarios regarding the degree of  
 1742 improvement that can be anticipated in recruitment and/or retention. As was the case in our  
 1743 original power computations, we will adopt the conservative approach of assuming that study  
 1744 dropouts provide no data. We propose that early termination be considered if the conditional  
 1745 power under the recruitment/retention scenarios the DSMB views as most realistic is less than 50%.  
 1746 Any final decision about recommending early termination will consider factors such as the impact of  
 1747 early stopping on information about secondary endpoints and covariate effects. It will also consider  
 1748 the adequacy of the measures that are proposed to increase recruitment and retention.

1749  
 1750 **II. Data Processing and Management**

1751  
 1752 A central focus of the DCC will be on the development and testing of a secure web based data entry and  
 1753 management system. In the sections that follow, we discuss the REDCap system that will serve our  
 1754 needs in this domain.

1755  
 1756 **REDCap**

1757 Data management will be accomplished using REDCap, a secure password protected and HIPAA  
 1758 compliant web-based system developed at Vanderbilt University that has become a workhorse for  
 1759 Clinical and Translational Science Awards around the country, has served as the data entry system of

1760 choice for more than 1400 research projects at Washington University, and has become a standard  
1761 data entry and management tool for the Division of Biostatistics. REDCap facilitates a variety of  
1762 quality control procedures such as drop down menus for categorical variables, range checks, and  
1763 skip logic. It also facilitates automated transfer to SAS where further quality control procedures will  
1764 be implemented and through which queries will be generated when errors or inappropriately  
1765 missing data are identified.

1766

### 1767 **Testing the Data Management System**

1768 After REDCap data entry screens have been created and before data entry personnel have entered  
1769 any test forms, the first step in testing the system will be internal to the DCC where at least three  
1770 sets of draft forms will be completed and entered into REDCap. The data will then be transferred to  
1771 SAS datasets and item by item comparisons between forms and SAS printouts will be performed.  
1772 The preliminary test forms will intentionally contain outlying and missing observations to confirm  
1773 that range checks and requirements for completing certain fields are functioning properly. A second  
1774 level of testing which will precede the enrollment of subjects will occur when data entry personnel  
1775 are asked, as part of their training and certification, to enter data from all data forms on at least  
1776 three individuals. In addition to confirming the convenience and completeness of the data entry  
1777 screens, these procedures will evaluate all components of the data management process ranging  
1778 from edit checking, to skip logic in REDCap, to the automated transfer of REDCap data to SAS, to the  
1779 correctness of the programs we write to create and store the SAS datasets. These procedures will be  
1780 closely integrated with searches for ambiguous wording, the training of data entry personnel, and  
1781 the modification of an original set of draft forms into a final version.

1782

### 1783 **Data Security and Confidentiality**

1784 Standard features of REDCap and automated procedures of the Division of Biostatistics provide a  
1785 high degree of certainty that subject confidentiality will be maintained and that data will never be  
1786 lost. In accordance with the two key HIPAA requirements, password protection will be required for  
1787 access to study computers and REDCap. Only authorized personnel will have access to the data  
1788 entry system and access will be restricted to data from one's own clinic. Data entered into REDCap  
1789 are encrypted when transferred to SAS. Standard security and confidentiality measures at the DCC  
1790 include requiring that employees sign confidentiality agreements, that personal identifiers are  
1791 included in electronic databases only under strong necessity, and that encryption is used when  
1792 identifiers are present in SAS datasets. Access to our Division computers is restricted to our faculty,  
1793 staff, and collaborators. Access to accounts that store data from this study will be restricted to DCC  
1794 personnel and the division's network manager. All file transfers to outside computers use secure  
1795 transfer methods which ensure that all such traffic is encrypted. The entire network wiring plant  
1796 within the Division is behind a firewall and is contained within space physically controlled by us.  
1797 Access to all computers and to REDCap is automatically logged.

1798

### 1799 **Forms and Datasets Manual**

1800 All data entered into REDCap will be transferred to SAS using automated procedures for use in  
1801 future data analyses and reports. Each dataset in the database will contain labels and formats. To  
1802 facilitate use of this database, the DCC will prepare and maintain a detailed "Forms and Datasets  
1803 Manual", an easy-to-use roadmap for finding the dataset where a particular data item is stored. The  
1804 key component of the manual will be a codebook which contains an alphabetical list of all variable  
1805 names in the entire database, with associated labels and formats for each variable. The codebook  
1806 will also contain the name of the dataset in which each variable is stored. In addition to the  
1807 codebook, the Forms and Datasets Manual will include detailed contents of each dataset, a



1808 comprehensive set of data forms with variable names next to each entry, and a format library. We  
1809 routinely use such manuals in large studies for a variety of reasons, the most important being that  
1810 they greatly facilitate data management and analysis by making it very easy to find where in a large  
1811 database an item on a particular form is stored.  
1812

1813 **Archiving Data**

1814 All data will be archived for long-term storage when the study is completed and datasets are  
1815 cleaned and closed. Decisions regarding the timing and procedures that determine eventual public  
1816 access to datasets will be made in accordance with institute guidelines. All publically accessible  
1817 datasets will first be de-identified using the confidentially principles mandated by HIPAA.  
1818

1819 **Quality Control**

1820 We have a broad view of quality control in clinical research as a multifaceted process that addresses  
1821 concerns such as the accuracy and completeness of computerized data, the common administration  
1822 of protocols across sites, monitoring adherence to protocol requirements, and the training and  
1823 certification of personnel. Other quality control measures we will implement include:  
1824

1825 **1. Data Accuracy and Completeness**

1826 REDCap has a number of built-in quality control features that help ensure accurate and  
1827 complete data and that are accomplished at the clinics when the data are entered. Other quality  
1828 control measures involve actions taken at the DCC, features of the data forms that help facilitate  
1829 high quality data, and steps taken at the clinic as data forms are completed. We already noted  
1830 that the system keeps a log of who entered or changed all data, a feature which permits us to  
1831 discuss with the data enterer any concerns we have about a particular data item. Other quality  
1832 control measures that will help ensure accurate and complete data include:  
1833

- 1834 a. Double data entry of selected forms where complete accuracy is judged to be most  
1835 critical to the study.
- 1836 b. Range checks will flag values that are outside a predefined acceptable range.
- 1837 c. Accept only a predefined set of values for categorical measures.
- 1838 d. All data forms will contain the identification number of the person who completed the  
1839 form, facilitating easy access to the source if there are legibility or other problems with a  
1840 form.
- 1841 e. Forms will frequently have a “not done” option so the associated missing data will be  
1842 understood as appropriate.
- 1843 f. Investigators and study coordinators will be expected to do visual checks of all  
1844 completed forms to confirm legibility, completeness, and reasonableness as each form  
1845 is filled out.

1846  
1847 Our strategy in the first item above of using double data entry for only those forms that contain  
1848 the most critical data is based both on our own experience and a literature that supports this  
1849 approach. Studies suggest that the number of errors that are detected by double data entry in a  
1850 well conducted study is 4-10 per 10,000 key strokes, with range checks detecting about half of  
1851 randomly introduced errors.<sup>57,58</sup> Moreover, analytic results are extremely robust to small  
1852 random error rates.<sup>59</sup> Based on these considerations and out of concern for the resource  
1853 expenditure that is required of double data entry, our longstanding approach has been to  
1854 employ this approach only for those variables and data forms that are most critical to the study.  
1855

1856  
1857  
1858  
1859  
1860  
1861  
1862  
1863  
1864  
1865  
1866  
1867  
1868  
1869  
1870  
1871  
1872  
1873  
1874  
1875  
1876  
1877  
1878  
1879  
1880  
1881  
1882  
1883  
1884  
1885  
1886  
1887  
1888  
1889  
1890  
1891  
1892  
1893  
1894  
1895  
1896  
1897  
1898  
1899  
1900  
1901  
1902  
1903

**2. Data Audits**

The DCC will conduct an annual item by item random audit of 10% of data. Logistical considerations will determine whether the audit will be performed during site visits or by the Project Manager at the DCC using requested copies of forms. Every item on the forms will be compared with computerized data and clinic specific error rates will be recorded. We will confirm that changes on forms have been initialed and documented, and all identified problems will be discussed with clinic personnel and, if necessary, with the Steering Committee. Following each audit, a detailed report will be distributed to all clinics. Audits will be timed as feasible to precede meetings of the DSMB so we can respond to questions about data quality.

**3. Quality Control of Forms and Data Entry System**

Section B above discussed the procedures for testing the data management system at the DCC itself. Closely integrated with those efforts will be approaches to field testing the data entry system, training data entry personnel, and ensuring that the wording of forms is unambiguous. To these ends, the following activities will precede enrollment of the first subject.

- a. Staff at each clinic will enter data from one set of draft forms in a formal search for ambiguous wording.
- b. Data collection personnel will collect data on two “practice” subjects (who may be friends or colleagues) with a view towards getting the outsiders view of ambiguity so we can subsequently modify the forms as needed. Outlying data values will be encouraged so they can be used in familiarizing data enterers with the quality control components of the data management system.
- c. Data collection personnel will test the relevant forms on two “real” subjects. These subjects will not become part of the study even though they may be technically eligible.
- d. The forms collected from the “practice” and the “real” subjects will be entered into REDCap to confirm the familiarity of data entry personnel with the system, as a test of the system itself, and as part of the certification process discussed.
- e. After these procedures yield potential modifications of the draft forms, the DCC will modify the REDCap screens and will perform a final set of internal tests focused on ensuring that any needed modifications have been correctly incorporated into the revised system.
- f. To facilitate the above series of sequential steps, the DCC and Steering Committee will develop a timeline for completing tasks, and the DCC will send reminders to relevant personnel as deadlines approach.

**4. Summary Reports**

The DCC will prepare summary reports of study progress in response to requests by the Steering Committee and the DSMB. It will also prepare regular reports which, using automated features to be built into our SAS database, will consider such issues as (1) recruitment rates, (2) the proportion of recruited subjects who are eligible, (3) missing form and data rates, (4) the time interval between completing a form and entering it on the computer, (5) compliance rates, and (6) adverse event rates. These reports will, with the exception of adverse events, be updated monthly and made available online through the study website. Because they will be site-specific as well as aggregate in their presentation, the reports will contribute significantly to our quality control efforts as they will help identify areas of inadequate performance at clinics. Although experience suggests that adverse events will be relatively uncommon in a behavioral study such as this, the adverse event report will differ from other reports in that severe events that may be

1904 study related will be reported within 72 hours to the IRB of Record and to the chair of the  
1905 DSMB.

### 1906 5. Site Visits

1908 The DCC will organize annual site visits to all clinics that will focus on a detailed review of study  
1909 procedures. Special additional site visits may occur if routine quality control measures  
1910 determine that a clinic is having difficulty with some aspect of the protocol. Site visitors will  
1911 prepare an agenda that will include observations of the performance of study procedures and of  
1912 the filing system that is used to store completed data forms. They will confirm that data forms  
1913 are correctly filed, that IRB approvals are available, and that changes on forms are appropriately  
1914 initialed and dated by the person who made the changes. In addition, site visitors may do  
1915 random data audits in accordance with section X.F.2. Site visits will generally be conducted by a  
1916 DCC staff person and by an investigator from another clinic.

## 1917 III. Statistical Considerations

### 1918 A. Statistical Analysis Plan

1919 Data will be analyzed with SAS using the intention-to-treat principle. P-values less than 0.05 will be  
1920 considered significant and all tests are two-sided. Details of how the intention-to-treat principle will be  
1921 implemented are contained in a later section.

### 1922 B. Primary Analysis

1923 The primary goal of this study is to determine whether the change in weight status among children who  
1924 have overweight/obesity (*Primary Specific Aim 1, DSMB approved protocol addenda, 11.2.18*) is superior  
1925 among those who are randomized to family-based treatment (FBT) as compared to those who are  
1926 randomized to usual care (UC) when treated in a primary care setting. The primary outcome measure in  
1927 children is the percent over the age- and sex-specific 50<sup>th</sup> BMI percentile. The specific question of  
1928 interest in the primary analysis is whether the change from baseline to 24 months in the intervention  
1929 group is greater in the FBT group than in the UC group.

1930 The primary analytic strategy reflects the fact that this is an individually randomized group treatment  
1931 (IRGT) trial.<sup>34</sup> An IRGT trial is one in which the individual, in this case the family, is the unit of  
1932 randomization. It differs from a classic individually randomized trial in that the intervention is either a  
1933 group intervention or, alternatively, is conducted by an agent who is responsible for implementing the  
1934 intervention in a defined set of individuals. In PLAN, participants are randomized at the family level and  
1935 only one randomly chosen eligible child (the index child) is included in the primary analysis. The  
1936 intervention is conducted by a coach who assumes responsibility for a set of families that receive  
1937 individualized interventions. Since the study has four sites with three coaches per site, the analysis plan  
1938 involves a nesting of the coach within the site. *Some sites have backup and floating coaches that are*  
1939 *involved in delivering FBT to study participants, which will also be accounted for when outcome data is*  
1940 *analyzed (This change was made on 12.4.18 prior to review and approval by the DSMB, DSMB*  
1941 *approved protocol addenda on 11.18.19).* While this nesting suggests a classic cluster randomized trial,  
1942 an IRGT trial is different because the nesting applies only to the intervention group. Since the control  
1943 group, in this case the UC group, has no nesting factor in an IRGT trial, a proper analysis must reflect the  
1944 fact that in an IRGT trial, the intervention group and the control group must use different covariance  
1945 structures.

1951 With the above comments in mind and with the focus of the study being on a between-group  
1952 comparison of the change from baseline to 24 months, the primary analysis will be an analysis of  
1953 covariance with the 24-month value as the dependent variable and with the baseline value as a  
1954 predictor variable. The statistical model we employ reflects the parametrization described by Baldwin  
1955 and Colleagues.<sup>60</sup> It takes the initial form  $Y_{24_{ij}} = \beta_{0j} + \beta_{1j}X_{ij} + Y_{0_{ij}} + e_{ij}$ . In this model,  $Y_{24_{ij}}$  is the 24-month  
1956 value of the percent over the age and sex matched 50<sup>th</sup> BMI percentile (the primary outcome) for  
1957 subject  $i$  and cluster  $j$ , with the “clusters” being defined by the coach in the intervention group and by  
1958 individual children in the control group;  $\beta_{0j}$  and  $\beta_{1j}X_{ij}$  are the intercept and intervention effect for cluster  
1959  $j$ ;  $Y_{0_{ij}}$  is the baseline value of the outcome measure; and  $e_{ij}$  is the normally distributed error term. *In*  
1960 *these models, the intercept and baseline are fixed effects while the intervention effect is random (DSMB*  
1961 *approved protocol addenda, 11.2.18)*. To reflect the partial clustering structure of the IRGT design, the  
1962 above expression is modified by using the cluster-level equations  $\beta_{0j} = \lambda_{00}$  and  $\beta_{1j} = \lambda_{10} + \mu_{1j}$  to describe  
1963 how the coefficients  $\beta_{0j}$  and  $\beta_{1j}$  vary across clusters. *The reparametrization of  $\beta_{1j}$  yields two random*  
1964 *effects (DSMB approved protocol addenda, 11.2.18)* and the term  $\mu_{1j}$  permits between-cluster variability  
1965 in the outcome measure only within the intervention group (coded as 1). Substituting in the initial  
1966 equation above yields the final model:

$$Y_{24_{ij}} = \lambda_{00} + \lambda_{10}X_{ij} + \mu_{1j} X_{ij} + Y_{0_{ij}} + e_{ij}$$

1967  
1968  
1969 Using PROC MIXED in SAS, separate covariance structures will be fit to the FBT group and the UC group  
1970 to account for the fact that the coach is nested within the site in the FBT group while there is no such  
1971 nesting in the UC group. All analyses other than the above are secondary or exploratory analyses. One  
1972 of those secondary analyses will supplement the primary analysis by adjusting for the sex and race of  
1973 the participating child, family income, the educational level of the participating parent, and whether  
1974 there are one or two parents in the household. These secondary analyses will provide insight regarding  
1975 the impact the covariates may have on the primary outcome.

### 1977 **1. Sample Size and Statistical Power**

1978 Power computations for PLAN employ simulations and two-sided tests at the 0.05 level of  
1979 significance. The simulations reflect the planned primary analysis of covariance and the fact  
1980 that this is an individually randomized group treatment trial with the coach (N=3 per site) nested  
1981 within the site (N=4 sites) in the FBT group but with no such nesting in the UC group. The  
1982 analysis of covariance that is simulated in the power computations treats the 24-month value of  
1983 the outcome measure as the dependent variable and the baseline value as a covariate. The use  
1984 of this approach reflects the primary study goal of comparing 24-month values across groups,  
1985 with the outcome being compared being percent over normalized BMI in the participating child.  
1986 Each result is based on 1000 simulations.

1987  
1988 Tabulated power values employ sample sizes of 528 and that are between 65% and 95% of that  
1989 total. Effect size estimates are generated using considerations and preliminary data discussed  
1990 below. Usual care data involving an intervention and subjects most similar to our UC group is  
1991 provided by Kalarchian<sup>61</sup> who randomized 81 8-12-year-old children with obesity to a usual care  
1992 control condition and found an average percent overweight change of  $-0.17 \pm 10.08$  at 1 year.  
1993 We expect some deterioration in this group at 2 years but will assume conservatively for the  
1994 purpose of power computations that the two-year change will be  $0 \pm 10.08$  in the UC group in  
1995 the proposed research. Our estimated change in the FBT group begins with a review of seven  
1996 studies<sup>20,62-67</sup> authored by Dr. Epstein. There were 314 overweight/obese children in those  
1997 studies who received FBT interventions similar to the one we will employ. When we combined

1998 the data for those 314 children, we found an overall average decrease in percent over BMI of  
1999  $10.6 \pm 15.3$  at 24 months.

2000  
2001 In translating the above decrease of  $10.6 \pm 15.3$  in percent over BMI at 24 months into the  
2002 setting of the proposed research, we emphasize that the seven referenced studies implemented  
2003 FBT in controlled academic settings where we anticipate better performance than is likely in the  
2004 family practices we will employ in this study. To estimate the degree to which the effect is likely  
2005 to be attenuated when we switch from highly controlled to more “real life” settings, we  
2006 considered the following. The child weight management intervention MEND (Mind, Exercise,  
2007 Nutrition, Do it) focused on children age 7-13 who exceeded the 91<sup>st</sup> weight percentile. MEND  
2008 employed both (1) a community-based mass-implementation intervention<sup>68</sup> involving many  
2009 programs and 9563 subjects who provided complete data and (2) a rigorous randomized trial<sup>69</sup>  
2010 (N=116) analogous to the seven Epstein studies referenced in the preceding paragraph. The 12-  
2011 month results were reductions in BMI of  $0.79 \text{ kg/m}^2$  in the community study as compared to  
2012  $1.04 \text{ kg/m}^2$  in the intervention arm of the randomized trial. Thus, the reduction in the  
2013 community-based MEND intervention was 76.0% of the magnitude that was observed in the  
2014 family-based arm of the randomized trial.

2015  
2016 Based on this 76.0%, our computations conservatively assume changes in the intervention group  
2017 that are 50%, 60%, and 70% of the previously observed change of  $10.6 \pm 15.3$  that was observed  
2018 in the rigorous academic environment of Dr. Epstein’s studies.<sup>20,62-67</sup> Thus, we base our power  
2019 on a comparison of projected reductions of  $5.3 \pm 15.3$  (50% of  $10.6 \pm 15.3$ ),  $6.4 \pm 15.3$  (60% of  
2020 10.6), and  $7.4 \pm 15.3$  (70% of 10.6) in the FBT group as compared to  $0 \pm 10.08$  in the UC group.  
2021 In addition, given projected standard deviations of 15.3 and 10.08 in the two groups, we use the  
2022 maximum and the mean of those two values and thereby compute power assuming standard  
2023 deviations of both 15.3 and 12.7. In performing the calculations summarized below, we  
2024 emphasize that we will have actual or imputed 24-month data on all subjects. To see details of  
2025 how we will impute the 24 month values when necessary, please see the section below titled  
2026 “Implementation of the Intention-to-Treat Principle.”

2027  
2028 Table 1 contains the results of the power computations using the parameters discussed above,  
2029 assuming the compound symmetry covariance structure in both study arms and assuming an  
2030 intraclass correlation coefficient (ICC) in the UC group of 0.01 and ICCs in the FBT group of 0.04,  
2031 0.06, 0.10, and 0.15. We assume a small ICC in the UC group of 0.01 because there is no  
2032 clustering within that group meaning that the ICC should be essentially zero. While we do not  
2033 have data with which to estimate the ICC in the FBT group, we note that many cluster trials that  
2034 involve group interventions have reported ICCs in the 0.01 to 0.05 range. Since the PLAN  
2035 intervention is individualized and since we expect PLAN children to have no contact with one  
2036 another, we do not face the impact on the ICC that is present in many cluster trials. This argues  
2037 for a very small ICC in the FBT group. By contrast, the fact that the same coach will be  
2038 responsible for multiple children will inevitably increase the ICC above where it might otherwise  
2039 be. Based on these considerations, we tabulate power for ICCs in the FBT group that range from  
2040 0.04 to 0.15. However, the many other studies that have used group interventions while  
2041 yielding ICCs below 0.05 suggests that the ICC ultimately observed in PLAN will be substantially  
2042 less than 0.1.

2043  
2044 Results in Table 1 indicate that if we recruit 100% of our original target of 528 families, power  
2045 will be excellent for all tabulated scenarios with an ICC in the FBT group of 0.1 or less. For an ICC

2046 no bigger than 0.1, power remains adequate for most scenarios if we recruit at least 80% of the  
 2047 target (N = 432). If recruitment is below the 80% figure, an adequate power of at least 0.8  
 2048 requires either the smaller of the two tabulated standard deviations or a mean difference that is  
 2049 at least 60% of the value observed in Dr. Epstein’s studies (difference at least 6.4).  
 2050

2051 **Table 1: Statistical power for two sided tests at the 0.05 level of significance.**

2052 Computations are for the primary outcome which is the percent over the 50<sup>th</sup> percentile of BMI in  
 2053 children. Results are generated using 1000 simulations of the primary analytic model: an analysis of  
 2054 covariance with the 24-month value as the dependent variable and the baseline value as a covariate.  
 2055 The analysis reflects the fact that this is an individually randomized group treatment trial in which the  
 2056 coach is nested within the site within the FBT group but which is different from a classic cluster  
 2057 randomized trial in that there is no such nesting within the control (UC) group. The total number of  
 2058 randomized families is assumed to range from 65% to 100% of the target of 528. Tabulations assume an  
 2059 ICC of 0.01 in the UC group and of 0.04, 0.06, 0.10, and 0.15 in the FBT group, mean differences of 5.3,  
 2060 6.4 and 7.4 (which represent 50%, 60%, and 70% of observed results in previous studies), and standard  
 2061 deviations of 12.7 and 15.3.

2062 *(N’s Adjusted Below, DSMB approved protocol addenda, 9.29.19).*

ICC		SD	Mean diff	Statistical power associated with sample sizes ranging from 65% to 100% of original target of 528								
FBT grp	UC grp			N=528 (100%)	N=502 (95%)	N=476 (90%)	N=449 (85%)	N=422 (80%)	N=396 (75%)	N=370 (70%)	N=344 (65%)	
0.04	0.01	12.7	5.3	0.95	0.95	0.94	0.92	0.93	0.92	0.89	0.89	
			6.4	0.99	0.98	0.99	0.98	0.99	0.98	0.98	0.98	0.97
			7.4	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.99	1.00
		15.3	5.3	0.84	0.83	0.83	0.81	0.80	0.76	0.76	0.76	0.74
			6.4	0.96	0.94	0.95	0.92	0.91	0.91	0.91	0.88	0.87
			7.4	0.99	0.99	0.99	0.98	0.97	0.97	0.97	0.97	0.96
0.06	0.01	12.7	5.3	0.92	0.91	0.90	0.90	0.88	0.87	0.85	0.84	
			6.4	0.98	0.98	0.98	0.98	0.97	0.96	0.95	0.95	0.95
			7.4	1.00	1.00	1.00	1.00	0.99	0.99	0.99	0.99	0.99
		15.3	5.3	0.80	0.79	0.77	0.78	0.74	0.73	0.70	0.68	0.68
			6.4	0.92	0.91	0.92	0.91	0.88	0.87	0.85	0.84	0.84
			7.4	0.97	0.97	0.96	0.97	0.96	0.95	0.93	0.93	0.94
0.10	0.01	12.7	5.3	0.85	0.83	0.81	0.83	0.80	0.80	0.76	0.76	
			6.4	0.95	0.94	0.94	0.93	0.91	0.92	0.91	0.88	0.88
			7.4	0.98	0.98	0.98	0.98	0.98	0.97	0.97	0.97	0.97
		15.3	5.3	0.69	0.68	0.69	0.63	0.67	0.65	0.62	0.60	0.60
			6.4	0.84	0.82	0.84	0.81	0.81	0.77	0.76	0.78	0.78
			7.4	0.94	0.94	0.92	0.92	0.91	0.89	0.89	0.89	0.87
0.15	0.01	12.7	5.3	0.73	0.75	0.71	0.72	0.69	0.70	0.70	0.68	
			6.4	0.86	0.85	0.83	0.85	0.85	0.84	0.83	0.81	0.81
			7.4	0.95	0.95	0.95	0.94	0.94	0.93	0.93	0.93	0.92
		5.3	0.57	0.59	0.55	0.56	0.53	0.53	0.52	0.52	0.52	

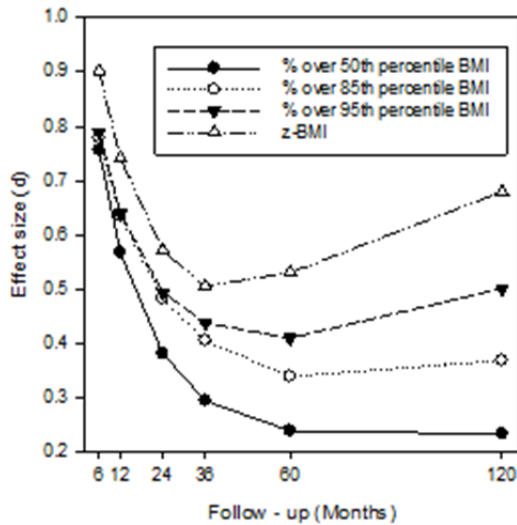
		15.	6.4	0.73	0.74	0.70	0.73	0.71	0.67	0.68	0.65
		3	7.4	0.86	0.82	0.86	0.83	0.82	0.81	0.80	0.79

**2. Rationale for Percent Over BMI as the Primary Dependent Variable for Child Weight Change**

We will use the percent over the 50<sup>th</sup> percentile BMI for our primary dependent measure for the children.<sup>61</sup> This is commonly labeled as percent over BMI. This measure compares the child BMI to children who are at the average BMI for same age and sex. Twenty percent over the average value is approximately equivalent to the 85<sup>th</sup> BMI percentile. Using this metric, based on our previous research,<sup>20</sup> we expect a reduction in percent over BMI at 2 years of at least 5.3 due to the impact of the intervention. One of the strengths of this measure is the large database of studies that have used this measure.

There are other approaches to assessing child relative weight change, which include percent over the 95<sup>th</sup> BMI percentile and zBMI. Percent over the 85<sup>th</sup> or 95<sup>th</sup> BMI percentile is a recently developed measure that has an advantage of comparing children to children with overweight or obesity, rather than to the average weight child. In other words, when using the percent over the 85<sup>th</sup> BMI percentile, a positive number means the child is overweight, and a negative number means they are below the 85<sup>th</sup> BMI percentile. We have assessed the relationship between values obtained using the percent over 50 versus percent over 85 or percent over 95 in a sample of 987 children, and to no surprise, they are correlated greater than 0.98. However, this does not mean they are equivalent. Using our database of children for whom we have 10-year follow-up,<sup>62,63</sup> we have also calculated the effect sizes for a sample of 193 children who we have studied for 10 years, which provides the largest and only dataset of truly long-term changes in the behavioral childhood obesity literature. The effect sizes for the different measures are similar at the end of treatment, being about 0.80, but they diverge as the length of the follow-up increases. As shown in Figure 1 below, the effect size gets smaller as length of follow-up increases, up to approximately the five-year follow-up, when the effect size increases for the percent over 85 and percent over 95, but not for the percent over 50. Thus, the percent over 50 that we have been using is the most conservative approach to assessing change in child relative weight among the percent overweight measures.

**Figure 1. Effect size for zBMI at follow-up.**



We have also included changes in zBMI over time for comparison. As can be seen in Figure 1, zBMI has the greatest effect sizes at all-time points. zBMI also compares BMI values to population values based on the child's age and sex and attempts to standardize the values using z-scores. Reductions in zBMI scores are obtained when child weight decreases in relationship to their growth. The z-scores that are used to calculate zBMI are also the basis for calculating the 85<sup>th</sup> and 95<sup>th</sup> BMI percentiles. While zBMI has been used in studies, it has been criticized in part since baseline zBMI correlates negatively with change, while all other measures of child relative weight discussed show a positive relationship. In other words, using zBMI children with the lowest zBMI values show larger changes,

2108 while children with higher zBMI values show smaller changes.

2109  
2110 It is also possible to use BMI values, which do not take into account the child's age or sex. There  
2111 are two major disadvantages of this approach. First, a child may show a reduction in relative  
2112 weight to height for the other dependent measures, but an increase in BMI. This makes  
2113 determination of success challenging, as you would not expect a child who is showing an  
2114 increase in BMI to be successful. This is due to the fact that population based child BMI curves  
2115 show an increase throughout development until about age 18, so that an increase in absolute  
2116 BMI may be a reduction in BMI relative to normal growth for children that age and sex.  
2117 Secondly, since boys and girls differ in their rates of maturation in terms of height and weight  
2118 trajectories and height and weight velocity, an absolute change in BMI may have very different  
2119 meanings for boys and girls as they develop.

2120  
2121 **3. Longitudinal Analyses of Child Outcome Data**

2122 Secondary analyses involving the child will look more comprehensively at the pattern of change  
2123 over time. While there is no specific literature on the use of mixed model repeated measures  
2124 analyses in IRGT trials, these analyses are known to inflate the type I error in cluster trials<sup>70</sup> and  
2125 it is likely that this also occurs in IRGT trials. The general recommendation is therefore that  
2126 random coefficient models that may use different covariance structures in the two study arms  
2127 should be employed in the longitudinal analysis of IRGT trials.<sup>70</sup> With that in mind our secondary  
2128 analysis of child outcome data will apply these models to all data collected at baseline and at 6,  
2129 12, 18 and 24 months. In light of the fact that weight changes in intervention studies sometimes  
2130 occur more quickly at the beginning with a subsequent leveling off at later time points, these  
2131 analyses will explore non-linear possibilities such as quadratic models. They will also adjust for  
2132 the same covariates that were listed in the secondary analysis of the primary outcome to  
2133 understand the impact of the covariates on longitudinal change.

2134  
2135 **4. Covariance Structures and Missing Data**

2136 There are two key considerations that will guide us as we pursue these secondary random  
2137 coefficient models: (1) the selection of appropriate covariance structures and (2) the handling of  
2138 missing data.

2139  
2140 **5. Selection of a Covariance Structure**

2141 PROC MIXED in SAS contains many covariance structure options, including the ability to identify  
2142 covariance structures that are specific to the UC group and the FBT group separately. Our  
2143 model-selection process for choosing the appropriate covariance structures will reflect several  
2144 considerations including information criteria; the pattern of change in the correlation between  
2145 observations as the time between measurements increases; and the *a priori* preference for  
2146 structures that, all other things being equal, minimize the number of parameters that must be  
2147 estimated; and whether data collection is equally spaced. *While confirmation will have to await*  
2148 *the availability of the final dataset, we anticipate using an unstructured covariance structure in*  
2149 *the primary analysis (DSMB approved protocol addenda, 11.2.18).*

2150  
2151 **6. Missing Data**

2152 Our handling of missing data begins with consideration of the pattern of missingness. If missing  
2153 data in longitudinal analyses are missing completely at random or at random, they do not  
2154 produce bias. In this setting, we will apply our random coefficient models to all data that are  
2155 available. However, because this approach can yield a meaningful decrease in statistical power if



2156 large amounts of data are missing, we will use multiple imputation<sup>71-73</sup>(using PROC MI in SAS) to  
2157 impute missing values when missingness is excessive and will treat this imputation approach as  
2158 a sensitivity analysis. When data are not missing at random, ignoring the pattern of missingness  
2159 can yield biased analyses.

2160  
2161 We will begin our consideration of missing data while the trial is being implemented so we can  
2162 minimize the amount and best understand the pattern of missingness. First, we will do  
2163 everything we can to determine why subjects drop out of the study early and we will ask non-  
2164 dropouts the reason for missing a particular visit. If data are missing, for example, because of  
2165 bad weather, it may be likely that they are randomly missing whereas a family that drops out  
2166 because the child is not losing weight will suggest non-ignorable missingness. Information such  
2167 as this will help guide our analytic strategy. Second, we will encourage subjects who wish to  
2168 drop out early to continue to provide key follow-up data, at 24 months in particular. Our  
2169 experience is that many dropouts appreciate the scientific value of their contributions and are  
2170 willing to cooperate in this way. Third and most importantly, we will do all we can do avoid  
2171 dropout and missing data in the first place. In the recently completed 24-month multicenter  
2172 COMPASS study, we collected 24-month data on 165 of 172 children in randomized families  
2173 (95.9%) and 18-month data on five of the 7 who were missing at 24 months. Because the  
2174 COMPASS intervention was performed at our own facilities with us having complete control, the  
2175 dropout rate is likely to be higher in the proposed research where we rely on family practices.  
2176 Nevertheless, if we can come close to the low missing data rate in COMPASS, the potential  
2177 problem posed by missingness will be very limited.

2178  
2179 *The section that follows on the implementation of the intention-to-treat principle provides*  
2180 *further insight into the handling of missing data (DSMB approved protocol addenda, 11.2.18).*

## 2181 **7. Implementation of the Intention-to-Treat Principle**

2182  
2183 The primary analysis will be an intention-to-treat analysis of the child that includes all subjects.  
2184 Recalling that the primary analysis involves an analysis of covariance with the 24-month value of  
2185 percent over BMI (the primary outcome measure) as the dependent variable, the inclusion of all  
2186 subjects will reflect the following three considerations.

- 2187 1. If the 24-month value of the primary outcome is available, the child will be included in the  
2188 primary analysis without the need for further considerations.
- 2189 2. If the 24-month value of height and/or weight (the defining components of the primary  
2190 outcome) is missing and the child had height and weight data collected by his or her  
2191 pediatrician at a clinic visit that occurred within 30 days of the targeted 24-month PLAN  
2192 assessment, the following considerations will be used in imputing the 24-month value to be  
2193 used in the primary analysis. Those considerations are designed to account for the  
2194 anticipated imprecision of values measured at the pediatrician's office.
  - 2195 a. Within each clinic, a regression model that will allow us to impute 24-month values  
2196 will be generated. Using all PLAN children who attend a particular clinic and who  
2197 have both precisely measured PLAN height and weight data and less precise height  
2198 and weight data measured at the clinic within 30 days of the PLAN measurement,  
2199 clinic-specific regression models will separately predict the true height and weight  
2200 using the age and sex of the subject as well as the height and weight value  
2201 measured at the clinic. The goal will be to perform these calculations on a clinic-  
2202 specific basis because the causes and magnitude of measurement error may differ  
2203

2204 from clinic to clinic. However, if the number of subjects at a clinic who have the  
2205 requisite height and weight data is less than 15 (less than 5 times the number of  
2206 predictors), we will use all data from all clinics at the relevant study site to perform  
2207 the desired imputation.

- 2208 b. Recalling that the children of interest in this scenario have clinic data collected  
2209 within 30 days of the targeted 24-month PLAN assessment, the clinic-specific height  
2210 and weight value calculated above will be used to impute the PLAN 24 month values  
2211 from the contemporaneous value measured at the clinic. This imputed value will be  
2212 used in the primary analysis.
- 2213 c. If there is no clinic visit within 30 days of the 24-month target but there are visits  
2214 both before and after the 24-month time point, we will interpolate linearly between  
2215 predicted height and weight values at those time points to determine the predicted  
2216 24-month value. *Because we will only employ this option if height and weight data  
2217 are available no more than three months before and three months after the target  
2218 date for the 24-month visit, we anticipate that this interpolation approach will be  
2219 performed infrequently in practice (DSMB approved protocol addenda, 11.2.18).*
- 2220 3. If the 24-month value of height and/or weight is missing and the child did not have height  
2221 and weight data collected by his or her pediatrician at a clinic visit that took place within 30  
2222 days of the planned 24-month assessment and did not have height and weight data  
2223 measured at the clinic *within three months* both before and after the targeted 24-month  
2224 visit, the 24-month value will be imputed using multiple imputation *(DSMB approved  
2225 protocol addenda, 11.2.18)*. Variables that will be used to facilitate the imputation process  
2226 will be baseline height and weight, age, sex, and race. Any height and weight data collected  
2227 using PLAN assessments at 6, 12, or 18 months will also be included in the multiple  
2228 imputation.

2229  
2230 *Two points about the methods discussed in this section are in order. First, the rationale for  
2231 using multiple imputation only after it has been determined that clinic visit data are not  
2232 available as a vehicle for imputing values is as follows. We anticipate that while values  
2233 measured at the clinic will not employ the same rigor that will be employed in our protocol  
2234 governed visits every six months, it is likely that the magnitude of the error will be relatively  
2235 small and probably systematic rather than random within clinics. We therefore anticipate  
2236 that this use of real measured data will yield more accurate results than multiple imputation.  
2237 This is especially so for individuals who provide no data beyond their baseline measurement.*

2238  
2239 *The second point concerns the definition of a missed visit. The goal for all clinics is that PLAN  
2240 participants should attend their six-month visits within  $\pm$  30 days of the target date.  
2241 However, we will not declare a given visit as having been missed until 3 months after the  
2242 target date. For example, if the six-month visit has not occurred by nine months, the six-  
2243 month visit will be declared to be missing and will therefore need to be imputed for analyses  
2244 that include these intermediate time points. With the six-month visit having been declared  
2245 missing, the next visit will be defined to be the twelve-month visit and the target date for it  
2246 to occur will be twelve months after the randomization date. We recognize that a three-  
2247 month difference between a scheduled visit and the actual visit is substantial, especially for  
2248 growing children. But the use of this three-month difference before a visit will be declared  
2249 missing will minimize the number of missed visits. Moreover, using the methods discussed in  
2250 the last section of this analysis plan, we will account for any between-group differences in*

2251 *time to the final study visit when we perform the primary analysis (DSMB approved protocol*  
2252 *addenda, 11.2.18).*

2253

## 2254 **8. Assessing the Appropriateness of Analytic Strategies**

2255 In addition to the above concerns about covariance structures and missing data, we will  
2256 routinely give careful attention to the appropriateness of the analyses we perform. For example,  
2257 t-tests comparing baseline values across groups will be performed only after assessing equal  
2258 variance and normality assumptions, with data transformations being pursued if assumptions  
2259 are violated and Wilcoxon's test being a nonparametric alternative if an appropriate  
2260 transformation cannot be found. Similar attention will be given to the appropriateness of  
2261 random coefficient models where the distributional properties of variables will be evaluated and  
2262 residual plots will be examined. To ensure that our conclusions are robust in the face of outlying  
2263 values, sensitivity analyses that may exclude or attenuate outlying values will be pursued. The  
2264 latter considerations will ensure that we are appropriately cautious about any conclusion that  
2265 might have been altered if 1 or 2 subjects with outlying values had not been in the study or had  
2266 had less extreme data points.

2267

### 2268 **C. Analysis of Secondary Aim 1 (DSMB approved protocol addenda, 11.2.18).**

2269 **The goal of secondary aim 1 is to compare the effectiveness of the FBT group with that of the UC**  
2270 **group in the participating parent.** The primary outcome variable in the parent is BMI. Since BMI is a  
2271 continuous variable measured at the same time points as was the case with the participating child, the  
2272 data analytic strategy for this secondary analysis is identical to what was described for the child.

2273

### 2274 **C. Analysis of Secondary Aim 2 (DSMB approved protocol addenda, 11.2.18).**

2275 **The goal of this aim is to determine if the weight loss impacts of FBT extend beyond the participating**  
2276 **child by assessing the intervention in overweight/obese siblings.** We hypothesize that FBT will be  
2277 superior to UC for weight-eligible siblings. Analytic strategies will be similar to those used in the primary  
2278 aim, the key difference being that while prior data<sup>74</sup> support our hypothesis of FBT benefits for siblings,  
2279 power for this aim may be limited. The most important reason for this is that we have chosen not to  
2280 require that participating children have a weight-eligible sibling because of the recruitment challenge  
2281 such a requirement would pose. Prior data from the NHLBI-funded COMPASS study we coordinated at  
2282 Washington University indicate that among 377 screened families with a participating child, 163 (43.2%)  
2283 had at least one age (age 2-18) and weight-eligible sibling. Based on these numbers, we expect that  
2284 there will be about 228 (= 43.2% of 528) participating families with at least one eligible sibling, with the  
2285 actual number recruited being somewhat smaller because some siblings will choose not to participate.

2286

2287 While the above sample size may not provide the robust statistical power that would be ideal, we  
2288 emphasize that this is a secondary aim that will study by far the largest number of overweight/obese  
2289 siblings ever evaluated in this setting. Thus, this aim will provide a unique set of data that will yield  
2290 valuable insights into whether FBT may benefit non-participating siblings while generating preliminary  
2291 effect size data to guide future studies. A positive finding would provide a compelling incentive for the  
2292 future dissemination of FBT to family practices. In cases where more than one eligible sibling is available,  
2293 we will enroll the sibling whose age is closest to that of the study child. Data analyses will reflect the  
2294 wide age eligibility range for siblings and current uncertainty regarding the impact of sibling age on  
2295 outcome. We will address this uncertainty by adjusting for sibling age and whether the sibling is older or  
2296 younger than the participating child, with particular concern for the possibility that sibling age may have  
2297 a non-linear relationship with FBT effectiveness. The wide age eligibility range for siblings reflects our  
2298 desire to maximize information generated about this population and the limited resource expenditure

2299 that is required to study these non-participants. We will also adjust for whether the sex of the sibling is  
2300 the same as that of the targeted child since prior data suggest that same sex siblings respond better  
2301 than opposite sex siblings.<sup>19</sup>  
2302

2303 ***E. Analysis of Secondary Aim 3 (DSMB approved protocol addenda, 11.2.18).***

2304 **The goal of this aim is to assess changes in delay discounting for children and parents assigned to FBT**  
2305 **versus UC and to assess the relationship between those changes and weight control.** We hypothesize  
2306 that FBT will be associated with reductions in delay discounting for children and parents compared with  
2307 UC, and that the degree of change in delay discounting will be related to success in weight control. *All*  
2308 *analyses in this aim will be performed separately for the index child and the index parent (DSMB*  
2309 *approved protocol addenda, 11.2.18).* Delay discounting will be measured using the k-value detailed by  
2310 Johnson and Bickel.<sup>75</sup> These parameters will be measured at baseline, 12, and 24 months. One set of  
2311 analyses in this aim will involve random coefficient models that compare the pattern of change in the k  
2312 value in the UC group with corresponding changes in the FBT group. We will also use bivariate linear  
2313 mixed models implemented by PROC MIXED in SAS<sup>76</sup> to evaluate the association between changing k-  
2314 values and changes in weight.  
2315

2316 ***D. Analysis of Secondary Aim 4 (DSMB approved protocol addenda, 11.2.18).***

2317 **The goal of this aim is to examine participant level baseline predictors of outcomes, with the**  
2318 **measures of interest being parental inconsistency and environmental enrichment.** We hypothesize  
2319 that FBT, as compared to UC, will benefit families with higher parental inconsistency and less enriched  
2320 environments. Parental inconsistency will be measured using a validated parenting style inventory<sup>77</sup>  
2321 while environmental enrichment will be evaluated using questions from the HOME<sup>78</sup> scale developed by  
2322 Rosenberg et al<sup>79</sup> and the Land Use Mix-Diversity subscale from the Neighborhood Environment  
2323 Walkability Scale (NEWS)<sup>80</sup> that we have employed previously<sup>81</sup> in a pediatric weight loss study involving  
2324 FBT. The same random coefficient models with two covariance structures that we described earlier with  
2325 the same IRGT design will be applied here with the modification that we will focus on the two baseline  
2326 measures of current interest (parental inconsistency and environmental enrichment) as covariates.  
2327 Because we anticipate that the efficacy of the intervention may be influenced by these measures, we  
2328 will also evaluate interaction terms between group assignment and both our parental inconsistency and  
2329 environmental enrichment measures. The analyses will be performed separately in both participating  
2330 children and parents.  
2331

2332 **D. Analysis of Exploratory Aim 1**

2333 **The goal of this exploratory aim is to examine provider attitudes towards evidence-based treatment**  
2334 **at baseline and perceptions of FBT at mid study (after experience with the intervention has been**  
2335 **gained) as predictors of providers' future intention to use co-located FBT in their practices at the end**  
2336 **of the study.** We hypothesize that positive provider attitudes toward evidence-based treatment and  
2337 perceptions of FBT will predict their intention to incorporate FBT into their practice settings. Appendix C  
2338 provides details of the measures we will use in this aim. Because a provider's intention to incorporate  
2339 FBT into their practice settings is measured on a broad scale ranging from 0% to 100%, we will treat the  
2340 variable as a continuous variable and expect that random coefficient models will again be appropriate.  
2341 Specifically, we plan to implement these models using PROC MIXED in SAS, with the provider nested  
2342 within sites in those analyses. A strength of the planned analysis is that the anticipated 185 providers at  
2343 the four sites will provide a rich opportunity to understand predictors of future intentions regarding the  
2344 use of FBT. An uncertainty is that we currently have little data with which to predict the distribution of  
2345 the of the 0% to 100% response variable. It is possible, therefore, that analyses in this exploratory aim  
2346 will require data transformations, breaking the outcome measure into categories, or the use of

2347 generalized estimating equations instead of mixed models. It should be noted that in contrast to earlier  
2348 analyses, analyses of this aim do not involve group assignment and do not therefore reflect the overall  
2349 IRGT trial design. Thus, only one covariance structure will be required.

2350  
2351

#### 2352 **E. Sensitivity Analyses**

2353 Sensitivity analyses to be performed in PLAN are as follows.

2354

- 2355 1. A modified intention-to-treat analysis of the primary outcome in which subjects who provided  
2356 no follow-up data are excluded. These analyses will include imputed 24-month data using  
2357 subjects who did provide data beyond baseline but who did not provide 24-month data.
- 2358 2. To further facilitate an understanding of the impact of missing data on the primary result, the  
2359 primary analysis will be repeated without imputation and using only subjects who provide both  
2360 baseline and 24-month primary outcome data.
- 2361 3. A per protocol dataset will be defined as including all subjects who attend at least 80% of the  
2362 prescribed sessions. Sensitivity analyses will assess whether applying the primary analysis to the  
2363 per protocol dataset yields the same result as the primary ITT analysis. *All control group subjects  
2364 who do not drop out of the study will be considered to be part of the per protocol dataset. We  
2365 recognize that this implies a somewhat different definition in the two study arms. But we do not  
2366 consider this to be a problem since this is a sensitivity analysis whose goal is to repeat the  
2367 primary analysis in a different setting (DSMB approved protocol addenda, 11.2.18).*
- 2368 4. Random coefficient models that potentially use different covariance structures in the two study  
2369 arms will include all primary outcome data collected at baseline, 6, 12, 18, and 24 months. Since  
2370 weight change often occurs at a more rapid rate early in a weight loss study, these sensitivity  
2371 analyses will include an exploration of non-linear possibilities such as quadratic models. They  
2372 will also assess contrasts that compare changes from baseline to 24 months across groups in  
2373 order to use an alternative model for testing the central hypothesis of the primary analysis.
- 2374 5. Repeat the primary analysis after adjusting for baseline covariates. The covariates to be used  
2375 are the race and sex of the participating child, family income, the educational level of the  
2376 participating parent, and whether there are one or two parents in the household.

2377

#### 2378 **F. The Time Between Randomization and the Measurement of the Primary Outcome**

2379 The time between randomization and the measurement of the primary outcome will vary among  
2380 participants and will potentially differ between groups. Our approach to addressing the potential  
2381 impact of this reality is described below.

2382 Our first step in addressing this issue will involve an assessment of whether the time to the outcome  
2383 measure differs across groups. To address this question, we will compare Kaplan Meier survival curves  
2384 measuring time to assessment using a generalized Wilcoxon test. The Wilcoxon test will be used instead  
2385 of a logrank test because dropouts in weight loss studies tend to occur early and because the Wilcoxon  
2386 test is more sensitive to early dropout than the logrank test. In performing these analyses, subjects who  
2387 provide no data beyond baseline will be assumed to be on study for one month. To ensure consistency  
2388 across all participants, one month will also be added to the follow-up time of children who do provide  
2389 data beyond baseline. If the Wilcoxon test yields non-significant results, we will not modify our  
2390 covariate-adjusted secondary analyses. If the Wilcoxon test suggests that there is a between-group  
2391 difference in time to the final assessment, we will adjust for the time to the final assessment in the  
2392 covariate-adjusted analyses. Similar considerations will determine whether the time to the 24 month  
2393 assessment will serve as a covariate in the sensitivity analyses discussed above that involve random  
2394 coefficient models, that include data collected at all intermediate time points, and that employ

2395 statistical contrasts to compare the change from baseline to the final assessment across groups. In all of  
2396 these analyses, the median time to the final follow-up along with 95% confidence bounds will be  
2397 calculated.  
2398

### 2399 **G. Analysis of Exploratory Aim 2**

2400 Twelve PLAN coaches will be asked to participate in an audio-recorded semi-structured interview;  
2401 interested coaches will provide consent over the phone and will be asked a series of questions by a  
2402 trained post-doctoral researcher on the study. The questions are based on the coaches' discussions with  
2403 FBT families pre-COVID and amid-COVID regarding food cost, perception, and behaviors. The telephone  
2404 interviews are voluntary and will be completed based on the coaches' availability. All responses will be  
2405 de-identified and aggregated with the other coaches' responses. The data will be transcribed, and  
2406 summary data will be compiled. The audio file will be destroyed once the data has been transcribed and  
2407 aggregated. *(Pending DSMB approval)*  
2408

### 2409 **Measures to Minimize Bias**

#### 2410 **1. Enrollment and Randomization Procedures**

2411 The DCC will use the REDCap randomization module to create an online password protected  
2412 randomization system that will facilitate the random assignment of families. When the website  
2413 is entered, the user will provide information that establishes the eligibility of the family. Group  
2414 assignments will be revealed only if all eligibility criteria are satisfied. To avoid temporal bias,  
2415 randomization will be blocked within clinic using random block sizes in order to preclude the  
2416 possibility that investigators might know in advance the assignment of the last family in a  
2417 particular block.  
2418  
2419

#### 2420 **2. Standardization of Height and Weight Measurements**

2421 Verifications for collecting and entering the data for the height and weights will be followed to  
2422 decrease bias. All stadiometers and scales used will be calibrated and consistent between all  
2423 sites. PLAN coaches and assessors will be trained and tested on protocols for obtaining these  
2424 measures. All weight measurements will be taken according to a uniform protocol and written  
2425 on hard copy measurement sheets. The handwritten weights will be manually entered into the  
2426 REDCap database by a blinded measurement coach, which will eliminate potential measurement  
2427 bias and minimize errors in data entry *(DSMB approved change, 11.18.19)*. Both the written  
2428 record and the measure in REDCap will be verified. *Hard copy height and weight measurement*  
2429 *forms will be uploaded to the secure REDCap database to allow the CCC, DCC and TFC to check*  
2430 *for transcription and/or unit of measurement errors.* Any malfunctions of equipment will be  
2431 reported to the study staff to resolve immediately. Any measurements outside of the range of  
2432 normal will be flagged in REDCap and staff notified to retake measurements.  
2433

#### 2434 **3. Masking Procedures**

2435 Masking refers to no knowledge regarding treatment assignment. It is not the same as  
2436 concealment, which refers to random assignment to groups. Treatment masking represents an  
2437 extension of concealment, to minimize bias in how participants assigned to different groups are  
2438 treated. In the current study, the research assistants and coaches who are doing the  
2439 measurements will be blinded, or masked as to treatment assignment, and the PIs for the  
2440 Clinical Coordinating Center and Training and Fidelity Cores (Drs. Epstein and Wilfley) and the  
2441 DSMB will be masked as to treatment assignment. However, it is impossible to mask families,  
2442 the family's PLAN coach, or pediatricians to group assignment. Families and PLAN coaches will

2443 know the intervention arm by the very nature of implementing a behavioral intervention.  
2444 Pediatricians will not be told group assignment, but that is possible to discern since they may  
2445 see FBT families coming to their clinic more than the UC families.  
2446

#### 2447 **Masking of Assessment Staff**

2448 We recognize the importance of blinding research personnel who are collecting data to  
2449 study arms. The primary height and weight data will be collected coaches conduct  
2450 assessments for each other's families at the different pediatric sites (for which they will be  
2451 blinded to those families). Families will be explained that they are to not discuss anything  
2452 regarding their group assignment, how often they come to the pediatric office or their  
2453 coaches and the measurement assessor has to remain blinded to their treatment arm.  
2454

2455 Coaches will be blinded to the families' randomization. They will conduct assessments,  
2456 home visits, remote assessments, and AE data collection.  
2457

2458 There are three coaches at each site, with *some sites having backup and floating coaches*  
2459 *that are involved in delivering FBT to study participants. A backup coach delivers treatment*  
2460 *for another coach's caseload in the event that a coach goes on vacation, leaves the position,*  
2461 *or is otherwise unable to complete treatment with their families. Backup coaches are*  
2462 *assigned based on coach letter assignment (i.e., coach B is the backup for coach A, coach A is*  
2463 *the backup for coach C, coach C is the backup for coach B). This ensures that there is always*  
2464 *a blinded measurement coach to complete assessments. A floating coach delivers treatment*  
2465 *to families at multiple pediatric practices regardless of coach assignment. Floating coaches*  
2466 *remain blinded to other caseloads, but see families at different practices when a practice's*  
2467 *coach does not have space in their caseload for more families (**This change was made on***  
2468 ***12.4.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on***  
2469 ***11.18.19**). The plan is for Coach 1 to collect height and weight for families assigned to Coach*  
2470 *2, Coach 2 will collect height and weight for families assigned to Coach 3, and Coach 3 will*  
2471 *collect height and weight for families assigned to Coach 1. Thus, coaches will not collect*  
2472 *height and weight measures from families from their caseload. We will use block scheduling*  
2473 *to reduce travel time (e.g., Coach 1 can do assessments at Coach 2's site one Friday per*  
2474 *month).*  
2475

2476 *In order to mask assessment of outcome measures, all sites have implemented blinded*  
2477 *measurement coaches that complete assessments and AE data collection, so that the PLAN*  
2478 *coaches can focus on treatment. Coaches will remain blinded to group assignment outside of*  
2479 *their caseload (**This change was made on 2.28.18 prior to review and approval by the***  
2480 ***DSMB, DSMB approved protocol addenda on 11.2.18**). To further ensure blinding, families*  
2481 *will be notified that the assessor is unaware of their group assignment and will be asked not*  
2482 *to discuss the frequency of them coming in to the practice, their group assignment, or the*  
2483 *coach they normally see (**DSMB approved protocol addenda, 3.18.19**).*  
2484

2485 Although not possible to guarantee that coaches are blind to condition for families that are  
2486 not in their caseload due to the families not being blinded, use of a standard protocol (see  
2487 **Appendix C**) ensures objective and reliable measurement of the primary outcome. Assessors  
2488 will be blind to prior heights/weights, further protecting against assessment bias.  
2489

2490  
2491  
2492  
2493  
2494  
2495  
2496  
2497  
2498  
2499  
2500  
2501  
2502  
2503  
2504  
2505  
2506  
2507  
2508  
2509  
2510  
2511  
2512  
2513  
2514  
2515  
2516  
2517  
2518  
2519  
2520  
2521  
2522  
2523  
2524  
2525  
2526  
2527  
2528  
2529  
2530  
2531  
2532  
2533  
2534  
2535  
2536

### **Reducing Bias in Unmasked Groups**

We recognize that there are numerous ways that the PLAN coaches or pediatricians can treat FBT UC families differently. We have several approaches to reduce bias. We are able to standardize interactions with PLAN coaches through extensive training, supervision and fidelity checks, which can help reduce bias from the PLAN coaches. Part of the training will include instructions not to state or imply that FBT may be better than usual care. We will not be directly training or assessing fidelity for usual care, as that would deviate from the reason for using UC as the control condition. However, we will be collecting information on usual care practices from participating providers at baseline and 24 months via REDCap surveys. Group assignment will not be in the families' charts, and unless a family directly says something to the pediatrician, the pediatrician may be unaware of group assignment.

## **II. Study Administration**

### **Study Website**

A study website will be used to: 1) provide information to families about FBT; 2) provide downloadable manuals for the Traffic Light Eating Plan and Activity Program; 3) manage the EFT component of the intervention; and 4) provide tools for cooking, getting more physical activity, and parenting skills. Quizzes to assess mastery of educational materials will be implemented on the study website, with multiple versions of quizzes on each module available with the recognition that some people will acquire the information more slowly than others. Families will have access to traditional paper and pencil self-monitoring, and consistent with current implementation of FBT, after self-monitoring skill is acquired, families can choose to use traditional or technology-based recording. Information on learning the modules, and eating, exercise, and parenting change will be coordinated in an online family dashboard. Families will have access to the family dashboard for feedback, and PLAN coaches will have access to the dashboard to assess patient progress, assist with problem solving, and communicate with families to structure solutions.

The website will also contain password-protected sections that are for internal use by study personnel and will serve as a repository for study documents as well as a communications hub for the study. The study website will be created and maintained by the CCC. The DCC will be responsible for uploading to the website documents under its purview such as regular reports prepared for DSMB and Steering Committee meetings, the forms and datasets manual, lists of certified personnel, and instructions on the use of the data entry system. The website will not contain protected health information.

### **Conflicts of Interest**

Dr. Schechtman has a long history of collaboration with Dr. Wilfley, the PI for the TFC and of the WU clinical site for the proposed research, and because both reside at WU, there is at least the appearance of a potential for conflict of interest. We will take two steps in addressing this issue. First, the reports we regularly generate regarding the progress of the study will be separated by clinic and shared with the SEC and/or DSMB whenever potential problems with clinical sites, including the WU clinical site, are identified. Second, we have asked a colleague, Dr. Mae Gordon (Professor of Ophthalmology and Biostatistics at WU), to address any concerns about the performance of the WU clinical site should Dr. Schechtman feel conflicted. Dr. Gordon has not worked previously with Dr. Wilfley and has years of experience as Director of the DCC for several NIH-funded clinical trials, including at least one where a participating clinic was at WU.



2537 Disagreements regarding any of the study functions will be resolved by discussion and vote of the  
2538 SEC.

2539

2540 **Publications and Presentations Policy**

2541 The Steering Committee will manage the oversight and coordination of publication and presentation  
2542 materials. The DCC director, along with members of the Steering Committee, will participate in a  
2543 subcommittee defining publication policies, prioritizing when multiple papers and abstracts  
2544 challenge resources, and encouraging the involvement of junior investigators in the dissemination of  
2545 study results. The DCC director will oversee the creation of a publications and presentations  
2546 database that will facilitate the tracking of completed publications. He will also facilitate the  
2547 development of an automated reminder system for study investigators of abstract due dates and  
2548 pending timelines for preparing material for publications and presentations. The publications  
2549 database will be stored on the study website.

2550

2551 **Protocol Amendments**

2552 All protocol amendments will be submitted to the UB IRB and DSMB for approval, and any  
2553 consequent changes will be documented in the study database. Amendments will not be  
2554 implemented until both the UB IRB and DSMB have given their approval.

2555

2556 **Protocol Deviations**

2557 A protocol deviation is any noncompliance with the approved protocol, Good Clinical Practice (GCP),  
2558 or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the  
2559 participant, the investigator, or the study site staff. As a result of deviations, corrective actions are  
2560 to be developed by the site and implemented promptly. These practices are consistent with ICH E6:  
2561 4.5 Compliance with Protocol (sections 4.5.1, 4.5.2, and 4.5.3), 5.1 Quality Assurance and Quality  
2562 Control (section 5.1.1), and 5.20 Noncompliance (sections 5.20.1, and 5.20.2). It is the responsibility  
2563 of the site to use continuous vigilance to identify and report deviations within working days of  
2564 identification of the protocol deviation, or within working days of the scheduled protocol-required  
2565 activity. All deviations must be addressed in study source documents, reported to Program Official.  
2566 Protocol deviations must be sent to the IRB of Record per their guidelines. The site PI/study staff is  
2567 responsible for knowing and adhering to their IRB requirements. Further details about the handling  
2568 of protocol deviations will be included in the MOP.

2569

2570

2571 **III. References**

2572

- 2573 1. Whitaker RC, Pepe MS, Wright JA, Seidel KD, Dietz WH. Early adiposity rebound and the risk of  
2574 adult obesity. *Pediatrics*. 1998;101(3):E5.
- 2575 2. Whitaker RC, Wright JA, Pepe MS, Seidel KD, Dietz WH. Predicting obesity in young adulthood  
2576 from childhood and parental obesity. *N Engl J Med*. 1997;337(13):869-873.
- 2577 3. Morrison JA, Glueck CJ, Wang P. Childhood risk factors predict cardiovascular disease, impaired  
2578 fasting glucose plus type 2 diabetes mellitus, and high blood pressure 26 years later at a mean  
2579 age of 38 years: the Princeton-lipid research clinics follow-up study. *Metabolism*.  
2580 2012;61(4):531-541.
- 2581 4. Fallon EM, Tanofsky-Kraff M, Norman AC, et al. Health-related quality of life in overweight and  
2582 nonoverweight black and white adolescents. *J Pediatr*. 2005;147(4):443-450.
- 2583 5. Schwimmer JB, Burwinkle TM, Varni JW. Health-related quality of life of severely obese children  
2584 and adolescents. *JAMA*. 2003;289(14):1813-1819.
- 2585 6. Charney E, Goodman HC, McBride M, Lyon B, Pratt R. Childhood antecedents of adult obesity.  
2586 do chubby infants become obese adults? *N Engl J Med*. 1976;295(1):6-9.
- 2587 7. Oliveria SA, Ellison RC, Moore LL, Gillman MW, Garrahie EJ, Singer MR. Parent-child relationships  
2588 in nutrient intake: the Framingham Children's Study. *Am J Clin Nutr*. 1992;56(3):593-598.
- 2589 8. Contento IR, Basch C, Shea S, et al. Relationship of mothers' food choice criteria to food intake  
2590 of preschool children: identification of family subgroups. *Health Educ Q*. 1993;20(2):243-259.
- 2591 9. Brown R, Ogden J. Children's eating attitudes and behaviour: a study of the modelling and  
2592 control theories of parental influence. *Health Educ Res*. 2004;19(3):261-271.
- 2593 10. Wardle J. Parental influences on children's diets. *The Proceedings of the Nutrition Society*.  
2594 1995;54(3):747-758.
- 2595 11. Epstein LH, Paluch RA, Roemmich JN, Beecher MD. Family-based obesity treatment, then and  
2596 now: twenty-five years of pediatric obesity treatment. *Health Psychol*. 2007;26(4):381-391.
- 2597 12. Epstein LH, Paluch RA, Wrotniak BH, et al. Cost-effectiveness of family-based group treatment  
2598 for child and parental obesity. *Child Obes*. 2014;10(2):114-121.
- 2599 13. Barton M. Screening for obesity in children and adolescents: US preventive services task force  
2600 recommendation statement. *Pediatrics*. 2010;125(2):361-367.
- 2601 14. Bock DE, Robinson T, Seabrook JA, et al. The Health Initiative Program for Kids (HIP Kids): effects  
2602 of a 1-year multidisciplinary lifestyle intervention on adiposity and quality of life in obese  
2603 children and adolescents--a longitudinal pilot intervention study. *BMC Pediatr*. 2014;14:296.
- 2604 15. Steele RG, Aylward BS, Jensen CD, Cushing CC, Davis AM, Bovaird JA. Comparison of a family-  
2605 based group intervention for youths with obesity to a brief individual family intervention: a  
2606 practical clinical trial of positively fit. *J Pediatr Psychol*. 2012;37(1):53-63.
- 2607 16. Wilfley DE, Tibbs TL, Van Buren DJ, Reach KP, Walker MS, Epstein LH. Lifestyle interventions in  
2608 the treatment of childhood overweight: a meta-analytic review of randomized controlled trials.  
2609 *Health Psychol*. 2007;26(5):521-532.
- 2610 17. Epstein LH, Myers MD, Raynor HA, Saelens BE. Treatment of pediatric obesity. *Pediatrics*.  
2611 1998;101(3 Pt 2):554-570.
- 2612 18. Jelalian E, Saelens BE. Empirically supported treatments in pediatric psychology: pediatric  
2613 obesity. *J Pediatr Psychol*. 1999;24(3):223-248.
- 2614 19. Epstein LH, Paluch RA, Raynor HA. Sex differences in obese children and siblings in family-based  
2615 obesity treatment. *Obes Res*. 2001;9(12):746-753.
- 2616 20. Epstein LH, Valoski A, Wing RR, McCurley J. Ten-year follow-up of behavioral, family-based  
2617 treatment for obese children. *JAMA*. 1990;264(19):2519-2523.

- 2618 21. Epstein LH, Valoski A, Wing RR, McCurley J. Ten-year outcomes of behavioral family-based  
2619 treatment for childhood obesity. *Health Psychol.* 1994;13(5):373-383.
- 2620 22. Wrotniak BH, Epstein LH, Paluch RA, Roemmich JN. Parent weight change as a predictor of child  
2621 weight change in family-based behavioral obesity treatment. *Arch Pediatr Adolesc Med.*  
2622 2004;158(4):342-347.
- 2623 23. Wrotniak BH, Epstein LH, Paluch RA, Roemmich JN. The relationship between parent and child  
2624 self-reported adherence and weight loss. *Obes Res.* 2005;13(6):1089-1096.
- 2625 24. Barlow SE. Expert committee recommendations regarding the prevention, assessment, and  
2626 treatment of child and adolescent overweight and obesity: summary report. *Pediatrics.*  
2627 2007;120 Suppl 4:S164-192.
- 2628 25. van Gerwen M, Franc C, Rosman S, Le Vaillant M, Pelletier-Fleury N. Primary care physicians'  
2629 knowledge, attitudes, beliefs and practices regarding childhood obesity: a systematic review.  
2630 *Obes Rev.* 2009;10(2):227-236.
- 2631 26. Caprio S. Treating child obesity and associated medical conditions. *Future Child.* 2006;16(1):209-  
2632 224.
- 2633 27. Klein JD, Sesselberg TS, Johnson MS, et al. Adoption of body mass index guidelines for screening  
2634 and counseling in pediatric practice. *Pediatrics.* 2010;125(2):265-272.
- 2635 28. Sesselberg TS, Klein JD, O'Connor KG, Johnson MS. Screening and counseling for childhood  
2636 obesity: results from a national survey. *J Am Board Fam Med.* 2010;23(3):334-342.
- 2637 29. Harwood MD, O'Brien KA, Carter CG, Eyberg SM. Mental health services for preschool children  
2638 in primary care: a survey of maternal attitudes and beliefs. *J Pediatr Psychol.* 2009;34(7):760-  
2639 768.
- 2640 30. Aarons GA. Mental health provider attitudes toward adoption of evidence-based practice: the  
2641 Evidence-Based Practice Attitude Scale (EBPAS). *Ment Health Serv Res.* 2004;6(2):61-74.
- 2642 31. Scott SD, Plotnikoff RC, Karunamuni N, Bize R, Rodgers W. Factors influencing the adoption of an  
2643 innovation: an examination of the uptake of the Canadian Heart Health Kit (HHK). *Implement Sci.*  
2644 2008;3:41.
- 2645 32. Godin G, Kok G. The theory of planned behavior: a review of its applications to health-related  
2646 behaviors. *Am J Health Prom.* 1996;11(2):87-98.
- 2647 33. Sheeran P. Intention—behavior relations: A conceptual and empirical review. *Eur Rev Soc*  
2648 *Psychol.* 2002;12(1):1-36.
- 2649 34. Pals SL, Murray DM, Alfano CM, Shadish WR, Hannan PJ, Baker WL. Individually randomized  
2650 group treatment trials: a critical appraisal of frequently used design and analytic approaches.  
2651 *Am J Public Health.* 2008;98(8):1418-24.
- 2652 35. Kuczmariski RJ, Ogden CL, Guo SS, et al. 2000 CDC growth charts for the united states: methods  
2653 and development. *Vital and health statistics Series 11, Data from the national health survey.*  
2654 2002(246):1-190.
- 2655 36. Panel NOEIE. Clinical guidelines on the identification, evaluation, and treatment of overweight  
2656 and obesity in adults--The evidence report. National Institutes of Health. *Obes Res.* 1998;6 Suppl  
2657 2:51s-209s.
- 2658 37. Bickel WK, Marsch LA. Toward a behavioral economic understanding of drug dependence: delay  
2659 discounting processes. *Addiction.* 2001;96(1):73-86.
- 2660 38. Bonato DP, Boland FJ. Delay of gratification in obese children. *Addict Behav.* 1983;8(1):71-74.
- 2661 39. Johnson WG, Parry W, Drabman RS. The performance of obese and normal size children on a  
2662 delay of gratification task. *Addict Behav.* 1978;3(3-4):205-208.
- 2663 40. Bourget V, White DR. Performance of overweight and normal-weight girls on delay of  
2664 gratification tasks. *Int J Eat Disord.* 1984;3(3):63-71.
- 2665 41. Bloom BS. *Human characteristics and school learning.* McGraw-Hill; 1976.

- 2666 42. Epstein LH, McKenzie SJ, Valoski A, Klein KR, Wing RR. Effects of mastery criteria and contingent  
2667 reinforcement for family-based child weight control. *Addict Behav.* 1994;19(2):135-145.
- 2668 43. Whitlock EP, O'Connor EA, Williams SB, Beil TL, Lutz KW. Effectiveness of weight management  
2669 interventions in children: a targeted systematic review for the USPSTF. *Pediatrics.*  
2670 2010;125(2):e396-418.
- 2671 44. Chen X, Beydoun MA, Wang Y. Is sleep duration associated with childhood obesity? A systematic  
2672 review and meta-analysis. *Obesity.* 2008;16(2):265-274.
- 2673 45. Daniel TO, Stanton CM, Epstein LH. The future is now: comparing the effect of episodic future  
2674 thinking on impulsivity in lean and obese individuals. *Appetite.* 2013;71:120-125.
- 2675 46. Daniel TO, Stanton CM, Epstein LH. The future is now: reducing impulsivity and energy intake  
2676 using episodic future thinking. *Psychol Sci.* 2013;24(11):2339-2342.
- 2677 47. Daniel TO, Said M, Stanton CM, Epstein LH. Episodic future thinking reduces delay discounting  
2678 and energy intake in children. *Eat Behav.* 2015;18:20-24.
- 2679 48. Lin H, Epstein LH. Living in the moment: effects of time perspective and emotional valence of  
2680 episodic thinking on delay discounting. *Behav Neurosci.* 2014;128(1):12-19.
- 2681 49. Wilfley DE, Stein RI, Saelens BE, et al. Efficacy of maintenance treatment approaches for  
2682 childhood overweight: a randomized controlled trial. *JAMA.* 2007;298(14):1661-1673.
- 2683 50. Wilfley DE, Van Buren DJ, Theim KR, et al. The use of biosimulation in the design of a novel  
2684 multilevel weight loss maintenance program for overweight children. *Obesity.* 2010;18 Suppl  
2685 1:S91-98.
- 2686 51. MacLean PS, Wing RR, Davidson T, et al. NIH working group report: Innovative research to  
2687 improve maintenance of weight loss. *Obesity.* 2015;23(1):7-15.
- 2688 52. Wing RR, Lang W, Wadden TA, et al. Benefits of modest weight loss in improving cardiovascular  
2689 risk factors in overweight and obese individuals with type 2 diabetes. *Diabetes Care.*  
2690 2011;34(7):1481-1486.
- 2691 53. Van Gaal LF, Mertens IL, Ballaux D. What is the relationship between risk factor reduction and  
2692 degree of weight loss? *Eur Heart J Suppl.* 2005;7(suppl L):L21-L26.
- 2693 54. Chesla CA, Fisher L, Skaff MM, Mullan JT, Gilliss CL, Kanter R. Family predictors of disease  
2694 management over one year in Latino and European American patients with type 2 diabetes. *Fam*  
2695 *Process.* 2003;42(3):375-390.
- 2696 55. Fisher L, Chesla CA, Chun KM, et al. Patient-appraised couple emotion management and disease  
2697 management among Chinese American patients with type 2 diabetes. *J Fam Psychol.*  
2698 2004;18(2):302-310.
- 2699 56. Fisher L, Skaff MM, Chesla CA, et al. Disease management advice provided to African-American  
2700 and Chinese-American patients with type 2 diabetes. *Diabetes Care.* 2004;27(9):2249-2250.
- 2701 57. Neaton JD, Duchene AG, Svendsen KH, Wentworth D. An examination of the efficiency of some  
2702 quality assurance methods commonly employed in clinical trials. *Stat Med.* 1990;9(1-2):115-123;  
2703 discussion 124.
- 2704 58. Hosking JD, Newhouse MM, Bagniewska A, Hawkins BS. Data collection and transcription.  
2705 *Control Clin Trials.* 1995;16(2 Suppl):66s-103s.
- 2706 59. Day S, Fayers P, Harvey D. Double data entry: what value, what price? *Controlled clinical trials.*  
2707 1998;19(1):15-24.
- 2708 60. Baldwin, S. A., Bauer, D. J., Stice, E., & Rohde, P. Evaluating models for partially clustered  
2709 designs. *Psychol Methods.* 2011; 16(2), 149.
- 2710 61. Kalarchian MA, Levine MD, Arslanian SA, et al. Family-based treatment of severe pediatric  
2711 obesity: randomized, controlled trial. *Pediatrics.* 2009;124(4):1060-1068.
- 2712 62. Epstein LH, Wing RR, Koeske R, Andrasik F, Ossip DJ. Child and parent weight loss in family-based  
2713 behavior modification programs. *J Consul Clin Psychol.* 1981;49(5):674-685.

- 2714 63. Epstein LH, Wing RR, Koeske R, Valoski A. A comparison of lifestyle exercise, aerobic exercise,  
2715 and calisthenics on weight loss in obese children. *Behav Ther.* 1985;16(4):345-356.
- 2716 64. Epstein LH, Paluch RA, Gordy CC, Saelens BE, Ernst MM. Problem solving in the treatment of  
2717 childhood obesity. *J Consult Clin Psychol.* 2000;68(4):717-721.
- 2718 65. Epstein LH, Paluch RA, Gordy CC, Dorn J. Decreasing sedentary behaviors in treating pediatric  
2719 obesity. *Arch Pediatr Adolesc Med.* 2000;154(3):220-226.
- 2720 66. Epstein LH, Paluch RA, Kilanowski CK, Raynor HA. The effect of reinforcement or stimulus control  
2721 to reduce sedentary behavior in the treatment of pediatric obesity. *Health Psychol.*  
2722 2004;23(4):371-380.
- 2723 67. Epstein LH, Roemmich JN, Stein RI, Paluch RA, Kilanowski CK. The challenge of identifying  
2724 behavioral alternatives to food: clinic and field studies. *Ann Behav Med.* 2005;30(3):201-209.
- 2725 68. Fagg J, Chadwick PM, Cole TJ, et al. From trial to population: a study of a family-based  
2726 community intervention for childhood overweight implemented at scale. *Int J Obes (2005).*  
2727 2014;38(10):1343-1349.
- 2728 69. Sacher PM, Kolotourou M, Chadwick PM, et al. Randomized controlled trial of the MEND  
2729 program: a family-based community intervention for childhood obesity. *Obesity.* 2010;18 Suppl  
2730 1:S62-68.
- 2731 70. Murray DM, Hannan PJ, Wolfinger RD, Baker WL, Dwyer JH. Analysis of data from group-  
2732 randomized trials with repeat observations on the same groups. *Stat Med* 1998;17(14):1581-  
2733 600.
- 2734 71. Rubin D. *Multiple imputation for nonresponse in surveys.* New York: John Wiley & Sons; 1987.
- 2735 72. Rubin D. Multiple Imputation after 18+ years. *J Am Stat Assoc.* 1996;91:473-489.
- 2736 73. Schafer J. *Analysis of incomplete multivariate data.* New York: Chapman & Hall; 1997.
- 2737 74. Epstein LH, Nudelman S, Wing RR. Long-term effects of family-based treatment for obesity on  
2738 nontreated family members. *Behav Ther.* 1987;18(2):147-152.
- 2739 75. Johnson MW, Bickel WK. Within-subject comparison of real and hypothetical money rewards in  
2740 delay discounting. *J Exp Anal Behav.* 2002;77(2):129-146.
- 2741 76. Thiebaut R, Jacqmin-Gadda H, Chene G, Leport C, Commenges D. Bivariate linear mixed models  
2742 using SAS proc MIXED. *Comput Methods Programs Biomed.* 2002;69(3):249-256.
- 2743 77. Krohne H, Pulsack A. *Das Erziehungsstil-Inventar (ESI): Manual.* 2nd ed. Germany: Beltz Test  
2744 Weinheim; 1995.
- 2745 78. Strauss RS, Knight J. Influence of the home environment on the development of obesity in  
2746 children. *Pediatrics.* 1999;103(6):e85.
- 2747 79. Rosenberg DE, Sallis JF, Kerr J, et al. Brief scales to assess physical activity and sedentary  
2748 equipment in the home. *Int J Behav Nutr Phys Activ.* 2010;7:10.
- 2749 80. Cerin E, Saelens BE, Sallis JF, Frank LD. Neighborhood environment walkability scale: validity and  
2750 development of a short form. *Med Sci Sports Exerc.* 2006;38(9):1682-1691.
- 2751 81. Best JR, Theim KR, Gredysa DM, et al. Behavioral economic predictors of overweight children's  
2752 weight loss. *J Consult Clin Psychol.* 2012;80(6):1086-1096.
- 2753
- 2754

2755 **IV. Appendices**

2756

2757 **A. Consent Form Samples:** *(Adjusted Primary Aim and added that there is an increased risk*  
2758 *posed to participants by using third-party platforms, this change was made on 5.23.18 prior to*  
2759 *review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).*

2760 **B. Coronavirus Addendum:** Added to address the changes in assessments due to social  
2761 distancing as a result of the serious nature of Covid-19 (UB IRB approved 5.19.20; DSMB  
2762 approved protocol addenda on 5.7.20)

2763

2764



**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018

875 Ellicott St. | Buffalo, NY 14203

UB Federal wide Assurance ID#: FWA00008824

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS  
TREATMENT IMPLEMENTED IN PRIMARY CARE**

**Sibling Adult Consent to Participate in a Research Study**

**Version Date: 07-18-2018**

**Investigators: Leonard H. Epstein, PhD**

**Why am I being invited to take part in a research study?**

You are being invited to take part in a research study because:

- You are an adult sibling of a child participating in a study through your doctor's office.
- You are able to read the English language.
- You fall into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex).

This research study is supported by a grant through the National Heart Blood and Lung Institute (NHBLI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

**What should I know about a research study?**

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

**Who can I talk to?**

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your child's doctor's office. You can also contact the research participant advocate at 716-888-4845 or [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

2807 This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to  
2808 them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu) if:

- 2809 ● You have questions about your rights as a participant in this research
- 2810 ● Your questions, concerns, or complaints are not being answered by the research team.
- 2811 ● You cannot reach the research team.
- 2812 ● You want to talk to someone besides the research team.
- 2813 ● You want to get information or provide input about this research.

2814

2815 **Why is this research being done?**

2816 The goal of this study is to determine whether a specific kind of weight loss treatment called family-  
2817 based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the  
2818 primary care setting. Extensive information has been gathered by our research team about the  
2819 treatment of childhood overweight and obesity. But there is still much to learn about how the treatment  
2820 should be incorporated into various medical settings. Such as primary care and how it effects siblings  
2821 living with participating parents and children.

2822

2823 **How long will the research last?**

2824 We expect that you will be in this treatment and research study for 24 months.

2825

2826 **How many people will be studied?**

2827 We expect about 132 families will be in this research study in your geographical location. Out of 528  
2828 families in the entire study nationally.

2829

2830 **What happens if I say yes, I want to be in this research?**

2831 To determine if your family is eligible to participate, you and your family will be asked to complete an  
2832 eligibility assessment at an orientation session about this study. Your height and weight will be  
2833 measured.

2834

2835 If your family is eligible for this research study and agrees to participate, you will attend the baseline  
2836 assessment with your sibling. You will complete a baseline assessment and an initial appointment with  
2837 your doctor. Your family will be randomized to one of two treatment conditions described below.

2838

2839

2840



2841 **Groups**

2842 At the start of the study, your family will be assigned to one of two groups. Participants in one group will  
2843 receive the current standard of care offered by their physician for the treatment of childhood weight  
2844 management. Participants in the second group will receive family-based behavioral treatment for  
2845 weight management (FBT).

2846 FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and  
2847 their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral  
2848 techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1)  
2849 The Traffic Light Eating Plan uses RED, YELLOW, and GREEN labels for food to guide families toward the  
2850 goal of eating nutritious foods. 2) The Traffic Light Activity Program also uses RED, YELLOW and GREEN  
2851 labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) A  
2852 variety of behavioral techniques including changing and controlling your environment. tracking eating  
2853 and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior  
2854 change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT  
2855 also involves making changes in the home. So that weight loss or prevention of weight gain may extend  
2856 to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

2857 The group that your family will be in/the treatment you get will be chosen by chance. Like flipping a  
2858 coin. Neither you nor your sibling's doctor will choose what treatment your family will receive. Your  
2859 family will have an equal chance of being assigned to each group. You will be informed of the group your  
2860 family is in following an initial physician visit.

2861

2862 **Treatment Schedule**

2863 Every family will follow their pediatrician recommended schedule of appointments for weight  
2864 management. Families in the group receiving FBT will additionally complete at least 26 sessions with the  
2865 FBT PLAN Coach during the 24 months of the study. The amount of sessions completed within this range  
2866 will be based on progress through the program. The amount will vary for each family. You will not  
2867 attend the sessions with the PLAN Coach.

2868 **Assessments, Interviews, Questionnaires**

2869 You will attend five major assessments throughout the entire 2 years of the study:

- 2870 ● 1 Baseline assessment upon starting study (0 months)
- 2871 ● 3 Measurement assessments during the study (6, 12, and 18 months)
- 2872 ● 1 Follow-up assessment at end of study (24 months)

2873 Each major assessment will take approximately 30-90 minutes to complete at your child's pediatric  
2874 office, or a home visit can be arranged.

2875

2876 **What are my responsibilities if I take part in this research?**  
2877 If you take part in this research, you will be responsible to attend the baseline assessment, all  
2878 measurement assessments, and the follow-up assessment. Your participation in any other meetings  
2879 with your family are voluntary. Weight measurements at these times are also voluntary and can be used  
2880 as data.

2881  
2882 **What happens if I do not want to be in this research?**  
2883 Your participation in this research study is voluntary. You may choose not to enroll in this study. There  
2884 are no other research alternatives other than to participate in this study.

2885  
2886 **What happens if I say yes, but I change my mind later?**  
2887 You can leave the research at any time. It will not be held against you, or affect your family's  
2888 participation in the study. You do not have to answer every question. You may refuse to answer any  
2889 questions that you do not want to answer.

2890 If you decide to leave the research, you may not receive full compensation for your participation. If you  
2891 decide to leave the research, contact the investigator at the contact information included below. If you  
2892 stop being in the research, already collected data may not be removed from the study database. You will  
2893 be asked whether the investigator can collect data from your routine medical care.

2894  
2895 **Is there any way being in this study could be bad for me?**  
2896 There are certain risks and discomforts that may be associated with this research. They include:

2897  
2898 **Likely**  
2899 ● You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to  
2900 attend assessments.

2901 **Less Likely**  
2902 ● You may find having your height and weight measured uncomfortable.

2903 **Rare**  
2904 ● Although this treatment usually prevents the development of eating disorder problems, in rare  
2905 cases it may increase them.

2906 ● The use of online platforms is associated with risks involving breaches of confidentiality. We  
2907 implement many layers of security to limit these risks as much as possible within our website  
2908 and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security  
2909 measures and carry their own risks if your family chooses to use them to supplement your  
2910 participation in this study.

2911  
2912 **Will being in this study help me in any way?**  
2913 We cannot promise any benefits to you or others from your taking part in this research. This study may  
2914 provide information that will help you to lose weight and keep it off. However, we cannot guarantee  
2915 that you will receive any benefits from this study.

2916  
2917 **What happens to the information collected for the research?**

2918 Efforts will be made to limit the use and disclosure of your personal information, including research  
2919 study and medical or education records, to people who have a need to review this information. We  
2920 cannot promise complete secrecy. Organizations that may inspect and copy your information include  
2921 the IRB and other representatives of this organization. Information related to you will be treated in strict  
2922 confidence to the extent provided by law. Your identity will be coded and will not be associated with any  
2923 published results. Your code number and identity will be kept in a locked file of the Principal  
2924 Investigator. The only connection between your participation in this study and the study itself will be  
2925 this signed consent form. If you withdraw from the study, no further data will be collected. Any  
2926 information that has been provided may be retained by the researchers and analyzed. In order to  
2927 monitor this research study, representatives from the Institutional Review Board (IRB) and other federal  
2928 agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection)  
2929 may inspect the research records which may reveal your identity. A description of this clinical trial will  
2930 be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include  
2931 information that can identify you. At most, the web site will include a summary of the results. You can  
2932 search this web site at any time. Federal law provides additional protections of your medical records and  
2933 related health information. These are described in the HIPAA section of this document.

2934

2935 **Can I be removed from the research without my OK?**

2936 The principal investigator of the study can remove you from the research study without your approval.  
2937 Possible reasons for removal include need for hospitalization for physical or psychological reasons.

2938

2939 **What else do I need to know?**

2940 This research is being funded by the National Institutes of Health, specifically the National Heart, Lung  
2941 and Blood Institute (NHLBI).

2942 If you need medical care because of taking part in this research study, contact the investigator and/or  
2943 speak with your doctor and medical care will be made available. Generally, this care will be billed to you,  
2944 your insurance or other third party. The University at Buffalo has no program to pay for medical care for  
2945 research-related injury.

2946

2947

2948

2949 **HIPAA: Authorization for the Use and Disclosure of Identifiable Health  
2950 Information for Research Purposes**

2951 This section describes information about you and about your health that will be obtained by the  
2952 researchers when you participate in the research study. Health information is considered "protected  
2953 health information" when it may directly identify you as an individual. By signing this form you are  
2954 agreeing to permit the researchers and/or other parties (described in detail below) to have access to  
2955 this information. If there are any parts of this form that you do not understand, please be sure to ask us  
2956 for further clarification.

2957 **A. What protected health information will be collected about you as part of this research  
2958 study?**

2959  Information from your full medical records (height, weight, dietary restrictions and  
2960 physical activity restrictions).

2961  New Health Information created from study related tests, procedures, visits, and/or  
2962 questionnaires as described in this consent form.

2963 **B. Who is authorized to provide or collect this information?**

2964  Principal Investigator or designee

2965 **C. With whom may your protected health information be shared?**

2966 Your health information may be shared with others outside of the research group for purposes  
2967 directly related to the conduct of this research study or as required by law, including but not  
2968 limited to:

2969  Clinical staff not involved in this research study who may become involved in your  
2970 care if it is potentially relevant to your treatment.

2971  The sponsor of this research study (**National Heart, Lung and Blood Institutes**  
2972 **(NHLBI)** cooperative group, etc., or its agents.

2973  The organization(s) responsible for administering this research (e.g., Research  
2974 Foundation of SUNY, University at Buffalo, Washington University, Nationwide  
2975 Children's Hospital, University of Rochester).

2976  Other medical investigators/centers/institutions participating in this research study.

2977 Your information may also be shared with individuals or entities responsible for general  
2978 administration, oversight and compliance of research activities. Examples of this include the  
2979 institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring  
2980 Boards, an Institutional Review Board, The Research Foundation of the State University of New  
2981 York, University at Buffalo Foundation Services, and accrediting bodies, or with certain  
2982 government oversight agencies that have authority over the research including the Department  
2983 of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National  
2984 Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your  
2985 information may also be shared with other entities as permitted or required by law. All  
2986 reasonable efforts will be used to protect the confidentiality of your individually identifiable  
2987 health information that may be shared with others as described above.

2988 All reasonable efforts will be used to protect the confidentiality of your protected health  
2989 information. There is the potential for individually identifiable information and the associated  
2990 health information obtained with this authorization to be re-disclosed by the recipient(s). After  
2991 such a disclosure, the information may no longer be protected by the terms of this authorization  
2992 against further re-disclosure.

2993 **D. How long will this information be kept by the Principal Investigator?**

2994  This authorization has no expiration date. The researchers may continue to rely on this  
2995 authorization to obtain and use protected health information about you unless you  
2996 revoke this authorization in writing.

2997  Your protected health information will go into a database that will be maintained  
2998 indefinitely. Any future study using this information that falls outside the scope of this  
2999 current study will be required to follow guidelines designed to govern access to that  
3000 information and to protect the privacy of that information.

3001 **E. What are your rights after signing this authorization?**

3002 You have the right to revoke this authorization at any time. If you withdraw your authorization,  
3003 no additional efforts to collect individually identifiable health information about you will be  
3004 made. You should know, however, that protected health information acquired using this

3005 authorization prior to its withdrawal may continue to be used to the extent that the  
3006 investigator(s) have already relied on your permission to conduct the research. If you chose to  
3007 withdraw this authorization, you must do so in writing to the following individual(s):

3008  
3009  
3010  
3011  
3012  
3013  
3014  
3015  
3016

**Leonard H. Epstein, Ph.D.**  
**University at Buffalo Department of Pediatrics**  
**Division of Behavioral Medicine**  
**3435 Main Street**  
**G56 Farber Hall**  
**Buffalo, NY 14214**  
**Phone: 716-829-3400**

3017 If you send us a request to withdraw your authorization, we will forward that request to the  
3018 institutions we have shared it with in order to collect your individually identifiable health  
3019 information.

3020  
3021

**F. What will happen if you decide not to sign this authorization?**

3022  
3023  
3024  
3025  
3026  
3027

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

3028

**Signature Block for Capable Adult**

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.	
Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

3029



3030  
3031  
3032  
3033  
3034  
3035  
3036  
3037  
3038  
3039  
3040  
3041  
3042  
3043  
3044  
3045  
3046  
3047  
3048  
3049  
3050  
3051  
3052  
3053  
3054  
3055  
3056  
3057  
3058  
3059  
3060  
3061  
3062  
3063  
3064  
3065  
3066  
3067  
3068  
3069  
3070  
3071  
3072  
3073

**THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT  
IMPLEMENTED IN PRIMARY CARE**

**Sibling Assent to be in a Research Study - (for Children 7-13 years of age)**

**Version Date: 07-18-2018**

**Investigators: Leonard H. Epstein, PhD**

**Who are we?**

My name is Dr. Leonard H. Epstein and I am a researcher at the UB. I work in the Department of Pediatrics.

**Why are we meeting with you?**

We want to tell you about a study that involves children like yourself. We want to see if you would like to be in this study too.

**Why are we doing this study?**

We want to look at siblings of kids participating in a study through your doctor’s office.

**What will happen to you if you are in the study?**

You, your sibling, and a parent will first come to the doctor’s office. We will tell you about this study. It teaches kids about healthy eating and activities. We will ask you if you want to be a part of the study. If you want to, we will ask to you come back for more visits.

You will be asked to come in 5 times over 2 years so we can measure your height and weight. This will be done in private. Only your parent, your sibling, and the study member will be with you. You do not have to answer any questions if you don’t want to. You do not have to do any activities you do not want to do.

**What are the good things and bad things that may happen to you if you are in the study?**

Most Likely:

*Good:* You can learn how you are growing.

Maybe:

*Good:* You could learn what is like to be in a research study. You might lose weight.

*Bad:* You might not like getting your height and weight taken.

**Do you have to be in the study?**

No you don’t. No one will get angry or upset with you if you don’t want to do this. If you do not want to be in the study at any time, it will not affect your family being in the study. Just tell us if you don’t want

3074 to be in the study. And remember, you can change your mind later if you decide you don't want to be in  
3075 the study anymore.

3076  
3077 **Do you have any questions?**

3078 You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk  
3079 to someone else at any time during the study. You can call:

3080  
3081 Name of contact person on the study: *Leonard H. Epstein, Ph.D.*  
3082 Phone Number: *(716) 829-3400*

3083  
3084

3085 **Signature Block for Sibling Assent of Child**

Your signature documents your permission to take part in this research.	
Signature of subject	Date
Printed Name of Subject	

3086  
3087 I certify that the nature and purpose, the potential benefits and possible risks associated with  
3088 participation in this research study have been explained to the above individual and that any questions  
3089 about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent	Date
Printed name of person obtaining consent	

3090  
3091

3092  
3093  
3094  
3095  
  
3096  
3097  
3098  
3099  
3100  
3101  
3102  
3103  
3104  
3105  
3106  
3107  
3108  
3109  
  
3110  
3111  
3112  
3113  
3114  
3115  
3116  
3117  
3118  
3119  
3120  
3121  
3122  
3123  
3124  
3125  
3126  
3127  
3128  
3129  
3130  
  
3131  
3132  
  
3133  
3134  
3135

**University at Buffalo Institutional Review Board (UBIRB)**  
Office of Research Compliance | Clinical and Translational Research Center Room 5018  
875 Ellicott St. | Buffalo, NY 14203  
UB Federal wide Assurance ID#: FWA00008824

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE**

*Sibling Assent of a 14-17-year-old to Participate in a Research Study*

**Version Date: 07-18-2018**

**Investigators: Leonard H. Epstein, PhD**

**Why am I being invited to take part in a research study?**

You are being invited to take part in a research study because:

- You are a sibling between the ages of 14-17 able to read the English language and you fall into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex)

This research study is supported by a grant through the National Heart Blood and Lung Institutes (NHBLI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully and ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

**What should I know about a research study?**

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

**Who can I talk to?**

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your doctor's office, or you can contact the research participant advocate at 716-888-4845 or [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu) if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.



- 3136
- You want to talk to someone besides the research team.
- 3137
- You want to get information or provide input about this research.

3138

3139 **Why is this research being done?**

3140 The goal of this study is to determine whether a specific kind of weight loss treatment called family-  
3141 based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the  
3142 primary care setting. Extensive information has been gathered by our research team about the  
3143 treatment of childhood overweight and obesity, but there is still much to learn about how the treatment  
3144 should be incorporated into various medical settings, such as primary care and how it effects siblings  
3145 living with participating parents and children.

3146

3147 **How long will the research last?**

3148 We expect that you will be in this treatment and research study for 24 months.

3149

3150 **How many people will be studied?**

3151 We expect about 132 families will be in this research study in your geographical location, out of 528  
3152 families in the entire study nationally.

3153

3154 **What happens if I say yes, I want to be in this research?**

3155 To determine if your family is eligible to participate, you and your family will be asked to complete an  
3156 eligibility assessment at an orientation session about this study. Your height and weight will be  
3157 measured.

3158 If your family is eligible for this research study and agrees to participate, you will attend the baseline  
3159 assessment with your sibling. After the baseline assessment and an initial appointment with your  
3160 sibling's doctor, your family will be randomized to one of two treatment conditions described below.  
3161 Additionally, approximately every 6 months, you will get your height and weight measurements taken.

3162 **Groups**

3163 At the start of the study, your family will be assigned to one of two groups. Participants in one group will  
3164 receive the current standard of care offered by their physician for the treatment of childhood weight  
3165 management. Participants in the second group will receive family-based behavioral treatment for  
3166 weight management (FBT). FBT is a behavioral weight-control intervention that aims to make weight  
3167 changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet,  
3168 activity, behavioral techniques, parenting, and social facilitation in children and their parents. The  
3169 treatment includes: 1) The Traffic Light Eating Plan, which uses RED, YELLOW, GREEN labels for food to  
3170 guide families toward the goal of eating nutritious foods; 2) the Traffic Light Activity Program, which also  
3171 uses RED, YELLOW and GREEN labels for different levels of exercise to increase physical activity and  
3172 reducing inactive behaviors; and 3) a variety of behavioral techniques including changing and controlling  
3173 your environment, tracking eating and physical activity, setting goals, problem solving, setting up a  
3174 reward system, incentives for behavior change and weight loss, finding substitutes for unhealthy foods,  
3175 and improving positive parenting. FBT also involves making changes in the home, so weight loss or  
3176 prevention of weight gain may extend to members of the family who are not regularly attending  
3177 treatment sessions (e.g., siblings and spouse).

3178 The group that your family will be in, will be chosen by chance, like flipping a coin. Neither you nor your  
3179 sibling's doctor will choose what treatment your family will receive. Your family will have an equal  
3180 chance of being assigned to each group. You will be informed of the group your family is in following an  
3181 initial physician visit.

3182 **Treatment Schedule**

3183 Every family will follow their pediatricians recommended schedule of appointments for weight  
3184 management. Families in the group receiving FBT will additionally complete at least 26 sessions with the  
3185 FBT interventionist during the 24 months of the study. The amount of sessions completed within this  
3186 range will be based on progress through the program and will vary for each family. You will not attend  
3187 the sessions with the PLAN coach.

3188 **Assessments, Interviews, Questionnaires**

3189 You will attend five major assessments throughout the entire 2 years of the study:

- 3190 ● 1 Baseline assessment upon starting study (0 months)
- 3191 ● 3 Measurement assessments during the study (6, 12, and 18 months)
- 3192 ● 1 Follow-up assessment at end of study (24 months)

3193 Each major assessment will take approximately 30-90 minutes to complete at your sibling's pediatric  
3194 office, or a home visit can be arranged. Your height and weight will be taken at each major assessment.

3195  
3196 **What are my responsibilities if I take part in this research?**

3197 If you take part in this research, you will be responsible to attend the baseline assessment, all  
3198 measurement assessments, and the follow-up assessment. Your participation in any other meetings  
3199 with your family are voluntary. Weight measurements at these times are also voluntary and can be used  
3200 as data.

3201  
3202 **What happens if I do not want to be in this research?**

3203 Your participation in this research study is voluntary. You may choose not to enroll in this study, it will  
3204 not affect your family being in the study. ***There are no other research alternatives other than to***  
3205 ***participate in this study.***

3206  
3207 **What happens if I say yes, but I change my mind later?**

3208 You can leave the research at any time, it will not be held against you. You do not have to answer every  
3209 question and may refuse to answer any questions that you do not want to answer.

3210 If you decide to leave the research, you may not receive full compensation for your participation. If you  
3211 decide to leave the research, contact the investigator at the contact information included below. If you  
3212 stop being in the research, already collected data may not be removed from the study database. You will  
3213 be asked whether the investigator can collect data from your routine medical care.

3214  
3215 **Is there any way being in this study could be bad for me?**

3216 There are certain risks and discomforts that may be associated with this research. They include:

3217 **Likely**

- 3218 ● You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to  
3219 attend assessments.

3220 **Less Likely**

- 3221 ● You may find having your height and weight measured uncomfortable.

3222 **Rare**

- 3223 ● Although this treatment usually prevents the development of eating disorder problems, in rare  
3224 cases it may increase them.
- 3225 ● The use of online platforms is associated with risks involving breaches of confidentiality. We  
3226 implement many layers of security to limit these risks as much as possible within our website  
3227 and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security  
3228 measures and carry their own risks if your family chooses to use them to supplement your  
3229 participation in this study.

3230 **Will being in this study help me in any way?**

3231 We cannot promise any benefits to you or others from your taking part in this research. This study may  
3232 provide information that will help you to lose weight and keep it off. However, we cannot guarantee  
3233 that you will receive any benefits from this study.

3234

3235 **What happens to the information collected for the research?**

3236 Efforts will be made to limit the use and disclosure of your personal information, including research  
3237 study and medical or education records, to people who have a need to review this information. We  
3238 cannot promise complete secrecy. Organizations that may inspect and copy your information include  
3239 the IRB and other representatives of this organization. Information related to you will be treated in strict  
3240 confidence to the extent provided by law. Your identity will be coded and will not be associated with any  
3241 published results. Your code number and identity will be kept in a locked file of the Principal  
3242 Investigator. The only connection between your participation in this study and the study itself will be  
3243 this signed consent form. If you withdraw from the study, no further data will be collected, but any  
3244 information that has been provided may be retained by the researchers and analyzed. In order to  
3245 monitor this research study, representatives from the Institutional Review Board (IRB) and other federal  
3246 agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection)  
3247 may inspect the research records which may reveal your identity. A description of this clinical trial will  
3248 be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include  
3249 information that can identify you. At most, the web site will include a summary of the results. You can  
3250 search this web site at any time.

3251

3252 **Can I be removed from the research without my OK?**

3253 The principal investigator of the study can remove you from the research study without your approval.  
3254 Possible reasons for removal include need for hospitalization for physical or psychological reasons.

3255

3256 **What else do I need to know?**

3257 This research is being funded by the National Institutes of Health, specifically the National Heart, Lung  
3258 and Blood Institute (NHLBI).

3259 If you need medical care because of taking part in this research study, contact the investigator and/or  
3260 speak with your doctor and medical care will be made available. Generally, this care will be billed to you,  
3261 your insurance, or other third party. The University at Buffalo has no program to pay for medical care for  
3262 research-related injury.

3263

3264

**Signature Block for Assent of Child**

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

_____ Signature of subject	_____ Date
_____ Printed name of subject	
I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.	
_____ Signature of person obtaining consent	_____ Date
_____ Printed name of person obtaining consent	

3265  
3266  
3267



**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018  
875 Ellicott St. | Buffalo, NY 14203

**THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT  
IMPLEMENTED IN PRIMARY CARE**

**Participating Child Assent to be in a Research Study (for Children 7-13 yrs. of  
age)**

**Version Date: 07-18-2018**

**Investigators: Leonard H. Epstein, Ph.D.**

**Who are we?**

My name is Dr. Leonard H. Epstein and I am a researcher at the University at Buffalo. I work in the Department of Pediatrics.

**Why are we meeting with you?**

We want to tell you about a study that involves children like yourself. We want to see if you would like to be in this study too.

**Why are we doing this study?**

We want to look at a certain kind of weight loss program for kids. We want to know if it will work at a doctor's office.

**What will happen to you if you are in the study?**

You and a parent will first come to the doctor's office. We will tell you about this study that teaches kids about healthy eating and activities. We will ask you if you want to be a part of the study. If you do, we will measure your height and weight. We will ask you to answer some questions about yourself and your parents. You will do a task that asks you to make choices between different amounts of money. If you want to, we will ask to you come back for more visits.

After this, you and your parent will be put in one of two groups:

- If you are in one group, you will follow the recommendations of your doctor.
- If you are in the other group, you could come to your doctor's office once a week. You would do this for 2 years. This would be at least 26 visits. At the visits you would meet with someone from the study. Your weight will be taken. You will learn about healthy food. We will teach you fun ways to exercise.

Every 6 months we will ask you some questions about yourself. We will measure your height and weight. At your baseline, 12-month and Follow-up appointments, we will ask you to do a computer task that asks you to make choices between different amounts of money.

3313 You do not have to answer any questions that you do not want to answer. You do not have to do any  
3314 activities that you do not want to do.

3315

3316 **What are the good things and bad things that may happen to you if you are in the study?**

3317 *Most Likely:* You can have fun learning about healthy food and exercise. You could become healthy.

3318

3319 *Maybe:* You could become hungry when trying to eat healthy. Your muscles could feel sore from  
3320 exercise. That will go away once you are used to exercising.

3321

3322 **Do you have to be in the study?**

3323 No you don't. No one will get angry or upset with you if you don't want to do this. Just tell us if you  
3324 don't want to be in the study. Also, you can change your mind later if you decide you don't want to be in  
3325 the study anymore.

3326

3327 **Do you have any questions?**

3328 You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk  
3329 to someone else at any time during the study. You can call:

3330

3331 Name of contact person on the study: *Leonard H. Epstein, Ph.D.* Phone Number: *(716) 829-3400*

3332

3333

3334

**Signature Block for Assent of Child**

3335

Your signature documents your permission to take part in this research.		
Signature of subject		Date
Printed name of subject		
I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.		
Signature of person obtaining consent		Date
Printed name of person obtaining consent		

3336

3337



3338  
3339 **University at Buffalo Institutional Review Board (UBIRB)**

3340 Office of Research Compliance | Clinical and Translational Research Center Room 5018

3341 875 Ellicott St. | Buffalo, NY 14203

3342 UB Federal wide Assurance ID#: FWA00008824

3343 **Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS**  
3344 **TREATMENT IMPLEMENTED IN PRIMARY CARE**

3345  
3346 **Adult Consent (Non-Participating Parent) to Participate in a Research Study**

3347  
3348 **Version Date: 07-18-2018**

3349  
3350 **Investigators: Leonard H. Epstein, Ph.D.**

3351  
3352 **Why am I being invited to take part in a research study?**

3353 You are being invited to take part in a research study because:

- 3354
  - You are a parent of a child participating in a study through your child's doctor's office.
- 3355
  - You are able to read the English.

3356 This research study is supported by a grant through the National Heart, Lung and Blood Institutes  
3357 (NHLBI). Research studies only include individuals who choose to take part in them. Your decision to  
3358 take part in this study is entirely voluntary. Please read this information carefully. Ask questions about  
3359 anything you do not understand before deciding whether or not to participate. You may also take home  
3360 an unsigned copy of this consent form to think about participating or if you wish to discuss this matter  
3361 with your family or your personal doctor. Please take your time to make your decision. Do not sign this  
3362 form unless you have had the chance to ask questions and have received satisfactory answers.

3363  
3364 **What should I know about a research study?**

- 3365
  - Someone will explain this research study to you.
- 3366
  - Whether or not you take part is up to you.
- 3367
  - You can choose not to take part.
- 3368
  - You can agree to take part and later change your mind.
- 3369
  - Your decision will not be held against you.
- 3370
  - You can ask all the questions you want before you decide.

3371  
3372 **Who can I talk to?**

3373 If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research  
3374 team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at  
3375 your child's doctor's office, or you can contact the research participant advocate at 716-888-4845 or  
3376 [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

3377 This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to  
3378 them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu) if:

- 3379
  - You have questions about your rights as a participant in this research

- 3380 ● Your questions, concerns, or complaints are not being answered by the research team.
- 3381 ● You cannot reach the research team.
- 3382 ● You want to talk to someone besides the research team.
- 3383 ● You want to get information or provide input about this research.

3384

**Why is this research being done?**

3386 The goal of this study is to determine whether a specific kind of weight loss treatment called family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the  
3387 primary care setting. Extensive information has been gathered by our research team about the  
3388 treatment of childhood overweight and obesity. But there is still much to learn about how the treatment  
3389 should be incorporated into various medical settings. Such as primary care and how it effects siblings  
3390 living with participating parents and children.

3392

**How long will the research last?**

3394 We expect that you will be in this treatment and research study for 24 months.

3395

**How many people will be studied?**

3397 We expect about 132 families will be in this research study in your geographical location. Out of 528  
3398 families in the entire study nationally.

3399

**What happens if I say yes, I want to be in this research?**

3401 To determine if you are eligible to participate, you will be asked to complete an eligibility assessment at  
3402 an orientation session about this study. Your height and weight will be measured.

3403 If you are eligible for this research study and agree to participate, you will attend the baseline  
3404 assessment with your participating child(ren), and the participating parent. After the baseline  
3405 assessment your participating family members will attend an initial appointment with your child's  
3406 doctor. Your family will be randomized to one of two treatment conditions described below.  
3407 Additionally, you will get your height and weight measurements taken at 24 months.

**Groups**

3409 At the start of the study, your family will be assigned to one of two groups. Participants in one group will  
3410 receive the current standard of care offered by their physician for the treatment of childhood weight  
3411 management. Participants in the second group will receive family-based behavioral treatment for  
3412 weight management (FBT).

3413 FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and  
3414 their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral  
3415 techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1)  
3416 The Traffic Light Eating Plan, which uses RED; YELLOW; and GREEN labels for food to guide families  
3417 toward the goal of eating nutritious foods. 2) The Traffic Light Activity Program, which also uses RED;  
3418 YELLOW; and GREEN labels for different levels of exercise to increase physical activity and reducing  
3419 inactive behaviors. 3) a variety of behavioral techniques including changing and controlling your  
3420 environment; tracking eating and physical activity; setting goals; problem solving; setting up a reward  
3421 system; incentives for behavior change and weight loss; finding substitutes for unhealthy foods; and  
3422 improving positive parenting. FBT also involves making changes in the home. So weight loss or  
3423 prevention of weight gain may extend to members of the family who are not regularly attending  
3424 treatment sessions (e.g., siblings and spouse).



3425 The group that your family will be in/the treatment they get will be chosen by chance, like flipping a  
3426 coin. Neither parent nor your child’s doctor will choose what treatment they get. Your participating  
3427 family members will have an equal chance of being assigned to each group. Your family will be informed  
3428 of the group they are in following an initial physician visit.

3429 **Treatment Schedule**

3430 Every family will follow their pediatricians recommended schedule of appointments for weight  
3431 management. Families in the group receiving FBT will additionally complete at least 26 sessions with the  
3432 FBT interventionist during the 24 months of the study. The amount of sessions completed within this  
3433 range will be based on progress through the program. The amount will vary for each family. You will not  
3434 attend the sessions with the PLAN coach.

3435 **Assessments, Interviews, Questionnaires**

3436 You will attend two major assessments throughout the entire 2 years of the study:

- 3437 ● 1 Baseline assessment upon starting study (0 months)
- 3438 ● 1 Follow-up assessment at end of study (24 months)

3439 Each major assessment will take approximately 15 minutes to complete at your child’s pediatric office,  
3440 or a home visit can be arranged. Your height and weight will be taken at each major assessment.

3441

3442 **What are my responsibilities if I take part in this research?**

3443 If you take part in this research, you will be responsible to get your height taken at baseline and weight  
3444 taken at baseline and final assessment sessions. Your participation in any other meetings with your  
3445 family are voluntary. Weight measurements at these times are also voluntary and can be used as data.

3446

3447 **What happens if I do not want to be in this research?**

3448 Your participation in this research study is voluntary. You may choose not to enroll in this study it will  
3449 not affect your family being in the study. There are no other research alternatives other than to  
3450 participate in this study.

3451

3452 **What happens if I say yes, but I change my mind later?**

3453 You can leave the research at any time. It will not be held against you, or affect your family’s  
3454 participation in the study. You do not have to answer every question. You may refuse to answer any  
3455 questions that you do not want to answer.

3456 If you decide to leave the research, you may not receive full compensation for your participation. If you  
3457 decide to leave the research, contact the investigator at the contact information included below. If you  
3458 stop being in the research, already collected data may not be removed from the study database. You will  
3459 be asked whether the investigator can collect data from your routine medical care.

3460

3461 **Is there any way being in this study could be bad for me?**

3462 There are certain risks and discomforts that may be associated with this research. They include:

3463 **Likely**

- 3464 ● You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to  
3465 attend assessments.

3466 **Less Likely**

- 3467 ● You may find having your height and weight measured uncomfortable.

3468 **Rare**

3469       • Although this treatment usually prevents the development of eating disorder problems, in rare  
3470 cases it may increase them.

3471       • The use of online platforms is associated with risks involving breaches of confidentiality. We  
3472 implement many layers of security to limit these risks as much as possible within our website  
3473 and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security  
3474 measures and carry their own risks if your family chooses to use them to supplement your  
3475 participation in this study.

3476 **Will being in this study help me in any way?**

3477 We cannot promise any benefits to you or others from your family taking part in this research. This  
3478 study may provide information that will help you to lose weight and keep it off. However, we cannot  
3479 guarantee that you will receive any benefits from this study.

3480

3481 **What happens to the information collected for the research?**

3482 Efforts will be made to limit the use and disclosure of your personal information, including research  
3483 study and medical or education records, to people who have a need to review this information. We  
3484 cannot promise complete secrecy. Organizations that may inspect and copy your information include  
3485 the IRB and other representatives of this organization. Information related to you will be treated in strict  
3486 confidence to the extent provided by law. Your identity will be coded and will not be associated with any  
3487 published results. Your code number and identity will be kept in a locked file of the Principal  
3488 Investigator. The only connection between your participation in this study and the study itself will be  
3489 this signed consent form. If you withdraw from the study, no further data will be collected. Any  
3490 information that has been provided may be retained by the researchers and analyzed. In order to  
3491 monitor this research study, representatives from the Institutional Review Board (IRB) and other federal  
3492 agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection)  
3493 may inspect the research records which may reveal your identity. A description of this clinical trial will  
3494 be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include  
3495 information that can identify you. At most, the web site will include a summary of the results. You can  
3496 search this web site at any time. Federal law provides additional protections of your medical records and  
3497 related health information. These are described in the HIPAA section of this document.

3498 **Can I be removed from the research without my OK?**

3499 The principal investigator of the study can remove you from the research study without your approval.  
3500 Possible reasons for removal include need for hospitalization for physical or psychological reasons.

3501

3502 **What else do I need to know?**

3503 This research is being funded by the National Institutes of Health, specifically the National Heart, Lung  
3504 and Blood Institute (NHLBI).

3505 If you need medical care because of taking part in this research study, contact the investigator and/or  
3506 speak with your doctor and medical care will be made available. Generally, this care will be billed to you,  
3507 your insurance, or other third party. The University at Buffalo has no program to pay for medical care for  
3508 research-related injury.

3509

3510 **HIPAA: Authorization for the Use and Disclosure of Identifiable Health**  
3511 **Information for Research Purposes**

3512 This section describes information about you and about your health that will be obtained by the  
3513 researchers when you participate in the research study. Health information is considered "protected  
3514 health information" when it may directly identify you as an individual. By signing this form you are  
3515 agreeing to permit the researchers and/or other parties (described in detail below) to have access to  
3516 this information. If there are any parts of this form that you do not understand, please be sure to ask us  
3517 for further clarification.

3518 **A. What protected health information will be collected about you as part of this research**  
3519 **study?**

3520  Specific information from your medical records related to height and weight.

3521  New Health Information created from study related tests, procedures, visits, and/or  
3522 questionnaires as described in this consent form.

3523

3524 **B. Who is authorized to provide or collect this information?**

3525  Principal Investigator or designee

3526

3527 **C. With whom may your protected health information be shared?**

3528 Your health information may be shared with others outside of the research group for purposes  
3529 directly related to the conduct of this research study or as required by law, including but not  
3530 limited to:

3531  Clinical staff not involved in this research study who may become involved in you and  
3532 your child's care if it is potentially relevant to your treatment.

3533  The sponsor of this research study (National Heart, Lung and Blood Institutes (NHLBI)  
3534 cooperative group, etc., or its agents.

3535  The organization(s) responsible for administering this research (e.g., Research  
3536 Foundation of SUNY, University at Buffalo, Washington University, Nationwide  
3537 Children's Hospital, University of Rochester).

3538  Other medical investigators/centers/institutions participating in this research study.

3539 Your information may also be shared with individuals or entities responsible for general  
3540 administration, oversight and compliance of research activities. Examples of this include the  
3541 institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring  
3542 Boards, an Institutional Review Board, The Research Foundation of the State University of New  
3543 York, University at Buffalo Foundation Services, and accrediting bodies, or with certain  
3544 government oversight agencies that have authority over the research including the Department  
3545 of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National  
3546 Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your  
3547 information may also be shared with other entities as permitted or required by law. All  
3548 reasonable efforts will be used to protect the confidentiality of your individually identifiable  
3549 health information that may be shared with others as described above.

3550 All reasonable efforts will be used to protect the confidentiality of your protected health  
3551 information. There is the potential for individually identifiable information and the associated  
3552 health information obtained with this authorization to be re-disclosed by the recipient(s). After

3553 such a disclosure, the information may no longer be protected by the terms of this authorization  
3554 against further re-disclosure.

3555

3556

3557 **D. How long will this information be kept by the Principal Investigator?**

3558  This authorization has no expiration date. The researchers may continue to rely on this  
3559 authorization to obtain and use protected health information about you unless you  
3560 revoke this authorization in writing.

3561  Your protected health information will go into a database that will be maintained  
3562 indefinitely. Any future study using this information that falls outside the scope of this  
3563 current study will be required to follow guidelines designed to govern access to that  
3564 information and to protect the privacy of that information.

3565 **E. What are your rights after signing this authorization?**

3566 You have the right to revoke this authorization at any time. If you withdraw your authorization,  
3567 no additional efforts to collect individually identifiable health information about you will be  
3568 made. You should know, however, that protected health information acquired using this  
3569 authorization prior to its withdrawal may continue to be used to the extent that the  
3570 investigator(s) have already relied on your permission to conduct the research. If you chose to  
3571 withdraw this authorization, you must do so in writing to the following individual(s):

3572

3573

3574

3575

3576

3577

3578

3579

3580

3581

3582

3583

3584

3585

3586

3587

3588

3589

3590

3591

3592

**Leonard H. Epstein, Ph.D.**

**University at Buffalo Department of Pediatrics**

**Division of Behavioral Medicine**

**3435 Main Street**

**G56 Farber Hall**

**Buffalo, NY 14214**

**Phone: 716-829-3400**

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

**F. What will happen if you decide not to sign this authorization?**

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

**Signature Block for Capable Adult**

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or

misconduct of those involved in the research.	
Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

3593  
3594  
3595



**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018

875 Ellicott St. | Buffalo, NY 14203

UB Federal wide Assurance ID#: FWA00008824

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE**

**Parental Permission for Targeted Child to Participate in a Research Study**

**Version Date: 07-18-2018**

**Investigators: Leonard H. Epstein, Ph.D.**

**Why is my child being invited to take part in a research study?**

Your child is being invited to take part in a research study because:

- You are an adult able to read the English language. You have reported no current learning disabilities, medical problems, or psychiatric problems.
- Your child is between the ages of 6 and 12 years old, falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex), and your child has at least one parent that is willing to participate in the study.

This research study is supported by a grant through the National Heart Lung Blood Institutes (NHLBI). Research studies only include individuals who choose to take part in them. Your decision for your child to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

**What should my child and I know about a research study?**

- Someone will explain this research study to you and your child.
- Whether or not your child takes part is up to you and your child.
- You and your child can choose for your child not to take part.
- You and your child can agree to take part and later change your mind.
- You and your child's decision will not be held against you.
- You and your child can ask all the questions you want before you decide.

**Who can my child and I talk to?**

If you or your child has questions, concerns, or complaints, or think the research has hurt your child, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your child's doctor's office. You can also contact the research participant advocate at 716-888-4845 or [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu) if:

- 3639 ● You have questions about your child’s rights as a participant in this research
- 3640 ● Your questions, concerns, or complaints are not being answered by the research team.
- 3641 ● You cannot reach the research team.
- 3642 ● You want to talk to someone besides the research team.
- 3643 ● You want to get information or provide input about this research.

3644

**Why is this research being done?**

3646 The goal of this study is to determine whether a specific kind of weight loss treatment called family-  
3647 based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the  
3648 primary care setting. Extensive information has been gathered by our research team about the  
3649 treatment of childhood overweight and obesity. But there is still much to learn about how the treatment  
3650 should be incorporated into various medical settings. Such as primary care.

3651

3652 Your child has been asked to participate because he/she is between the ages of 6 and 12 years old, falls  
3653 into the overweight or obese weight category (defined as at or above the 85th percentile for age and  
3654 sex), and your child has at least one parent that is willing to participate in the study.

3655

**How long will the research last?**

3657 We expect that your child will be in this treatment and research study for 24 months.

3658

**How many people will be studied?**

3660 We expect about 132 families will be in this research study in your geographical location, out of 528  
3661 families in the entire study nationally.

3662

**What happens if I say yes, my child wants to be in this research?**

3664 To determine if your child is eligible to participate, you and your child will be asked to complete an  
3665 eligibility assessment at an orientation session about this study. You and your child’s height and weight  
3666 will be measured, and standard questions regarding medical and psychological history will be asked by a  
3667 trained interviewer to determine eligibility.

3668 If your family is eligible for this research study and agrees to participate, you and your child will be asked  
3669 to come to your pediatric office to complete a baseline assessment (detailed below). Additionally, we  
3670 hope to collect information about how participation in FBT may affect others in your home. Therefore, if  
3671 you have another child who meets eligibility criteria (between the ages of 2-18 who is at or above the  
3672 85th percentile for age and sex), we ask that this child also attend the baseline assessment. After the  
3673 baseline assessment and an initial appointment with your child’s doctor, your family will be randomized  
3674 to one of two treatment conditions described below.

3675

**Groups**

3677 At the start of the study, your family will be assigned to one of two groups. Participants in one group  
3678 will receive the current standard of care offered by their physician for the treatment of childhood  
3679 weight management. Participants in the second group will receive family-based behavioral treatment  
3680 for weight management (FBT).

3681 FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and  
3682 their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral  
3683 techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1)  
3684 The Traffic Light Eating Plan uses RED; YELLOW; GREEN labels for food to guide families toward the goal

3685 of eating nutritious foods. 2) The Traffic Light Activity Program also uses RED; YELLOW; and GREEN  
3686 labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a  
3687 variety of behavioral techniques including changing and controlling your environment; tracking eating  
3688 and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior  
3689 change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT  
3690 also involves making changes in the home. So that weight loss or prevention of weight gain may extend  
3691 to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

3692 The group that your family will be in/the treatment you get will be chosen by chance. Like flipping a  
3693 coin. Neither you nor your doctor will choose what treatment your family will receive. Your family will  
3694 have an equal chance of being assigned to each group. You will be informed of the group your family is  
3695 in and your treatment following an initial physician visit.

### 3696 **Treatment Schedule**

3697 Every family will follow their pediatricians recommended schedule of appointment for weight  
3698 management. Families in the group receiving FBT will additionally complete at least 26 sessions with the  
3699 FBT PLAN coach during the 24 months of the study. The amount of session completed within this range  
3700 will be based on progress through the program. The amount will vary for each family.

### 3701 **Assessments, Interviews, Questionnaires**

3702 Attendance will be taken and both you and your child will be weighed at every session. In addition, there  
3703 will be five major assessments throughout the entire 2 years of the study:

- 3704 ● 1 Baseline assessment upon starting study (0 months)
- 3705 ● 3 Measurement assessments during the study (6, 12, and 18 months)
- 3706 ● 1 Follow-up assessment at end of study (24 months)

3707 Each major assessment will take approximately 30-90 minutes to complete at your child's pediatric  
3708 office, or a home visit can be arranged. Height and weight will be taken on you and your child as well as  
3709 the identified other family members (if applicable). Your height will be taken at the beginning of the  
3710 study, and your child(ren)'s height will be taken at each major assessment. You and your participating  
3711 child will also complete short questionnaires. At your baseline, 12-month, and follow-up appointment,  
3712 you will be asked to complete a computer task. You both will be asked questions about parenting  
3713 behaviors and the home food and activity environment. Throughout the study, you will have access to a  
3714 website that contains study materials and interactive tools. At the very end of the study, the PLAN  
3715 coach will review your child's chart to collect data on Usual Care.

### 3716 **Audio Recording**

3717 Your interviews and individual family and will be audiotaped or digitally recorded for research purposes,  
3718 but you will not be identified on the recording and the recordings will not be labeled with your name.  
3719 Recording the sessions is the best way to make sure we collect accurate information. It also helps us  
3720 make sure that all our staff delivers the study to participants in the same way. The recordings will be  
3721 stored on password-protected computers with restricted access within the University at Buffalo, and  
3722 then transferred to Washington University School of Medicine. The recordings will be labeled only with  
3723 your study ID, date, and session number. The Principal Investigator and research staff may use these  
3724 recordings for purposes of evaluation, treatment, research, and training related to this study.  
3725 Recordings may also be used to train staff implementing these or similar interventions at other sites.  
3726 The recordings will be destroyed at the end of the study when all data analysis is complete. You do not  
3727 have to agree to be audio recorded in order to participate in this study.

3728 **Please check and initial below if you agree for you and your child to be audio recorded during your**  
3729 **sessions with the PLAN coach:**



3730 \_\_\_\_\_ YES, PARENT INITIAL \_\_\_\_\_ , I give my permission to be audio recorded  
3731 during sessions with a PLAN Coach. Date: \_\_\_\_\_

3732

3733 \_\_\_\_\_ NO, PARENT INITIAL \_\_\_\_\_ , I do **not give** my permission to be audio recorded  
3734 during sessions with a PLAN Coach. Date: \_\_\_\_\_

3735

3736 **What are my child’s responsibilities if he/she takes part in this research?**

3737 If your child takes part in this research, he/she will be responsible to: attend the baseline assessment,  
3738 attend all measurement assessments, attend at least 26 treatment sessions if your family is in the group  
3739 receiving FBT, and attend the follow-up assessment.

3740 **What happens if my child does not want to be in this research?**

3741 Your child’s participation in this research study is voluntary. You or your child may choose not to enroll  
3742 in this study. There are no other research alternatives other than to participate in this study.

3743 **What happens if my child and I say yes, but change our mind later?**

3744 Your child can leave the research at any time. It will not be held against him/her. Your child does not  
3745 have to answer every question. He/she may refuse to answer any questions that he/she does not want  
3746 to answer.

3747 If your child decides to leave the research, you may not be able to find this kind of family treatment in  
3748 your area outside of this research study. Other types of treatment may be available in your community.  
3749 In which case we will provide a list of these and how to find them if you prefer this option. However you  
3750 and/or your insurance company would be responsible for any costs associated with these options. You  
3751 also may not receive full compensation for your participation. If your child decides to leave the research,  
3752 contact the investigator at the contact information included below. If your child stops being in the  
3753 research, already collected data may not be removed from the study database. You will be asked  
3754 whether the investigator can collect data from your child’s routine medical care.

3755

3756 **Is there any way being in this study could be bad for my child?**

3757 There are certain risks and discomforts that may be associated with this research. They include:

3758 **Likely**

- 3759 ● Your child might feel hungry when dieting or sore after exercising.

3760 **Less Likely**

- 3761 ● Your child may find some of the questions embarrassing or be uncomfortable having his/her  
3762 height and weight measured.

- 3763 ● There may be some family disagreements as issues of family functioning; communication; and  
3764 discipline are discussed.

- 3765 ● Your child may be inconvenienced at times by having to miss school activities, meetings, etc., to  
3766 attend assessments and family sessions.

3767 **Rare**

- 3768 ● There is a risk of audio recordings being lost. All recordings will be immediately stored in a  
3769 locked drawer or saved to a password-protected computer in the research office after the  
3770 individual family and group weight loss and maintenance sessions. Your family name will not be  
3771 on these recordings, which will be identified only by a study ID number.

3772 ● The use of online platforms is associated with risks involving breaches of confidentiality. We  
3773 implement many layers of security to limit these risks as much as possible within our website  
3774 and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security  
3775 measures and carry their own risks if your family chooses to use them to supplement your  
3776 participation in this study.

3777 ● In addition, although this treatment usually prevents the development of eating disorder  
3778 problems, in rare cases it may increase them.

3779 **Other Risks**

3780 ● In this study your child will be given a physical activity goal. Given that some people may have  
3781 medical risks associated with increasing their physical activity, these recommendations for your  
3782 child will be given in consultation with his/her doctor.

3783 ● **Randomization** - As mentioned before, this study has two groups. Because chance decides  
3784 which group your child will be in, the treatment your child receives as part of this study may not  
3785 be what your own doctor would choose for your child.

3786

3787 **Will being in this study help my child in any way?**

3788 We cannot promise any benefits to you, your child, or others from your taking part in this research.  
3789 However, possible benefits could include your child losing weight, becoming more physically active, and  
3790 eating more healthfully as a result of participation. In addition, maintaining weight loss may lead to  
3791 better relationships and better mood. However, we cannot guarantee your child will receive any  
3792 benefits from this study. This study may provide information that will help other children inside and  
3793 outside your household to lose weight and keep it off.

3794

3795 **What happens to the information collected for the research?**

3796 Efforts will be made to limit the use and disclosure of your child's personal information, including  
3797 research study and medical or education records, to people who have a need to review this information.  
3798 We cannot promise complete secrecy. Organizations that may inspect and copy your child's information  
3799 include the IRB and other representatives of this organization. Information related to your child will be  
3800 treated in strict confidence to the extent provided by law. Your child's identity will be coded and will not  
3801 be associated with any published results. Your child's code number and identity will be kept in a locked  
3802 file of the Principal Investigator. The only connection between your child's participation in this study and  
3803 the study itself will be this signed consent form. All recordings of the sessions will be kept in a locked file  
3804 of the Principal Investigator until the end of the study. At which point they will be destroyed. If your  
3805 child withdraws from the study, no further data will be collected. Any information that has been  
3806 provided may be retained by the researchers and analyzed. In order to monitor this research study,  
3807 representatives from the Social and Behavioral Sciences Institutional Review Board (SBSIRB) and other  
3808 federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research  
3809 Protection) may inspect the research records which may reveal your child's identity. A description of this  
3810 clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will  
3811 not include information that can identify your child. At most, the web site will include a summary of the  
3812 results. You can search this web site at any time. Federal law provides additional protections of your  
3813 child's medical records and related health information. These are described in the HIPAA section of this  
3814 document.

3815

3816

3817

3818 **Can my child be removed from the research without our OK?**

3819 The principal investigator of the study can remove your child from the research study without your or  
3820 your child’s approval. Possible reasons for removal include need for hospitalization for physical or  
3821 psychological reasons. We will tell you about any new information that may affect your child’s health,  
3822 welfare, or choice to stay in the research.

3823  
3824 **What else do my child and I need to know?**

3825 This research is being funded by the National Institutes of Health, specifically the National Heart, Lung  
3826 and Blood Institute (NHLBI).

3827 If your child needs medical care because of taking part in this research study, contact the investigator  
3828 and/or speak with your doctor and medical care will be made available. Generally, this care will be billed  
3829 to you, your insurance or other third party. The University at Buffalo has no program to pay for medical  
3830 care for research-related injury. If your child agrees to take part in this research study, we will pay your  
3831 family up to \$175 for your time and effort. The amount you are paid depends upon your attendance to  
3832 visits in the study.

3833  
3834 **HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research**  
3835 **Purposes**

3836 This section describes information about your child and about your child’s health that will be obtained  
3837 by the researchers when your child participates in the research study. Health information is considered  
3838 "protected health information" when it may directly identify your child as an individual. By signing this  
3839 form you are agreeing to permit the researchers and/or other parties (described in detail below) to have  
3840 access to this information. If there are any parts of this form that you do not understand, please be sure  
3841 to ask us for further clarification.

3842 **A. What protected health information will be collected about your child as part of this**  
3843 **research study?**

3844  Information from your child’s full medical records.

3845  New Health Information created from study related tests, procedures, visits, and/or  
3846 questionnaires as described in this consent form.

3847 **B. Who is authorized to provide or collect this information?**

3848  Principal Investigator or designee

3849 **C. With whom may your child’s protected health information be shared?**

3850 Your child’s health information may be shared with others outside of the research group for  
3851 purposes directly related to the conduct of this research study or as required by law, including  
3852 but not limited to:

3853  Clinical staff not involved in this research study who may become involved in your  
3854 child’s care if it is potentially relevant to your treatment.

3855  The sponsor of this research study (**National Heart, Lung and Blood Institutes**  
3856 **(NHLBI)** cooperative group, etc., or its agents.

3857  The organization(s) responsible for administering this research (e.g., Research  
3858 Foundation of SUNY, University at Buffalo, Washington University, Nationwide  
3859 Children’s Hospital, University of Rochester).

3860   √   Other medical investigators/centers/institutions participating in this research study.

3861 Your child’s information may also be shared with individuals or entities responsible for general  
3862 administration, oversight and compliance of research activities. Examples of this include the  
3863 institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring  
3864 Boards, an Institutional Review Board, The Research Foundation of the State University of New  
3865 York, University at Buffalo Foundation Services, and accrediting bodies, or with certain  
3866 government oversight agencies that have authority over the research including the Department of  
3867 Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes  
3868 of Health (NIH), and the Office of Human Research Protections (OHRP). Your child’s information  
3869 may also be shared with other entities as permitted or required by law. All reasonable efforts will  
3870 be used to protect the confidentiality of your child’s individually identifiable health information  
3871 that may be shared with others as described above.

3872 All reasonable efforts will be used to protect the confidentiality of your child’s protected health  
3873 information. There is the potential for individually identifiable information and the associated  
3874 health information obtained with this authorization to be re-disclosed by the recipient(s). After  
3875 such a disclosure, the information may no longer be protected by the terms of this authorization  
3876 against further re-disclosure.

3877

3878 **D. How long will this information be kept by the Principal Investigator?**

3879   √   This authorization has no expiration date. The researchers may continue to rely on this  
3880 authorization to obtain and use protected health information about your child unless  
3881 you revoke this authorization in writing.

3882   √   Your child’s protected health information will go into a database that will be maintained  
3883 indefinitely. Any future study using this information that falls outside the scope of this  
3884 current study will be required to follow guidelines designed to govern access to that  
3885 information and to protect the privacy of that information.

3886 **E. What are your rights after signing this authorization?**

3887 You have the right to revoke this authorization at any time. If you withdraw your authorization,  
3888 no additional efforts to collect individually identifiable health information about your child will  
3889 be made. You should know, however, that protected health information acquired using this  
3890 authorization prior to its withdrawal may continue to be used to the extent that the  
3891 investigator(s) have already relied on your permission to conduct the research. If you chose to  
3892 withdraw this authorization, you must do so in writing to the following individual(s):

3893

3894 **Leonard H. Epstein, Ph.D.**  
3895 **University at Buffalo Department of Pediatrics**  
3896 **Division of Behavioral Medicine**  
3897 **3435 Main Street**  
3898 **G56 Farber Hall**  
3899 **Buffalo, NY 14214**  
3900 **Phone: 716-829-3400**

3901

3902 If you send us a request to withdraw your authorization, we will forward that request to the  
3903 institutions we have shared it with in order to collect your individually identifiable health  
3904 information.

3905

3906 **F. What will happen if you decide not to sign this authorization?**

3907

3908 Refusing to sign this authorization will not affect the present or future care your child receives at  
3909 this institution and will not cause any penalty or loss of benefits to which you are otherwise  
3910 entitled. If you decide not to sign this authorization, you and your child will not be able to  
3911 participate in the research study.

3912

3913  
3914

**Signature Block for Parental Permission**

Your signature documents your permission for the named child to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

- Parent
- Individual legally authorized to consent to the child's general medical care (See note below)

**Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Assent Process

- 3915  Child is birth-6 yrs. old - Assent is not required
- 3916  Child is 7-17 yrs. old – A separate Assent Document is to be signed by the child
- 3917  Assent will be obtained Verbally
- 3918  Assent has been waived by the IRB
- 3919

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent

Date

Printed name of person obtaining consent

3920  
3921

3922  
3923  
3924  
3925  
3926  
3927  
3928  
  
3929  
3930  
3931  
3932  
3933  
3934  
3935  
3936  
3937  
3938  
3939  
3940  
3941  
3942  
3943  
3944  
3945  
3946  
3947  
  
3948  
3949  
3950  
3951  
3952  
3953  
3954  
3955  
3956  
3957  
3958  
3959  
3960  
3961  
3962  
3963  
3964



**University at Buffalo Institutional Review Board (UBIRB)**  
Office of Research Compliance | Clinical and Translational Research Center Room 5018  
875 Ellicott St. | Buffalo, NY 14203  
UB Federal wide Assurance ID#: FWA00008824

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT  
IMPLEMENTED IN PRIMARY CARE**

**Parental Permission of Sibling to Participate in a Research Study**

**Version Date: 07-18-2018**

**Investigators: Leonard H. Epstein, PhD**

**Why is my child being invited to take part in a research study?**

Your child is being invited to take part in a research study because:

- You are an adult able to read the English language. You have reported no current learning disabilities, medical problems, or psychiatric problems.
- You have a child between the ages of 2-18 years old that falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex) and is willing to participate by getting his/her height and weight taken every 6 months over the two-year study.
- You have another child between the ages of 6 and 12 years old that falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex), and your child has at least one parent that is willing to participate in the study.

This research study is supported by a grant through the National Heart Lung Blood Institutes (NHLBI). Research studies only include individuals who choose to take part in them. Your decision for your child to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

**What should my child and I know about a research study?**

- Someone will explain this research study to you and your child.
- Whether or not your child takes part is up to you and your child.
- You and your child can choose for your child not to take part.
- You and your child can agree to take part and later change your mind.
- You and your child's decision will not be held against you.
- You and your child can ask all the questions you want before you decide.

3965 **Who can my child and I talk to?**

3966 If you or your child has questions, concerns, or complaints, or think the research has hurt your child, talk  
3967 to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the  
3968 PLAN coach at your child’s doctor’s office. You can also contact the research participant advocate at  
3969 716-888-4845 or [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

3970 This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to  
3971 them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu) if:

- 3972 ● You have questions about your child’s rights as a participant in this research
- 3973 ● Your questions, concerns, or complaints are not being answered by the research team.
- 3974 ● You cannot reach the research team.
- 3975 ● You want to talk to someone besides the research team.
- 3976 ● You want to get information or provide input about this research.

3977  
3978 **Why is this research being done?**

3979 The goal of this study is to determine whether a specific kind of weight loss treatment called family-  
3980 based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the  
3981 primary care setting. Extensive information has been gathered by our research team about the  
3982 treatment of childhood overweight and obesity. But there is still much to learn about how the treatment  
3983 should be incorporated into various medical settings, such as primary care.

3984  
3985 Your child has been asked to participate because he/she is between the ages of 2 and 18 years old, falls  
3986 into the overweight or obese weight category (defined as at or above the 85th percentile for age and  
3987 sex), has one sibling who is also considered overweight or obese (BMI greater than 25), and has at least  
3988 one parent that is willing to participate in the study.

3989  
3990 **How long will the research last?**

3991 We expect that your child will be in this research study for 24 months.

3992  
3993 **How many people will be studied?**

3994 We expect about 132 families will be in this research study in your geographical location, out of 528  
3995 families in the entire study nationally.

3996  
3997 **What happens if I say yes, my child wants to be in this research?**

3998 To determine if your child is eligible to participate you, your participating (target) child, and this  
3999 participating sibling will be asked to complete an eligibility assessment at an orientation session about  
4000 this study. You and your children’s height and weight will be measured.

4001 If your family is eligible for this research study and agrees to participate, the participating sibling  
4002 (between the ages of 2-18 who is at or above the 85th percentile for age and sex) will attend the  
4003 baseline assessment with you and your target child. After the baseline assessment and an initial  
4004 appointment with your child’s doctor, your family will be randomized to one of two treatment  
4005 conditions described below.

4006 **Groups**

4007 At the start of the study, your family will be assigned to one of two groups. Participants in one group will  
4008 receive the current standard of care offered by their physician for the treatment of childhood weight  
4009 management. FBT is a behavioral weight-control intervention that aims to make weight changes in both  
4010 a child and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral



4011 techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1)  
4012 The Traffic Light Eating Plan uses RED; YELLOW; and GREEN labels for food to guide families toward the  
4013 goal of eating nutritious foods. 2) The Traffic Light Activity Program also uses RED; YELLOW; and GREEN  
4014 labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a  
4015 variety of behavioral techniques including changing and controlling your environment; tracking eating  
4016 and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior  
4017 change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT  
4018 also involves making changes in the home. So weight loss or prevention of weight gain may extend to  
4019 members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

4020 The group that your family will be in/the treatment you get will be chosen by chance. Like flipping a  
4021 coin. Neither you nor your doctor will choose what treatment your family will receive. Your family will  
4022 have an equal chance of being assigned to each group. You will be informed of the group your family is  
4023 in and your treatment following an initial physician visit.

4024

#### 4025 **Treatment Schedule**

4026 Every family will follow their pediatrician recommended schedule of appointments for weight  
4027 management to have at least 4 visits with their child's doctor over the course of the 24 months of the  
4028 study. Families in the group receiving FBT will additionally complete at least 26 sessions with the FBT  
4029 PLAN coach during the 24 months of the study. The amount of session completed within this range will  
4030 be based on progress through the program. The amount will vary for each family. The participating  
4031 sibling will not attend the sessions with the PLAN coach.

4032

#### 4033 **Assessments, Interviews, Questionnaires**

4034 The participating sibling will attend five major assessments throughout the entire 2 years of the study:

- 4035 ● 1 Baseline assessment upon starting study (0 months)
- 4036 ● 3 Measurement assessments during the study (6, 12, and 18 months)
- 4037 ● 1 Follow-up assessment at end of study (24 months)

4038 Each major assessment will take approximately 30-90 minutes to complete at your child's pediatric  
4039 office, or a home visit can be arranged. Height and weight will be taken on you, your participating child,  
4040 as well as the participating sibling and identified other family members (if applicable).

#### 4041 **What are my child's responsibilities if he/she takes part in this research?**

4042 If your child (participating sibling) takes part in this research, he/she will be responsible to attend the  
4043 baseline assessment, the three measurement assessments, and the follow-up assessment to obtain  
4044 height and weight information. Your child's (participating sibling) participation in any other meetings  
4045 with your family are voluntary. Weight measurements at these times are also voluntary and can be used  
4046 as data.

4047

4048

4049 **What happens if my child does not want to be in this research?**

4050 Your child's participation in this research study is voluntary. You or your child may choose not to enroll  
4051 in this study. There are no other research alternatives other than to participate in this study.

4052

4053 **What happens if my child and I say yes, but change our mind later?**

4054 Your child can leave the research at any time. It will not be held against him/her. Your child does not  
4055 have to answer every question. He/she may refuse to answer any questions that he/she does not want  
4056 to answer. If your participating sibling child leaves the research, this will not affect the status of you or  
4057 your participating (target) child in the study.

4058 If you or your child decides to leave the research, you may not be able to find this kind of family  
4059 treatment in your area outside of this research study. Other types of treatment may be available in your  
4060 community. In which case we will provide a list of these and how to find them if you prefer this option.  
4061 However you and/or your insurance company would be responsible for any costs associated with these  
4062 options. You also may not receive full compensation for your participation. If your child decides to leave  
4063 the research, contact the investigator at the contact information included below. If your child stops  
4064 being in the research, already collected data may not be removed from the study database. You will be  
4065 asked whether the investigator can collect data from your child's routine medical care.

4066

4067 **Is there any way being in this study could be bad for my child?**

4068 There are certain risks and discomforts that may be associated with this research. They include:

4069 **Likely**

- 4070 ● You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to  
4071 attend assessments.

4072 **Less Likely**

- 4073 ● Your child may be uncomfortable having his/her height and weight measured.

4074 **Rare**

- 4075 ● In addition, although this treatment usually prevents the development of eating disorder  
4076 problems, in rare cases it may increase them.
- 4077 ● The use of online platforms is associated with risks involving breaches of confidentiality. We  
4078 implement many layers of security to limit these risks as much as possible within our website  
4079 and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security  
4080 measures and carry their own risks if your family chooses to use them to supplement your  
4081 participation in this study.

4082 **Will being in this study help my child in any way?**

4083 We cannot promise any benefits to you, your child, or others from your taking part in this research. This  
4084 study may provide information that will help your child to lose weight and keep it off. However, we  
4085 cannot guarantee your child will receive any benefits from this study.

4086

4087 **What happens to the information collected for the research?**

4088 Efforts will be made to limit the use and disclosure of your child's personal information, including  
4089 research study and medical or education records, to people who have a need to review this information.  
4090 We cannot promise complete secrecy. Organizations that may inspect and copy your child's information  
4091 include the IRB and other representatives of this organization. Information related to your child will be  
4092 treated in strict confidence to the extent provided by law. Your child's identity will be coded and will not

4093 be associated with any published results. Your child's code number and identity will be kept in a locked  
4094 file of the Principal Investigator. The only connection between your child's participation in this study and  
4095 the study itself will be this signed consent form. All recordings of the sessions will be kept in a locked file  
4096 of the Principal Investigator until the end of the study. At which point they will be destroyed. If your  
4097 child withdraws from the study, no further data will be collected. Any information that has been  
4098 provided may be retained by the researchers and analyzed. In order to monitor this research study,  
4099 representatives from the Social and Behavioral Sciences Institutional Review Board (SBSIRB) and other  
4100 federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research  
4101 Protection) may inspect the research records which may reveal your child's identity. A description of this  
4102 clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will  
4103 not include information that can identify your child. At most, the web site will include a summary of the  
4104 results. You can search this web site at any time. Federal law provides additional protections of your  
4105 child's medical records and related health information. These are described in the HIPAA section of this  
4106 document.

4107

4108 **Can my child be removed from the research without our OK?**

4109 The principal investigator of the study can remove your child from the research study without your or  
4110 your child's approval. Possible reasons for removal include need for hospitalization for physical or  
4111 psychological reasons. We will tell you about any new information that may affect your child's health,  
4112 welfare, or choice to stay in the research.

4113

4114 **What else do my child and I need to know?**

4115 This research is being funded by the National Institutes of Health, specifically the National Heart, Lung  
4116 and Blood Institute (NHLBI).

4117 If your child needs medical care because of taking part in this research study, contact the investigator  
4118 and/or speak with your doctor and medical care will be made available. Generally, this care will be billed  
4119 to you, your insurance or other third party. The University at Buffalo has no program to pay for medical  
4120 care for research-related injury. If your child agrees to take part in this research study, we will pay your  
4121 family up to \$175 for your time and effort. The amount you are paid depends upon your attendance to  
4122 visits in the study.

4123

4124 **HIPAA: Authorization for the Use and Disclosure of Identifiable Health  
4125 Information for Research Purposes**

4126 This section describes information about your child and about your child's health that will be obtained  
4127 by the researchers when your child participates in the research study. Health information is considered  
4128 "protected health information" when it may directly identify your child as an individual. By signing this  
4129 form you are agreeing to permit the researchers and/or other parties (described in detail below) to have  
4130 access to this information. If there are any parts of this form that you do not understand, please be sure  
4131 to ask us for further clarification.

4132

4133 **A. What protected health information will be collected about your child as part of this  
4134 research study?**

4135  Information from your child's full medical records.

4136  New Health Information created from study related tests, procedures, visits, and/or  
4137 questionnaires as described in this consent form.

4138 **B. Who is authorized to provide or collect this information?**

4139  Principal Investigator or designee

4140 **C. With whom may your child's protected health information be shared?**

4141 Your child's health information may be shared with others outside of the research group for  
4142 purposes directly related to the conduct of this research study or as required by law, including  
4143 but not limited to:

4144  Clinical staff not involved in this research study who may become involved in your  
4145 child's care if it is potentially relevant to your treatment.

4146  The sponsor of this research study (**National Heart, Lung and Blood Institutes**  
4147 **(NHLBI)** cooperative group, etc., or its agents.

4148  The organization(s) responsible for administering this research (e.g., Research  
4149 Foundation of SUNY, University at Buffalo, Washington University, Nationwide  
4150 Children's Hospital, University of Rochester).

4151  Other medical investigators/centers/institutions participating in this research study.

4152 Your child's information may also be shared with individuals or entities responsible for general  
4153 administration, oversight and compliance of research activities. Examples of this include the  
4154 institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring  
4155 Boards, an Institutional Review Board, The Research Foundation of the State University of New  
4156 York, University at Buffalo Foundation Services, and accrediting bodies, or with certain  
4157 government oversight agencies that have authority over the research including the Department  
4158 of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National  
4159 Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your child's  
4160 information may also be shared with other entities as permitted or required by law. All  
4161 reasonable efforts will be used to protect the confidentiality of your child's individually  
4162 identifiable health information that may be shared with others as described above.

4163 All reasonable efforts will be used to protect the confidentiality of your child's protected health  
4164 information. There is the potential for individually identifiable information and the associated  
4165 health information obtained with this authorization to be re-disclosed by the recipient(s). After  
4166 such a disclosure, the information may no longer be protected by the terms of this authorization  
4167 against further re-disclosure.

4168 **D. How long will this information be kept by the Principal Investigator?**

4169  This authorization has no expiration date. The researchers may continue to rely on this  
4170 authorization to obtain and use protected health information about you unless you  
4171 revoke this authorization in writing.

4172  Your child's protected health information will go into a database that will be maintained  
4173 indefinitely. Any future study using this information that falls outside the scope of this  
4174 current study will be required to follow guidelines designed to govern access to that  
4175 information and to protect the privacy of that information.

4176 **E. What are your rights after signing this authorization?**

4177 You have the right to revoke this authorization at any time. If you withdraw your authorization,  
4178 no additional efforts to collect individually identifiable health information about your child will  
4179 be made. You should know, however, that protected health information acquired using this

4180 authorization prior to its withdrawal may continue to be used to the extent that the  
4181 investigator(s) have already relied on your permission to conduct the research. If you chose to  
4182 withdraw this authorization, you must do so in writing to the following individual(s):

4183

4184

**Leonard H. Epstein, Ph.D.**

4185

**University at Buffalo Department of Pediatrics**

4186

**Division of Behavioral Medicine**

4187

**3435 Main Street**

4188

**G56 Farber Hall**

4189

**Buffalo, NY 14214**

4190

**Phone: 716-829-3400**

4191

4192 If you send us a request to withdraw your authorization, we will forward that request to the  
4193 institutions we have shared it with in order to collect your individually identifiable health  
4194 information.

4195

4196

**F. What will happen if you decide not to sign this authorization?**

4197

4198 Refusing to sign this authorization will not affect the present or future care your child receives at  
4199 this institution and will not cause any penalty or loss of benefits to which you are otherwise  
4200 entitled. If you decide not to sign this authorization, you and your child will not be able to

4201

4202

4203

**Signature Block for Parental Permission**

Your signature documents your permission for the named child to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

\_\_\_\_\_  
Printed name of child

\_\_\_\_\_  
Signature of parent or individual legally authorized to consent to the child's general medical care

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of parent or individual legally authorized to consent to the child's general medical care

- Parent
- Individual legally authorized to consent to the child's general medical care (See note below)

**Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

**Assent Process**

- Child is birth-6 yrs. old - Assent is not required
- Child is 7-17 yrs. old – A separate Assent Document is to be signed by the child
- Assent will be obtained Verbally
- Assent has been waived by the IRB

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

\_\_\_\_\_  
Signature of person obtaining consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of person obtaining consent

4204

4205

4206

4207



**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018

875 Ellicott St. | Buffalo, NY 14203

UB Federal wide Assurance ID#: FWA00008824

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE**

**Parental Permission of Sibling to Participate in a Research Study – Chart Review**

**Version Date: 1.2.19**

**Investigators: Leonard H. Epstein, PhD**

**Why is my child being invited to take part in a research study?**

Your child is being invited to take part in a research study because:

- You are an adult able to read the English language. You have reported no current learning disabilities, medical problems, or psychiatric problems.
- You have a child between the ages of 6 and 12 years old that falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex), and your child has at least one parent who also is considered overweight or obese (BMI greater than 25).
- You have another child between the ages of 2-18 years old that is willing to grant access to his/her Medical Records for height, weight, age, and sex data and/or participate by getting his/her height and weight taken every 6 months over the two year study.

This research study is supported by a grant through the National Heart Lung Blood Institute (NHLBI). Research studies only include individuals who choose to take part in them. Your decision for your child to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

**What should my child and I know about a research study?**

- Someone will explain this research study to you and your child.
- Whether or not your child takes part is up to you and your child.
- You and your child can choose for your child not to take part.
- You and your child can agree to take part and later change your mind.
- You and your child's decision will not be held against you.
- You and your child can ask all the questions you want before you decide.

4252 **Who can my child and I talk to?**

4253 If you or your child has questions, concerns, or complaints, or think the research has hurt your  
4254 child, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may  
4255 also contact the PLAN coach at your child’s doctor’s office. You can also contact the research  
4256 participant advocate at 716-888-4845 or [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

4257 This research has been reviewed and approved by an Institutional Review Board (“IRB”). You  
4258 may talk to them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu) if:

- 4259 ● You have questions about your child’s rights as a participant in this research
- 4260 ● Your questions, concerns, or complaints are not being answered by the research team.
- 4261 ● You cannot reach the research team.
- 4262 ● You want to talk to someone besides the research team.
- 4263 ● You want to get information or provide input about this research.

4264

4265 **Why is this research being done?**

4266 The goal of this study is to determine whether a specific kind of weight loss treatment called  
4267 family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be  
4268 included in the primary care setting. Extensive information has been gathered by our research  
4269 team about the treatment of childhood overweight and obesity. But there is still much to learn  
4270 about how the treatment should be incorporated into various medical settings, such as primary  
4271 care.

4272

4273 Your child has been asked to participate because he/she is between the ages of 2 and 18 years old  
4274 and may fall into the overweight or obese weight category (defined as at or above the 85th  
4275 percentile for age and sex) and has at least one parent and one sibling who are also considered  
4276 overweight or obese (BMI greater than 25) that are participating in this study.

4277

4278 **How long will the research last?**

4279 We expect that your child will be in this research study for 24 months.

4280

4281 **How many people will be studied?**

4282 We expect about 132 families will be in this research study in your geographical location, out of  
4283 528 families in the entire study nationally.

4284

4285 **What happens if I say yes, my child wants to be in this research?**

4286 If your family is eligible for this research study and agrees to participate, the participating sibling  
4287 (between the ages of 2-18) will grant access to his/her Medical Records at specified time points  
4288 (i.e., 0, 6, 12, 18, & 24 months) and/or attend the baseline assessment with you and your target  
4289 child to get his/her height and weight taken. After the baseline assessment and an initial  
4290 appointment with your child’s doctor, your family will be randomized to one of two treatment  
4291 conditions described below.

4292 **Groups**

4293 At the start of the study, your family will be assigned to one of two groups. Participants in one  
4294 group will receive the current standard of care offered by their physician for the treatment of  
4295 childhood weight management. FBT is a behavioral weight-control intervention that aims to  
4296 make weight changes in both a child and their participating parent. FBT is a well-tested



4297 treatment that targets diet, activity, behavioral techniques, parenting, and social facilitation in  
4298 children and their parents. The treatment includes: 1) The Traffic Light Eating Plan uses RED;  
4299 YELLOW; and GREEN labels for food to guide families toward the goal of eating nutritious  
4300 foods. 2) The Traffic Light Activity Program also uses RED; YELLOW; and GREEN labels for  
4301 different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a  
4302 variety of behavioral techniques including changing and controlling your environment; tracking  
4303 eating and physical activity; setting goals; problem solving; setting up a reward system;  
4304 incentives for behavior change and weight loss; finding substitutes for unhealthy foods; and  
4305 improving positive parenting. FBT also involves making changes in the home. So weight loss or  
4306 prevention of weight gain may extend to members of the family who are not regularly attending  
4307 treatment sessions (e.g., siblings and spouse).

4308 The group that your family will be in/the treatment you get will be chosen by chance. Like  
4309 flipping a coin. Neither you nor your doctor will choose what treatment your family will receive.  
4310 Your family will have an equal chance of being assigned to each group. You will be informed of  
4311 the group your family is in and your treatment following an initial physician visit.

4312

### 4313 **Treatment & Assessment Schedule**

4314 Every family will follow their pediatrician recommended schedule of appointments for weight  
4315 management to have at least 4 visits with their child's doctor over the course of the 24 months of  
4316 the study.

4317 The participating sibling will grant access to Medical Records and/or attend five major  
4318 assessments throughout the entire 2 years of the study:

- 4319 ● 1 Baseline assessment upon starting study (0 months)
- 4320 ● 3 Measurement assessments during the study (6, 12, and 18 months)
- 4321 ● 1 Follow-up assessment at end of study (24 months)

4322 Each major assessment will take approximately 30-90 minutes to complete at your child's  
4323 pediatric office, or a home visit can be arranged. Height and weight will be taken on you, your  
4324 participating child, as well as the participating sibling and identified other family members (if  
4325 applicable).

### 4326 **What are my child's responsibilities if he/she takes part in this research?**

4327 If your child (participating sibling) takes part in this research, he/she will be responsible to attend  
4328 the baseline assessment, the three measurement assessments, and the follow-up assessment to  
4329 obtain height and weight information. Your child's (participating sibling) participation in any  
4330 other meetings with your family are voluntary. Weight measurements at these times are also  
4331 voluntary and can be used as data.

### 4332 **What happens if my child does not want to be in this research?**

4333 Your child's participation in this research study is voluntary. You or your child may choose not  
4334 to enroll in this study. There are no other research alternatives other than to participate in this  
4335 study.

4336

### 4337 **What happens if my child and I say yes, but change our mind later?**

4338 Your child can leave the research at any time. It will not be held against him/her. Your child does  
4339 not have to answer every question. He/she may refuse to answer any questions that he/she does

4340 not want to answer. If your participating sibling child leaves the research, this will not affect the  
4341 status of you or your participating (target) child in the study.

4342 If you or your child decides to leave the research, you may not be able to find this kind of family  
4343 treatment in your area outside of this research study. Other types of treatment may be available  
4344 in your community. In which case we will provide a list of these and how to find them if you  
4345 prefer this option. However, you and/or your insurance company would be responsible for any  
4346 costs associated with these options. You also may not receive full compensation for your  
4347 participation. If your child decides to leave the research, contact the investigator at the contact  
4348 information included below. If your child stops being in the research, already collected data may  
4349 not be removed from the study database. You will be asked whether the investigator can collect  
4350 data from your child's routine medical care.

4351

4352 **Is there any way being in this study could be bad for my child?**

4353 There are certain risks and discomforts that may be associated with this research. They include:

4354

4355

4356 **Likely**

4357 ● You may be inconvenienced at times by having to miss work, school activities, meetings,  
4358 etc., to attend assessments.

4359 ● Your child might feel hungry when dieting, sore after exercising, or experience common exercise  
4360 injuries (i.e., sprains, shin splints, tendonitis, muscle pulls, strains, etc).

4361 **Less Likely**

4362 ● Your child may be uncomfortable having his/her height and weight measured.

4363 **Rare**

4364 ● In addition, although this treatment usually prevents the development of eating disorder  
4365 problems, in rare cases it may increase them.

4366 ● The use of online platforms is associated with risks involving breaches of confidentiality.  
4367 We implement many layers of security to limit these risks as much as possible within our  
4368 website and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their  
4369 own security measures and carry their own risks if your family chooses to use them to  
4370 supplement your participation in this study.

4371 **Will being in this study help my child in any way?**

4372 We cannot promise any benefits to you, your child, or others from your taking part in this  
4373 research. This study may provide information that will help your child to lose weight and keep it  
4374 off. However, we cannot guarantee your child will receive any benefits from this study.

4375

4376 **What happens to the information collected for the research?**

4377 Efforts will be made to limit the use and disclosure of your child's personal information,  
4378 including research study and medical or education records, to people who have a need to review  
4379 this information. We cannot promise complete secrecy. Organizations that may inspect and copy  
4380 your child's information include the IRB and other representatives of this organization.

4381 Information related to your child will be treated in strict confidence to the extent provided by  
4382 law. Your child's identity will be coded and will not be associated with any published results.  
4383 Your child's code number and identity will be kept in a locked file of the Principal Investigator.  
4384 The only connection between your child's participation in this study and the study itself will be  
4385 this signed consent form. All recordings of the sessions will be kept in a locked file of the  
4386 Principal Investigator until the end of the study. At which point they will be destroyed. If your  
4387 child withdraws from the study, no further data will be collected. Any information that has been  
4388 provided may be retained by the researchers and analyzed. In order to monitor this research  
4389 study, representatives from the Social and Behavioral Sciences Institutional Review Board  
4390 (SBSIRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP  
4391 (Office of Human Research Protection) may inspect the research records which may reveal your  
4392 child's identity. A description of this clinical trial will be available on  
4393 <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include  
4394 information that can identify your child. At most, the web site will include a summary of the  
4395 results. You can search this web site at any time. Federal law provides additional protections of  
4396 your child's medical records and related health information. These are described in the HIPAA  
4397 section of this document.

4398

4399 **Can my child be removed from the research without our OK?**

4400 The principal investigator of the study can remove your child from the research study without  
4401 your or your child's approval. Possible reasons for removal include need for hospitalization for  
4402 physical or psychological reasons. We will tell you about any new information that may affect  
4403 your child's health, welfare, or choice to stay in the research.

4404

4405 **What else do my child and I need to know?**

4406 This research is being funded by the National Institutes of Health, specifically the National  
4407 Heart, Lung and Blood Institute (NHLBI).

4408 If your child needs medical care because of taking part in this research study, contact the  
4409 investigator and/or speak with your doctor and medical care will be made available. Generally,  
4410 this care will be billed to you, your insurance or other third party. The University at Buffalo has  
4411 no program to pay for medical care for research-related injury. If your child agrees to take part in  
4412 this research study, we will pay your family up to \$175 for your time and effort. The amount you  
4413 are paid depends upon your attendance to visits in the study.

4414

4415 **HIPAA: Authorization for the Use and Disclosure of Identifiable Health  
4416 Information for Research Purposes**

4417 This section describes information about your child and about your child's health that will be  
4418 obtained by the researchers when your child participates in the research study. Health  
4419 information is considered "protected health information" when it may directly identify your child  
4420 as an individual. By signing this form, you are agreeing to permit the researchers and/or other  
4421 parties (described in detail below) to have access to this information. If there are any parts of this  
4422 form that you do not understand, please be sure to ask us for further clarification.

4423 **A. What protected health information will be collected about your child as part of  
4424 this research study?**

4425  Information from your child's full medical records.

4426  New Health Information created from study related tests, procedures, visits, and/or  
4427 questionnaires as described in this consent form.

4428 **B. Who is authorized to provide or collect this information?**

4429  Principal Investigator or designee

4430 **C. With whom may your child's protected health information be shared?**

4431 Your child's health information may be shared with others outside of the research group  
4432 for purposes directly related to the conduct of this research study or as required by law,  
4433 including but not limited to:

4434  Clinical staff not involved in this research study who may become involved in  
4435 your child's care if it is potentially relevant to your treatment.

4436  The sponsor of this research study (**National Heart, Lung and Blood Institute**  
4437 (**NHLBI**) cooperative group, etc., or its agents.

4438  The organization(s) responsible for administering this research (e.g., Research  
4439 Foundation of SUNY, University at Buffalo, Washington University,  
4440 Nationwide Children's Hospital, University of Rochester).

4441  Other medical investigators/centers/institutions participating in this research  
4442 study.

4443 Your child's information may also be shared with individuals or entities responsible for  
4444 general administration, oversight and compliance of research activities. Examples of this  
4445 include the institution's Privacy and Security Officers or other internal oversight staff,  
4446 Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of  
4447 the State University of New York, University at Buffalo Foundation Services, and  
4448 accrediting bodies, or with certain government oversight agencies that have authority  
4449 over the research including the Department of Health and Human Services (HHS), the  
4450 Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the  
4451 Office of Human Research Protections (OHRP). Your child's information may also be  
4452 shared with other entities as permitted or required by law. All reasonable efforts will be  
4453 used to protect the confidentiality of your child's individually identifiable health  
4454 information that may be shared with others as described above.

4455 All reasonable efforts will be used to protect the confidentiality of your child's protected  
4456 health information. There is the potential for individually identifiable information and the  
4457 associated health information obtained with this authorization to be re-disclosed by the  
4458 recipient(s). After such a disclosure, the information may no longer be protected by the  
4459 terms of this authorization against further re-disclosure.

4460 **D. How long will this information be kept by the Principal Investigator?**

4461  This authorization has no expiration date. The researchers may continue to rely  
4462 on this authorization to obtain and use protected health information about you  
4463 unless you revoke this authorization in writing.

4464  Your child's protected health information will go into a database that will be  
4465 maintained indefinitely. Any future study using this information that falls outside

4466 the scope of this current study will be required to follow guidelines designed to  
4467 govern access to that information and to protect the privacy of that information.

4468 **E. What are your rights after signing this authorization?**

4469 You have the right to revoke this authorization at any time. If you withdraw your  
4470 authorization, no additional efforts to collect individually identifiable health information  
4471 about your child will be made. You should know, however, that protected health  
4472 information acquired using this authorization prior to its withdrawal may continue to be  
4473 used to the extent that the investigator(s) have already relied on your permission to  
4474 conduct the research. If you chose to withdraw this authorization, you must do so in  
4475 writing to the following individual(s):

4476 **Leonard H. Epstein, Ph.D.**  
4477 **University at Buffalo Department of Pediatrics**  
4478 **Division of Behavioral Medicine**  
4479 **3435 Main Street**  
4480 **G56 Farber Hall**  
4481 **Buffalo, NY 14214**  
4482 **Phone: 716-829-3400**

4483 If you send us a request to withdraw your authorization, we will forward that request to  
4484 the institutions we have shared it with in order to collect your individually identifiable  
4485 health information.

4486

4487 **F. What will happen if you decide not to sign this authorization?**

4488 Refusing to sign this authorization will not affect the present or future care your child  
4489 receives at this institution and will not cause any penalty or loss of benefits to which you  
4490 are otherwise entitled. If you decide not to sign this authorization, you and your child will  
4491 not be able to participate.

4492  
4493

### Signature Block for Parental Permission

Your signature documents your permission for the named child to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.	
_____	
Printed name of child	
Signature of parent or individual legally authorized to consent to the child's general medical care	Date
_____	
Printed name of parent or individual legally authorized to consent to the child's general medical care	<input type="checkbox"/> Parent <input type="checkbox"/> Individual legally authorized to consent to the child's general medical care (See note below)
<b>Note:</b> Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.	
_____	
<b>Assent Process</b>	
<input type="checkbox"/> Child is birth-6 yrs. old - Assent is not required <input type="checkbox"/> Child is 7-17 yrs. old – A separate Assent Document is to be signed by the child <input type="checkbox"/> Assent will be obtained verbally <input type="checkbox"/> Assent has been waived by the IRB	
I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.	
Signature of person obtaining consent	Date
_____	_____
Printed name of person obtaining consent	

4494  
4495  
4496  
4497  
4498  
4499  
4500  
4501  
4502  
4503



**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018  
875 Ellicott St. | Buffalo, NY 14203  
UB Federal wide Assurance ID#: FWA00008824

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS  
TREATMENT IMPLEMENTED IN PRIMARY CARE**

**PLAN Coach Adult Consent to Participate in a Research Study**

**Version Date: 07-18-2018**

**Investigators: Leonard H. Epstein, Ph.D.**

**Why am I being invited to take part in a research study?**

You are being invited to take part in a research study because you are a PLAN coach delivering family-based treatment (FBT) into a practice-based research network associated with University at Buffalo, Washington University, University of Rochester, or Nationwide Children’s Hospital.

This research study is supported by a grant through the National Heart Lung and Blood Institute (NHBLI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully and ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about the study. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

**What should I know about a research study?**

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

**Who can I talk to?**

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 716-829-3400 for Dr. Leonard Epstein. You may also contact the research participant advocate at 716-888-4845 or [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu) if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

- 4549 ● You want to talk to someone besides the research team.
- 4550 ● You want to get information or provide input about this research.

4551

**Why is this research being done?**

4552 There is currently a gap between the use of evidence-based treatment for children with obesity and its  
4553 use within the community. The rationale behind this study is to understand how best to implement  
4554 these interventions in primary care settings. We chose to test these implementation methods using FBT  
4555 because it has been established as an effective, short- and long term treatment for weight loss  
4556 psychotherapy that focuses on linking healthy dietary and physical activity behaviors to a child’s overall  
4557 environment (e.g., parents, peers, school) and overcoming barriers by using problem solving techniques.  
4558 FBT is an evidence-based treatment for overweight and obesity as well as for eating disorders.

4560

4561 The goal of this study is to determine whether FBT for children who are overweight can be included in  
4562 the primary care setting by using a co-located PLAN coach. Extensive information has been gathered by  
4563 our research team about the treatment of childhood obesity, but there is still much to learn about how  
4564 the treatment should be incorporated into various medical settings, such as primary care. Families at  
4565 your assigned practices have been asked to participate because they have a child between the ages of 6  
4566 and 12 years old who is overweight (defined as at or above the 85th percentile for body mass index),  
4567 and have at least one parent who is willing to participate in the study.

4568

**How long will the research last?**

4569 We expect that you will be in this research study for 5 years.

4570

**How many people will be studied?**

4571 We expect about 3 PLAN coaches will be in this research study in your geographical location out of  
4572 approximately 12 PLAN coaches in the entire study nationally at 4 different clinical sites.

4574

**What happens if I say yes, I want to be in this research?**

4576 By reading and signing this form, you agree to answer questions about yourself and your thoughts and  
4577 opinions regarding your job, childhood obesity, and childhood obesity treatments, including FBT.

4578

4579 Additionally, you allow audio recordings collected for the purpose of quality control of treatment to be  
4580 used for research purposes. After reading and signing this form, the following procedures will occur:

4581

- 4582 ● You will complete a demographics form and take a baseline assessment to measure your  
4583 knowledge in the area of obesity and evidence-based intervention prior to completing training.

4584

- 4585 ● Following training, you will complete the same assessment to assess your growth of knowledge  
4586 and opinions of obesity and the evidence-based intervention.

4587

- 4588 ● At multiple time points during the study you will be asked to submit audio recordings of sessions  
4589 you have with families to ensure the quality of care being delivered and for assessing your  
4590 fidelity to the training protocol. These audio recordings may be transcribed and no identifying  
4591 information will be presented to the public.

4592

- 4593 ● At multiple time points during the study, you will be asked to complete a short assessment on  
4594 your thoughts regarding the study and evidence-based interventions.

4595



- 4596                   o The assessments taken during this study will only be reported in aggregate form to the  
4597                   public and will exclude any identifying information.

4598

4599 **What are my responsibilities if I take part in this research?**

4600 If you take part in this research, you will be responsible to: answer several questionnaires and have your  
4601 FBT sessions recorded.

4602

4603 **What happens if I do not want to be in this research?**

4604 If you have agreed to treat families for the study, treatment related tasks will be considered part of your  
4605 job responsibilities, not as part of the research. You are not required to participate in the PLAN coach  
4606 research portion of the study. You may choose not to fill out questionnaires regarding the  
4607 implementation of FBT into the primary care practice; however, there are certain questions we will ask  
4608 you to answer in your role as a care provider on the study. You may also choose not to have your audio  
4609 recordings be used for research purposes (separate section at the end); however, you will still be asked  
4610 to record and submit treatment sessions in your role as a care provider on the study for quality control  
4611 purposes.

4612

4613 **What happens if I say yes, but I change my mind later?**

4614 You can leave the research at any time; it will not be held against you and will not impact your current  
4615 job status.

4616

4617 If you decide to leave the research, contact the investigator. You will be asked to withdraw your  
4618 participation in writing. There will be no penalty or loss of benefits to which you are otherwise entitled.

4619

4620 **Is there any way being in this study could be bad for me?**

4621 A risk of participating in this study is that confidential information about you may be accidentally  
4622 disclosed. We will use our best efforts to keep the information about you secure, and we think the risk  
4623 of accidental disclosure is very small.

4624

4625 In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor  
4626 inconvenience.

4627

4628 **Will being in this study help me in any way?**

4629 We cannot promise any benefits to you or others from your taking part in this research. However,  
4630 possible benefits include:

4631

- 4632                   ● Learning how evidence-based treatments for childhood obesity may function in primary care  
4633                   and gaining insight into how it may be effective for treatment of childhood obesity.
- 4634
- 4635                   ● Other people might benefit from this study due to identification of the best way to train PLAN  
4636                   coaches in FBT best practices. This may lead to more widespread adoption of evidence-based  
4637                   childhood obesity treatments into primary care.

4638

4639 **What happens to the information collected for the research?**

4640 Efforts will be made to limit the use and disclosure of your personal information, including research  
4641 study and medical or education records, to people who have a need to review this information. We  
4642 cannot promise complete secrecy. Organizations that may inspect and copy your information include  
4643 the IRB and other representatives of this organization.

4644 The information you provide in this study will be strictly confidential and will not be provided to your  
4645 employer and will not impact your current job status in the workplace.

4646  
4647 Information related to you will be treated in strict confidence to the extent provided by law. Your  
4648 identity will be coded and will not be associated with any published results. Your code number and  
4649 identity will be kept in a locked file of the Principal Investigator. The only connection between your  
4650 participation in this study and the study itself will be this signed consent form. If you withdraw from the  
4651 study, no further data will be collected, but any information that has been provided may be retained by  
4652 the researchers and analyzed. In order to monitor this research study, representatives from the  
4653 Institutional Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health)  
4654 and OHRP (Office of Human Research Protection) may inspect the research records which may reveal  
4655 your identity. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as  
4656 required by U.S. Law. This web site will not include information that can identify you. At most, the web  
4657 site will include a summary of the results. You can search this website at any time.

4658  
4659 **Can I be removed from the research without my OK?**

4660 The principal investigator of the study can remove you from the research study without your approval.  
4661 Possible reasons from removal include: lack of adherence to study protocol.

4662  
4663 **What else do I need to know?**

4664 This research is being funded by the National Institutes of Health, specifically the National Heart, Lung  
4665 and Blood Institute (NHLBI).

4666 You will not be paid for participating in this study.

4667  
4668 **Audio Recording Permission:**

4669 Your initial below documents your permission to use audio recorded sessions for *research purposes*:

4670 \_\_\_\_\_ Yes, I give my permission to use my audio recorded sessions for research purposes.

4671 \_\_\_\_\_ No, **I do not** give my permission to use my audio recorded sessions for research purposes.

4672 **Signature Block for Capable Adult**

Your signature documents your permission to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.	
Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date

Printed name of person obtaining consent

4673  
4674  
4675  
4676

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process

Date

Printed name of person witnessing consent process

4677  
4678

4679  
4680  
4681  
4682  
  
4683  
4684  
4685  
4686  
4687  
4688  
4689  
4690  
4691  
4692  
4693  
4694  
4695  
4696  
4697  
4698  
4699  
4700  
4701  
4702  
4703  
4704  
4705  
4706  
4707  
4708  
4709  
4710  
4711  
4712  
4713  
4714  
4715  
4716  
4717  
  
4718  
4719  
  
4720  
4721  
4722  
4723

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS  
TREATMENT IMPLEMENTED IN PRIMARY CARE**

*Adult Primary Care Provider Consent to Participate in a Research Study*

**Version Date: 07-18-2018**

**Investigators: Leonard H. Epstein, Ph.D.**

**Why am I being invited to take part in a research study?**

You are being invited to take part in a research study because you are a provider who is part of a practice-based research network with University at Buffalo, Washington University, University of Rochester, or Nationwide Children’s Hospital.

You are being invited to take part in a research study supported by a grant through the National Heart Blood Lung Institutes(NHBLI). Research studies only include individuals who choose to take part in them.

Your decision to take part in this study is entirely voluntary. Please read this information carefully and ask questions about anything you do not understand before deciding whether or not to participate.

You may also take home an unsigned copy of this consent form to think about or if you wish to discuss this matter with your family. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

**What should I know about a research study?**

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

**Who can I talk to?**

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 716-829-3400 for Dr. Leonard Epstein. You may also contact the research participant advocate at 716-888-4845 or [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu) if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.

- 4724 ● You want to get information or provide input about this research.  
4725

4726 **Why is this research being done?**

4727 This is a research study. We invite you to participate in this research study by the University at Buffalo  
4728 because you are a provider at a primary care practice that has indicated interest in participating in this  
4729 study.

4730

4731 There is currently a gap between the use of evidence-based treatment for children with obesity and its  
4732 use within the community. The rationale behind this study is to test the effectiveness of FBT in primary  
4733 care settings, and to understand how best to implement these interventions in primary care settings.

4734 We chose to test FBT because it has been established as an effective treatment for weight loss in  
4735 children in the short- and long term and may have a positive impact on others in the household. FBT is a  
4736 manual-based psychotherapy that focuses on linking healthy dietary and physical activity behaviors to a  
4737 child's overall environment (e.g., parents, peers, school) and overcoming barriers by using problem  
4738 solving techniques.

4739

4740 The goal of this study is to determine whether family-based weight loss treatment (FBT) for children  
4741 who are overweight/obese can be included in the primary care setting by using a co-located PLAN  
4742 Coach. Extensive information has been gathered by our research team about the treatment of childhood  
4743 obesity, but there is still much to learn about how the treatment should be incorporated into various  
4744 medical settings, such as primary care. Families at your practice have been asked to participate because  
4745 they have a child who is between the ages of 6 and 12 years old, is overweight/obese (defined as at or  
4746 above the 85th percentile for body mass index), and have at least one parent who is willing to  
4747 participate in the study.

4748

4749 **How long will the research last?**

4750 We expect that you will be in this research study for 4 years.

4751

4752 **How many people will be studied?**

4753 We expect about 3 primary care providers will be in this research study in your geographical location,  
4754 and similar numbers of primary care providers at three other sites nationally.

4755 **What happens if I say yes, I want to be in this research?**

4756 Currently, the practice you work in has agreed to participate in this research study. By reading and  
4757 signing this form, you agree to answer questions about yourself and your thoughts and opinions  
4758 regarding your job, childhood obesity, and childhood obesity treatments, including FBT. After reading  
4759 and signing this form, the following procedures will occur:

- 4760
- 4761 ● You will be asked about your demographics, job, attitudes, and prior knowledge of FBT and  
4762 obesity care delivery. The assessments will take about 20 minutes to complete. You are free to  
4763 skip any questions you don't want to answer.
  - 4764 ● You will be asked to give permission for PLAN coaches to review participant charts at the end of  
4765 the study to gather data on Usual Care.
- 4766

4767 The treatment that participants will get will be chosen by chance, like flipping a coin. You will not choose  
4768 which treatment participants will get. You will not know which treatment participants will get, however,  
4769 some participants will inevitably inform you of their group assignment in the normal course of events.

4770

4771 **What are my responsibilities if I take part in this research?**

4772 If you take part in this research, you will be responsible to: answer several questionnaires about the  
4773 study.

4774

4775 **What happens if I do not want to be in this research?**

4776 If you have agreed to treat families with Usual Care for the study, you are not required to participate in  
4777 the provider research portion of the study. You may choose not to fill out questionnaires regarding the  
4778 implementation of FBT into the primary care practice; however, there are certain questions we will ask  
4779 you to answer in your role as a care provider on the study.

4780

4781 **What happens if I say yes, but I change my mind later?**

4782 You can leave the research at any time. It will not be held against you and will not impact your current  
4783 job status.

4784

4785 If you decide to leave the research, contact the investigator. You will be asked to withdraw your  
4786 participation in writing. There will be no penalty or loss of benefits to which you are otherwise entitled.

4787

4788 **Is there any way being in this study could be bad for me?**

4789 A risk of participating in this study is that confidential information about you may be accidentally  
4790 disclosed. We will use our best efforts to keep the information about you secure, and we think the risk  
4791 of accidental disclosure is very small.

4792

4793 In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor  
4794 inconvenience.

4795  
4796

4797 **Will being in this study help me in any way?**

4798 We cannot promise any benefits to you or others from your taking part in this research. However,  
4799 possible benefits include:

- 4800
- 4801 ● Learning how evidence-based treatments for childhood obesity may function in primary care  
4802 and gaining insight into how it may be effective for treatment of childhood obesity.
  - 4803
  - 4804 ● Other people might benefit from this study due to identification of the best way to train  
4805 providers in expert recommendations. This may lead to more widespread adoption of evidence-  
4806 based treatments into primary care.
- 4807

4808

4809 **What happens to the information collected for the research?**

4810 Efforts will be made to limit the use and disclosure of your personal information, including research  
4811 study and medical or education records, to people who have a need to review this information. We  
4812 cannot promise complete secrecy. Organizations that may inspect and copy your information include  
4813 the IRB and other representatives of this organization.

4814 The information you provide in this study will be strictly confidential and will not be provided to your  
4815 employer and will not impact your current job status in the workplace.

4816

4817 Information related to you will be treated in strict confidence to the extent provided by law. Your  
4818 identity will be coded and will not be associated with any published results. Your code number and  
4819 identity will be kept in a locked file of the Principal Investigator. The only connection between your  
4820 participation in this study and the study itself will be this signed consent form. If you withdraw from the  
4821 study, no further data will be collected, but any information that has been provided may be retained by  
4822 the researchers and analyzed. In order to monitor this research study, representatives from the  
4823 Institutional Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health)  
4824 and OHRP (Office of Human Research Protection) may inspect the research records which may reveal  
4825 your identity. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as  
4826 required by U.S. Law. This web site will not include information that can identify you. At most, the web  
4827 site will include a summary of the results. You can search this website at any time.

4828

4829 **Can I be removed from the research without my OK?**

4830 The principal investigator of the study can remove you from the research study without your approval.  
4831 Possible reasons from removal include: lack of adherence to study protocol.

4832

4833 **What else do I need to know?**

4834 This research is being funded by the National Institutes of Health, specifically the National Heart, Lung  
4835 and Blood Institute (NHLBI).

4836 *You will not be paid for participating in this study.*

4837

4838

**Signature Block for Capable Adult**

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. Your signature documents your permission to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

4839 Do you agree to allow us to send your protected health information via email?

4840 We will only send you PLAN related emails and we will not share your email with anyone.

4841  Yes

4842  No

4843

4844 If yes, please provide your preferred email address below.

4845 \_\_\_\_\_

4846 Please verify your preferred email.

4847 \_\_\_\_\_

4848 If yes, please provide your preferred phone number below.

4849 \_\_\_\_\_

4850 Please verify your preferred phone number.

4851 \_\_\_\_\_

4852

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

**Type your name below:**

\_\_\_\_\_  
Typed Signature of Primary Care Provider

\_\_\_\_\_  
Date

4853

4854





**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018

875 Ellicott St. | Buffalo, NY 14203

UB Federal wide Assurance ID#: FWA00008824

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS  
TREATMENT IMPLEMENTED IN PRIMARY CARE**

**Parent Adult Consent to Participate in a Research Study**

**Version Date: 07-18-2018**

**Investigators: Leonard H. Epstein, Ph.D.**

**Why am I being invited to take part in a research study?**

You and your child are being invited to take part in a research study because:

- You are an adult able to read the English language. You have reported no current learning disabilities, medical problems, or psychiatric problems.
- You have a child between the ages of 6 and 12 years old. Falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex). You are interested in weight loss and are willing to participate in the study.

This research study is supported by a grant through the National Heart Lung and Blood Institute (NHLBI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

**What should I know about a research study?**

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

4893 **Who can I talk to?**

4894 If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research  
4895 team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at  
4896 your child’s doctor’s office. You can also contact the research participant advocate at 716-888-4845 or  
4897 [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

4898 This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to  
4899 them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu)

4900 if:

- 4901 ● You have questions about your rights as a participant in this research
- 4902 ● Your questions, concerns, or complaints are not being answered by the research team.
- 4903 ● You cannot reach the research team.
- 4904 ● You want to talk to someone besides the research team.
- 4905 ● You want to get information or provide input about this research.

4906

4907 **Why is this research being done?**

4908 The goal of this study is to determine whether a specific kind of weight loss treatment called family-  
4909 based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the  
4910 primary care setting. Extensive information has been gathered by our research team about the  
4911 treatment of childhood overweight and obesity. But there is still much to learn about how the treatment  
4912 should be incorporated into various medical settings, such as primary care.

4913

4914 **How long will the research last?**

4915 We expect that you will be in this treatment and research study for 24 months.

4916

4917 **How many people will be studied?**

4918 We expect about 132 families will be in this research study in your geographical location. Out of 528  
4919 families in the entire study nationally.

4920

4921 **What happens if I say yes, I want to be in this research?**

4922 To determine if your family is eligible to participate, you and your child will be asked to complete an  
4923 eligibility assessment at an orientation session about this study. You and your child’s height and weight  
4924 will be measured. Standard questions regarding medical and psychological history will be asked by a  
4925 trained interviewer to determine eligibility.

4926 If your family is eligible for this research study and agrees to participate, you and your child will be asked  
4927 to come to your pediatric office to complete a baseline assessment (detailed below). Additionally, we  
4928 hope to collect information about how participation in FBT may affect others in your home. Therefore, if  
4929 you have another child who meets eligibility criteria (between the ages of 2-18 who is at or above the  
4930 85th percentile for age and sex), we ask that this child also attend the baseline assessment. After the  
4931 baseline assessment and an initial appointment with your child’s doctor, your family will be randomized  
4932 to one of two treatment conditions described below.

4933 **Groups**

4934 At the start of the study, your family will be assigned to one of two groups. Participants in one group will  
4935 receive the current standard of care offered by their physician for the treatment of childhood weight  
4936 management. Participants in the second group will receive family-based behavioral treatment for  
4937 weight management (FBT). FBT is a behavioral weight-control intervention that aims to make weight

4938 changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet,  
4939 activity, behavioral techniques, parenting, and social facilitation in children and their parents. The  
4940 treatment includes: 1) The Traffic Light Eating Plan uses RED; YELLOW; and GREEN labels for food to  
4941 guide families toward the goal of eating nutritious foods. 2) The Traffic Light Activity Program, also uses  
4942 RED; YELLOW; and GREEN labels for different levels of exercise to increase physical activity and reducing  
4943 inactive behaviors. 3) a variety of behavioral techniques including changing and controlling your  
4944 environment; tracking eating and physical activity; setting goals; problem solving; setting up a reward  
4945 system; incentives for behavior change and weight loss; finding substitutes for unhealthy foods; and  
4946 improving positive parenting. FBT also involves making changes in the home. So weight loss or  
4947 prevention of weight gain may extend to members of the family who are not regularly attending  
4948 treatment sessions (e.g., siblings and spouse).

4949 The group that your family will be in/the treatment you get will be chosen by chance. Like flipping a  
4950 coin. Neither you nor your doctor will choose what treatment your family will receive. Your family will  
4951 have an equal chance of being assigned to each group. You will be informed of the group your family is  
4952 in and your treatment following an initial physician visit.

4953

#### 4954 **Treatment Schedule**

4955 Every family will follow their pediatrician's recommended schedule of appointments for weight  
4956 management to have at least 4 visits with their child's doctor over the course of the 24 months of the  
4957 study. Families in the group receiving FBT will additionally complete at least 26 sessions with the FBT  
4958 PLAN Coach during the 24 months of the study. The amount of sessions completed within this range will  
4959 be based on progress through the program and will vary for each family.

#### 4960 **Assessments, Interviews, Questionnaires**

4961 Attendance will be taken and both you and your child will be weighed at every session. In addition, there  
4962 will be five major assessments throughout the entire 2 years of the study:

- 4963 ● 1 Baseline assessment upon starting study (0 months)
- 4964 ● 3 Treatment assessments during the study (6, 12, and 18 months)
- 4965 ● 1 Follow-up assessment at end of study (24 months)

4966 Each major assessment will take approximately 30-90 minutes to complete at your child's pediatric  
4967 office, or a home visit can be arranged. Height and weight will be taken on you and your child as well as  
4968 the identified other family members (if applicable). Your height will be taken at the beginning of the  
4969 study, and your child(ren)'s height will be taken at each major assessment. You and your participating  
4970 child will also complete short questionnaires. You both will be asked questions about parenting  
4971 behaviors and the home food and activity environment. At your baseline, 12-month, and follow-up  
4972 appointments, you will be asked to complete a computer task. Throughout the study, you will have  
4973 access to a website that contains study materials and interactive tools.

4974

#### 4975 **Audio Recording**

4976 Your interviews and individual family will be audiotaped or digitally recorded for research purposes, but  
4977 you will not be identified on the recording and the recordings will not be labeled with your name.

4978 Recording the sessions is the best way to make sure we collect accurate information. It also helps us  
4979 make sure that all our staff delivers the study to participants in the same way. The recordings will be  
4980 stored on password-protected computers with restricted access within the University at Buffalo, and

4981 then transferred to Washington University School of Medicine. The recordings will be labeled only with  
4982 your study ID, date, and session number. The Principal Investigator and research staff may use these  
4983 recordings for purposes of evaluation, treatment, research, and training related to this study.  
4984 Recordings may also be used to train staff implementing these or similar interventions at other sites.  
4985 The recordings will be destroyed at the end of the study when all data analysis is complete. You do not  
4986 have to agree to be audio recorded in order to participate in this study.

4987 Please check and initial below if you agree or do not agree to give permission for you and your child to  
4988 be audio recorded during your sessions with the PLAN coach.

4989

4990 YES \_\_\_\_\_ NO \_\_\_\_\_ Parent INITIAL \_\_\_\_\_ Date: \_\_\_\_\_

4991

4992 **What are my responsibilities if I take part in this research?**

4993 If you take part in this research, you will be responsible to attend the baseline assessment, all treatment  
4994 assessments, at least 26 treatment sessions if your family is in the group receiving FBT, and the follow-  
4995 up assessment.

4996

4997 **What happens if I do not want to be in this research?**

4998 Your participation in this research study is voluntary. You may choose not to enroll in this study. There  
4999 are no other research alternatives other than to participate in this study.

5000

5001 **What happens if I say yes, but I change my mind later?**

5002 You can leave the research at any time. It will not be held against you. You do not have to answer every  
5003 question and may refuse to answer any questions that you do not want to answer.

5004 If you decide to leave the research, you may not be able to find this kind of family treatment in your  
5005 area outside of this research study. Other types of treatment may be available in your community. In  
5006 which case we will provide a list of these and how to find them if you prefer this option. However, you  
5007 and/or your insurance company would be responsible for any costs associated with these options. You  
5008 also may not receive full compensation for your participation. If you decide to leave the research,  
5009 contact the investigator at the contact information included below. If you stop being in the research,  
5010 already collected data may not be removed from the study database. You will be asked whether the  
5011 investigator can collect data from your routine medical care.

5012

5013 **Is there any way being in this study could be bad for me?**

5014 There are certain risks and discomforts that may be associated with this research. They include:

5015 **Likely**

- 5016
  - You might feel hungry when dieting or sore after exercising.

5017 **Less Likely**

- 5018
  - You may find some of the questions embarrassing or be uncomfortable having your height and  
5019 weight measured.

- 5020
  - There may be some family disagreements as issues of family functioning; communication; and  
5021 discipline are discussed.

- 5022 ● You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to  
5023 attend assessments and family sessions.

5024 **Rare**

- 5025 ● There is a risk of audio recordings being lost. All recordings will be immediately stored in a  
5026 locked drawer or saved to a password-protected computer in the research office after the  
5027 individual family and group weight loss and maintenance sessions. Your family name will not be  
5028 on these recordings, which will be identified only by a study ID number.

- 5029 ● The use of online platforms is associated with risks involving breaches of confidentiality. We  
5030 implement many layers of security to limit these risks as much as possible within our website  
5031 and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security  
5032 measures and carry their own risks if your family chooses to use them to supplement your  
5033 participation in this study.

- 5034 ● In addition, although this treatment usually prevents the development of eating disorder  
5035 problems, in rare cases it may increase them.

5036 **Other Risks**

- 5037 ● In this study you will be given a physical activity goal. Given that some people may have medical  
5038 risks associated with increasing their physical activity, these recommendations for your child will  
5039 be given in consultation with his/her doctor. As an adult, you may consider getting approval  
5040 from your doctor for setting physical activity goals. Adult participants will be responsible for  
5041 consulting their doctor for approval.

- 5042 ● **Randomization** - As mentioned before, this study has two groups. Because chance decides  
5043 which group you will be in, the treatment you receive as part of this study may not be what your  
5044 own doctor would choose for you.

5045 **Will being in this study help me in any way?**

5046 We cannot promise any benefits to you or others from your taking part in this research. However,  
5047 possible benefits could include you and your child losing weight, becoming more physically active, and  
5048 eating more healthfully as a result of participation. In addition, maintaining weight loss may lead to  
5049 better relationships and better mood. However, we cannot guarantee that you or your child will receive  
5050 any benefits from this study. This study may also provide information that will help other children inside  
5051 and outside your household to lose weight and keep it off.

5052 **What happens to the information collected for the research?**

5053 Efforts will be made to limit the use and disclosure of your personal information, including research  
5054 study and medical or education records, to people who have a need to review this information. We  
5055 cannot promise complete secrecy. Organizations that may inspect and copy your information include  
5056 the IRB and other representatives of this organization. Information related to you will be treated in strict  
5057 confidence to the extent provided by law. Your identity will be coded and will not be associated with any  
5058 published results. Your code number and identity will be kept in a locked file of the Principal  
5059 Investigator. The only connection between your participation in this study and the study itself will be  
5060 this signed consent form. All recordings of the sessions will be kept in a locked file of the Principal  
5061 Investigator until the end of the study. At which point they will be destroyed. If you withdraw from the  
5062 study, no further data will be collected. Any information that has been provided may be retained by the  
5063 researchers and analyzed. In order to monitor this research study, representatives from the Institutional  
5064 Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP  
5065

5066 (Office of Human Research Protection) may inspect the research records which may reveal your identity.  
5067 A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S.  
5068 Law. This web site will not include information that can identify you. At most, the web site will include a  
5069 summary of the results. You can search this web site at any time. Federal law provides additional  
5070 protections of your medical records and related health information. These are described in the HIPAA  
5071 section of this document.  
5072

5073 **Can I be removed from the research without my OK?**

5074 The principal investigator of the study can remove you from the research study without your approval.  
5075 Possible reasons for removal include need for hospitalization for physical or psychological reasons.  
5076

5077 **What else do I need to know?**

5078 This research is being funded by the National Institutes of Health, specifically the National Heart, Lung  
5079 and Blood Institutes (NHLBI). If you need medical care because of taking part in this research study,  
5080 contact the investigator and/or speak with your doctor and medical care will be made available.  
5081 Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo  
5082 has no program to pay for medical care for research-related injury. If you agree to take part in this  
5083 research study, we will pay you up to \$175 for your time and effort. The amount you are paid depends  
5084 upon your attendance to visits in the study.  
5085

5086 **HIPAA: Authorization for the Use and Disclosure of Identifiable Health**  
5087 **Information for Research Purposes**

5088 This section describes information about you and about your health that will be obtained by the  
5089 researchers when you participate in the research study. Health information is considered "protected  
5090 health information" when it may directly identify you as an individual. By signing this form you are  
5091 agreeing to permit the researchers and/or other parties (described in detail below) to have access to  
5092 this information. If there are any parts of this form that you do not understand, please be sure to ask us  
5093 for further clarification.

5094 **A. What protected health information will be collected about you as part of this research**  
5095 **study?**

5096  Specific information from your medical records related to height, weight, dietary  
5097 restrictions, and physical activity restrictions.

5098  New Health Information created from study related tests, procedures, visits, and/or  
5099 questionnaires as described in this consent form.

5100 **B. Who is authorized to provide or collect this information?**

5101  Principal Investigator or designee  
5102

5103 **C. With whom may your protected health information be shared?**

5104 Your health information may be shared with others outside of the research group for purposes  
5105 directly related to the conduct of this research study or as required by law, including but not  
5106 limited to:

5107  Clinical staff not involved in this research study who may become involved in you and  
5108 your child's care if it is potentially relevant to your treatment.

5109  The sponsor of this research study (***National Heart, Lung and Blood Institutes***  
5110 ***(NHLBI)*** cooperative group, etc., or its agents.

5111  The organization(s) responsible for administering this research (e.g., Research  
5112 Foundation of SUNY, University at Buffalo, Washington University, Nationwide  
5113 Children's Hospital, University of Rochester).

5114  Other medical investigators/centers/institutions participating in this research study.

5115 Your information may also be shared with individuals or entities responsible for general  
5116 administration, oversight and compliance of research activities. Examples of this include the  
5117 institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring  
5118 Boards, an Institutional Review Board, The Research Foundation of the State University of New  
5119 York, University at Buffalo Foundation Services, and accrediting bodies, or with certain  
5120 government oversight agencies that have authority over the research including the Department  
5121 of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National  
5122 Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your  
5123 information may also be shared with other entities as permitted or required by law. All  
5124 reasonable efforts will be used to protect the confidentiality of your individually identifiable  
5125 health information that may be shared with others as described above.

5126 All reasonable efforts will be used to protect the confidentiality of your protected health  
5127 information. There is the potential for individually identifiable information and the associated  
5128 health information obtained with this authorization to be re-disclosed by the recipient(s). After  
5129 such a disclosure, the information may no longer be protected by the terms of this authorization  
5130 against further re-disclosure.

5131 **D. How long will this information be kept by the Principal Investigator?**

5132  This authorization has no expiration date. The researchers may continue to rely on this  
5133 authorization to obtain and use protected health information about you unless you  
5134 revoke this authorization in writing.

5135  Your protected health information will go into a database that will be maintained  
5136 indefinitely. Any future study using this information that falls outside the scope of this  
5137 current study will be required to follow guidelines designed to govern access to that  
5138 information and to protect the privacy of that information.

5139 **E. What are your rights after signing this authorization?**

5140 You have the right to revoke this authorization at any time. If you withdraw your authorization,  
5141 no additional efforts to collect individually identifiable health information about you will be  
5142 made. You should know, however, that protected health information acquired using this  
5143 authorization prior to its withdrawal may continue to be used to the extent that the  
5144 investigator(s) have already relied on your permission to conduct the research. If you chose to  
5145 withdraw this authorization, you must do so in writing to the following individual(s):

5146  
5147 **Leonard H. Epstein, Ph.D.**  
5148 **University at Buffalo Department of Pediatrics**  
5149 **Division of Behavioral Medicine**  
5150 **3435 Main Street**  
5151 **G56 Farber Hall**

5152  
5153  
5154  
5155  
5156  
5157  
5158  
5159  
5160  
5161  
5162  
5163  
5164  
5165  
5166  
5167

**Buffalo, NY 14214**  
**Phone: 716-829-3400**

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

**F. What will happen if you decide not to sign this authorization?**

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

**Signature Block for Capable Adult**

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.	
Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

5168  
5169  
5170  
5171





**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018  
875 Ellicott St. | Buffalo, NY 14203

**THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT  
IMPLEMENTED IN PRIMARY CARE**

**PILOT Participating Child Assent to be in a Research Study  
(for Children 7-13 years of age)**

**Version Date: 07-18-2018**

**Investigators: Leonard H. Epstein, PhD**

**Who are we?**

My name is Dr. Leonard H. Epstein and I am a researcher at the University at Buffalo. I work in the Department of Pediatrics.

**Why are we meeting with you?**

We want to tell you about a study that involves children like yourself. We want to see if you would like to be in this study too.

**Why are we doing this study?**

We want to look at a certain kind of weight loss program for kids. We want to know if it will work at a doctor's office.

**What will happen to you if you are in the study?**

You and a parent will first come to the doctor's office. We will tell you about this study that teaches kids about healthy eating and activities. We will ask you if you want to be a part of the study. If you do, we will measure your height and weight. We will ask you to answer some questions about yourself and your parents. You will do a task that asks you to make choices between different amounts of money. If you want to, we will ask to you come back for more visits.

After this, you and your parent will visit the doctor's office once a week for 3 months. At the visits you would meet with someone from the study. This would be at least 12 visits. Your height and weight will be taken. You will learn about healthy food. We will teach you fun ways to exercise.

At your first visit and at your last visit, we will ask you some questions about yourself. We will measure your height and weight. At your baseline and Follow-up appointment, we will ask you to do a computer task that asks you to make choices between different amounts of money.

You do not have to answer any questions that you do not want to answer. You do not have to do any activities that you do not want to do.

5217 **What are the good things and bad things that may happen to you if you are in the study?**  
 5218 *Most Likely:* You can have fun learning about healthy food and exercise. You could become healthy.  
 5219  
 5220 *Maybe:* You could become hungry when trying to eat healthy. Your muscles could feel sore from  
 5221 exercise. That will go away once you are used to exercising.  
 5222

5223 **Do you have to be in the study?**  
 5224 No you do not. No one will get angry or upset with you if you don't want to do this. Just tell us if you do  
 5225 not want to be in the study. And remember, you can change your mind later if you decide you do not  
 5226 want to be in the study anymore.  
 5227

5228 **Do you have any questions?**  
 5229 You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk  
 5230 to someone else at any time during the study. You can call:  
 5231

5232 Name of contact person on the study: *Leonard H. Epstein, Ph.D.* Phone Number: *(716) 829-3400*  
 5233  
 5234

**Signature Block for Assent of Child**

Your signature documents your permission to take part in this research.		
Signature of subject		Date
Printed name of subject		
I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.		
Signature of person obtaining consent		Date
Printed name of person obtaining consent		

5235  
 5236



**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018

875 Ellicott St. | Buffalo, NY 14203

UB Federal wide Assurance ID#: FWA00008824

5237  
5238  
5239  
5240  
5241  
  
5242  
5243  
5244  
5245  
5246  
5247  
5248  
5249  
5250  
5251  
5252  
5253  
5254  
5255  
5256  
5257  
  
5258  
5259  
5260  
5261  
5262  
5263  
5264  
5265  
5266  
5267  
5268  
5269  
5270  
5271  
5272  
5273  
5274  
5275

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE**

**PILOT Parental Permission for Targeted Child to Participate in a Research Study**

**Version Date: 07-18-2018**

**Investigators: Leonard H. Epstein, Ph.D.**

**Why is my child being invited to take part in a research study?**

Your child is being invited to take part in a pilot research study because:

- You are an adult able to read the English language. You have reported no current learning disabilities, medical problems, or psychiatric problems.
- Your child is between the ages of 7 and 12 years old. Your child falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex). Your child has at least one parent who is interested in participating in the study.

This research study is supported by a grant through the National Heart, Lung and Blood Institutes (NHLBI). Research studies only include individuals who choose to take part in them. Your decision for your child to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating. You may wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

**What should my child and I know about a research study?**

- Someone will explain this research study to you and your child.
- Whether or not your child takes part is up to you and your child.
- You and your child can choose for your child not to take part.
- You and your child can agree to take part and later change your mind.
- You and your child's decision will not be held against you.
- You and your child can ask all the questions you want before you decide.

5276 **Who can my child and I talk to?**

5277 If you or your child has questions, concerns, or complaints, or think the research has hurt your child, talk  
5278 to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the  
5279 PLAN coach at your child’s doctor’s office; or you can contact the research participant advocate at 716-  
5280 888-4845 or [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

5281 This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to  
5282 them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu) if:

- 5283 ● You have questions about your child’s rights as a participant in this research.
- 5284 ● Your questions, concerns, or complaints are not being answered by the research team.
- 5285 ● You cannot reach the research team.
- 5286 ● You want to talk to someone besides the research team.
- 5287 ● You want to get information or provide input about this research.

5288

5289 **Why is this research being done?**

5290 The goal of this pilot study is to determine whether a specific kind of weight loss treatment called  
5291 family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the  
5292 primary care setting. Extensive information has been gathered by our research team about the  
5293 treatment of childhood overweight and obesity, but there is still much to learn about how the treatment  
5294 should be incorporated into various medical settings, such as primary care.

5295

5296 Your child has been asked to participate because he/she is between the ages of 7 and 12 years old, falls  
5297 into the overweight or obese weight category (defined as at or above the 85th percentile for age and  
5298 sex), and has at least one parent who is interested in participating in the study.

5299

5300 **How long will the research last?**

5301 We expect that your child will be in this treatment and research study for 3 months.

5302

5303 **How many people will be studied?**

5304 We expect about 6 families will be in pilot phase of this research study in your geographical location.

5305

5306 **What happens if I say yes, my child wants to be in this research?**

5307 To determine if your child is eligible to participate: you and your child will be asked to complete an  
5308 eligibility assessment at an orientation session about this study. You and your child’s height and weight  
5309 will be measured. Standard questions regarding medical and psychological history will be asked by a  
5310 trained interviewer to determine eligibility.

5311 If your family is eligible for this research study and agrees to participate: you and your child will be asked  
5312 to come to your pediatric office to complete a baseline assessment (detailed below). After the baseline  
5313 assessment, your family will be enrolled. You will meet with a PLAN coach weekly.

5314

5315

5316 **Group**

5317 At the start of the study, your family will be assigned to receive family-based behavioral treatment for  
5318 weight management (FBT). FBT is a behavioral weight-control intervention that aims to make weight  
5319 changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet,  
5320 activity, behavioral techniques, parenting, and social facilitation in children and their parents. The  
5321 treatment includes: 1) The Traffic Light Eating Plan, which uses RED, YELLOW, GREEN labels for food to  
5322 guide families toward the goal of eating nutritious foods; 2) the Traffic Light Activity Program, which also  
5323 uses RED, YELLOW and GREEN labels for different levels of exercise to increase physical activity and  
5324 reducing inactive behaviors; and 3) a variety of behavioral techniques including changing and controlling  
5325 your environment, tracking eating and physical activity, setting goals, problem solving, setting up a  
5326 reward system, incentives for behavior change and weight loss, finding substitutes for unhealthy foods,  
5327 and improving positive parenting. FBT also involves making changes in the home. Weight loss or  
5328 prevention of weight gain may extend to members of the family who are not regularly attending  
5329 treatment sessions (e.g., siblings and spouse).

5330 **Treatment Schedule**

5331 Every family will receive FBT and will complete at least 12 sessions with the FBT PLAN Coach during the 3  
5332 months of the study.

5333 **Assessments, Interviews, Questionnaires**

5334 Attendance will be taken and both you and your child will be weighed at every session. In addition, there  
5335 will be two major assessments throughout the entire 3 months of the pilot study:

- 5336 ● 1 Baseline assessment upon starting study (0 months)
- 5337 ● 1 Follow-up assessment at end of study (3 months)

5338 Each major assessment will take approximately 30-90 minutes to complete at your child's pediatric  
5339 office, or a home visit can be arranged. Height and weight will be taken on you and your child. Your  
5340 height will be taken at the beginning of the study. Your child's height will be taken at each major  
5341 assessment. At your baseline and Follow-up appointment, we will ask you to do a computer task that  
5342 asks you to make choices between different amounts of money.

5343 **Audio Recording**

5344 Your interviews and individual family will be audiotaped or digitally recorded for research purposes. You  
5345 will not be identified on the recording and the recordings will not be labeled with your name. Recording  
5346 the sessions is the best way to make sure we collect accurate information. It also helps us make sure  
5347 that all our staff delivers the study to participants in the same way. The recordings will be stored on  
5348 password-protected computers with restricted access within the University at Buffalo; then transferred  
5349 to Washington University School of Medicine. The recordings will be labeled only with your study ID,  
5350 date, and session number. The Principal Investigator and research staff may use these recordings for  
5351 purposes of evaluation, treatment, research, and training related to this study. Recordings may also be  
5352 used to train staff implementing these or similar interventions at other sites. The recordings will be  
5353 destroyed at the end of the study when all data analysis is complete. You do not have to agree to be  
5354 audio recorded in order to participate in this study.

5355

5356 **Please check and initial below if you agree for you and your child to be audio recorded during your**  
5357 **sessions with the PLAN coach:**

5358

5359 \_\_\_\_\_ YES, PARENT INITIAL \_\_\_\_\_, I give my permission to be audio recorded during  
5360 sessions with a PLAN Coach. Date: \_\_\_\_\_

5361

5362 \_\_\_\_\_ NO, PARENT INITIAL \_\_\_\_\_, I do **not give** my permission to be audio recorded  
5363 during sessions with a PLAN Coach. Date: \_\_\_\_\_

5364 **What are my child's responsibilities if he/she takes part in this research?**

5365 If your child takes part in this pilot research, he/she will be responsible to: attend the baseline  
5366 assessment, follow-up assessment, and attend at least 12 treatment sessions if your family is in the  
5367 group receiving FBT.

5368

5369 **What happens if my child does not want to be in this research?**

5370 Your child's participation in this pilot research study is voluntary. You or your child may choose not to  
5371 enroll in this study. There are no other research alternatives other than to participate in this study.

5372

5373 **What happens if my child and I say yes, but change our mind later?**

5374 Your child can leave the pilot research at any time. It will not be held against him/her. Your child does  
5375 not have to answer every question and may refuse to answer any questions that he/she does not want  
5376 to answer.

5377 If your child decides to leave the pilot research, you may not be able to find this kind of family treatment  
5378 in your area outside of this research study. Other types of treatment may be available in your  
5379 community, in which case we will provide a list of these and how to find them if you prefer this option.  
5380 You and/or your insurance company would be responsible for any costs associated with these options.  
5381 You also may not receive full compensation for your participation if your child decides to leave the  
5382 research. Contact the investigator at the contact information included below if your child decides to  
5383 leave the study. If your child stops being in the research, already collected data may not be removed  
5384 from the study database. You will be asked whether the investigator can collect data from your child's  
5385 routine medical care.

5386

5387 **Is there any way being in this study could be bad for my child?**

5388 There are certain risks and discomforts that may be associated with this research.

5389 They include:

5390

5391 **Likely**

- 5392 ● Your child might feel hungry when dieting or sore after exercising.

5393 **Less Likely**

- 5394 ● Your child may find some of the questions embarrassing or be uncomfortable having his/her  
5395 height and weight measured.

- 5396 ● There may be some family disagreements as issues of family functioning, communication, and  
5397 discipline are discussed.

- 5398 ● Your child may be inconvenienced at times by having to miss school activities, meetings, etc., to  
5399 attend assessments and family sessions.

5400 **Rare**

- 5401
- 5402
- 5403
- 5404
- There is a risk of audio recordings being lost. All recordings will be immediately stored in a locked drawer or saved to a password-protected computer in the research office after the individual family and group weight loss and maintenance sessions. Your family name will not be on these recordings, which will be identified only by a study ID number.
- 5405
- 5406
- 5407
- 5408
- 5409
- The use of online platforms is associated with risks involving breaches of confidentiality. We implement many layers of security to limit these risks as much as possible within our website and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security measures and carry their own risks if your family chooses to use them to supplement your participation in this study.
- 5410
- 5411
- In addition, although this treatment usually prevents the development of eating disorder problems, in rare cases it may increase them.

5412 **Other Risks**

- 5413
- 5414
- 5415
- In this study your child will be given a physical activity goal. Given that some people may have medical risks associated with increasing their physical activity, these recommendations for your child will be given in consultation with his/her doctor.

5416

5417 **Will being in this study help my child in any way?**

5418 We cannot promise any benefits to you, your child, or others from your taking part in this research.

5419 However, possible benefits could include your child losing weight, becoming more physically active, and

5420 eating more healthfully as a result of participation. In addition, maintaining weight loss may lead to

5421 better relationships and better mood. However, we cannot guarantee your child will receive any

5422 benefits from this study. This study may provide information that will help other children inside and

5423 outside your household to lose weight and keep it off.

5424

5425 **What happens to the information collected for the research?**

5426 Efforts will be made to limit the use and disclosure of your child's personal information, including

5427 research study and medical or education records, to people who have a need to review this information.

5428 We cannot promise complete secrecy. Organizations that may inspect and copy your child's information

5429 include the IRB and other representatives of this organization. Information related to your child will be

5430 treated in strict confidence to the extent provided by law. Your child's identity will be coded and will not

5431 be associated with any published results. Your child's code number and identity will be kept in a locked

5432 file of the Principal Investigator. The only connection between your child's participation in this study and

5433 the study itself will be this signed consent form. All recordings of the sessions will be kept in a locked file

5434 of the Principal Investigator until the end of the study, at which point they will be destroyed. If your

5435 child withdraws from the study, no further data will be collected, but any information that has been

5436 provided may be retained by the researchers and analyzed. In order to monitor this research study,

5437 representatives from the Institutional Review Board (IRB) and other federal agencies such as NIH

5438 (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the

5439 research records which may reveal your child's identity. A description of this clinical trial will be available

5440 on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include information that

5441 can identify your child. At most, the web site will include a summary of the results. You can search this

5442 web site at any time. Federal law provides additional protections of your child's medical records and

5443 related health information. These are described in the HIPAA section of this document.

5444

5445 **Can my child be removed from the research without our OK?**

5446 The principal investigator of the study can remove your child from the research study without you or  
5447 your child's approval. Possible reasons for removal include need for hospitalization for physical or  
5448 psychological reasons. We will tell you about any new information that may affect your child's health,  
5449 welfare, or choice to stay in the research.

5450

5451 **What else do my child and I need to know?**

5452 This research is being funded by the National Institutes of Health, specifically the National Heart, Lung  
5453 and Blood Institute (NHLBI).

5454 If your child needs medical care because of taking part in this research study, contact the investigator  
5455 and/or speak with your doctor and medical care will be made available. Generally, this care will be billed  
5456 to you, your insurance or other third party. The University at Buffalo has no program to pay for medical  
5457 care for research-related injury. If your child agrees to take part in this research study, we will pay your  
5458 family up to \$30 for your time and effort. The amount you are paid depends upon your attendance to  
5459 visits in the study.

5460

5461 **HIPAA: Authorization for the Use and Disclosure of Identifiable Health**  
5462 **Information for Research Purposes**

5463 This section describes information about your child and about your child's health that will be obtained  
5464 by the researchers when your child participates in the research study. Health information is considered  
5465 "protected health information" when it may directly identify your child as an individual. By signing this  
5466 form, you are agreeing to permit the researchers and/or other parties (described in detail below) to  
5467 have access to this information. If there are any parts of this form that you do not understand, please be  
5468 sure to ask us for further clarification.

5469 **A. What protected health information will be collected about your child as part of this**  
5470 **research study?**

5471  Information from your child's full medical records.

5472  New Health Information created from study related tests, procedures, visits, and/or  
5473 questionnaires as described in this consent form.

5474 **B. Who is authorized to provide or collect this information?**

5475  Principal Investigator or designee

5476 **C. With whom may your child's protected health information be shared?**

5477 Your child's health information may be shared with others outside of the research group for  
5478 purposes directly related to the conduct of this research study or as required by law, including  
5479 but not limited to:

5480  Clinical staff not involved in this research study who may become involved in your  
5481 child's care if it is potentially relevant to your treatment.

5482  The sponsor of this research study (**National Heart, Lung and Blood Institutes**  
5483 **(NHLBI)** cooperative group, etc., or its agents.

5484  The organization(s) responsible for administering this research (e.g., Research  
5485 Foundation of SUNY, University at Buffalo, Washington University, Nationwide  
5486 Children's Hospital, University of Rochester).

5487  Other medical investigators/centers/institutions participating in this research study.



5488 Your child's information may also be shared with individuals or entities responsible for general  
5489 administration, oversight and compliance of research activities. Examples of this include the  
5490 institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring  
5491 Boards, an Institutional Review Board, The Research Foundation of the State University of New  
5492 York, University at Buffalo Foundation Services, and accrediting bodies, or with certain  
5493 government oversight agencies that have authority over the research including the Department  
5494 of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National  
5495 Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your child's  
5496 information may also be shared with other entities as permitted or required by law. All  
5497 reasonable efforts will be used to protect the confidentiality of your child's individually  
5498 identifiable health information that may be shared with others as described above.

5499 All reasonable efforts will be used to protect the confidentiality of your child's protected health  
5500 information. There is the potential for individually identifiable information and the associated  
5501 health information obtained with this authorization to be re-disclosed by the recipient(s). After  
5502 such a disclosure, the information may no longer be protected by the terms of this authorization  
5503 against further re-disclosure.

5504 **D. How long will this information be kept by the Principal Investigator?**

5505   √   This authorization has no expiration date. The researchers may continue to rely on this  
5506 authorization to obtain and use protected health information about your child unless  
5507 you revoke this authorization in writing.

5508   √   Your child's protected health information will go into a database that will be maintained  
5509 indefinitely. Any future study using this information that falls outside the scope of this  
5510 current study will be required to follow guidelines designed to govern access to that  
5511 information and to protect the privacy of that information.

5512

5513 **E. What are your rights after signing this authorization?**

5514 You have the right to revoke this authorization at any time. If you withdraw your authorization,  
5515 no additional efforts to collect individually identifiable health information about your child will  
5516 be made. You should know, however, that protected health information acquired using this  
5517 authorization prior to its withdrawal may continue to be used to the extent that the  
5518 investigator(s) have already relied on your permission to conduct the research. If you chose to  
5519 withdraw this authorization, you must do so in writing to the following individual(s):

5520

5521 **Leonard H. Epstein, Ph.D.**  
5522 **University at Buffalo Department of Pediatrics**  
5523 **Division of Behavioral Medicine**  
5524 **3435 Main Street**  
5525 **G56 Farber Hall**  
5526 **Buffalo, NY 14214**  
5527 **Phone: 716-829-3400**

5528

5529 If you send us a request to withdraw your authorization, we will forward that request to the  
5530 institutions we have shared it with in order to collect your individually identifiable health  
5531 information.

5532

5533 **F. What will happen if you decide not to sign this authorization?**

5534

5535 Refusing to sign this authorization will not affect the present or future care your child receives at  
5536 this institution and will not cause any penalty or loss of benefits to which you are otherwise  
5537 entitled. If you decide not to sign this authorization, you and your child will not be able to  
5538 participate in the research study.

5539

5540

**Signature Block for Parental Permission**

Signature documents your permission for the named child to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

\_\_\_\_\_  
Printed name of child

\_\_\_\_\_  
Signature of parent or individual legally authorized to consent to the child's general medical care

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of parent or individual legally authorized to consent to the child's general medical care

- Parent
- Individual legally authorized to consent to the child's general medical care (See note below)

**Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

\_\_\_\_\_  
Assent Process

- Child is birth-6 yrs. old - Assent is not required
- Child is 7-17 yrs. old – A separate Assent Document is to be signed by the child
- Assent will be obtained Verbally
- Assent has been waived by the IRB

5541

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

\_\_\_\_\_  
Signature of person obtaining consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of person obtaining consent

5542

5543



**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018

875 Ellicott St. | Buffalo, NY 14203

UB Federal wide Assurance ID#: FWA00008824

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS  
TREATMENT IMPLEMENTED IN PRIMARY CARE**

**PILOT Parent Adult Consent to Participate in a Research Study**

**Version Date: 07-18-2018**

**Investigators: Leonard H. Epstein, Ph.D.**

**Why am I being invited to take part in a research study?**

You and your child are being invited to take part in a pilot research study because:

- You are an adult able to read the English language. You have reported no current learning disabilities, medical problems, or psychiatric problems.
- You have a child between the ages of 7 and 12 years old that falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex), and you are interested in weight loss and participating in the study.

This research study is supported by a grant through the National Heart Lung and Blood Institute (NHBLI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

**What should I know about a research study?**

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

5582 **Who can I talk to?**

5583 If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research  
5584 team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at  
5585 your child’s doctor’s office. You can also contact the research participant advocate at 716-888-4845 or  
5586 [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

5587 This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to  
5588 them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu)

5589 If:

- 5590 ● You have questions about your rights as a participant in this research
  - 5591 ● Your questions, concerns, or complaints are not being answered by the research team.
  - 5592 ● You cannot reach the research team.
  - 5593 ● You want to talk to someone besides the research team.
  - 5594 ● You want to get information or provide input about this research.
- 5595

5596 **Why is this research being done?**

5597 The goal of this pilot study is to determine whether a specific kind of weight loss treatment called  
5598 family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the  
5599 primary care setting. Extensive information has been gathered by our research team about the  
5600 treatment of childhood overweight and obesity. But there is still much to learn about how the treatment  
5601 should be incorporated into various medical settings, such as primary care.

5602

5603 **How long will the research last?**

5604 We expect that you will be in this treatment and research study for 3 months.

5605

5606 **How many people will be studied?**

5607 We expect about 6 families will be in the pilot phase of this research study.

5608

5609 **What happens if I say yes, I want to be in this research?**

5610 To determine if your family is eligible to participate, you and your child will be asked to complete an  
5611 eligibility assessment at an orientation session about this study. You and your child’s height and weight  
5612 will be measured, and standard questions regarding medical and psychological history will be asked by a  
5613 trained interviewer to determine eligibility.

5614 If your family is eligible for this research study and agrees to participate, you and your child will be asked  
5615 to come to your pediatric office to complete a baseline assessment (detailed below). After the baseline  
5616 assessment, your family will be enrolled. You will meet with a PLAN coach weekly.

5617

5618 **Group**

5619 At the start of the study, your family will be assigned to receive family-based behavioral treatment for  
5620 weight management (FBT). FBT is a behavioral weight-control intervention that aims to make weight  
5621 changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet,  
5622 activity, behavioral techniques, parenting, and social facilitation in children and their parents. The  
5623 treatment includes: 1) The Traffic Light Eating Plan uses RED; YELLOW; and GREEN labels for food to  
5624 guide families toward the goal of eating nutritious foods. 2) The Traffic Light Activity Program also uses  
5625 RED; YELLOW; and GREEN labels for different levels of exercise to increase physical activity and reducing  
5626 inactive behaviors. 3) a variety of behavioral techniques including changing and controlling your  
5627 environment, tracking eating and physical activity, setting goals, problem solving, setting up a reward

5628 system, incentives for behavior change and weight loss, finding substitutes for unhealthy foods, and  
5629 improving positive parenting. FBT also involves making changes in the home. So that weight loss or  
5630 prevention of weight gain may extend to members of the family who are not regularly attending  
5631 treatment sessions (e.g., siblings and spouse).

5632

5633 **Treatment Schedule**

5634 Every family will receive FBT and will complete at least 12 sessions with the FBT PLAN coach during the 3  
5635 months of the study.

5636

5637 **Assessments, Interviews, Questionnaires**

5638 Attendance will be taken and both you and your child will be weighed at every session. In addition, there  
5639 will be two major assessments throughout the entire 3 months of the pilot study:

- 5640 ● 1 Baseline assessment upon starting study (0 months)
- 5641 ● 1 Follow-up assessment at end of study (3 months)

5642 Both major assessments will take approximately 30-90 minutes to complete at your child's pediatric  
5643 office, or a home visit can be arranged. Height and weight will be taken on you and your child. Your  
5644 height will be taken at the beginning of the study, and your child's height will be taken at each major  
5645 assessment. At your baseline and follow-up appointment, we will ask you to do a computer task that  
5646 asks you to make choices between different amounts of money.

5647

5648 **Audio Recording**

5649 Your interviews and individual family will be audiotaped or digitally recorded for research purposes, but  
5650 you will not be identified on the recording and the recordings will not be labeled with your name.

5651 Recording the sessions is the best way to make sure we collect accurate information. It also helps us  
5652 make sure that all our staff delivers the study to participants in the same way. The recordings will be  
5653 stored on password-protected computers with restricted access within the University at Buffalo, and  
5654 then transferred to Washington University School of Medicine. The recordings will be labeled only with  
5655 your study ID, date, and session number. The Principal Investigator and research staff may use these  
5656 recordings for purposes of evaluation, treatment, research, and training related to this study.

5657 Recordings may also be used to train staff implementing these or similar interventions at other sites.

5658 The recordings will be destroyed at the end of the study when all data analysis is complete. You do not  
5659 have to agree to be audio recorded in order to participate in this study.

5660

5661

5662 **Please check and initial below if you agree or do not agree to give permission for you and your child to**  
5663 **be audio recorded during your sessions with the PLAN coach.**

5664  **YES** \_\_\_\_\_, Yes, I give my permission to be audio recorded during sessions with a PLAN coach

5665  **NO** \_\_\_\_\_, No, **I do not** give my permission to be audio recorded during sessions with a PLAN  
5666 coach

5667 Parent INITIAL \_\_\_\_\_ Date: \_\_\_\_\_

5668 **What are my responsibilities if I take part in this research?**

5669 If you take part in this pilot research, you will be responsible to attend the baseline assessment, 3 month  
5670 follow-up assessment, and attend at least 12 treatment sessions.

5671

5672 **What happens if I do not want to be in this research?**

5673 Your participation in this pilot research study is voluntary. You may choose not to enroll in this study.

5674 There are no other research alternatives other than to participate in this study.

5675

5676 **What happens if I say yes, but I change my mind later?**

5677 You can leave the pilot research at any time. It will not be held against you. You do not have to answer  
5678 every question. You may refuse to answer any questions that you do not want to answer.

5679 If you decide to leave the research, you may not be able to find this kind of family treatment in your  
5680 area outside of this research study. Other types of treatment may be available in your community. In  
5681 which case we will provide a list of these and how to find them if you prefer this option. However, you  
5682 and/or your insurance company would be responsible for any costs associated with these options. You  
5683 also may not receive full compensation for your participation. If you decide to leave the research,  
5684 contact the investigator at the contact information included below. If you stop being in the research,  
5685 already collected data may not be removed from the study database. You will be asked whether the  
5686 investigator can collect data from your routine medical care.

5687

5688 **Is there any way being in this study could be bad for me?**

5689 There are certain risks and discomforts that may be associated with this research. They include:

5690 **Likely**

5691 ● You might feel hungry when dieting or sore after exercising.

5692 **Less Likely**

5693 ● You may find some of the questions embarrassing or be uncomfortable having your height and  
5694 weight measured.

5695 ● There may be some family disagreements as issues of family functioning, communication, and  
5696 discipline are discussed.

5697 ● You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to  
5698 attend assessments and family sessions.

5699 **Rare**

5700 ● There is a risk of audio recordings being lost. All recordings will be immediately stored in a  
5701 locked drawer or saved to a password-protected computer in the research office after the  
5702 individual family and group weight loss and maintenance sessions. Your family name will not be  
5703 on these recordings, which will be identified only by a study ID number.

5704 ● The use of online platforms is associated with risks involving breaches of confidentiality. We  
5705 implement many layers of security to limit these risks as much as possible within our website  
5706 and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security  
5707 measures and carry their own risks if your family chooses to use them to supplement your  
5708 participation in this study.

5709 ● In addition, although this treatment usually prevents the development of eating disorder  
5710 problems, in rare cases it may increase them.

5711 **Other Risks**

5712 ● In this study you will be given a physical activity goal. Given that some people may have medical  
5713 risks associated with increasing their physical activity, these recommendations for your child will  
5714 be given in consultation with his/her doctor. As an adult, you may consider getting approval  
5715 from your doctor for setting physical activity goals. Adult participants will be responsible for  
5716 consulting their doctor for approval.

5717 **Will being in this study help me in any way?**

5718 We cannot promise any benefits to you or others from your taking part in this research. However,  
5719 possible benefits could include you and your child losing weight, becoming more physically active, and  
5720 eating more healthfully as a result of participation. In addition, maintaining weight loss may lead to  
5721 better relationships and better mood. However, we cannot guarantee that you or your child will receive  
5722 any benefits from this study. This study may also provide information that will help other children inside  
5723 and outside your household to lose weight and keep it off.

5724

5725 **What happens to the information collected for the research?**

5726 Efforts will be made to limit the use and disclosure of your personal information, including research  
5727 study and medical or education records, to people who have a need to review this information. We  
5728 cannot promise complete secrecy. Organizations that may inspect and copy your information include  
5729 the IRB and other representatives of this organization. Information related to you will be treated in strict  
5730 confidence to the extent provided by law. Your identity will be coded and will not be associated with any  
5731 published results. Your code number and identity will be kept in a locked file of the Principal  
5732 Investigator. The only connection between your participation in this study and the study itself will be  
5733 this signed consent form. All recordings of the sessions will be kept in a locked file of the Principal  
5734 Investigator until the end of the study. At which point they will be destroyed. If you withdraw from the  
5735 study, no further data will be collected. Any information that has been provided may be retained by the  
5736 researchers and analyzed. In order to monitor this research study, representatives from the Institutional  
5737 Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP  
5738 (Office of Human Research Protection) may inspect the research records which may reveal your identity.  
5739 A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S.  
5740 Law. This web site will not include information that can identify you. At most, the web site will include a  
5741 summary of the results. You can search this web site at any time. Federal law provides additional  
5742 protections of your medical records and related health information. These are described in the HIPAA  
5743 section of this document.

5744

5745 **Can I be removed from the research without my OK?**

5746 The principal investigator of the study can remove you from the research study without your approval.  
5747 Possible reasons for removal include need for hospitalization for physical or psychological reasons.

5748

5749 **What else do I need to know?**



5750 This research is being funded by the National Institutes of Health, specifically the National Heart, Lung  
5751 and Blood Institutes (NHLBI). If you need medical care because of taking part in this research study,  
5752 contact the investigator and/or speak with your doctor and medical care will be made available.  
5753 Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo  
5754 has no program to pay for medical care for research-related injury. If you agree to take part in this  
5755 research study, we will pay you up to \$30 for your time and effort. The amount you are paid depends  
5756 upon your attendance to visits in the study.

5757  
5758 **HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research**  
5759 **Purposes**

5760 This section describes information about you and about your health that will be obtained by the  
5761 researchers when you participate in the research study. Health information is considered "protected  
5762 health information" when it may directly identify you as an individual. By signing this form, you are  
5763 agreeing to permit the researchers and/or other parties (described in detail below) to have access to  
5764 this information. If there are any parts of this form that you do not understand, please be sure to ask us  
5765 for further clarification.

5766 **A. What protected health information will be collected about you as part of this research**  
5767 **study?**

5768  Specific information from your full medical records related to your height, weight, dietary  
5769 restrictions, and physical activity restrictions.

5770  
5771  New Health Information created from study related tests, procedures, visits, and/or  
5772 questionnaires as described in this consent form.

5773 **B. Who is authorized to provide or collect this information?**

5774  Principal Investigator or designee

5775  
5776 **C. With whom may your protected health information be shared?**

5777 Your health information may be shared with others outside of the research group for purposes  
5778 directly related to the conduct of this research study or as required by law, including but not  
5779 limited to:

5780  Clinical staff not involved in this research study who may become involved in you and  
5781 your child's care if it is potentially relevant to your treatment.

5782  The sponsor of this research study (**National Heart, Lung and Blood Institutes**  
5783 **(NHLBI)** cooperative group, etc., or its agents.

5784  The organization(s) responsible for administering this research (e.g., Research  
5785 Foundation of SUNY, University at Buffalo, Washington University, Nationwide  
5786 Children's Hospital, University of Rochester).

5787  Other medical investigators/centers/institutions participating in this research study.

5788 Your information may also be shared with individuals or entities responsible for general  
5789 administration, oversight and compliance of research activities. Examples of this include the  
5790 institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring  
5791 Boards, an Institutional Review Board, The Research Foundation of the State University of New  
5792 York, University at Buffalo Foundation Services, and accrediting bodies, or with certain  
5793 government oversight agencies that have authority over the research including the Department  
5794 of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National  
5795 Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your  
5796 information may also be shared with other entities as permitted or required by law. All  
5797 reasonable efforts will be used to protect the confidentiality of your individually identifiable  
5798 health information that may be shared with others as described above.

5799 All reasonable efforts will be used to protect the confidentiality of your protected health  
5800 information. There is the potential for individually identifiable information and the associated  
5801 health information obtained with this authorization to be re-disclosed by the recipient(s). After  
5802 such a disclosure, the information may no longer be protected by the terms of this authorization  
5803 against further re-disclosure.

5804 **D. How long will this information be kept by the Principal Investigator?**

5805  This authorization has no expiration date. The researchers may continue to rely on this  
5806 authorization to obtain and use protected health information about you unless you  
5807 revoke this authorization in writing.

5808  Your protected health information will go into a database that will be maintained  
5809 indefinitely. Any future study using this information that falls outside the scope of this  
5810 current study will be required to follow guidelines designed to govern access to that  
5811 information and to protect the privacy of that information.

5812 **E. What are your rights after signing this authorization?**

5813 You have the right to revoke this authorization at any time. If you withdraw your authorization,  
5814 no additional efforts to collect individually identifiable health information about you will be  
5815 made. You should know, however, that protected health information acquired using this  
5816 authorization prior to its withdrawal may continue to be used to the extent that the  
5817 investigator(s) have already relied on your permission to conduct the research. If you chose to  
5818 withdraw this authorization, you must do so in writing to the following individual(s):

5819 **Leonard H. Epstein, Ph.D.**  
5820 **University at Buffalo Department of Pediatrics**  
5821 **Division of Behavioral Medicine**  
5822 **3435 Main Street**  
5823 **G56 Farber Hall**  
5824 **Buffalo, NY 14214**  
5825 **Phone: 716-829-3400**

5826  
5827 If you send us a request to withdraw your authorization, we will forward that request to the  
5828 institutions we have shared it with in order to collect your individually identifiable health  
5829 information.  
5830

5831  
5832  
5833  
5834  
5835

**F. What will happen if you decide not to sign this authorization?**

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

5836

**Signature Block for Capable Adult**

Your signature documents your permission to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

---

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

5837  
5838  
5839  
5840  
  
5841  
5842  
5843  
5844  
5845  
5846  
5847  
5848  
5849  
5850  
5851  
5852  
5853  
5854  
5855  
5856  
5857  
5858  
5859  
5860  
5861



**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018  
875 Ellicott St. | Buffalo, NY 14203

**THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT  
IMPLEMENTED IN PRIMARY CARE**

**Participating Child Assent to be in a Research Study (for Children 7-13 yrs. of  
age)**

**Version Date: 6.25.19**

**Investigators: Leonard H. Epstein, PhD.**

**Who are we?**

My name is Dr. Leonard H. Epstein and I am a researcher at the University at Buffalo. I work in the Department of Pediatrics.

**Why are we meeting with you?**

You have aged into a different age group of 7-13 year olds. We need you to assent to continue participating in this weight loss program for kids.

**Why are we doing this study?**

We want to look at a certain kind of weight loss program for kids. We want to know if it will work at a doctor's office.

**What will happen to you if you continue to participate in the study?**

You will continue to come to the doctor's office like before, nothing has changed. You will keep coming in to get your height and weight measured and fill out surveys.

You and your parent will continue to be a part of one of two groups:

- If you are in one group, you follow the recommendations of your doctor.
- If you are in the other group, you come to your doctor's office once a week for 2 years. This happens for at least 26 visits. At the visits you meet with someone from the study. Your weight is taken and you learn about healthy food. We teach you fun ways to exercise.

Every 6 months we ask you some questions about yourself. We continue to measure your height and weight. At your 12-month and follow-up appointments, we ask you to do a computer task that asks you to make choices between different amounts of money.

You do not have to answer any questions that you do not want to answer. You do not have to do any activities that you do not want to do.

**What are the good things and bad things that may happen to you if you continue to be a part of the study?**

5907 *Most Likely:* You can have fun learning about healthy food and exercise. You could become healthy.

5908

5909 *Maybe:* You could become hungry when trying to eat healthy. Your muscles could feel sore from  
5910 exercise. That will go away once you are used to exercising. You might experience common exercise  
5911 injuries (i.e., sprains, shin splints, tendonitis, muscle pulls, strains, etc).

5912

5913 **Do you have to continue to be in the study?**

5914 No you don't. No one will get angry or upset with you if you don't want to do this. Just tell us if you  
5915 don't want to continue to be in the study. Also, you can change your mind later if you decide you don't  
5916 want to be in the study anymore.

5917

5918 **Do you have any questions?**

5919 You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk  
5920 to someone else at any time during the study. You can call:

5921

5922 Name of contact person on the study: *Leonard H. Epstein, Ph.D.* Phone Number: *(716) 829-3400*

5923

5924

5925

**Signature Block for Assent of Child**

5926

Your signature documents your permission to continue to take part in this research.		
Signature of subject		Date
Printed name of subject		
I certify that the nature and purpose, the potential benefits and possible risks associated with continued participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.		
Signature of person obtaining consent		Date
Printed name of person obtaining consent		

5927

5928 *(This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol*  
5929 *addenda, 10.25.19).*

5930

5931



**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018

875 Ellicott St. | Buffalo, NY 14203

UB Federal wide Assurance ID#: FWA00008824

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS  
TREATMENT IMPLEMENTED IN PRIMARY CARE**

**Targeted Child Ages 14-17 Assent to Participate in a Research Study**

**Version Date: 7.8.19**

**Investigators: Leonard H. Epstein, PhD.**

**Why am I being asked to continue in this research study?**

You are being asked to assent to continue in this research study because:

- You have aged into a different age group of 14-17 years.

This research study is supported by a grant through the National Heart Lung and Blood Institute (NHLBI). Research studies only include individuals who choose to take part in them. Your decision to continue in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to continue to participate. You may also take home an unsigned copy of this consent form to think about continuing to participate or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

**What should I know about a research study?**

- Someone will explain this research study to you.
- Whether or not you continue is up to you.
- You can choose not to continue.
- You can agree to continue and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

5967 **Who can I talk to?**

5968 If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research  
5969 team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at  
5970 your child’s doctor’s office. You can also contact the research participant advocate at 716-888-4845 or  
5971 [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

5972 This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to  
5973 them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu) if:

- 5974 ● You have questions about your rights as a participant in this research
- 5975 ● Your questions, concerns, or complaints are not being answered by the research team.
- 5976 ● You cannot reach the research team.
- 5977 ● You want to talk to someone besides the research team.
- 5978 ● You want to get information or provide input about this research.

5979

5980 **Why is this research being done?**

5981 The goal of this study is to determine whether a specific kind of weight loss treatment called family-  
5982 based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the  
5983 primary care setting. Extensive information has been gathered by our research team about the  
5984 treatment of childhood overweight and obesity. But there is still much to learn about how the treatment  
5985 should be incorporated into various medical settings, such as primary care.

5986

5987 **How long will the research last?**

5988 We expect that you will be in this treatment and research study for 24 months from your original start  
5989 of the study.

5990

5991 **How many people will be studied?**

5992 We expect about 132 families will be in this research study in your geographical location. Out of 528  
5993 families in the entire study nationally.

5994

5994 **What happens if I say yes, I want to continue to be in this research?**

5995 You will continue your participation as before and no components of the research study have changed.  
5996 As a reminder, you will continue to be asked to come to your pediatric office to complete assessment  
5997 appointments (detailed below).

5998

5998 **Groups**

5999 Your family has been assigned to one of two groups. Participants in one group receive the current  
6000 standard of care offered by their physician for the treatment of childhood weight management.  
6001 Participants in the second group receive family-based behavioral treatment for weight management  
6002 (FBT). FBT is a behavioral weight-control intervention that aims to make weight changes in both a child  
6003 and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral  
6004 techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1)  
6005 The Traffic Light Eating Plan uses RED; YELLOW; and GREEN labels for food to guide families toward the  
6006 goal of eating nutritious foods. 2) The Traffic Light Activity Program, also uses RED; YELLOW; and GREEN  
6007 labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a  
6008 variety of behavioral techniques including changing and controlling your environment; tracking eating  
6009 and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior  
6010 change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT  
6011 also involves making changes in the home. So weight loss or prevention of weight gain may extend to  
6012 members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).



6013 The group that your family is in/the treatment you receive was chosen by chance. Like flipping a coin.  
6014 Neither you nor your doctor chose what treatment your family is receiving.

#### 6015 **Treatment Schedule**

6016 Every family will follow their pediatrician's recommended schedule of appointments for weight  
6017 management to have at least 4 visits with their child's doctor over the course of the 24 months of the  
6018 study. Families in the group receiving FBT will additionally complete at least 26 sessions with the FBT  
6019 PLAN Coach during the 24 months of the study. The amount of sessions completed within this range will  
6020 be based on progress through the program and will vary for each family.

#### 6021 **Assessments, Interviews, Questionnaires**

6022 Attendance will be taken and you will continue to be weighed at every session. In addition, there are  
6023 five major assessments throughout the entire 2 years of the study:

- 6024 ● 1 Baseline assessment upon starting study (0 months)
- 6025 ● 3 Treatment assessments during the study (6, 12, and 18 months)
- 6026 ● 1 Follow-up assessment at end of the study (24 months)

6027 Each major assessment takes approximately 30-90 minutes to complete at your pediatric office, or a  
6028 home visit can be arranged. Height and weight is taken on you as well as the identified other family  
6029 members (if applicable). Your height was taken at the beginning of the study and will be taken at each  
6030 major assessment. You will also complete short questionnaires. You as well as the identified other family  
6031 members will be asked questions about parenting behaviors and the home food and activity  
6032 environment. At your baseline, 12-month, and follow-up appointments, you will be asked to complete a  
6033 computer task. Throughout the study, you will have access to a website that contains study materials  
6034 and interactive tools.

#### 6035 **Audio Recording**

6036 Your interviews and individual family will be audiotaped or digitally recorded for research purposes, but  
6037 you will not be identified on the recording and the recordings will not be labeled with your name.  
6038 Recording the sessions is the best way to make sure we collect accurate information. It also helps us  
6039 make sure that all our staff delivers the study to participants in the same way. The recordings will be  
6040 stored on password-protected computers with restricted access within the University at Buffalo, and  
6041 then transferred to Washington University School of Medicine. The recordings will be labeled only with  
6042 your study ID, date, and session number. The Principal Investigator and research staff may use these  
6043 recordings for purposes of evaluation, treatment, research, and training related to this study.  
6044 Recordings may also be used to train staff implementing these or similar interventions at other sites.  
6045 The recordings will be destroyed at the end of the study when all data analysis is complete.

#### 6046 **What are my responsibilities if I continue to take part in this research?**

6047 If you continue to take part in this research, you will be responsible to attend all treatment assessments,  
6048 at least 26 treatment sessions if your family is in the group receiving FBT, and the follow-up assessment.  
6049

#### 6050 **What happens if I do not want to continue to be in this research?**

6051 Your participation in this research study is voluntary. You may choose not to continue in this study.  
6052 There are no other research alternatives other than to participate in this study.  
6053

#### 6054 **What happens if I say yes, but I change my mind later?**

6055 You can leave the research at any time. It will not be held against you. You do not have to answer every  
6056 question and may refuse to answer any questions that you do not want to answer.

6057 If you decide to leave the research, you may not be able to find this kind of family treatment in your  
6058 area outside of this research study. Other types of treatment may be available in your community. In  
6059 which case we will provide a list of these and how to find them if you prefer this option. However, you  
6060 and/or your insurance company would be responsible for any costs associated with these options. You  
6061 also may not receive full compensation for your participation. If you decide to leave the research,  
6062 contact the investigator at the contact information included above. If you stop being in the research,  
6063 already collected data may not be removed from the study database. You will be asked whether the  
6064 investigator can collect data from your routine medical care.  
6065

6066 **Is there any way continuing to be in this study could be bad for me?**

6067 There are certain risks and discomforts that may be associated with this research. They include:

6068 **Likely**

- 6069 ● You might feel hungry when dieting, sore after exercising, or experience common exercise  
6070 injuries (i.e., sprains, shin splints, tendonitis, muscle pulls, strains, etc).

6071 **Less Likely**

- 6072 ● You may find some of the questions embarrassing or be uncomfortable having your height and  
6073 weight measured.
- 6074 ● There may be some family disagreements as issues of family functioning; communication; and  
6075 discipline are discussed.
- 6076 ● You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to  
6077 attend assessments and family sessions.

6078

6079

6080 **Rare**

- 6081 ● There is a risk of audio recordings being lost. All recordings will be immediately stored in a  
6082 locked drawer or saved to a password-protected computer in the research office after the  
6083 individual family and group weight loss and maintenance sessions. Your family name will not be  
6084 on these recordings, which will be identified only by a study ID number.
- 6085 ● The use of online platforms is associated with risks involving breaches of confidentiality. We  
6086 implement many layers of security to limit these risks as much as possible within our website  
6087 and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security  
6088 measures and carry their own risks if your family chooses to use them to supplement your  
6089 participation in this study.
- 6090 ● In addition, although this treatment usually prevents the development of eating disorder  
6091 problems, in rare cases it may increase them.

6092 **Other Risks**

- 6093 ● In this study you will be given a physical activity goal. Given that some people may have medical  
6094 risks associated with increasing their physical activity, these recommendations will be given in  
6095 consultation with your doctor. Participants will be responsible for consulting their doctor for  
6096 approval.

6097 **Will continuing to be in this study help me in any way?**

6098 We cannot promise any benefits to you or others from your continuing to take part in this research.  
6099 However, possible benefits could include you losing weight, becoming more physically active, and eating  
6100 more healthfully as a result of participation. In addition, maintaining weight loss may lead to better  
6101 relationships and better mood. However, we cannot guarantee that you will receive any benefits from  
6102 this study. This study may also provide information that will help other children inside and outside your  
6103 household to lose weight and keep it off.

6104

6105 **What happens to the information collected for the research?**

6106 Efforts will be made to limit the use and disclosure of your personal information, including research  
6107 study and medical or education records, to people who have a need to review this information. We  
6108 cannot promise complete secrecy. Organizations that may inspect and copy your information include  
6109 the IRB and other representatives of this organization. Information related to you will be treated in strict  
6110 confidence to the extent provided by law. Your identity will be coded and will not be associated with any  
6111 published results. Your code number and identity will be kept in a locked file of the Principal  
6112 Investigator. The only connection between your participation in this study and the study itself will be  
6113 this signed consent form. All recordings of the sessions will be kept in a locked file of the Principal  
6114 Investigator until the end of the study. At which point they will be destroyed. If you withdraw from the  
6115 study, no further data will be collected. Any information that has been provided may be retained by the  
6116 researchers and analyzed. In order to monitor this research study, representatives from the Institutional  
6117 Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP  
6118 (Office of Human Research Protection) may inspect the research records which may reveal your identity.  
6119 A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S.  
6120 Law. This web site will not include information that can identify you. At most, the web site will include a  
6121 summary of the results. You can search this web site at any time. Federal law provides additional  
6122 protections of your medical records and related health information.

6123

6124 **Can I be removed from the research without my OK?**

6125 The principal investigator of the study can remove you from the research study without your  
6126 approval. Possible reasons for removal include need for hospitalization for physical or  
6127 psychological reasons.

6128

6129 **What else do I need to know?**

6130 This research is being funded by the National Institutes of Health, specifically the National Heart, Lung  
6131 and Blood Institutes (NHLBI). If you need medical care because of taking part in this research study,  
6132 contact the investigator and/or speak with your doctor and medical care will be made available.  
6133 Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo  
6134 has no program to pay for medical care for research-related injury. If you agree to continue to take part  
6135 in this research study, we will pay your parents up to \$175 for your family's time and effort. The amount  
6136 your parents are paid depends upon your attendance to visits in the study.

6137

6138

**Signature Block for 14-17 year-old**

6139

Your signature documents your permission to continue to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

6140

6141

6142 *(This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol*

6143 *addenda, 10.25.19).*

6144



**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018

875 Ellicott St. | Buffalo, NY 14203

**THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT  
IMPLEMENTED IN PRIMARY CARE**

**Sibling Assent to be in a Research Study - (for Children 7-13 years of age)**

**Version Date: 6.25.19**

**Investigators: Leonard H. Epstein, PhD.**

**Who are we?**

My name is Dr. Leonard H. Epstein and I am a researcher at the UB. I work in the Department of Pediatrics.

**Why are we meeting with you?**

You have aged into a different age group of 7-13 year olds. We need you to assent to continue participating in this weight loss program for kids.

**Why are we doing this study?**

We want to look at siblings of kids participating in a study through your doctor's office.

**What will happen to you if you continue to participate in the study?**

You will continue to come to the doctor's office like before, nothing has changed. You will keep coming in for a total of 5 times over 2 years so we can measure your height and weight. This will be done in private. Only your parent, your sibling, and the study member will be with you. You do not have to answer any questions if you don't want to. You do not have to do any activities you do not want to do.

**What are the good things and bad things that may happen to you if you continue to be a part of the study?**

Most Likely:

*Good:* You can learn how you are growing.

Maybe:

*Good:* You could learn what is like to be in a research study. You might lose weight.

*Bad:* You might not like getting your height and weight taken. You might feel hungry when dieting, sore after exercising, or experience common exercise injuries (i.e., sprains, shin splints, tendonitis, muscle pulls, strains, etc).

**Do you have to continue to be in the study?**

No you don't. No one will get angry or upset with you if you don't want to do this. If you do not want to be in the study at any time, it will not affect your family being in the study. Just tell us if you don't want

6189 to be in the study. And remember, you can change your mind later if you decide you don't want to be in  
6190 the study anymore.

6191  
6192 **Do you have any questions?**

6193 You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk  
6194 to someone else at any time during the study. You can call:

6195  
6196 Name of contact person on the study: *Leonard H. Epstein, Ph.D.*  
6197 Phone Number: *(716) 829-3400*

6198  
6199

6200 **Signature Block for Sibling Assent of Child**

Your signature documents your permission to continue to take part in this research.	
Signature of subject	Date
Printed Name of Subject	

6201

6202 I certify that the nature and purpose, the potential benefits and possible risks associated with continued  
6203 participation in this research study have been explained to the above individual and that any questions  
6204 about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent	Date
Printed name of person obtaining consent	

6205  
6206  
6207  
6208  
6209

*(This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda, 10.25.19).*

6210  
6211  
6212  
6213  
  
6214  
6215  
6216  
6217  
6218  
6219  
6220  
6221  
6222  
6223  
6224  
6225  
  
6226  
6227  
6228  
6229  
6230  
6231  
6232  
6233  
6234  
6235  
6236  
6237  
6238  
6239  
6240  
6241  
6242  
6243  
6244  
6245  
6246  
  
6247  
6248  
  
6249  
6250  
6251  
6252  
6253

**University at Buffalo Institutional Review Board (UBIRB)**  
Office of Research Compliance | Clinical and Translational Research Center Room 5018  
875 Ellicott St. | Buffalo, NY 14203  
UB Federal wide Assurance ID#: FWA00008824

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS  
TREATMENT IMPLEMENTED IN PRIMARY CARE**

*Sibling Assent of a 14-17-year-old to Participate in a Research Study*

**Version Date: 7.8.19**

**Investigators: Leonard H. Epstein, PhD.**

**Why am I being invited to take part in a research study?**

You are being asked to assent to continue in this research study because:

- You have aged into a different age group of 14-17 years.

This research study is supported by a grant through the National Heart Blood and Lung Institutes (NHBLI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully and ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

**What should I know about a research study?**

- Someone will explain this research study to you.
- Whether or not you continue is up to you.
- You can choose not to continue.
- You can agree to continue and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

**Who can I talk to?**

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your child’s doctor’s office. You can also contact the research participant advocate at 716-888-4845 or [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu) if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

6254

6255 **Why is this research being done?**

6256 The goal of this study is to determine whether a specific kind of weight loss treatment called family-  
6257 based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the  
6258 primary care setting. Extensive information has been gathered by our research team about the  
6259 treatment of childhood overweight and obesity, but there is still much to learn about how the treatment  
6260 should be incorporated into various medical settings, such as primary care and how it effects siblings  
6261 living with participating parents and children.

6262

6263 **How long will the research last?**

6264 We expect that you will be in this treatment and research study for 24 months from your original start  
6265 of the study.

6266

6267 **How many people will be studied?**

6268 We expect about 132 families will be in this research study in your geographical location, out of 528  
6269 families in the entire study nationally.

6270

6271 **What happens if I say yes, I want to continue to be in this research?**

6272 You will continue your participation as before and no components of the research study have changed.  
6273 As a reminder, you will continue to be asked to come to your pediatric office to complete assessment  
6274 appointments (detailed below).

6275 **Groups**

6276 Your family has been assigned to one of two groups. Participants in one group receive the current  
6277 standard of care offered by their physician for the treatment of childhood weight management.  
6278 Participants in the second group receive family-based behavioral treatment for weight management  
6279 (FBT). FBT is a behavioral weight-control intervention that aims to make weight changes in both a child  
6280 and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral  
6281 techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1)  
6282 The Traffic Light Eating Plan uses RED; YELLOW; and GREEN labels for food to guide families toward the  
6283 goal of eating nutritious foods. 2) The Traffic Light Activity Program, also uses RED; YELLOW; and GREEN  
6284 labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a  
6285 variety of behavioral techniques including changing and controlling your environment; tracking eating  
6286 and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior  
6287 change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT  
6288 also involves making changes in the home. So weight loss or prevention of weight gain may extend to  
6289 members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

6290 The group that your family is in/the treatment you receive was chosen by chance. Like flipping a coin.  
6291 Neither you nor your doctor chose what treatment your family is receiving.

6292 **Treatment Schedule**

6293 Every family will follow their pediatricians recommended schedule of appointments for weight  
6294 management. Families in the group receiving FBT will additionally complete at least 26 sessions with the  
6295 FBT interventionist during the 24 months of the study. The amount of session completed within this  
6296 range will be based on progress through the program and will vary for each family. You will not attend  
6297 the sessions with the PLAN coach.

6298 **Assessments, Interviews, Questionnaires**

6299 You will continue to attend five major assessments throughout the entire 2 years of the study:



- 6300 ● 1 Baseline assessment upon starting study (0 months)
- 6301 ● 3 Measurement assessments during the study (6, 12, and 18 months)
- 6302 ● 1 Follow-up assessment at end of study (24 months)

6303 Each major assessment takes approximately 30-90 minutes to complete at your sibling’s pediatric office,  
 6304 or a home visit can be arranged. Your height and weight will continue to be taken at each major  
 6305 assessment.

6306  
 6307 **What are my responsibilities if I continue to take part in this research?**

6308 If you continue to take part in this research, you will be responsible to attend all measurement  
 6309 assessments and the follow-up assessment. Your continued participation in any other meetings with  
 6310 your family are voluntary. Weight measurements at these times are also voluntary and can be used as  
 6311 data.

6312  
 6313 **What happens if I do not want to continue to be in this research?**

6314 Your continued participation in this research study is voluntary. You may choose not to continue in this  
 6315 study, it will not affect your family being in the study. *There are no other research alternatives*  
 6316 *other than to participate in this study.*

6317  
 6318 **What happens if I say yes, but I change my mind later?**

6319 You can leave the research at any time, it will not be held against you. You do not have to answer every  
 6320 question and may refuse to answer any questions that you do not want to answer.

6321 If you decide to leave the research, you may not receive full compensation for your participation. If you  
 6322 decide to leave the research, contact the investigator at the contact information included below. If you  
 6323 stop being in the research, already collected data may not be removed from the study database. You will  
 6324 be asked whether the investigator can collect data from your routine medical care.

6325  
 6326 **Is there any way continuing to be in this study could be bad for me?**

6327 There are certain risks and discomforts that may be associated with this research. They include:

6328  
 6329 **Likely**

- 6330 ● You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to  
 6331 attend assessments.
- 6332 ● You might feel hungry when dieting, sore after exercising, or experience common exercise  
 6333 injuries (i.e., sprains, shin splints, tendonitis, muscle pulls, strains, etc).

6334 **Less Likely**

- 6335 ● You may find having your height and weight measured uncomfortable.

6336 **Rare**

- 6337 ● Although this treatment usually prevents the development of eating disorder problems, in rare  
 6338 cases it may increase them.
- 6339 ● The use of online platforms is associated with risks involving breaches of confidentiality. We  
 6340 implement many layers of security to limit these risks as much as possible within our website  
 6341 and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security

6342 measures and carry their own risks if your family chooses to use them to supplement your  
6343 participation in this study.

6344 **Will continuing to participate in this study help me in any way?**

6345 We cannot promise any benefits to you or others from your continuing to take part in this research. This  
6346 study may provide information that will help you to lose weight and keep it off. However, we cannot  
6347 guarantee that you will receive any benefits from this study.

6348

6349 **What happens to the information collected for the research?**

6350 Efforts will be made to limit the use and disclosure of your personal information, including research  
6351 study and medical or education records, to people who have a need to review this information. We  
6352 cannot promise complete secrecy. Organizations that may inspect and copy your information include  
6353 the IRB and other representatives of this organization. Information related to you will be treated in strict  
6354 confidence to the extent provided by law. Your identity will be coded and will not be associated with any  
6355 published results. Your code number and identity will be kept in a locked file of the Principal  
6356 Investigator. The only connection between your participation in this study and the study itself will be  
6357 this signed consent form. If you withdraw from the study, no further data will be collected, but any  
6358 information that has been provided may be retained by the researchers and analyzed. In order to  
6359 monitor this research study, representatives from the Institutional Review Board (IRB) and other federal  
6360 agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection)  
6361 may inspect the research records which may reveal your identity. A description of this clinical trial will  
6362 be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include  
6363 information that can identify you. At most, the web site will include a summary of the results. You can  
6364 search this web site at any time.

6365

6366

6367

6368 **Can I be removed from the research without my OK?**

6369 The principal investigator of the study can remove you from the research study without your approval.  
6370 Possible reasons for removal include need for hospitalization for physical or psychological reasons.

6371

6372 **What else do I need to know?**

6373 This research is being funded by the National Institutes of Health, specifically the National Heart, Lung  
6374 and Blood Institute (NHLBI).

6375 If you need medical care because of taking part in this research study, contact the investigator and/or  
6376 speak with your doctor and medical care will be made available. Generally, this care will be billed to you,  
6377 your insurance, or other third party. The University at Buffalo has no program to pay for medical care for  
6378 research-related injury.

6379

6380

**Signature Block for Assent of Child**

Your signature documents your permission to continue to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

\_\_\_\_\_  
Signature of subject

\_\_\_\_\_  
Date

Printed name of subject

I certify that the nature and purpose, the potential benefits and possible risks associated with continued participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent

Date

Printed name of person obtaining consent

6381

6382

6383

6384

*(This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda, 10.25.19).*



**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical and Translational Research Center Room 5018

875 Ellicott St. | Buffalo, NY 14203

UB Federal wide Assurance ID#: FWA00008824

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS  
TREATMENT IMPLEMENTED IN PRIMARY CARE**

**Sibling Adult Consent to Participate in a Research Study**

**Version Date: 6.25.19**

**Investigators: Leonard H. Epstein, PhD.**

**Why am I being invited to continue in this research study?**

You are being asked to assent to continue in this research study because:

- You have aged into a different age group of 14-17 years.

This research study is supported by a grant through the National Heart Blood and Lung Institute (NHBLI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

**What should I know about a research study?**

- Someone will explain this research study to you.
- Whether or not you continue is up to you.
- You can choose not to continue.
- You can agree to continue and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

**Who can I talk to?**

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your child's doctor's office. You can also contact the research participant advocate at 716-888-4845 or [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu).

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email [ub-irb@buffalo.edu](mailto:ub-irb@buffalo.edu) if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

- 6428 ● You want to talk to someone besides the research team.
- 6429 ● You want to get information or provide input about this research.

6430

6431 **Why is this research being done?**

6432 The goal of this study is to determine whether a specific kind of weight loss treatment called family-  
6433 based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the  
6434 primary care setting. Extensive information has been gathered by our research team about the  
6435 treatment of childhood overweight and obesity. But there is still much to learn about how the treatment  
6436 should be incorporated into various medical settings. Such as primary care and how it effects siblings  
6437 living with participating parents and children.

6438

6439 **How long will the research last?**

6440 We expect that you will be in this treatment and research study for 24 months from your original start  
6441 of the study.

6442

6443 **How many people will be studied?**

6444 We expect about 132 families will be in this research study in your geographical location. Out of 528  
6445 families in the entire study nationally.

6446

6447 **What happens if I say yes, I want to continue to be in this research?**

6448 You will continue your participation as before and no components of the research study have changed.  
6449 As a reminder, you will continue to be asked to come to your pediatric office to complete assessment  
6450 appointments (detailed below).

6451 **Groups**

6452 Your family has been assigned to one of two groups. Participants in one group receive the current  
6453 standard of care offered by their physician for the treatment of childhood weight management.  
6454 Participants in the second group receive family-based behavioral treatment for weight management  
6455 (FBT).

6456 FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and  
6457 their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral  
6458 techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1)  
6459 The Traffic Light Eating Plan uses RED; YELLOW; and GREEN labels for food to guide families toward the  
6460 goal of eating nutritious foods. 2) The Traffic Light Activity Program, also uses RED; YELLOW; and GREEN  
6461 labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a  
6462 variety of behavioral techniques including changing and controlling your environment; tracking eating  
6463 and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior  
6464 change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT  
6465 also involves making changes in the home. So weight loss or prevention of weight gain may extend to  
6466 members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

6467 The group that your family is in/the treatment you receive was chosen by chance. Like flipping a coin.  
6468 Neither you nor your doctor chose what treatment your family is receiving.

6469 **Treatment Schedule**

6470 Every family will follow their pediatrician recommended schedule of appointments for weight  
6471 management. Families in the group receiving FBT will additionally complete at least 26 sessions with the  
6472 FBT PLAN Coach during the 24 months of the study. The amount of sessions completed within this range

6473 will be based on progress through the program. The amount will vary for each family. You will not  
6474 attend the sessions with the PLAN Coach.

6475 **Assessments, Interviews, Questionnaires**

6476 You will attend five major assessments throughout the entire 2 years of the study:

- 6477 ● 1 Baseline assessment upon starting study (0 months)
- 6478 ● 3 Measurement assessments during the study (6, 12, and 18 months)
- 6479 ● 1 Follow-up assessment at end of study (24 months)

6480 Each major assessment will take approximately 30-90 minutes to complete at your pediatric office, or a  
6481 home visit can be arranged. Height and weight measurements will be taken at each major assessment.

6482 **What are my responsibilities if I continue to take part in this research?**

6483 If you take part in this research, you will be responsible to attend all measurement assessments and the  
6484 follow-up assessment. Your participation in any other meetings with your family are voluntary. Weight  
6485 measurements at these times are also voluntary and can be used as data.

6486

6487 **What happens if I do not want to continue to be in this research?**

6488 Your participation in this research study is voluntary. You may choose not to continue in this study.

6489 There are no other research alternatives other than to participate in this study.

6490

6491 **What happens if I say yes, but I change my mind later?**

6492 You can leave the research at any time. It will not be held against you, or affect your family's  
6493 participation in the study. You do not have to answer every question. You may refuse to answer any  
6494 questions that you do not want to answer.

6495 If you decide to leave the research, you may not receive full compensation for your participation. If you  
6496 decide to leave the research, contact the investigator at the contact information included below. If you  
6497 stop being in the research, already collected data may not be removed from the study database. You will  
6498 be asked whether the investigator can collect data from your routine medical care.

6499

6500 **Is there any way continuing to be in this study could be bad for me?**

6501 There are certain risks and discomforts that may be associated with this research. They include:

6502 **Likely**

- 6503 ● You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to  
6504 attend assessments.

6505 **Less Likely**

- 6506 ● You may find having your height and weight measured uncomfortable.

6507

6508 **Will continuing to be in this study help me in any way?**

6509 We cannot promise any benefits to you or others from your continued participation in this research. This  
6510 study may provide information that will help you to lose weight and keep it off. However, we cannot  
6511 guarantee that you will receive any benefits from this study.

6512

6513 **What happens to the information collected for the research?**

6514 Efforts will be made to limit the use and disclosure of your personal information, including research  
6515 study and medical or education records, to people who have a need to review this information. We

6516 cannot promise complete secrecy. Organizations that may inspect and copy your information include  
6517 the IRB and other representatives of this organization. Information related to you will be treated in strict  
6518 confidence to the extent provided by law. Your identity will be coded and will not be associated with any  
6519 published results. Your code number and identity will be kept in a locked file of the Principal  
6520 Investigator. The only connection between your participation in this study and the study itself will be  
6521 this signed consent form. If you withdraw from the study, no further data will be collected. Any  
6522 information that has been provided may be retained by the researchers and analyzed. In order to  
6523 monitor this research study, representatives from the Institutional Review Board (IRB) and other federal  
6524 agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection)  
6525 may inspect the research records which may reveal your identity. A description of this clinical trial will  
6526 be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include  
6527 information that can identify you. At most, the web site will include a summary of the results. You can  
6528 search this web site at any time. Federal law provides additional protections of your medical records and  
6529 related health information. These are described in the HIPAA section of this document.

6530

6531 **Can I be removed from the research without my OK?**

6532 The principal investigator of the study can remove you from the research study without your approval.  
6533 Possible reasons for removal include need for hospitalization for physical or psychological reasons.

6534 **What else do I need to know?**

6535 This research is being funded by the National Institutes of Health, specifically the National Heart, Lung  
6536 and Blood Institute (NHLBI).

6537 If you need medical care because of taking part in this research study, contact the investigator and/or  
6538 speak with your doctor and medical care will be made available. Generally, this care will be billed to you,  
6539 your insurance or other third party. The University at Buffalo has no program to pay for medical care for  
6540 research-related injury.

6541

6542 **HIPAA: Authorization for the Use and Disclosure of Identifiable Health  
6543 Information for Research Purposes**

6544 This section describes information about you and about your health that will be obtained by the  
6545 researchers when you participate in the research study. Health information is considered "protected  
6546 health information" when it may directly identify you as an individual. By signing this form you are  
6547 agreeing to permit the researchers and/or other parties (described in detail below) to have access to  
6548 this information. If there are any parts of this form that you do not understand, please be sure to ask us  
6549 for further clarification.

6550 **A. What protected health information will be collected about you as part of this research  
6551 study?**

6552  Information from your full medical records (height, weight, dietary restrictions and  
6553 physical activity restrictions).

6554  New Health Information created from study related tests, procedures, visits, and/or  
6555 questionnaires as described in this consent form.

6556 **B. Who is authorized to provide or collect this information?**

6557  Principal Investigator or designee

6558 **C. With whom may your protected health information be shared?**

6559 Your health information may be shared with others outside of the research group for purposes  
6560 directly related to the conduct of this research study or as required by law, including but not  
6561 limited to:

6562  Clinical staff not involved in this research study who may become involved in your  
6563 care if it is potentially relevant to your treatment.

6564  The sponsor of this research study (**National Heart, Lung and Blood Institutes**  
6565 (**NHLBI**) cooperative group, etc., or its agents.

6566  The organization(s) responsible for administering this research (e.g., Research  
6567 Foundation of SUNY, University at Buffalo, Washington University, Nationwide  
6568 Children's Hospital, University of Rochester).

6569  Other medical investigators/centers/institutions participating in this research study.

6570 Your information may also be shared with individuals or entities responsible for general  
6571 administration, oversight and compliance of research activities. Examples of this include the  
6572 institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring  
6573 Boards, an Institutional Review Board, The Research Foundation of the State University of New  
6574 York, University at Buffalo Foundation Services, and accrediting bodies, or with certain  
6575 government oversight agencies that have authority over the research including the Department  
6576 of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National  
6577 Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your  
6578 information may also be shared with other entities as permitted or required by law. All  
6579 reasonable efforts will be used to protect the confidentiality of your individually identifiable  
6580 health information that may be shared with others as described above.

6581 All reasonable efforts will be used to protect the confidentiality of your protected health  
6582 information. There is the potential for individually identifiable information and the associated  
6583 health information obtained with this authorization to be re-disclosed by the recipient(s). After  
6584 such a disclosure, the information may no longer be protected by the terms of this authorization  
6585 against further re-disclosure.

6586 **D. How long will this information be kept by the Principal Investigator?**

6587  This authorization has no expiration date. The researchers may continue to rely on this  
6588 authorization to obtain and use protected health information about you unless you  
6589 revoke this authorization in writing.

6590  Your protected health information will go into a database that will be maintained  
6591 indefinitely. Any future study using this information that falls outside the scope of this  
6592 current study will be required to follow guidelines designed to govern access to that  
6593 information and to protect the privacy of that information.

6594 **E. What are your rights after signing this authorization?**

6595 You have the right to revoke this authorization at any time. If you withdraw your authorization,  
6596 no additional efforts to collect individually identifiable health information about you will be  
6597 made. You should know, however, that protected health information acquired using this  
6598 authorization prior to its withdrawal may continue to be used to the extent that the  
6599 investigator(s) have already relied on your permission to conduct the research. If you chose to  
6600 withdraw this authorization, you must do so in writing to the following individual(s):



6601  
6602  
6603  
6604  
6605  
6606  
6607  
6608  
6609  
6610  
6611  
6612  
6613  
6614  
6615  
6616  
6617  
6618  
6619  
6620  
6621

**Leonard H. Epstein, Ph.D.**  
**University at Buffalo Department of Pediatrics**  
**Division of Behavioral Medicine**  
**3435 Main Street**  
**G56 Farber Hall**  
**Buffalo, NY 14214**  
**Phone: 716-829-3400**

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

**F. What will happen if you decide not to sign this authorization?**

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to continue to participate in the research study.

6622

**Signature Block for Capable Adult**

Your signature documents your permission to continue to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject		Date
Printed name of subject		
Signature of person obtaining consent		Date
Printed name of person obtaining consent		

6623

6624

6625 *(This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol*  
6626 *addenda, 10.25.19).*

6627

6628  
6629  
6630  
6631  
  
6632  
6633  
6634  
  
6635  
6636  
6637  
6638  
6639  
6640  
6641  
6642  
  
6643  
6644  
6645  
6646  
6647  
  
6648  
6649  
6650  
6651  
6652  
  
6653  
6654  
  
6655

**University at Buffalo Institutional Review Board (UBIRB)**  
Office of Research Compliance | Clinical and Translational Research Center Room 5018  
875 Ellicott St. | Buffalo, NY 14203  
UB Federalwide Assurance ID#: FWA00008824

**Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT  
IMPLEMENTED IN PRIMARY CARE**

**Addendum: Parental Permission for Targeted Child to Participate in a Research Study**

**Version Date: 9.6.19**

**Investigators: Leonard H. Epstein, PhD, Denise Wilfley, PhD, Stephen Cook, MD, MPH, Ihuoma Eneli, MD, MS, FAAP**

**Change of Assessment Compensation:**

In the initial consent form that you signed, we indicated that ‘if your child agrees to take part in this research study, we will pay your family up to \$175 for your time and effort. The amount you are paid depends upon your attendance to visits in the study’. However, the compensation for the 24-month assessment has increased from \$50 to \$100. This brings total potential compensation to \$225. The amount you are paid depends upon your attendance to visits in the study.

In addition, each participating site will give participants tickets when they attend an assessment. Each participant will have a chance of accumulating up to 4 tickets depending on the number of assessments they attend (i.e., 6, 12, 18, & 24 month appointments). The number of winning tickets will be proportional to the number of families randomized at each site. Each winning ticket is worth \$50.00. Please let the PLAN staff member know if you have any questions.

To ensure that each family is aware of this change to the consent form, please sign where indicated below:

6656

6657

**Signature Block for Capable Adult**

6658

Your signature documents your permission to continue to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.	
Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

6659

6660 *(DSMB approved protocol addenda, 10.25.19).*

6661

6662

**University at Buffalo Institutional Review Board (UBIRB)**  
Office of Research Compliance | Clinical and Translational Research Center Room 5018  
875 Ellicott St. | Buffalo, NY 14203  
UB Federalwide Assurance ID#: FWA00008824

6663  
6664 **Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS**  
6665 **TREATMENT IMPLEMENTED IN PRIMARY CARE**  
6666

6667 **Addendum: Assessment Protocol in Response to Coronavirus Pandemic (COVID-19)**  
6668

6669 **Date: 4.14.2020**  
6670

6671 **Investigators: Leonard H. Epstein, PhD, Denise Wilfley, PhD, Stephen Cook, MD, MPH,**  
6672 **Ihuoma Eneli, MD, MS, FAAP**  
6673

6674 **Change of Assessment Protocol:**

6675 Due to the recent Coronavirus Disease (COVID-19) pandemic, we have modified our assessment  
6676 protocols to adhere to public health guidelines as recommended by the Center for Disease  
6677 Control and Prevention. In the initial consent form that you signed, we indicated “Each major  
6678 assessment takes approximately 30-90 minutes to complete at your pediatric office, or a home  
6679 visit can be arranged.” Assessments will now take place at your home using scales, measuring  
6680 tapes, and household objects to gather height and weight measurements that you will complete.  
6681 Any materials that you may need as described in our protocol, but you do not currently possess,  
6682 will be sent to your home by a PLAN With Families vendor (ie. Amazon) via postal mail at no  
6683 cost to you. A subset of 10 families from each site, will be asked to complete a second height  
6684 measurement one to two weeks after completing a remote assessment for quality control for an  
6685 additional payment of \$10.00.

6686  
6687 During the assessment, a PLAN staff member will call or video conference with you to guide  
6688 you through the measurement protocol to assist you through the process, and record your height  
6689 and weight data. Additionally, you will be sent online questionnaires to complete using your  
6690 personal computer, tablet, or smartphone, including a new questionnaire to assess your family’s  
6691 well-being during the current pandemic.

6692  
6693 Upon the lifting of social distancing recommendations, we will meet with your family at your  
6694 pediatric practice to gather your height and weight measurements based on our usual  
6695 standardized lab protocol. You will be compensated 50% of the normal assessment payment for  
6696 your self-conducted home measurement, and paid the remaining 50% at the in-person portion of  
6697 the assessment.

6698

6699

6700

6701

6702

**Signature Block for Capable Adult**

Your signature documents your permission to continue to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

\_\_\_\_\_  
Signature of subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of subject

\_\_\_\_\_  
Signature of person obtaining consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of person obtaining consent

6703 *(DSMB approved protocol addenda, 5.7.20).*

6704

6705

6706  
6707  
6708  
6709  
6710  
6711  
6712  
6713  
6714  
6715  
6716  
  
6717  
  
6718  
  
6719  
6720  
6721  
6722  
6723  
6724  
6725  
6726  
6727  
6728  
6729  
6730  
6731  
6732  
6733  
6734  
6735  
6736  
6737  
6738  
6739  
6740  
6741  
6742  
6743  
6744  
6745  
6746  
6747  
6748  
6749

C. Screening Measures

**INITIAL ELIGIBILITY SURVEY SCRIPT**

Introduce yourself and the PLAN program:

***“Hello, my name is (name), this research is being conducted by the National Institutes of Health to encourage healthy eating habits and promote healthy lifestyles changes for families. Our study is for families with a 6-12-year-old child and a parent, both of whom are overweight or obese. Additionally, overweight siblings and non-participating parents that are interested in the program will have the opportunity to participate as well.*”**

*Would you be interested in learning more about the study?*

**IF NO → Thank you for your time and consideration. END SCREEN.**

**IF YES → Do you have a few minutes right now for me to tell you more about the program and ask you a few questions to see if this program would be a good fit for your family?”**

If NO:

Schedule a follow-up call, verify phone number. Document contact in the tracking database:

***“Would there be a day/time that works better for you to talk more about the program? I can give you a call at a time that works best for you. What is your phone number? Or I could send you an email with a link to more information about the program. What is your email address?”*”**

If YES:

Describe the study:

***“Great! I want to let you know that specific personal questions will be asked during this phone screen and recorded into a private database maintained by Washington University in St. Louis, MO. This database will include your contact information and your answers to any specific eligibility criteria discussed during this phone screen.”*”**

***“Just to review, our program is called PLAN with Families. That stands for Primary care pediatrics, Learning, Activity, and Nutrition. The goal of the program is for you and your child to learn ways to become healthier and stay healthy.”*”**

***“In this study, we require that one child and one parent participate. The study will last about 2 years. To help us and you see what progress you make during your participation, you will complete some questionnaires, a short computer task, and have your height and weight taken 5 times over the 2 years. Since we think learning to be healthier is important for the whole family, you can include any other children you may have and your child’s other parent in the study, too, but you don’t have to. If one of your child’s siblings is involved in the study, he or she will only be asked to attend appointments every 6 months for height and weight measurements.”*”**

6750  
6751 *“All of the program meetings will be held here at your child’s doctor’s office. Your family will*  
6752 *have an opportunity to participate in one of two groups. The first group is a Family Based*  
6753 *Treatment (FBT) group where your family would meet regularly with a trained PLAN coach*  
6754 *to learn new information and skills related to health topics, such as calorie intake and*  
6755 *physical activity. The second group is called a Usual Care (UC) group where your family*  
6756 *would continue to receive the most up to date health information from working closely with*  
6757 *your child’s pediatrician.”*

6758  
6759 *“If your family is interested and you decide this study would be a good fit for you, you and*  
6760 *your child will be asked to come here to [practice name] to complete an orientation session.*  
6761 *After the orientation meeting, if you join the program, you will learn which group you and*  
6762 *your child will participate in.*

6763  
6764 *“Does this sound like a study you might be interested in for you and your family?”*

6765  
6766 If NO:  
6767 Thank them for their time, share your contact information:

6768  
6769 *“Thank you for your time. Here’s my contact information in case you change your mind or*  
6770 *have any questions.”*

6771  
6772 *“Here is a postcard from the program. On this card is our website,*  
6773 *<http://planwithfamilies.com> , where you can learn more about our program”*

6774  
6775 If MAYBE:  
6776 If the family would rather think about if the study is the right fit for them or if they seem  
6777 hesitant:

6778  
6779 *“If you would like to take some time to think about if the PLAN program is the right fit for*  
6780 *you and your family, that’s okay. I can follow-up with you in a few days. Would that be ok?”*

6781  
6782 *“Here is a postcard from the program. Please provide a contact number and a preferred time*  
6783 *to be reached. You can also check out the website <http://planwithfamilies.com> that is listed on*  
6784 *the card.”*

6785  
6786 If YES:  
6787 Begin Initial Eligibility Survey

6788  
6789 *“Great! In order to get started I need to ask you some questions first. Do you have a few*  
6790 *minutes to answer some questions?”*

6791  
6792 **INITIAL ELIGIBILITY SURVEY INTRODUCTION**

6793  
6794 *This survey is the first step in determining if the PLAN program is right for your family. This*  
6795 *survey is brief and should only take approximately 10 minutes.*



6796  
6797 ***Your participation in this survey is voluntary and you may stop the survey at any time. Any***  
6798 ***information related to you and your household will be kept confidential and will be stored in a***  
6799 ***secure database that is only accessible to the PLAN team.***  
6800 ***If you have questions at any time, please stop me and I will answer them for you. If you have***  
6801 ***questions in the future, feel free to contact me at (PLAN coach’s cell phone number). I will be***  
6802 ***happy to answer any questions or concerns that you or your family may have about our***  
6803 ***program! Do you have any questions at this time?”***

6804 **PARENT INFORMATION**

6805 ***The following questions must be answered by the parent or adult interested in enrolling in the***  
6806 ***PLAN program. If there are any questions that you do not wish to answer, please let me know***  
6807 ***and will move onto the next question.***

6808 ***Q: What is your first name? (\*Ask for spelling if necessary\*)*** \_\_\_\_\_

6809  
6810 ***Q: What is your last name? (\*Ask for spelling if necessary\*)*** \_\_\_\_\_

6811  
6812 ***Q: What is your address?***

6813 ***Street Address:*** \_\_\_\_\_

6814 ***Street Address, continued:*** \_\_\_\_\_

6815 ***City:*** \_\_\_\_\_

6816 ***State:*** \_\_\_\_\_

6817 ***Zip Code:*** \_\_\_\_\_

6818  
6819 ***Q: What is the best number at which to contact you?*** \_\_\_\_\_

6820  
6821 ***Q: What is the best email address to use to contact you?*** \_\_\_\_\_

6822  
6823 ***Q: Is your family planning to move from the area in the next two years?***

- 6824
  - *No*
  - *Yes*
  - *Refuse to answer*

6827 ***Q: What is your date of birth? (select from Calendar MM/DD/YYYY)***

6828 ***Q: What is your sex? Choose from dropdown menu:***

- 6829
  - *Male*
  - *Female*
  - *Other*
  - *Refuse*

6830  
6831  
6832  
6833  
6834 ***Q: What is your race?***

- 6835
  - *American Indian or Alaskan Native*
  - *Asian*
  - *Native Hawaiian or Other Pacific Islander*
  - *Black or African American, not of Hispanic Origin*
  - *White or Caucasian, not of Hispanic Origin*
  - *Hispanic or Latina/o*
  - *Other, please specify:*

6842 ○ *Other, please describe:* \_\_\_\_\_

6843 **Q: What is your height, in inches?** \_\_\_\_\_

6844

6845 **Q: What is your weight?** \_\_\_\_\_

6846

6847 **BMI Parent:** \_\_\_\_\_

6848

6849 **Q: When was your weight last taken? (Estimated if necessary MM/YYYY or YYYY)**

6850 \_\_\_\_\_

6851

6852 **Q: Are you able to complete, at minimum, a brisk 5-10-minute walk?**

6853 ● *Yes*

6854 ● *No*

6855 ● *Refuse to answer*

6856

6857 **Q: Have you had a concussion in the last 3 months?**

6858 ● *No*

6859 ● *Yes,*

6860 ○ **Date of concussion:** \_\_\_\_\_

6861 ○ **Please describe: (description, effects)** \_\_\_\_\_

6862

6863 **Q: How many children do you have?** \_\_\_\_\_

6864

6865 **Q: Do you have a child between the ages of 6-12 that you would like to enroll in this study?**

6866 ● *Yes*

6867 ● *No*

6868

6869 If family is ineligible:

6870 **“Thank you for your interest and answering these questions. A requirement of this program**  
6871 **is that the adult is joined by one of their children between the ages of 6-12 years old. Because**  
6872 **you do not have a child between these ages that you would like to enroll, the PLAN program is**  
6873 **not a good fit for your family. However, may we keep your information and contact you with**  
6874 **future projects for which you or your family may be a good match?”**

6875 ● *No*

6876 ● *Yes*

6877

6878 If family is eligible:

6879 **“Thank you for answering the survey questions about yourself. Next we will ask you to**  
6880 **answer some general information questions about your child.”**

6881

## 6882 CHILD INFORMATION

6883

6884 **“The following questions pertain to the child between the ages of 6-12 who you would like to**  
6885 **enroll in the PLAN program.”**

6886

6887 If family has two or more children between the ages of 6-12 years old:

6888 ***“It is great that your children are interested in participating! Unfortunately, we can only***  
6889 ***enroll once child as the participating child. We typically encourage the enrollment of the***  
6890 ***oldest sibling because s/he will serve as a role model for the younger sibling. However, we***  
6891 ***leave it up to our parents to decide which child would best fit our program.”***

6892  
6893 ***“If there are any questions that you do not wish to answer, please let me know.”***

6894  
6895 ***Q: What is the first name of the child you wish to enroll in the study? (\*Ask for spelling if***  
6896 ***necessary\*) \_\_\_\_\_***

6897  
6898 ***Q: What is the last name of the child you wish to enroll in the study? (\*Ask for spelling if***  
6899 ***necessary\*) \_\_\_\_\_***

6900  
6901 ***Q: Is this child:***

- 6902 ● ***Biological child***
- 6903 ● ***Adopted child***
- 6904 ● ***Step child***
- 6905 ● ***Foster child***
- 6906 ● ***Other relative***
  - 6907 ○ ***If other relative, please describe: \_\_\_\_\_***

6908  
6909 ***Q: What is the name of your child’s primary care physician? \_\_\_\_\_***

6910  
6911 ***Q: What is this \_\_\_\_\_’s date of birth? (select from Calendar MM/DD/YYYY)***

6912  
6913 ***Q: Child’s age: (will automatically populate) \_\_\_\_\_***

6914  
6915 ***Q: What is \_\_\_\_\_’s sex? Choose from dropdown menu:***

- 6916 ● ***Male***
- 6917 ● ***Female***
- 6918 ● ***Other***
- 6919 ● ***Refuse***

6920  
6921 ***Q: What is your child’s race?***

- 6922 ● ***American Indian or Alaskan Native***
- 6923 ● ***Asian***
- 6924 ● ***Native Hawaiian or Other Pacific Islander***
- 6925 ● ***Black or African American, not of Hispanic Origin***
- 6926 ● ***White or Caucasian, not of Hispanic Origin***
- 6927 ● ***Hispanic or Latina/o***
- 6928 ● ***Other, please specify:***
  - 6929 ○ ***Other, please describe: \_\_\_\_\_***

6930  
6931 ***Q: How much does this child weigh? \_\_\_\_\_***

6932

6933 **Q: When was his/her weight last measured? (Estimated if necessary MM/YYYY or YYYY)**  
6934 \_\_\_\_\_

6935  
6936 **Q: What is \_\_\_\_\_'s height in inches?** \_\_\_\_\_

6937  
6938 **Participating child's BMI:** \_\_\_\_\_

6939  
6940 **Q: Has this child had a concussion in the last 3 months?**

- 6941 ● **Yes**
- 6942 ○ **If yes, date of concussion: (M-D-Y)** \_\_\_\_\_
- 6943 ○ **Please explain (description, effects):** \_\_\_\_\_
- 6944 ● **No**
- 6945 ● **Refused**

6946 **Q: Is \_\_\_\_\_ able to complete, at minimum, a brisk 5-10-minute walk?**

- 6947 ● **Yes**
- 6948 ● **No**
- 6949 ● **Refused**

6950  
6951 If family is ineligible because there are no children between the ages of 6-12 in the household:  
6952 **Thank you for your interest and your willingness to answer these questions. A requirement of**  
6953 **this program is that the adult is joined by one of their children between the ages of 6-12 years'**  
6954 **old who meets certain criteria. Because you do not have a child between these ages that meets**  
6955 **our criteria, the PLAN program is not a good fit for your family. However, may we keep your**  
6956 **information and contact you with future projects for which you or your family may be a good**  
6957 **match?**

- 6958 ● **No**
- 6959 ● **Yes**

6960  
6961 If child has had a concussion in the last three months:

6962 **"One of our requirements is that the participating child has not had a concussion in the last**  
6963 **three months. This is because your child's performance on one of our program tasks may be**  
6964 **affected by concussion symptoms. Therefore, I would like to wait until \_\_\_\_ more months**  
6965 **have passed before continuing the screening process. Would that be okay with you?"**

6966 If YES: Coach will schedule a call back date/time.

6967 If NO: Thank them for their time.

6968  
6969 If family is eligible: The coach will proceed to asking questions regarding additional siblings.

6970  
6971 **ADDITIONAL SIBLING INFORMATION**

6972 **"We want the entire family to benefit from the program. Therefore, we offer an opportunity**  
6973 **for your child's siblings to participate, as well. The sibling(s) would have their height and**  
6974 **weight taken with you and your child at the 5 time points, as well as have access to the**  
6975 **information on healthy lifestyle that we provide."**

6976  
6977 **Do you have another child, who also meets the criteria for overweight/obesity, in your family**  
6978 **between the ages of 2-18 that you would like to enroll in this program as well?**

6979  
6980  
6981  
6982  
6983  
6984  
6985  
6986  
6987  
6988  
6989  
6990  
6991  
6992  
6993  
6994  
6995  
6996  
6997  
6998  
6999  
7000  
7001  
7002  
7003  
7004  
7005  
7006  
7007  
7008  
7009  
7010  
7011  
7012  
7013  
7014  
7015  
7016  
7017  
7018  
7019  
7020  
7021  
7022  
7023  
7024

**If YES:** “How many additional children would you like to enroll? You may enroll up to four additional children in the program.”

**If YES:** Move on INCLUDING all parts about participating sibling and collect the following information.

**If NO:** Move onto the “Wrapping Up” section below.

*The coach will ask the following questions for all non-participating siblings.*

**Q:** What is the first name of the second/third/fourth child you would like to enroll in the study? (\*Ask for spelling if necessary\*) \_\_\_\_\_

**Q:** What is the last name of the second/third/fourth child you wish to enroll in the study? (\*Ask for spelling if necessary\*) \_\_\_\_\_

**Q:** Is \_\_\_\_\_ your:

- Biological child
- Adopted child
- Step child
- Foster child
- Other relative
  - If other relative, please describe: \_\_\_\_\_

**Q:** What is the name of \_\_\_\_\_’s primary care physician? \_\_\_\_\_

**Q:** What is this \_\_\_\_\_’s date of birth? (select from Calendar MM/DD/YYYY)

**Q:** Age: (will automatically populate) \_\_\_\_\_

**Q:** What is this child’s sex? Choose from dropdown menu:

- Male
- Female
- Other
- Refuse

**Q:** How much does \_\_\_\_\_ weigh? \_\_\_\_\_

**Q:** When was his/her weight last measured? (Estimated if necessary MM/YYYY or YYYY)

\_\_\_\_\_

**Q:** What is \_\_\_\_\_’s height in inches? \_\_\_\_\_

**Q:** Non Participating Child’s BMI: (Automatically calculated) \_\_\_\_\_

**Q:** Has \_\_\_\_\_ had a concussion in the last 3 months?

- 7025 ● Yes
- 7026 ○ *If yes, date of concussion: (M-D-Y) \_\_\_\_\_*
- 7027 ○ *Please explain (description, effects): \_\_\_\_\_*

- 7028 ● No
- 7029 ● Refused

7030 **Q: Is \_\_\_\_\_ able to complete, at minimum, a brisk 5-10-minute walk?**

- 7031 ● Yes
- 7032 ● No
- 7033 ● Refused

7034

### 7035 READING LEVEL INFORMATION

7036 *The coach will ask this question about the participating child and any non-participating*

7037 *siblings:*

7038 **Q: Can \_\_\_\_\_ read and comprehend at a first grade level?**

- 7039 ● Yes
- 7040 ● No

7041

### WRAPPING UP

7042

7043 The coach will then wrap up the Initial Eligibility Survey:

7044 *“Thank you for answering the questions on the Initial Eligibility Survey. Next we will ask you*

7045 *to answer additional questions about you and your child’s medical and psychiatric histories on*

7046 *the Eligibility Survey. This survey usually takes between 15-20 minutes to complete. Do you*

7047 *have time for us to complete this survey right now?”*

7048

7049 If NO:

7050 Schedule a follow-up call, verify phone number. Document contact in the tracking database:

7051 *“Would there be a day/time that works better for you to talk more about the program?*

7052 *I can give you a call at a time that works best for you, or we could schedule another*

7053 *time to meet here at the office.”*

7054 If YES: Schedule a call (verify phone number) or in person meeting at the practice.

7055 Document contact in the database.

7056 If NO: Thank them for their time.

7057

7058 If YES:

7059 Begin Eligibility Phone Screen.

7060

7061

### ELIGIBILITY PHONE SCREEN SCRIPT

7062

7063 *“Just to review, our program is called Primary care pediatrics, Learning, Activity, and*

7064 *Nutrition, or PLAN for short. The goal of our program is for you and your child to learn ways*

7065 *to become healthier and stay healthy. In this program, we require that one child and one*

7066 *parent participate. The study will last about 2 years. During your participation in the program,*

7067 *we will look at your progress by asking you to complete some questionnaires, a short computer*

7068 *task, and have your height and weight taken 5 times over the 2 years.*

7069 *All of the meetings will be held here at your child’s doctor’s office. If interested, you and your*  
7070 *family, including the participating child and parent, non-participating parent, and*  
7071 *participating sibling/s will be asked to come to your child’s physician’s office to meet with the*  
7072 *PLAN coach to complete an orientation, height and weight measurements, and an assessment,*  
7073

7074 *Your family will have an opportunity to participate in one of two groups: A Family Based*  
7075 *Treatment group (FBT) where your family meets regularly with a trained health coach at the*  
7076 *practice, or the usual care group where your child will continue to receive standard care from*  
7077 *their doctor.*  
7078

7079 *Families are randomly selected into each group. Those in the group receiving Family Based*  
7080 *Treatment, or FBT, will additionally complete at least 26 sessions with the health coach*  
7081 *during the 24 months of the study. The amount of sessions completed within this range will be*  
7082 *based on progress through the program and will vary for each family. Participating siblings,*  
7083 *as well as the non-participating parent, will be asked to attend appointments every 6 months*  
7084 *for height and weight measurements.*  
7085

7086 *“Does this sound like a program you might be interested in for your family?”*  
7087

7088 If NO: Thank them for their time  
7089 If YES: Continue to *Eligibility Phone Screen*.

### ELIGIBILITY PHONE SCREEN

7091  
7092  
7093 *“Next, there are a few more questions to answer in order to determine your full eligibility for*  
7094 *this study. Some of these questions are a little repetitive from the questions that I asked you*  
7095 *during the Initial Eligibility Survey because I want to make sure all of the information that I*  
7096 *gather about your family is correct. Do you have any questions?”*  
7097

7098 *Q: We ask that one overweight parent attends and participates with the child in the program.*  
7099 *What is the first name of the parent interested in participating? \_\_\_\_\_*  
7100

7101 *Q: What is the participating parent’s last name? \_\_\_\_\_*  
7102

7103 *Q: Is [parent’s first name] willing to attend all treatment sessions and assessments with the*  
7104 *child over the next two years?*

- 7105 ● Yes
- 7106 ● No

7107  
7108 *Q: Parent BMI is \_\_\_\_\_ (answer is automatically generated)*  
7109

7110 *Q: Is the parent able to continue with the screen based on BMI?*

- 7111 ● Yes
  - 7112 ○ If yes, continue with screening.

- 7113 • *No*
- 7114 ○ *If no, follow the procedure listed below.*

7115  
7116 If the preferred participating parent is not overweight based on the reported height and weight  
7117 from the Initial Eligibility Survey:

7118 ***We require that the participating parent meets specific weight criteria. Unfortunately, your***  
7119 ***answers indicate that you do not meet these criteria. Is there another parent who meets the***  
7120 ***overweight criteria that would be interested in participating?***

7121  
7122 If NO: Thank them for their time

7123 If YES: Continue on with Eligibility Phone Screen by gathering information about the  
7124 parent who is eligible.

7125  
7126 ***Q: What is the name of your/ \_\_\_\_\_'s current physician? \_\_\_\_\_***

7127  
7128 ***Q: What is the physician's practice name? \_\_\_\_\_***

7129  
7130 ***Q: What is the practice address?***  
7131 ***Practice address: \_\_\_\_\_***  
7132 ***Practice address continued, if necessary: \_\_\_\_\_***  
7133 ***City, State, Zip: \_\_\_\_\_***

7134  
7135 ***Q: Practice phone number: \_\_\_\_\_***

7136  
7137 ***Q: We want the entire family to benefit from the program. Therefore, we offer an opportunity***  
7138 ***for your child's siblings to participate as well. The sibling would have his/her height and***  
7139 ***weight taken with you and your child at the 5 time points, as well as have access to the***  
7140 ***information on healthy lifestyles that we provide.***

7141 ***Do you have another child (a sibling of the child participating) that would be interested in***  
7142 ***participating?***

- 7143 • *Yes*
- 7144 • *No*

7145  
7146 ***Q: What are the ages of the children who would like to participate?***

- 7147 • *2*
- 7148 • *3*
- 7149 • *4*
- 7150 • *5*
- 7151 • *6*
- 7152 • *7*
- 7153 • *8*
- 7154 • *9*
- 7155 • *10*
- 7156 • *11*
- 7157 • *12*
- 7158 • *13*



- 7159 ● 14
- 7160 ● 15
- 7161 ● 16
- 7162 ● 17
- 7163 ● 18
- 7164 ● Over 18

7165  
7166 ***If age is < 2 or > 18:***

7167 ***“Unfortunately your child (participating sibling) does not meet the age criteria to participate***  
7168 ***in this study; however, this does not affect you and your other child’s ability to participate.”***

- 7169 ● *Move on with script EXCLUDING all parts about participating sibling.*
- 7170 ● *This is not an exclusionary criterion for the primary participating child and parent.*

7171  
7172 ***If age is 2-18:***

7173 ***“Would he/she be interested in participating in this study?”***

- 7174 ● *If yes, move on to INCLUDING all parts about participating sibling.*
  - 7175 ○ *If family has two children ages 6-12 years old, we will be encouraging that the*
  - 7176 *older sibling be the primary participant, as it is more likely the older sibling will*
  - 7177 *serve as a role-model for the younger sibling.*
  - 7178 ○ *In families where more than one eligible sibling is available, we will enroll the*
  - 7179 *sibling whose age is closest to that of the study child.*
- 7180 ● *If no, move on EXCLUDING all parts about participating sibling.*

7181  
7182 ***“Next, there are a few more questions related to your family’s medical and psychiatric***  
7183 ***histories. I will ask you specific personal questions. Your participation in this survey is***  
7184 ***voluntary and you may stop the survey at any time. Any information related to you and your***  
7185 ***household will be kept confidential and will be stored in a secure database that is only***  
7186 ***accessible to the PLAN team. Do you have any questions?”***

7187  
7188 ***“I will start by asking you questions about the child that would like to participate in the***  
7189 ***program.”***

7190  
7191 ***Q: What is your child’s first name?*** \_\_\_\_\_

7192  
7193 ***Q: Does \_\_\_\_\_ have any medical conditions or is s/he undergoing any medical***  
7194 ***treatment?”***

- 7195 ● *Yes*
  - 7196 ○ *If yes, can you describe the treatment?* \_\_\_\_\_
- 7197 ● *No*

7198  
7199 ***Q: Does \_\_\_\_\_ take any medications?***

- 7200 ● *Yes*
- 7201 ● *No*

7202  
7203 ***Q: How many medications?***

- 7204 ● *1*

- 7205 ● 2
- 7206 ● 3
- 7207 ● 4
- 7208 ● 5

7209

7210 **Q: Name of first medication:** \_\_\_\_\_

7211

7212 **Q: Dose:** \_\_\_\_\_

7213

7214 **Q: How often does your child take [medication]?**

- 7215 ● *Once per day*
- 7216 ● *Twice per day*
- 7217 ● *Three times per day*
- 7218 ● *Four times per day*
- 7219 ● *As needed*
- 7220 ● *Every other day*
- 7221 ● *Weekly*
- 7222 ● *Bi-weekly*
- 7223 ● *Monthly*
- 7224 ● *Only during the school week*

7225

7226 **Q: Years taking [medication]?**

- 7227 ● 0
- 7228 ● 1
- 7229 ● 2
- 7230 ● 3
- 7231 ● 4
- 7232 ● 5
- 7233 ● 6
- 7234 ● 7
- 7235 ● 8
- 7236 ● 9
- 7237 ● 10
- 7238 ● 11
- 7239 ● 12
- 7240 ● 13
- 7241 ● 14
- 7242 ● 15
- 7243 ● 16
- 7244 ● 17
- 7245 ● 18

7246

7247 **Q: Number of months [medication]?**

- 7248 ● 0
- 7249 ● 1
- 7250 ● 2

- 7251 ● 3
- 7252 ● 4
- 7253 ● 5
- 7254 ● 6
- 7255 ● 7
- 7256 ● 8
- 7257 ● 9
- 7258 ● 10
- 7259 ● 11

7260

**Q: Name of second medication:** \_\_\_\_\_

7262

**Q: Dose:** \_\_\_\_\_

7264

**Q: How often does your child take [medication]?**

- 7266 ● *Once per day*
- 7267 ● *Twice per day*
- 7268 ● *Three times per day*
- 7269 ● *Four times per day*
- 7270 ● *As needed*
- 7271 ● *Every other day*
- 7272 ● *Weekly*
- 7273 ● *Bi-weekly*
- 7274 ● *Monthly*
- 7275 ● *Only during the school week*

7276

**Q: Years taking [medication]?**

- 7278 ● 0
- 7279 ● 1
- 7280 ● 2
- 7281 ● 3
- 7282 ● 4
- 7283 ● 5
- 7284 ● 6
- 7285 ● 7
- 7286 ● 8
- 7287 ● 9
- 7288 ● 10
- 7289 ● 11
- 7290 ● 12
- 7291 ● 13
- 7292 ● 14
- 7293 ● 15
- 7294 ● 16
- 7295 ● 17
- 7296 ● 18

7297

7298 **Q: Number of months [medication]?**

- 7299 ● 0
- 7300 ● 1
- 7301 ● 2
- 7302 ● 3
- 7303 ● 4
- 7304 ● 5
- 7305 ● 6
- 7306 ● 7
- 7307 ● 8
- 7308 ● 9
- 7309 ● 10
- 7310 ● 11

7311

7312 **Q: Name of third medication:** \_\_\_\_\_

7313

7314 **Q: Dose:** \_\_\_\_\_

7315

7316 **Q: How often does your child take [medication]?**

- 7317 ● *Once per day*
- 7318 ● *Twice per day*
- 7319 ● *Three times per day*
- 7320 ● *Four times per day*
- 7321 ● *As needed*
- 7322 ● *Every other day*
- 7323 ● *Weekly*
- 7324 ● *Bi-weekly*
- 7325 ● *Monthly*
- 7326 ● *Only during the school week*

7327

7328 **Q: Years taking [medication]?**

- 7329 ● 0
- 7330 ● 1
- 7331 ● 2
- 7332 ● 3
- 7333 ● 4
- 7334 ● 5
- 7335 ● 6
- 7336 ● 7
- 7337 ● 8
- 7338 ● 9
- 7339 ● 10
- 7340 ● 11
- 7341 ● 12
- 7342 ● 13

- 7343 ● 14
- 7344 ● 15
- 7345 ● 16
- 7346 ● 17
- 7347 ● 18

7348

7349 **Q: Number of months [medication]?**

- 7350 ● 0
- 7351 ● 1
- 7352 ● 2
- 7353 ● 3
- 7354 ● 4
- 7355 ● 5
- 7356 ● 6
- 7357 ● 7
- 7358 ● 8
- 7359 ● 9
- 7360 ● 10
- 7361 ● 11

7362

7363 **Q: Name of fourth medication:** \_\_\_\_\_

7364

7365 **Q: Dose:** \_\_\_\_\_

7366

7367 **Q: How often does your child take [medication]?**

- 7368 ● *Once per day*
- 7369 ● *Twice per day*
- 7370 ● *Three times per day*
- 7371 ● *Four times per day*
- 7372 ● *As needed*
- 7373 ● *Every other day*
- 7374 ● *Weekly*
- 7375 ● *Bi-weekly*
- 7376 ● *Monthly*
- 7377 ● *Only during the school week*

7378

7379 **Q: Years taking [medication]?**

- 7380 ● 0
- 7381 ● 1
- 7382 ● 2
- 7383 ● 3
- 7384 ● 4
- 7385 ● 5
- 7386 ● 6
- 7387 ● 7
- 7388 ● 8

- 7389 ● 9
- 7390 ● 10
- 7391 ● 11
- 7392 ● 12
- 7393 ● 13
- 7394 ● 14
- 7395 ● 15
- 7396 ● 16
- 7397 ● 17
- 7398 ● 18

7399

**Q: Number of months [medication]?**

- 7401 ● 0
- 7402 ● 1
- 7403 ● 2
- 7404 ● 3
- 7405 ● 4
- 7406 ● 5
- 7407 ● 6
- 7408 ● 7
- 7409 ● 8
- 7410 ● 9
- 7411 ● 10
- 7412 ● 11

7413

**Q: Name of fifth medication: \_\_\_\_\_**

7415

**Q: Dose: \_\_\_\_\_**

7417

**Q: How often does your child take [medication]?**

- 7419 ● *Once per day*
- 7420 ● *Twice per day*
- 7421 ● *Three times per day*
- 7422 ● *Four times per day*
- 7423 ● *As needed*
- 7424 ● *Every other day*
- 7425 ● *Weekly*
- 7426 ● *Bi-weekly*
- 7427 ● *Monthly*
- 7428 ● *Only during the school week*

7429

**Q: Years taking [medication]?**

- 7431 ● 0
- 7432 ● 1
- 7433 ● 2
- 7434 ● 3

- 7435 ● 4
- 7436 ● 5
- 7437 ● 6
- 7438 ● 7
- 7439 ● 8
- 7440 ● 9
- 7441 ● 10
- 7442 ● 11
- 7443 ● 12
- 7444 ● 13
- 7445 ● 14
- 7446 ● 15
- 7447 ● 16
- 7448 ● 17
- 7449 ● 18

7450

**Q: Number of months [medication]?**

- 7452 ● 0
- 7453 ● 1
- 7454 ● 2
- 7455 ● 3
- 7456 ● 4
- 7457 ● 5
- 7458 ● 6
- 7459 ● 7
- 7460 ● 8
- 7461 ● 9
- 7462 ● 10
- 7463 ● 11

7464

7465

**Q: Does your child have any condition that would make him/her unable to exercise or limit the amount of exercise?"**

- 7468 ● Yes
- 7469
- 7470 ● No

7471

**Q: Has \_\_\_\_\_ ever had weight-related surgery such as gastric bypass?**

- 7473 ● Yes
- 7474 ● No

7475

**Q: Is your child currently participating in a weight loss or weight management program?**

- 7477 ● Yes
- 7478 ● No

7479

**Q: Does \_\_\_\_\_ have any food allergies or dietary restrictions?**

7480

- 7481 ● Yes
- 7482 ○ If yes, please list restrictions and/or allergies: \_\_\_\_\_
- 7483 ● No

7484  
7485 **Q: Has this child undergone any psychological treatment and/or counseling?"**

- 7486 ● Yes
- 7487 ○ If yes, please describe condition: \_\_\_\_\_
- 7488 ● No

7489  
7490 **Q: Has \_\_\_\_\_ ever been diagnosed with a psychiatric condition like depression or**  
7491 **anxiety?"**

- 7492 ● Yes
- 7493 ● No

7494  
7495 **Q: Has your child ever been diagnosed with a developmental delay, intellectual disability, or**  
7496 **Autism Spectrum Disorder?"**

- 7497 ● Yes
- 7498 ● No

7499  
7500 **Q: Is \_\_\_\_\_ able to speak and comprehend English at the first grade level?"**

- 7501 ● Yes
- 7502 ● No

7503

### PARENT QUESTIONS

7505

7506 **"Now I am going to ask you some questions about yourself."**

7507

7508 **Q: Are you \_\_\_\_\_'s biological, adoptive parent, or legal guardian?"**

- 7509 ● Yes
- 7510 ● No

7511

7512 **Q: Do you and your child live together full time?"**

- 7513 ● Yes
- 7514 ● No

7515 ○ If no, how often does \_\_\_\_\_ live with you? (closest percentage)

- 7516 ■ 0
- 7517 ■ 10
- 7518 ■ 20
- 7519 ■ 30
- 7520 ■ 40
- 7521 ■ 50
- 7522 ■ 60



- 7523  70
- 7524  80
- 7525  90
- 7526  100

7527  
7528 **Q: Please obtain detailed notes on family situation:** \_\_\_\_\_

7529  
7530 **Q: Who does \_\_\_\_\_ live with? List all in home, and their relationship to the**  
7531 **participating child:** \_\_\_\_\_

7532  
7533 **Q: Do you have another child or children [sibling(s) of the child participating] that would be**  
7534 **interested in participating?**

- 7535  Yes
- 7536  No

7537  
7538 **Q: If yes, how many children who are between the ages of 2-18 would like to participate?**

- 7539  1
- 7540  2
- 7541  3
- 7542  4

7543  
7544 **PARTICIPATING PARENT HEALTH**

7545  
7546 **Q: Do you have any medical conditions or are you undergoing any medical treatment?**

- 7547  Yes
- 7548  Notes: \_\_\_\_\_
- 7549  No

7550  
7551 **Q: Do you take any medications?**

- 7552  Yes
- 7553  **Q: How many medications do you currently take? (Select answer from**  
7554 **dropdown)**
  - 7555  1
  - 7556  2
  - 7557  3
  - 7558  4
  - 7559  5
  - 7560  6
  - 7561  7
- 7562  No

7563

7564 **Q: Name of first medication:** \_\_\_\_\_

7565

7566 **Q: What is your dose of [medication]?** \_\_\_\_\_

7567

7568 **Q: How often do you take [medication]?**

- 7569 ● *Once per day*
- 7570 ● *Twice per day*
- 7571 ● *Three times per day*
- 7572 ● *Four times per day*
- 7573 ● *As needed*
- 7574 ● *Every other day*
- 7575 ● *Weekly*
- 7576 ● *Bi-weekly*
- 7577 ● *Monthly*
- 7578 ● *Only during the school week*

7579

7580 **Q: How many years have you been taking [medication]?**

7581	● 0	7598	● 17	7615	● 34
7582	● 1	7599	● 18	7616	● 35
7583	● 2	7600	● 19	7617	● 36
7584	● 3	7601	● 20	7618	● 37
7585	● 4	7602	● 21	7619	● 38
7586	● 5	7603	● 22	7620	● 39
7587	● 6	7604	● 23	7621	● 40
7588	● 7	7605	● 24	7622	● 41
7589	● 8	7606	● 25	7623	● 42
7590	● 9	7607	● 26	7624	● 43
7591	● 10	7608	● 27	7625	● 44
7592	● 11	7609	● 28	7626	● 45
7593	● 12	7610	● 29	7627	● 46
7594	● 13	7611	● 30	7628	● 47
7595	● 14	7612	● 31	7629	● 48
7596	● 15	7613	● 32	7630	● 49
7597	● 16	7614	● 33	7631	● 50

7632

7633 **Q: How many months have you been taking [medication]?**

- 7634 ● 0
- 7635 ● 1
- 7636 ● 2
- 7637 ● 3
- 7638 ● 4
- 7639 ● 5
- 7640 ● 6
- 7641 ● 7
- 7642 ● 8

- 7643 ● 9
- 7644 ● 10
- 7645 ● 11

7646  
 7647 **Q: Name of second medication:** \_\_\_\_\_

7648  
 7649 **Q: What is your dose of [medication]?** \_\_\_\_\_

7650  
 7651 **Q: How often do you take [medication]?**

- 7652 ● Once per day
- 7653 ● Twice per day
- 7654 ● Three times per day
- 7655 ● Four times per day
- 7656 ● As needed
- 7657 ● Every other day
- 7658 ● Weekly
- 7659 ● Bi-weekly
- 7660 ● Monthly
- 7661 ● Only during the school week

7662  
 7663 **Q: How many years have you been taking [medication]?**

7664	● 0	7681	● 17	7698	● 34
7665	● 1	7682	● 18	7699	● 35
7666	● 2	7683	● 19	7700	● 36
7667	● 3	7684	● 20	7701	● 37
7668	● 4	7685	● 21	7702	● 38
7669	● 5	7686	● 22	7703	● 39
7670	● 6	7687	● 23	7704	● 40
7671	● 7	7688	● 24	7705	● 41
7672	● 8	7689	● 25	7706	● 42
7673	● 9	7690	● 26	7707	● 43
7674	● 10	7691	● 27	7708	● 44
7675	● 11	7692	● 28	7709	● 45
7676	● 12	7693	● 29	7710	● 46
7677	● 13	7694	● 30	7711	● 47
7678	● 14	7695	● 31	7712	● 48
7679	● 15	7696	● 32	7713	● 49
7680	● 16	7697	● 33	7714	● 50

7715  
 7716 **Q: How many months have you been taking [medication]?**

- 7717 ● 0
- 7718 ● 1
- 7719 ● 2
- 7720 ● 3
- 7721 ● 4
- 7722 ● 5

- 7723 • 6
- 7724 • 7
- 7725 • 8
- 7726 • 9
- 7727 • 10
- 7728 • 11

7729

7730 **Q: Name of third medication:** \_\_\_\_\_

7731

7732 **Q: What is your dose of [medication]?** \_\_\_\_\_

7733

7734 **Q: How often do you take [medication]?**

- 7735 • Once per day
- 7736 • Twice per day
- 7737 • Three times per day
- 7738 • Four times per day
- 7739 • As needed
- 7740 • Every other day
- 7741 • Weekly
- 7742 • Bi-weekly
- 7743 • Monthly
- 7744 • Only during the school week

7745

7746 **Q: How many years have you been taking [medication]?**

7747	• 0	7764	• 17	7781	• 34
7748	• 1	7765	• 18	7782	• 35
7749	• 2	7766	• 19	7783	• 36
7750	• 3	7767	• 20	7784	• 37
7751	• 4	7768	• 21	7785	• 38
7752	• 5	7769	• 22	7786	• 39
7753	• 6	7770	• 23	7787	• 40
7754	• 7	7771	• 24	7788	• 41
7755	• 8	7772	• 25	7789	• 42
7756	• 9	7773	• 26	7790	• 43
7757	• 10	7774	• 27	7791	• 44
7758	• 11	7775	• 28	7792	• 45
7759	• 12	7776	• 29	7793	• 46
7760	• 13	7777	• 30	7794	• 47
7761	• 14	7778	• 31	7795	• 48
7762	• 15	7779	• 32	7796	• 49
7763	• 16	7780	• 33	7797	• 50

7798

7799 **Q: How many months have you been taking [medication]?**

- 7800 • 0
- 7801 • 1
- 7802 • 2

- 7803 ● 3
- 7804 ● 4
- 7805 ● 5
- 7806 ● 6
- 7807 ● 7
- 7808 ● 8
- 7809 ● 9
- 7810 ● 10
- 7811 ● 11

7812  
 7813 **Q: Name of fourth medication:** \_\_\_\_\_

7814  
 7815 **Q: What is your dose of [medication]?** \_\_\_\_\_

7816  
 7817 **Q: How often do you take [medication]?**

- 7818 ● *Once per day*
- 7819 ● *Twice per day*
- 7820 ● *Three times per day*
- 7821 ● *Four times per day*
- 7822 ● *As needed*
- 7823 ● *Every other day*
- 7824 ● *Weekly*
- 7825 ● *Bi-weekly*
- 7826 ● *Monthly*
- 7827 ● *Only during the school week*

7828

7829	<b>Q:</b>	<b>How</b>	<b>many</b>	<b>years</b>	<b>have</b>	<b>you</b>	<b>been</b>	<b>taking</b>	<b>[medication]?</b>
7830	●	0		7847	●	17	7864	●	34
7831	●	1		7848	●	18	7865	●	35
7832	●	2		7849	●	19	7866	●	36
7833	●	3		7850	●	20	7867	●	37
7834	●	4		7851	●	21	7868	●	38
7835	●	5		7852	●	22	7869	●	39
7836	●	6		7853	●	23	7870	●	40
7837	●	7		7854	●	24	7871	●	41
7838	●	8		7855	●	25	7872	●	42
7839	●	9		7856	●	26	7873	●	43
7840	●	10		7857	●	27	7874	●	44
7841	●	11		7858	●	28	7875	●	45
7842	●	12		7859	●	29	7876	●	46
7843	●	13		7860	●	30	7877	●	47
7844	●	14		7861	●	31	7878	●	48
7845	●	15		7862	●	32	7879	●	49
7846	●	16		7863	●	33	7880	●	50

7881  
 7882 **Q: How many months have you been taking [medication]?**

- 7883 • 0
- 7884 • 1
- 7885 • 2
- 7886 • 3
- 7887 • 4
- 7888 • 5
- 7889 • 6
- 7890 • 7
- 7891 • 8
- 7892 • 9
- 7893 • 10
- 7894 • 11

7895  
 7896 **Q: Name of fifth medication:** \_\_\_\_\_

7897  
 7898 **Q: What is your dose of [medication]?** \_\_\_\_\_

7899  
 7900 **Q: How often do you take [medication]?**

- 7901 • *Once per day*
- 7902 • *Twice per day*
- 7903 • *Three times per day*
- 7904 • *Four times per day*
- 7905 • *As needed*
- 7906 • *Every other day*
- 7907 • *Weekly*
- 7908 • *Bi-weekly*
- 7909 • *Monthly*
- 7910 • *Only during the school week*

7911	<b>Q: How many years have you been taking [medication]?</b>					
7912	• 0	7929	• 16	7945	• 32	
7913	• 1	7930	• 17	7946	• 33	
7914	• 2	7931	• 18	7947	• 34	
7915	• 3	7932	• 19	7948	• 35	
7916	• 4	7933	• 20	7949	• 36	
7917	• 5	7934	• 21	7950	• 37	
7918	• 6	7935	• 22	7951	• 38	
7919	• 7	7936	• 23	7952	• 39	
7920	• 8	7937	• 24	7953	• 40	
7921	• 9	7938	• 25	7954	• 41	
7922	• 10	7939	• 26	7955	• 42	
7923	• 11	7940	• 27	7956	• 43	
7924	• 12	7941	• 28	7957	• 44	
7925	• 13	7942	• 29	7958	• 45	
7926	• 14	7943	• 30	7959	• 46	
7927	• 15	7944	• 31	7960	• 47	

7961 ● 48                                      7962 ● 49                                      7963 ● 50

7964

7965 **Q: How many months have you been taking [medication]?**

- 7966 ● 0
- 7967 ● 1
- 7968 ● 2
- 7969 ● 3
- 7970 ● 4
- 7971 ● 5
- 7972 ● 6
- 7973 ● 7
- 7974 ● 8
- 7975 ● 9
- 7976 ● 10
- 7977 ● 11

7978

7979 **Q: Name of sixth medication:** \_\_\_\_\_

7980

7981 **Q: What is your dose of [medication]?** \_\_\_\_\_

7982

7983 **Q: How often do you take [medication]?**

- 7984 ● Once per day
- 7985 ● Twice per day
- 7986 ● Three times per day
- 7987 ● Four times per day
- 7988 ● As needed
- 7989 ● Every other day
- 7990 ● Weekly
- 7991 ● Bi-weekly
- 7992 ● Monthly
- 7993 ● Only during the school week

7994

7995 **Q: How many years have you been taking [medication]?**

7996	● 0	8009	● 13	8022	● 26
7997	● 1	8010	● 14	8023	● 27
7998	● 2	8011	● 15	8024	● 28
7999	● 3	8012	● 16	8025	● 29
8000	● 4	8013	● 17	8026	● 30
8001	● 5	8014	● 18	8027	● 31
8002	● 6	8015	● 19	8028	● 32
8003	● 7	8016	● 20	8029	● 33
8004	● 8	8017	● 21	8030	● 34
8005	● 9	8018	● 22	8031	● 35
8006	● 10	8019	● 23	8032	● 36
8007	● 11	8020	● 24	8033	● 37
8008	● 12	8021	● 25	8034	● 38

8035	●	<b>39</b>	8039	●	<b>43</b>	8043	●	<b>47</b>
8036	●	<b>40</b>	8040	●	<b>44</b>	8044	●	<b>48</b>
8037	●	<b>41</b>	8041	●	<b>45</b>	8045	●	<b>49</b>
8038	●	<b>42</b>	8042	●	<b>46</b>	8046	●	<b>50</b>

8047

8048 **Q: How many months have you been taking [medication]?**

- 8049 ● **0**
- 8050 ● **1**
- 8051 ● **2**
- 8052 ● **3**
- 8053 ● **4**
- 8054 ● **5**
- 8055 ● **6**
- 8056 ● **7**
- 8057 ● **8**
- 8058 ● **9**
- 8059 ● **10**
- 8060 ● **11**

8061

8062 **Q: Name of seventh medication:** \_\_\_\_\_

8063

8064 **Q: What is your dose of [medication]?** \_\_\_\_\_

8065

8066 **Q: How often do you take [medication]?**

- 8067 ● **Once per day**
- 8068 ● **Twice per day**
- 8069 ● **Three times per day**
- 8070 ● **Four times per day**
- 8071 ● **As needed**
- 8072 ● **Every other day**
- 8073 ● **Weekly**
- 8074 ● **Bi-weekly**
- 8075 ● **Monthly**
- 8076 ● **Only during the school week**

8077

8078 **Q: How many years have you been taking [medication]?**

8079	●	<b>0</b>	8089	●	<b>10</b>	8099	●	<b>20</b>
8080	●	<b>1</b>	8090	●	<b>11</b>	8100	●	<b>21</b>
8081	●	<b>2</b>	8091	●	<b>12</b>	8101	●	<b>22</b>
8082	●	<b>3</b>	8092	●	<b>13</b>	8102	●	<b>23</b>
8083	●	<b>4</b>	8093	●	<b>14</b>	8103	●	<b>24</b>
8084	●	<b>5</b>	8094	●	<b>15</b>	8104	●	<b>25</b>
8085	●	<b>6</b>	8095	●	<b>16</b>	8105	●	<b>26</b>
8086	●	<b>7</b>	8096	●	<b>17</b>	8106	●	<b>27</b>
8087	●	<b>8</b>	8097	●	<b>18</b>	8107	●	<b>28</b>
8088	●	<b>9</b>	8098	●	<b>19</b>	8108	●	<b>29</b>



8109	●	30	8116	●	37	8123	●	44
8110	●	31	8117	●	38	8124	●	45
8111	●	32	8118	●	39	8125	●	46
8112	●	33	8119	●	40	8126	●	47
8113	●	34	8120	●	41	8127	●	48
8114	●	35	8121	●	42	8128	●	49
8115	●	36	8122	●	43	8129	●	50

8130

8131 **Q: How many months have you been taking [medication]?**

- 8132 ● 0
- 8133 ● 1
- 8134 ● 2
- 8135 ● 3
- 8136 ● 4
- 8137 ● 5
- 8138 ● 6
- 8139 ● 7
- 8140 ● 8
- 8141 ● 9
- 8142 ● 10
- 8143 ● 11

8144

8145 **Q: Do you have a condition that would make you unable to exercise or limit the amount of exercise?**

- 8147 ● Yes
- 8148 ● No

8149

8150 **Q: Have you ever had weight-related surgery such as gastric bypass?**

- 8151 ● Yes
- 8152 ● No

8153

8154 **Q: Are you or any other immediate family members currently participating in a weight loss or weight management program?**

- 8156 ● Yes
  - 8157 ○ Please describe: \_\_\_\_\_
- 8158 ● No

8159

8160 **Q: Would you or your family member be willing to stop their program if accepted into our program? (This is necessary to participate in the study.)**

- 8162 ● Yes
- 8163 ● No

8164

8165 **Q: Do you have any food allergies or food restrictions?**

- 8166 ● Yes
  - 8167 ○ Please list food allergies and/or restrictions: \_\_\_\_\_
- 8168 ● No

8169  
8170  
8171  
8172  
8173  
8174  
8175  
8176  
8177  
8178  
8179  
8180  
8181  
8182  
8183  
8184  
8185  
8186  
8187  
8188  
8189  
8190  
8191  
8192  
8193  
8194  
8195  
8196  
8197  
8198  
8199  
8200  
8201  
8202  
8203  
8204  
8205  
8206  
8207  
8208  
8209  
8210

***Q: Have you ever participated in any psychological treatment and/or counseling?***

- *Yes*
- *No*

***Q: Have you ever been diagnosed with a psychiatric condition such as depression or anxiety?***

- *Yes*
- *No*

***Q: Are you currently pregnant or plan to become pregnant in the next 2 years?***

- *Yes*
- *No*

***“Thank you for your willingness to answer all of these questions. We want to make sure your family has a great experience in our program. Let’s look at your eligibility status.”***

#### **PLAN EXCLUSIONARY CRITERIA**

- The participating parent is pregnant or planning on becoming pregnant during the 2-year study period.
- Participation to any degree in a weight management or weight loss program.
- Weight-related surgeries (e.g., gastric bypass) *if within the last 2 years.*
  - *Please note that the patient must be weight stable or gaining weight (cannot be losing weight) (DSMB approved protocol addenda, 11.2.18).*
- Medical condition altering the nutritional status or intestinal absorption (e.g., inflammatory bowel disease, diabetes).
- Medical condition that affects growth (e.g., genetic or metabolic disease/syndrome that is associated with obesity).
- Chronic medical condition, including: Type 1 diabetes, heart disease/failure, HIV/AIDS, muscular dystrophy, renal diseases, hypothyroidism (if untreated or treated with medication for less than 6 months).
- Severe restriction of that would inhibit family from reasonably following the Traffic Light Eating Plan.
- Significant developmental delays, intellectual disabilities, or Autism Spectrum Disorder.
- Unmanaged/active psychiatric conditions (e.g., binge eating disorder, schizophrenia) with impairing clinical symptoms (e.g., suicidality).
  - Further assessed in Pre-Orientation Surveys and follow-up clinical interviews
- Disability that prevents performance of physical activity at the level of a brisk walk.
  - Further assessed via PCP Medical Clearance Form
- Exclusionary medications:
  - Orlistat (Xenical), Phentermine, Sibutramine (Meridia), and Topiramate (Topamax) are exclusionary at all doses and durations

- 8211 ○ All other weight/growth-affecting medications should be noted (name, dose,  
8212 frequency, and duration) and brought to the attention of onsite physician

8213  
8214

8215 **Q: Does exclusionary criteria exist?**

- 8216 ● **Yes**

8217 ○ ***The following script can be used for these exclusionary issues: Unfortunately, it***  
8218 ***does not look like your family is eligible to participate in the study at this time.***  
8219 ***Because we are a research-based program, we must adhere to certain criteria***  
8220 ***and are not able to accept families where the parent or child (insert***  
8221 ***exclusionary criteria). However, I would like to continue to gather information***  
8222 ***from you so that we can keep your family in our database. This way, when we***  
8223 ***run another study that you or your child does qualify for, we can contact you to***  
8224 ***see if you are interested in participating. Would you like to proceed with the***  
8225 ***screening so that you will be in our database to contact for other studies your***  
8226 ***child may be eligible for?”***

- 8227 ■ **Yes**

8228 ● ***Continue to collect household information according to site***  
8229 ***specific rules.***

- 8230 ■ **No**

8231 ● ***Thank them for their time. END CALL.***

- 8232 ● **No**

8233

8234 **Q: Is the family eligible to participate?**

- 8235 ● **Yes**

8236 ○ Family creates website profile and coach collects household information.

- 8237 ● **No**

8238 ○ ***Thank them for their time.***

8239 ● ***Unsure (see below):*** If coach is unsure about whether or not the family is  
8240 eligible/eligible, s/he should follow-up with their project coordinator for clarification and  
8241 use the following script: ***Thank you for taking the time to answer all of these questions.***  
8242 ***At the moment, I have all of the information that I need. The next step is for me to***  
8243 ***review your responses in order to determine your eligibility status. I will follow-up with***  
8244 ***you within the next few days.***

8245

8246 ***If YES/ELIGIBLE:***

8247 ***“It appears your family is initially eligible for our study so the next step is for you and your***  
8248 ***child to complete a few online questionnaires. I will send you an e-mail link to these***  
8249 ***questionnaires after our phone call. The first three questionnaires will be for you to complete***  
8250 ***about you and your child. The final questionnaire should be completed by your child. Please***

8251 *be sure to complete these questionnaires at your earliest convenience. Also, there is the*  
8252 *possibility that you may need to complete a brief interview following these questionnaires. If*  
8253 *so, I will call you to schedule that interview, which can be done over the phone.”*

8254

8255 *Q: Is your email address [automatically generated]?*

8256 

- Yes

8257 

- No

8258 

- What is your email? \_\_\_\_\_

8259

8260 *“In the meantime, I would like to schedule you and your family for an orientation*  
8261 *appointment here at the office, which will last for approximately two hours. During the*  
8262 *orientation, you will be given a presentation on the study goals and procedures. You will have*  
8263 *an opportunity to ask questions and then decide if the study is right for you and your child. If*  
8264 *you decide you are not interested, your appointment will end. If you decide that you are*  
8265 *interested in participating after the orientation, you will complete several assessments and*  
8266 *schedule upcoming study appointments.*

8267

8268 *Both the participating parent and participating child need to attend in order to enroll in the*  
8269 *program. We will also need to collect measurements from any non-participating siblings and*  
8270 *non-participating parents. We do offer the option to have them attend the orientation session*  
8271 *as well. However, we recommend that they schedule an appointment separate from the*  
8272 *orientation session due to the length of the session. If these individuals do attend the session,*  
8273 *we recommend that they have a mode of transportation that is separate from the participating*  
8274 *child’s and participating parent’s.”*

8275

8276 *Q: Is the participant able to schedule at this time?*

8277 

- Yes

8278 

- If yes, when is the orientation appointment? \_\_\_\_\_

8279 

- No

8280

8281 *“We will call you and send you an e-mail reminder two days prior to the orientation session,*  
8282 *scheduled on (MM/DD/YYYY) at (HH:MM) at (pediatric office name). Do you have any*  
8283 *questions?”*

8284

8285 *If non-participating parent cannot come in with family:*

8286 *If the non-participating parent is not able to come in at the same time as the rest of the family,*  
8287 *they are able to come in at any time (based on health coach hours) to have their height and*  
8288 *weight taken and ask questions/get information from the health coach about the program.*

8289

8290 ***Q: Would the non-participating parent like to be contacted about the program and times when***  
8291 ***they can come in?***

8292       • *Yes*

8293       • *No*

8294

8295 ***Q: What is the best phone number to reach them?*** \_\_\_\_\_

8296

8297 ***Q: What is the best email address to reach them?*** \_\_\_\_\_

8298

8299 ***“Thank you for your time, and we look forward to seeing you soon!” END CALL.***

8300

8301 **Table 1. Exclusionary Medications**

Criteria	Medication	
Exclusionary at all doses and durations	Orlistat (Xenical) Phentermine Sibutramine (Meridia) Topiramate (Topamax)	
Exclusionary if at current dose for <6 months	Adderall (ADHD) Amourthyroid (hypothyroid) Carbamazepine (Tegretol) Celexa Clonidine (ADHD) Clozapine (Clozaril) Cyproheptadine (Periactin) Diethylproprion (Tenuate) Elavil Gabapentin Haloperidol Insulin Lithium Metformin Mirtazapine Neurotin Nortriptyline	Olanzapine (Zyprexa) Paroxetine Perphenazine Prozac Quetiapine (Seroquel) Risperidone (Risperdal) Sertraline Steroids (non-inhalant) Trazadone Tofranil Tricyclics Trileptal Valproate Valproic acid (Depakote/Depakene/Depacon) Ziprasidone (Geodon) Zyprexa
Exclusionary if started within past 6 months	Synthroid (hypothyroid)	

8302

8303

8304 **Patient Health Questionnaire (PHQ)**

8305

8306 This questionnaire is an important part of providing you with the best health care possible. Your answers  
 8307 will help in understanding problems that you may have. Please answer every question to the best of  
 8308 your ability unless you are requested to skip over a question.  
 8309

1. During the last 4 weeks, how much have you been bothered by any of the following problems?	<b>Not bothered</b>	<b>bothered a little</b>	<b>bothered a lot</b>	
a. Stomach pain				
b. Back pain				
c. Pain in your arms, legs, or joints (knees, hips, etc.)				
d. Menstrual cramps or other problems with your periods				
e. Pain or problems during sexual intercourse				
f. Headaches				
g. Chest pain				
h. Dizziness				
i. Fainting spells				
j. Feeling your heart pound or race				
k. Shortness of breath				
l. Constipation, loose bowels, or diarrhea				
m. Nausea, gas, or indigestion				
2. Over the last 2 weeks, how often have you been bothered by any of the following problems?	<b>Not at all</b>	<b>several days</b>	<b>more than half the days</b>	<b>every day</b>
a. Little interest or pleasure in doing things				
b. Feeling down, depressed, or hopeless				
c. Trouble falling or staying asleep, or sleeping too much				
d. Feeling tired or having little energy				
e. Poor appetite or overeating				
f. Feeling bad about yourself – or that you are a failure or have let yourself or your family down				
g. Trouble concentration on things, such as reading the newspaper or watching television				
h. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual				
i. Thoughts that you would be better off dead or of hurting yourself in some way				
3. Questions about anxiety.	<b>No</b>		<b>Yes</b>	

a. In the last 4 weeks, have you had an anxiety attack – suddenly feeling fear or panic?			
If “No”, go to question 5.			
b. Has this ever happened before?			
c. Do some of these attacks come suddenly out of the blue- that is, in situations where you don’t expect to be nervous or uncomfortable?			
d. Do these attacks bother you a lot or are you worried about having another attack?			
<b>4. Think about your last bad anxiety attack.</b>			
a. Were you short of breath?			
b. Did your heart race, pound, or skip?			
c. Did you have chest pain or pressure?			
d. Did you sweat?			
e. Did you feel as if you were choking?			
f. Did you have hot flashes or chills?			
g. Did you have nausea or an upset stomach, or the feeling that you were going to have diarrhea?			
h. Did you feel dizzy, unsteady, or faint?			
i. Did you have tingling or numbness in parts of your body?			
j. Did you tremble or shake?			
k. Were you afraid you were dying?			
<b>5. Over the last 4 weeks, how often have you been bothered by any of the following problems?</b>	<b>Not at all</b>	<b>Several days</b>	<b>More than half the days</b>
a. Feeling nervous, anxious, on edge, or worrying about a lot of different things.			
If “Not at all”, go to questions 6.			
b. Feeling restless so that it is hard to sit still.			
c. Getting very tired easily.			
d. Muscle tension, aches, or soreness.			
e. Trouble falling asleep or staying asleep.			
f. Trouble concentrating on things, such as reading a book or watching TV.			
g. Becoming easily annoyed or irritable.			
<b>6. Questions about eating.</b>	<b>No</b>		<b>Yes</b>
a. Do you often feel that you can’t control what or how much you eat?			
b. Do you often eat, within any 2-hour period, what most people would regard as an unusually large amount of food?			



If "No" to either a. or b., go to questions 9.				
c. Has this been as often, on average, as twice a week for the last 3 months?				
<b>7. In the last 3 months, have you often done any of the following in order to avoid gaining weight?</b>				
a. Made yourself vomit?				
b. Took more than twice the recommended dose of laxatives?				
c. Fasted – not eaten anything at all for at least 24 hours?				
d. Exercised for more than an hour specifically to avoid gaining weight after binge eating?				
8. If you checked "Yes" to any of these ways to avoid gaining weight, were any as often, on average, as twice a week?				
9. Do you ever drink alcohol (including beer or wine)?				
If "No", go to question 11.				
<b>10. Have any of the following happened to you more than once in the last 6 months?</b>				
a. You drank alcohol even though a doctor suggested that you stop drinking because of a problem with your health.				
b. You drank alcohol, were high from alcohol, or hung over while you were working, going to school, or taking care of children or other responsibilities.				
c. You missed or were late for work, school, or other activities because you were drinking or hung over.				
d. You had a problem getting along with other people while you were drinking.				
e. You drove a car after having several drinks or after drinking too much?				
11. If you checked off any problems on this questionnaire, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	difficult at all	somewhat difficult	very difficult	extremely difficult

8310  
8311  
8312

8313 **Pediatric Symptom Checklist**

8314 ©1988, M.S. Jellinek and J.M. Murphy, Massachusetts General Hospital

8315

8316 Emotional and physical health go together in children. Because parents are often the first to notice a  
 8317 problem with their child’s behavior, emotions or learning, you may help your child get the best care  
 8318 possible by answering these questions. Please mark under the heading that best fits your child.

	Never (0)	Sometimes (1)	Often (2)
1. Complains of aches/pains			
2. Spends more time alone			
3. Tires easily, has little energy			
4. Fidgety, unable to sit still			
5. Has trouble with a teacher			
6. Less interested in school			
7. Acts as if driven by a motor			
8. Daydreams too much			
9. Distracted easily			
10. Is afraid of new situations			
11. Feels sad, unhappy			
12. Is irritable, angry			
13. Feels hopeless			
14. Has trouble concentrating			
15. Less interest in friends			
16. Fights with others			
17. Absent from school			
18. School grades dropping			
19. Is down on him or herself			
20. Visits doctor with doctor finding nothing wrong			
21. Has trouble sleeping			
22. Worries a lot			
23. Wants to be with you more than before			
24. Feels he or she is bad			
25. Takes unnecessary risks			
26. Gets hurt frequently			
27. Seems to be having less fun			
28. Acts younger than children his or her age			
29. Does not listen to rules			
30. Does not show feelings			
31. Does not understand other people’s feelings			
32. Teases others			
33. Blames others for his or her troubles			
34. Takes things that do not belong to him or her			
35. Refuses to share			
<b>Total Score</b>			
	<b>No</b>	<b>Yes</b>	

Does your child have any emotional or behavioral problems for which she/he needs help?		
Are there any services that you would like your child to receive for these problems?		
If yes, what services?		

8319

8320

8321  
8322  
8323  
8324  
8325  
8326  
8327  
8328  
8329  
8330  
8331  
8332  
8333  
8334  
8335  
8336  
8337  
8338  
8339  
8340  
8341  
8342  
8343  
8344  
8345  
8346  
8347  
8348  
8349  
8350  
8351  
8352  
8353  
8354  
8355  
8356  
8357  
8358  
8359  
8360  
8361  
8362  
8363  
8364  
8365  
8366  
8367  
8368

**QUESTIONNAIRE ON EATING AND WEIGHT PATTERNS-5 - Parent**  
(QEWP-5-Parent)  
**Marian Tanofsky-Kraff, Susan Z. Yanovski, and Jack A. Yanovski**

1. During the past **three** months, did your child ever eat what most people, like their friends, would think was a REALLY BIG amount of food?  
YES                      NO                      IF NO, SKIP TO QUESTION 18
2. When your child ate a REALLY BIG amount of food, was it ever within a short time (2 hours or less)?  
YES                      NO                      IF NO, SKIP TO QUESTION 18
3. When your child ate a REALLY BIG amount of food, did you ever feel your child could not stop eating or control what or how much they were eating?  
YES                      NO                      IF NO, SKIP TO QUESTION 18
4. During the past **three** months, how often did your child eat like this--ate a REALLY BIG amount of food along with the feeling that their eating was out of control? There may have been some weeks where this did not happen—just give your best guess.  
\_\_\_\_ Less than 1 time a week  
\_\_\_\_ 1 time a week  
\_\_\_\_ 2 or 3 times a week  
\_\_\_\_ 4 to 7 times a week  
\_\_\_\_ 8 to 13 times a week  
\_\_\_\_ 14 or more times a week
5. When your child ate a REALLY BIG amount of food and felt like they could not control their eating, did they usually:  
YES      NO      Eat very fast?  
YES      NO      Eat until their stomach hurt or they felt sick to their stomach?  
YES      NO      Eat REALLY BIG amounts of food even when they were not hungry?  
YES      NO      Eat by themselves because they did not want anyone to see how much they ate?  
YES      NO      Feel REALLY BAD about themselves because of what or how much they were eating?
6. Think about a usual time when your child ate a REALLY BIG amount of food and felt they could not control their eating:
  - a. During that time, when did they start eating?  
\_\_\_\_ (8 AM to 12 Noon)  
\_\_\_\_ (12 Noon to 4 PM)  
\_\_\_\_ (4 PM to 8 PM)  
\_\_\_\_ (8 PM to 12 Midnight)  
\_\_\_\_ (12 Midnight to 8 AM)
  - b. For how long did they eat during this time?  
\_\_\_\_ hours  
\_\_\_\_ minutes

8369  
8370  
8371  
8372  
8373  
8374  
8375  
8376  
8377  
8378  
8379  
8380  
8381  
8382  
8383  
8384  
8385  
8386  
8387  
8388  
8389  
8390  
8391  
8392  
8393  
8394  
8395  
8396  
8397  
8398  
8399  
8400  
8401  
8402  
8403  
8404  
8405  
8406  
8407  
8408  
8409  
8410  
8411  
8412  
8413  
8414  
8415  
8416

c. As best as you can remember, please list **everything** your child ate or drank during this time. Be specific - include brand names where possible, and amounts as best you can guess.

---

---

---

---

---

---

d. At the time they started eating, how long had it been since your child had last eaten a meal or snack?

\_\_\_ hours  
\_\_\_ minutes

7. During the past **three** months, how bad did your child feel when they ate a REALLY BIG amount of food and felt their eating was out of control?

\_\_\_ Not bad at all  
\_\_\_ Just a little bad  
\_\_\_ Pretty bad  
\_\_\_ Very bad  
\_\_\_ Very, very bad

8. During the past **three** months, did your child ever make themselves vomit, throw up, or get sick in order to keep from gaining weight after eating like you described (when your child ate a REALLY BIG amount of food and felt their eating was out of control)?

YES NO

**IF YES:** How often, **in general**, did your child do that?

\_\_\_ Less than 1 time a week  
\_\_\_ 1 time a week  
\_\_\_ 2 to 3 times a week  
\_\_\_ 4 to 7 times a week  
\_\_\_ 8 to 13 times a week  
\_\_\_ 14 or more times a week

9. During the past **three** months, did your child ever take medicine to make them poop or have a bowel movement (laxatives) in order to keep from gaining weight after eating like you described (when your child ate a REALLY BIG amount of food and felt their eating was out of control)?

YES NO IF NO, SKIP TO QUESTION 11

10. Did your child take more medicine than the directions on the box or bottle say to take?

YES NO

**IF YES:** How often, **in general**, was that?

\_\_\_ Less than 1 time a week  
\_\_\_ 1 time a week

- 8417  2 to 3 times a week
- 8418  4 to 5 times a week
- 8419  6 to 7 times a week
- 8420  8 or more times a week

8421

8422 11. During the past **three** months, has your child ever taken medicine to make them pee or urinate

8423 (diuretics or water pills) in order to keep from gaining weight after eating like you described (when

8424 your child ate a REALLY BIG amount of food and felt their eating was out of control)?

8425 YES NO IF NO, SKIP TO QUESTION 13

8426

8427 12. Did your child take more medicine than the directions on the box or bottle say to take?

8428 YES NO

8429

8430 **IF YES: How often, in general, was that?**

- 8431  Less than 1 time a week
- 8432  1 time a week
- 8433  2 to 3 times a week
- 8434  4 to 5 times a week
- 8435  6 to 7 times a week
- 8436  8 or more times a week

8437

8438 13. During the past **three** months, did your child ever eat nothing at all for at least 24 hours (a full day)

8439 in order to keep from gaining weight after eating like you described (when your child ate a REALLY

8440 BIG amount of food and felt their eating was out of control)?

8441 YES NO

8442

8443 **IF YES: How often, in general, was that?**

- 8444  Less than 1 day a week
- 8445  1 day a week
- 8446  2 days a week
- 8447  3 days a week
- 8448  4 to 5 days a week
- 8449  More than 5 days a week

8450

8451 14. During the past **three** months, did your child ever exercise too much (for example, even though they

8452 were hurt or sick or it kept them from doing important things) MAINLY in order to keep from gaining

8453 weight after eating like you described (when your child ate a REALLY BIG amount of food and felt

8454 their eating was out of control)?

8455 YES NO

8456

8457 **IF YES: How often in general, was that?**

- 8458  Less than 1 time a week
- 8459  1 time a week
- 8460  2 to 3 times a week
- 8461  4 to 7 times a week
- 8462  8 to 13 times a week
- 8463  14 or more times a week

8464

8465 15. During the past **three** months, did your child ever take diet pills in order to keep from gaining  
8466 weight after eating like you described (when your child ate a REALLY BIG amount of food and felt  
8467 their eating was out of control)?

8468 YES NO IF NO, SKIP TO QUESTION 17

8469

8470 16. Did your child take more medicine than the directions on the box or bottle say to take?

8471 YES NO

8472

8473 **IF YES:** How often, **in general**, was that?

8474 \_\_\_ Less than 1 time a week

8475 \_\_\_ 1 time a week

8476 \_\_\_ 2 to 3 times a week

8477 \_\_\_ 4 to 5 times a week

8478 \_\_\_ 6 to 7 times a week

8479 \_\_\_ 8 or more times a week

8480

8481 17. During the past **three** months, how important has your child's weight or shape been in how they  
8482 feel about themselves as a person – as compared to other things in their life, such as their  
8483 schoolwork, friends, sports, or getting along with their family?

8484

8485 \_\_\_ Weight and shape were **not very important**

8486 \_\_\_ Weight and shape were **played a part** in how they felt about themselves

8487 \_\_\_ Weight and shape were **among the main things** that affected how they felt about  
8488 themselves

8489 \_\_\_ Weight and shape were **the most important things** that affected how  
8490 they felt about themselves

8491

8492 **Continue here after completing question 17 OR if you skipped to question 18 from Question 1, 2, or 3**

8493

8494 18. During the past **three** months, did your child ever have times when they felt that they could not  
8495 stop eating or control what or how much they were eating, but when they did **not** eat a REALLY BIG  
8496 amount of food?

8497 YES NO IF NO, SKIP TO QUESTION 32

8498

8499 19. During the past **three** months, how often did your child eat like this—felt that their eating was out  
8500 of control, but they did **not** eat a REALLY BIG amount of food. There may have been some weeks  
8501 where this did not happen—just give your best guess.

8502 \_\_\_ Less than 1 time a week

8503 \_\_\_ 1 time a week

8504 \_\_\_ 2 to 3 times a week

8505 \_\_\_ 4 to 7 times a week

8506 \_\_\_ 8 to 13 times a week

8507 \_\_\_ 14 or more times a week

8508

8509 20. When your child felt their eating was out of control but they did **not** eat a REALLY BIG amount of  
8510 food, did they usually:

8511 YES NO Eat very fast?

8512 YES NO Eat until their stomach hurt or they felt sick to their stomach?

8513 YES NO Eat REALLY BIG amounts of food even when they were not hungry?  
 8514 YES NO Eat by themselves because they did not want anyone to see how much they  
 8515 ate?  
 8516 YES NO Feel REALLY BAD about themselves because of what or how much they were  
 8517 eating?  
 8518

21. Think about a usual time when your child felt they could not stop eating or control what or how much they were eating, but they did **not** eat a REALLY BIG amount of food:

8521  
 8522 a. During that time, when did they start eating?  
 8523 \_\_\_\_ (8 AM to 12 Noon)  
 8524 \_\_\_\_ (12 Noon to 4 PM)  
 8525 \_\_\_\_ (4 PM to 8 PM)  
 8526 \_\_\_\_ (8 PM to 12 Midnight)  
 8527 \_\_\_\_ (12 Midnight to 8 AM)  
 8528

8529 b. For how long did they eat during this time?  
 8530 \_\_\_\_ hours  
 8531 \_\_\_\_ minutes  
 8532

8533 c. As best as you can remember, please list **everything** your child ate or drank during  
 8534 this time. Be specific - include brand names where possible, and amounts as best  
 8535 you can guess.  
 8536 \_\_\_\_\_  
 8537 \_\_\_\_\_  
 8538 \_\_\_\_\_  
 8539 \_\_\_\_\_  
 8540 \_\_\_\_\_  
 8541 \_\_\_\_\_  
 8542

8543 d. At the time they started eating, how long had it been since your child had last eaten a  
 8544 meal or snack?  
 8545 \_\_\_\_ hours  
 8546 \_\_\_\_ minutes  
 8547

22. During the past **three** months, how bad did your child feel that they could not stop eating or control what or how much they were eating even when they did **not** eat a REALLY BIG amount of food?

8550 \_\_\_\_ Not bad at all  
 8551 \_\_\_\_ Just a little bad  
 8552 \_\_\_\_ Pretty bad  
 8553 \_\_\_\_ Very bad  
 8554 \_\_\_\_ Very, very bad  
 8555

23. During the past **three** months, did your child ever make themselves vomit, throw up, or get sick in order to keep from gaining weight after eating like you described (when your child felt their eating was out of control but they did **not** eat a REALLY BIG amount of food)?

8559 YES  
 8560 NO



8561  
8562  
8563  
8564  
8565  
8566  
8567  
8568  
8569  
8570  
8571  
8572  
8573  
8574  
8575  
8576  
8577  
8578  
8579  
8580  
8581  
8582  
8583  
8584  
8585  
8586  
8587  
8588  
8589  
8590  
8591  
8592  
8593  
8594  
8595  
8596  
8597  
8598  
8599  
8600  
8601  
8602  
8603  
8604  
8605  
8606  
8607  
8608

**IF YES:** How often, **in general**, did your child do that?

- Less than 1 time a week
- 1 time a week
- 2 to 3 times a week
- 4 to 7 times a week
- 8 to 13 times a week
- 14 or more times a week

24. During the past **three** months, did your child ever take medicine to make them poop or have a bowel movement (laxatives) in order to keep from gaining weight after eating like you described (when your child felt their eating was out of control, but they did **not** eat a REALLY BIG amount of food)?

YES NO IF NO, SKIP TO QUESTION 26

25. Did your child take more medicine than the directions on the box or bottle say to take?

YES NO

**IF YES:** How often, **in general**, was that?

- Less than 1 time a week
- 1 time a week
- 2 to 3 times a week
- 4 to 5 times a week
- 6 to 7 times a week
- 8 or more times a week

26. During the past **three** months, has your child ever taken medicine to make them pee or urinate (diuretics or water pills) in order to keep from gaining weight after eating like you described (when your child felt their eating was out of control, but they did **not** eat a REALLY BIG amount of food)?

YES NO IF NO, SKIP TO QUESTION 28

27. Did your child take more medicine than the directions on the box or bottle say to take?

YES NO

**IF YES:** How often, **in general**, was that?

- Less than 1 time a week
- 1 time a week
- 2 to 3 times a week
- 4 to 5 times a week
- 6 to 7 times a week
- 8 or more times a week

28. During the past **three** months, did your child ever eat nothing at all for at least 24 hours (a full day) in order to keep from gaining weight after eating like you described (when your child felt their eating was out of control, but they did **not** eat a REALLY BIG amount of food)?

YES NO

**IF YES:** How often, **in general**, was that?

- 8609 \_\_\_\_\_ Less than 1 day a week  
8610 \_\_\_\_\_ 1 day a week  
8611 \_\_\_\_\_ 2 days a week  
8612 \_\_\_\_\_ 3 days a week  
8613 \_\_\_\_\_ 4 to 5 days a week  
8614 \_\_\_\_\_ More than 5 days a week  
8615

29. During the past **three** months, did your child ever exercise too much (for example, even though they were hurt or sick or it kept them from doing important things) MAINLY in order to keep from gaining weight after eating like you described (when your child felt their eating was out of control, but they did **not** eat a REALLY BIG amount of food)?

8620 YES NO

8621  
8622 **IF YES:** How often **in general**, was that?

- 8623 \_\_\_\_\_ Less than 1 time a week  
8624 \_\_\_\_\_ 1 time a week  
8625 \_\_\_\_\_ 2 to 3 times a week  
8626 \_\_\_\_\_ 4 to 7 times a week  
8627 \_\_\_\_\_ 8 to 13 times a week  
8628 \_\_\_\_\_ 14 or more times a week  
8629

30. During the past 3 months, did your child ever take diet pills in order to keep from gaining weight after eating like you described (when your child felt their eating was out of control, but they did **not** eat a REALLY BIG amount of food)?

8633 YES NO IF NO, SKIP TO QUESTION 32

31. Did your child take more medicine than the directions on the box or bottle say to take?

8636 YES NO

8637  
8638 **IF YES:** How often, **in general**, was that?

- 8639 \_\_\_\_\_ Less than 1 time a week  
8640 \_\_\_\_\_ 1 time a week  
8641 \_\_\_\_\_ 2 to 3 times a week  
8642 \_\_\_\_\_ 4 to 5 times a week  
8643 \_\_\_\_\_ 6 to 7 times a week  
8644 \_\_\_\_\_ 8 or more times a week  
8645

8646 **Continue here after completing question 31 OR if you skipped to question 32 from Question 18**  
8647

32. Please look at these drawings of people. Pick the person that matches your child's biological (birth) father's and mother's sizes. If you don't know their biological (birth) father or mother, don't pick anything for that parent.

8651  
8652  
8653 The QEWP-5-P is an adaptation of the QEWP-5. Yanovski SZ, Marcus MD, Wadden TA, Walsh BT. The  
8654 Questionnaire on Eating and Weight Patterns-5: an updated screening instrument for binge eating  
8655 disorder. Int J Eat Disord. 2015 Apr;48(3):259-61. doi: 10.1002/eat.22372. Epub 2014 Dec 26. Adapted  
8656 with permission.

8657

8658

8659 **PLAN ELIGIBILITY TRACKING FORM**

8660

8661 **Initial Eligibility Survey**

**Date**

8662 \_\_\_/\_\_\_/\_\_\_

8663 YES NO Child is between 6 and 12 years of age.

8664 YES NO Child's BMI is above the 85<sup>th</sup> percentile for sex and age.

8665 YES NO Parent's BMI is above 25kg/m<sup>2</sup>.

8666 YES NO Child and parent have not had a concussion in past 3 months.

8667 YES NO Child and parent are able to complete a brisk 5-10 minute walk.

8668 YES NO Family is not planning to move away within next 2 years.

8669 Notes:

8670 \_\_\_\_\_

8671 \_\_\_\_\_

8672 \_\_\_\_\_

8673 \_\_\_\_\_

8674 \_\_\_\_\_

8675 \_\_\_\_\_

8676 \_\_\_\_\_

8677 \_\_\_\_\_

8678

8679 **Eligibility Phone Screen**

**Date**

8680 \_\_\_/\_\_\_/\_\_\_

8681 YES NO Parent agrees to attend all treatment meetings.

8682 YES NO Child resides with targeted parent at least 50% of the time.

8683 YES NO Parent is child's biological or adoptive parent or legal guardian.

8684 YES NO Child and parent do not have any exclusionary medical conditions.

8685 YES NO Child and parent are not taking any exclusionary medications.

8686 YES NO Child and parent have not had any weight-related surgeries.

8687 YES NO Child and parent are not in a weight management/weight-loss program.

8688 YES NO Child and parent do not have severe restriction of diet.

8689 YES NO Child and parent do not have any significant intellectual delays, disabilities, or ASD.

8690 YES NO Child and parent do not have any unmanaged or active psychiatric conditions/symptoms  
8691 (self-report).

8692 YES NO Child and parent have no history of an eating disorder (self-report).

8693 YES NO Child and parent are able to speak/comprehend English at a 1<sup>st</sup> grade level (self-report).

8694 YES NO Parent is not pregnant or planning on becoming pregnant during study period.

8695 Notes:

8696 \_\_\_\_\_  
8697 \_\_\_\_\_  
8698 \_\_\_\_\_  
8699 \_\_\_\_\_  
8700 \_\_\_\_\_  
8701 \_\_\_\_\_  
8702 \_\_\_\_\_  
8703 \_\_\_\_\_  
8704 \_\_\_\_\_

8705 **Pre-Orientation Surveys (PHQ, PSC, QEWP-5 Parent and Child Report)** **Date**

8706 \_\_\_/\_\_\_/\_\_\_

8707 YES NO Child and parent do not have any unmanaged or active psychiatric  
8708 conditions/symptoms.

8709 YES NO Child and parent have no history of an eating disorder.

8710 Notes:

8711 \_\_\_\_\_  
8712 \_\_\_\_\_  
8713 \_\_\_\_\_  
8714 \_\_\_\_\_  
8715 \_\_\_\_\_  
8716 \_\_\_\_\_  
8717 \_\_\_\_\_  
8718 \_\_\_\_\_  
8719 \_\_\_\_\_

8720 **Follow-Up Interview (KSADS, SCID)** **Date**

8721 \_\_\_/\_\_\_/\_\_\_

8722 YES NO Did a PLAN Coach administer the KSADS for the child?

8723 Modules:

8724 \_\_\_\_\_  
8725 \_\_\_\_\_  
8726 \_\_\_\_\_

8727 YES NO Did a PLAN coach administer the SCID for the parent?

8728 Modules:

8729 \_\_\_\_\_  
8730 \_\_\_\_\_  
8731 \_\_\_\_\_  
8732 \_\_\_\_\_

8733 YES NO Child and parent do not have any unmanaged or active psychiatric  
8734 conditions/symptoms.

8735 YES NO Child and parent have no history of an eating disorder.

8736 Notes:

8737 \_\_\_\_\_  
8738 \_\_\_\_\_  
8739 \_\_\_\_\_  
8740 \_\_\_\_\_  
8741 \_\_\_\_\_  
8742 \_\_\_\_\_  
8743 \_\_\_\_\_  
8744 \_\_\_\_\_  
8745 \_\_\_\_\_

8746 **Orientation**

8747 YES NO Child's BMI is above the 85<sup>th</sup> percentile for sex and age.

8748 YES NO Parent's BMI is above 25kg/m<sup>2</sup>.

8749 YES NO Child and parent are able to speak/comprehend English at a 1<sup>st</sup> grade level (per the  
8750 WRAT).

8751 Notes:

8752 \_\_\_\_\_  
8753 \_\_\_\_\_  
8754 \_\_\_\_\_  
8755 \_\_\_\_\_  
8756 \_\_\_\_\_  
8757 \_\_\_\_\_  
8758 \_\_\_\_\_  
8759 \_\_\_\_\_  
8760 \_\_\_\_\_

8761 **Pre-Randomization**

8762 YES NO Child and parent received medical clearance from their PCPs.

8763 **YES NO Family is eligible for randomization.**

8764 Notes:

8765 \_\_\_\_\_  
8766 \_\_\_\_\_  
8767 \_\_\_\_\_  
8768 \_\_\_\_\_  
8769 \_\_\_\_\_  
8770 \_\_\_\_\_  
8771 \_\_\_\_\_

8772 **Assessment Measures**

8773 **Height and Weight Measurement Checklist.** (Primary Aim 1a & b and Secondary Aim 1)

8774

8775 **General Information for Measurements:**

8776 **HEIGHT RELIABILITY CRITERIA**

8777 Height measurements are to be within 0.3cm (3mm) of a reliable staff member. The above requirements  
8778 are to be met for 10 different height measurements (i.e., 10 participants measured by a reliable staff  
8779 member and the staff in training). If the reliable staff member and new staff member do not meet  
8780 acceptable reliability criteria, additional participants should be measured by both staff members until  
8781 adequate reliability is established.

- 8782 ● Reliability should be checked periodically throughout the study to assure that there is no  
8783 measurement drift between height assessors.
- 8784 ● Height and weight will be monitored and rechecked randomly to ensure accuracy of the data.
- 8785 ● Calibration of the stadiometer and scale will occur every so often to ensure the accuracy of the  
8786 equipment.

8787

8788 **HEIGHT PROCEDURES FOR CHILDREN AGES  $\geq$  4 YEARS AND ADULTS**

- 8789 1. *The participant should be barefoot or in thin socks.*
- 8790 2. *The PLAN coach will instruct the participant to stand up straight with his/her back against*  
8791 *stadiometer board. The coach should make sure that the participant is not standing on his/her*  
8792 *pants if long.*
- 8793 3. *Ask the participant to stand with his/her heels together and toes pointing out to form a “V”.*
- 8794 4. *The participant should be looking straight ahead with his/her arms at his/her sides.*
- 8795 5. *The PLAN coach should lightly rest headboard on top of the participant’s head to be sure that it*  
8796 *sits at the highest point of the head and then lift the head board out of the way.*
- 8797 6. *The coach should instruct the participant to take a deep breath in and stretch upwards while*  
8798 *s/he places both hands under the mastoid process of skull. The coach should then gently lift the*  
8799 *participant’s head, which will elongate the spine to ensure an accurate height reading.*
  - 8800 a. *The mastoid process of the skull is the bony projection of the temporal bone and is*  
8801 *located behind the ears.*
- 8802 7. *The coach should make sure there is an imaginary line between the participant’s eyes and ears*  
8803 *that runs parallel with the floor while the participant's eyes gaze forward.*
- 8804 8. *The coach should ensure that the participant's feet are firmly planted on the ground and that*  
8805 *s/he is not standing on his/her toes.*
- 8806 9. *The coach should take the height measurement.*
  - 8807 a. *The headboard should rest on highest point of the participant’s head and, if applicable,*  
8808 *should compress the participant’s hair.*
- 8809 10. *The coach should then ask the participant to step away from the height board.*
- 8810 11. *The coach will record the height on a hard copy of the “Height and Weight” REDCap form that*  
8811 *s/he will print off prior to the appointment.*
- 8812 12. *The coach will measure the height in millimeters. Then, the coach will read what this*  
8813 *measurement is in centimeters to the nearest decimal place (i.e., 65.7). If the height falls in*  
8814 *between two decimal places, the coach will record to the lower decimal place.*
- 8815 13. *The coach should repeat the process two times to check validity.*
  - 8816 a. *If the two height measurements are not within 0.3 centimeters of each other, the coach*  
8817 *will take two additional measurements.*
  - 8818 b. *The coach will repeat this process until s/he has two measurements that are within 0.3*  
8819 *centimeters of each other.*
  - 8820 c. *REDCap will take the mean of the last pair of measurements to determine the*  
8821 *participant’s BMI.*

- 8822 i. All measurements will remain in REDCap so that the total measurements taken  
8823 and the values of the measurements can be reviewed.
- 8824 14. The coach will enter the two height measurements into the participant's file in REDCap on the  
8825 "Height Tracking Form".
- 8826 15. Coaches will use their REDCap username and password to log on to the PLAN study in REDCap  
8827 via <https://redcap.wustl.edu/redcap/srvrs/>. They will then complete the following steps:
- 8828 a. Open the "Add/Edit Records" tab that is located on the left side of the screen.
- 8829 b. Select the appropriate Screening ID from the "Choose an existing Screening ID"  
8830 dropdown menu, which will take the coach to the "Record Home Page" for the family.
- 8831 c. Double click on the appropriate "Height and Weight Tracking Form".
- 8832 d. Complete the height portion of the Height and Weight Tracking Form.
- 8833 e. The coach will select the appropriate form status based on whether or not s/he has to  
8834 input more measurement data.
- 8835 f. The coach will click "Save & Exit Form".
- 8836 16. The coach should wipe down the scale pre and post measurement with a Lysol wipe if the  
8837 participant is bare footed.
- 8838

#### 8839 **MANUAL CALIBRATION OF THE HEAD SLIDE**

- 8840 1. All PLAN coaches will use 72 centimeter PVC pipes to calibrate their stadiometers.
- 8841 a. SR scales will cut 72 (+/- 0.3) centimeter PVC pipe sections with a laser cutter.
- 8842 b. The exact length of each pipe will be written on the pipe.
- 8843 c. A staff member from the University at Buffalo will retrieve the pipes and mail out them  
8844 out to each site.
- 8845 2. All PLAN coaches will take height measurements with their PVC pipes each time their  
8846 stadiometer is used.
- 8847 a. The stadiometer should always measure the known height of the PVC pipe that was  
8848 documented on the pipe.
- 8849 b. If the stadiometer measures the height of the PVC pipe as something different than the  
8850 known height, the coach will document the discrepancy. The coach will then make  
8851 arrangements to procure a new stadiometer
- 8852

#### 8853 **HEIGHT MEASUREMENT REPORT**

- 8854 1. The height measurements will be manually entered into REDCap for analysis of outcome  
8855 measures as well as written on hard copy of height and weight form (pdf form from REDCap).
- 8856 2. The reported height measurements will be exactly the same as the reading on the stadiometer,  
8857 which will provide an unbiased report of the height measurements (This change was made on  
8858 9.18.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on  
8859 11.2.18).
- 8860

#### 8861 **WEIGHT PROCEDURES**

- 8862 1. To begin, the PLAN coach should plug the SR Scale into a wall outlet. The coach should then  
8863 press the "Zero/Weigh" button that is located on the right side of the scale. The scale will be  
8864 operational when the display reads 0.00. The coach should ensure that the scale is recording  
8865 weight in pounds. If the scale is set to measure weight in kilograms, the coach will press the  
8866 toggle button next to the "Zero/Weigh" button to switch the unit measurement from kilograms  
8867 to pounds.
- 8868 2. In order to ensure accurate measurement, the coach should instruct the participant to do the  
8869 following:



- 8870 a. *The participant should empty out his/her pockets, and remove shoes and any heavy*  
8871 *clothing or accessories.*
- 8872 b. *The participant should always be weighed around the same time of the day.*  
8873 c. *The participant should always use the bathroom prior to being weighed.*  
8874 d. *The participant should follow similar eating and activity schedules.*
- 8875 3. *The coach will ask the participant to stand in the middle of the scale and instruct the participant*  
8876 *to do the following:*
- 8877 a. *The coach will ask the participant to remain still, have relaxed shoulders, and to have*  
8878 *his/her hands at his/her sides.*
- 8879 b. *The coach will ask the participant to look straight ahead.*  
8880 c. *The coach will tell the participant to stand with the same posture as on a balance beam*  
8881 *scale.*
- 8882 4. *The coach will wait for weight measurement to stabilize.*  
8883 a. *While standing to the left of the scale, the coach will monitor the digital readout.*
- 8884 5. *Once the measurement has stopped fluctuating, the coach will record the weight on a hard copy*  
8885 *of the "Height and Weight" REDCap form that s/he will print off prior to the appointment.*
- 8886 6. *The coach will repeat this procedure a second time.*  
8887 7. *The coach will instruct the participant to step off the scale.*  
8888 8. *The coach should wipe down the scale pre and post measurement with a Lysol wipe if the*  
8889 *participant is bare footed.*  
8890

#### **MANUAL CALIBRATION OF THE SCALE**

- 8891 1. *All PLAN coaches will use Pro-Form 15-pound kettle bells to calibrate their scales.*  
8892 a. *A staff member from the University at Buffalo will perform weight measurements with*  
8893 *all Pro-Form kettle bells on a calibrated scale.*  
8894 b. *The staff member will document the exact weight of each kettle bell.*  
8895 c. *The staff member will write the exact weight on a piece of painter's tape and tape it to*  
8896 *the kettle bell.*  
8897 d. *The staff member will mail out the kettle bells each site.*
- 8898 2. *All PLAN coaches will take weight measurements with their kettle bells each time their scale is*  
8899 *used.*  
8900 a. *The scale should always measure the known weight of the kettle bell that was*  
8901 *documented by the University at Buffalo on the painter's tape.*  
8902 b. *If the scale measures the weight of the kettle bell as something different than the known*  
8903 *weight, the coach will document the discrepancy. The coach will then make*  
8904 *arrangements to send the scale to SR Scales for re-calibration.*  
8905  
8906

#### **WEIGHT MEASUREMENT REPORT**

- 8907 1. *For analysis of outcome measures (see 11 in Weight Procedures above; (This change was made*  
8908 *on 9.18.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on*  
8909 *11.2.18).*  
8910 *Use of Weight App was discontinued (DSMB approved change, 11.18.19).Hard copy height and weight*  
8911 *measurement forms will be uploaded to the secure REDCap database to allow the CCC, DCC and TFC to*  
8912 *check for transcription and/or unit of measurement errors.*  
8913  
8914  
8915  
8916

#### **Remote assessments Protocol**

8918

### Step 1: Coach Instructions for CONTACTING FAMILY

8919

1. Schedule phone call with family to introduce the remote assessment, check for materials, review instructions, describe changes in payment, complete the AE survey, and to schedule an assessment date with a blinded measurement coach. *A random subset of families from each site will be asked to complete the height protocol for a second quality control measure of this remote height measurement.*

8920

8921

8922

8923

8924

- a. See email script if they do not answer the phone:

8925

*“Hello [Parent],*

8926

*Thank you for participating in the PLAN with Families Program! It is time for your family's [X] month assessment.*

8927

8928

*Because of the current unexpected circumstances, we will be conducting your assessment virtually. This means we will supply you with measurement equipment and call you to walk you through measuring yourself and your children.*

8929

8930

8931

*You will receive payment for this assessment. Please call, text, or email me so we discuss the details and schedule a date.*

8932

8933

*Thank you,*

8934

*[Name]*

8935

*[phone number]*

8936

- b. Introduction of remote assessment:

8937

- i. *“Due to unforeseen circumstances, our assessments for the measurement procedures have changed for the time being. At this time, we are asking families to complete height and weight measurements at home using equipment that you have or can be sent to you. With your permission, we will call you during the assessment to walk you through the procedures.”*

8938

8939

8940

8941

8942

- c. Describe payment procedure:

8943

- i. *“You will get the usual payment for this remote measurement.”*

8944

1. Remote payment will be sent by each site’s PC

8945

- a. Within 2-3 days of completing the remote measurement

8946

- b. UB checks, UR gift cards

8947

- i. Certified mail serves as receipt of payment

8948

- c. WU e-gift cards and NCH ClinCard will be instantaneous

8949

2. In-person payment will be directly given to the family as normal protocol procedures.

8950

8951

- d. Discuss consenting procedures: Electronic signature procedure through downloads or directly in REDCap)

8952

- 8953 i. "I will email you an addendum document for the remote assessment and  
8954 instructions for opening and signing the document. Can you please confirm your  
8955 correct and working email address where I can send this form? [Confirm email  
8956 address in REDCap]"
- 8957 ii. "To complete the consent form, you will need to open the email, download the  
8958 document and open the form in your "downloads folder" on your computer.  
8959 Open this file using the Adobe application, there will be blue squares and  
8960 rectangles which are interactive. You can select a box to either consent, or do  
8961 not consent. You will input the date, and then click the blue box below signature  
8962 to sign the document. A window will appear asking about a digital ID, if you  
8963 have a preset one with your correct name you may use it. If not, you can  
8964 configure a new one according to the instructions that will be included in my  
8965 email to you. Please contact me should you have any troubles or questions with  
8966 any step of this consenting process."
- 8967 iii. "Please send me a confirmation email when you receive the instructions and  
8968 consent form to your email."
- 8969 1. Follow-up with family 1 day after sending the email if you do not receive  
8970 confirmation.
- 8971 iv. **REDCap consent procedure:**
- 8972 1. "You will receive an email from me in a few minutes. In it, there will be a  
8973 link to the electronic consent form. Let me know when you have it open  
8974 so I can go over it with you. [wait]"
- 8975 2. "This consent form is telling you about some updates to the study and is  
8976 asking you to sign to agree to these changes."
- 8977 a. Addendum: "First, as you know we will be doing your  
8978 assessment remotely, meaning you will take heights and  
8979 weights for all the PLAN participants in the study. Second, we  
8980 will be paying your regular payment for the remote assessment  
8981 Third, we have changed the total payment for the 24 month  
8982 assessment from \$50 to \$100. Last, we have started a lottery  
8983 where you earn 1 chance to win an extra \$50 for every in  
8984 person assessment you attend."
- 8985 b. Reconsent: "I have sent a second email with another consent  
8986 form for [child] to sign. Now that [child] has turned [age], they  
8987 are old enough to sign a consent form for an older age group.  
8988 This consent is just asking [child] to sign so we can keep doing  
8989 the study just as we have in the past. There is nothing new in  
8990 this consent form."
- 8991 3. "Please take your time and read over the form(s). If you have any  
8992 questions, I can answer them. Whenever you are ready, you may scroll  
8993 to the bottom and "sign" your name with today's date. (For reconsent:

- 8994 Please make sure your child is the one to sign and not you.) I will stay on  
 8995 the line with you until you are ready.”
- 8996 e. Ask if they have:
- 8997 i. “In order to complete the measurement you will need the following pieces of  
 8998 equipment. Please let me know if any of the following are not available to you:
- 8999 1. PLAN Provided Weight Scale
- 9000 a. Is their mailing address correct?
- 9001 2. Carpenter’s Square
- 9002 3. Metal Measuring Tape
- 9003 4. Computer or phone access to internet and web camera
- 9004 a. If they don’t have these, ask if they have some form of camera  
 9005 to take a picture of the measurements. Pictures can be emailed  
 9006 to the measurement coach.
- 9007 ii. If these items are available:
- 9008 a. “Great. Please have these items ready at the time of your  
 9009 measurement, we will provide you with a PLAN weight scale  
 9010 through the mail. Please confirm your mailing address and any  
 9011 special delivery instructions for your residence.”
- 9012 iii. If an item(s) is not available:
- 9013 a. “We will mail a standardized scale and [item(s)] to your address  
 9014 for the assessment. Please confirm your mailing address and  
 9015 any special delivery instructions for your residence.”
- 9016 2. Contact PC to coordinate delivery of materials
- 9017 f. Schedule the family’s remote measurement
- 9018 i. “To allow time for materials to arrive for the measurement, we will schedule 2  
 9019 weeks out from this call.”
- 9020 ii. Give 2-3 possible days/times to schedule appointment.
- 9021 g. Complete AE survey according to protocol
- 9022 i. “At this time I have a 5-10 minute survey to go through with you. Is now a good  
 9023 time to complete this?”
- 9024 1. If yes, complete AE survey.
- 9025 2. If no, “is there a convenient day/time where I can contact you to  
 9026 complete this survey?” or email it to the family
- 9027 h. Notify family that necessary questionnaires will be emailed and should be completed  
 9028 before the measurement appointment through REDCap.
- 9029 i. If family does not have computer/phone access with internet:
- 9030 1. Surveys can be done over the phone BEFORE the appointment
- 9031 a. AEQ, DDs, FNPA, 24M Parent/Child
- 9032 2. Measurement instructions will be mailed to their address
- 9033 ii. Send reminder email 1 day before assessment if questionnaires are not  
 9034 complete

- 9035 i. Check when family’s next well child visit is to coordinate in person follow-up  
9036 measurement at a convenient date and time  
9037 i. “In addition to the remote measurement, we will also schedule a follow-up  
9038 measurement at the pediatric office. Does your child have an existing well-visit  
9039 appointment that would be convenient for you to schedule this follow-up?”  
9040 ii. If not, schedule a follow-up appointment that will take place in the summer  
9041 j. Ending the phone call  
9042 i. “Thank you so much for your time today, I will send you a 1 week and 1 day  
9043 reminder prior to your assessment. Please contact me with any changes or  
9044 questions in the meantime.”
- 9045 2. Record all assessment information into your site’s specific tracking spreadsheet.  
9046 a. Add date and time, and all other necessary information, (UB Assessments - Tracking,  
9047 WU, NCH, UR)  
9048 b. Include family’s consent for audio/video recording
- 9049 3. Contact a blinded measurement coach to run the assessment via video conference or phone.  
9050 a. For 24 month assessments, both the blinded assessor and the PLAN Coach should be  
9051 present
- 9052 4. Send video conference email link to family and assessor using <https://zoom.us/home?zcid=2478>  
9053 or Webex  
9054 a. Set the duration as 30 min, or 60 min for a 24 month assessment.  
9055 b. Set a password.  
9056 c. Attach Family Instructions for measurements
- 9057 5. Email all the surveys to the family through REDCap (see next section)
- 9058 6. Confirm assessment dates with family one week before and the day of the assessment  
9059 a. Include the call-in information and instruction sheet again.

9060

## 9061 **Step 2: PLAN Coach Instructions for FORMS AND PAPERWORK COMPLETION**

9062 **NOTE:** For 6, 12, and 18 month assessments, all surveys should be completed by families BEFORE the  
9063 assessment.

9064 For 24 month assessments, surveys should be completed by families BEFORE the assessment, AND the  
9065 PLAN Coach should attend the assessment to give FBT materials and finish payment AFTER the blinded  
9066 assessor leaves the call.

- 9067 1. For families doing 12- and 24-month assessments, have them complete the online  
9068 questionnaires.  
9069 a. At 12 month assessments: Child DD Validation, Child DD, Parent DD.  
9070 b. At 24 month assessments: Child DD Validation, Child DD, Parent DD, FN & PA, and 24  
9071 Month for both Child and Parent.  
9072 c. For families with internet access, use REDCap to send the online surveys.

- 9073 i. In the family’s REDCap record, click the circle that corresponds to the  
9074 questionnaire that needs to be sent
- 9075 ii. Under the “Survey Options” drop down menu, select “Compose Survey  
9076 Invitation”
- 9077 iii. Fill out the invitation form
- 9078 1. Send out immediately
- 9079 2. Check the box to enable reminders and choose to resend every 3 days  
9080 with recurrence up to 5 times
- 9081 3. Make sure it is your email address the email will be from, and choose  
9082 the participant’s email address to where it will be sent
- 9083 4. Type in subject line: “PLAN with Families 12/24 month survey”
- 9084 5. Compose a message in the text box.
- 9085 a. For example, “Hi [Name], Please click the link and complete the  
9086 questionnaire, following the directions provided. If you have  
9087 any questions, contact your PLAN coach at [phone number  
9088 here].”
- 9089 b. Be sure to clarify if that specific questionnaire needs to be filled  
9090 out by the parent or the child
- 9091 iv. Repeat for each questionnaire that needs to be completed
- 9092 d. For families who don’t have access to internet
- 9093 i. DD tasks, FNPA, and 24 Month Surveys can be done over the phone BEFORE the  
9094 assessment
- 9095 ii. Contact PC about mailing paper forms if necessary
- 9096 2. If the family needs a re-assent, re-consent, or an addendum:
- 9097 a. These will become forms in REDCap
- 9098 b. You will send them just like you send the surveys BEFORE the assessment
- 9099 c. In the subject line, use: “PLAN with Families Consent form for [Name of participant]”
- 9100 d. If they do not complete, the blinded assessor will have to go over them with the family  
9101 during the assessment
- 9102 i. They will have to send the REDCap form at beginning of assessment and check  
9103 to see if it is finished before they end the call.
- 9104 3. Payment
- 9105 a. Site specific payment procedures
- 9106 i. UB: PC will send a check via certified mail within 2-3 days of the assessment.
- 9107 1. There will be a receipt mailed with the check, please have the family  
9108 sign this receipt and text the PLAN or measurement coach a picture of  
9109 their signature.
- 9110 2. Follow-up with the family 1 week from the mailing date if a receipt  
9111 picture has not been submitted.
- 9112 ii. WU: PC will mail a VISA gift card or email an Amazon e-gift card within 2-3 days  
9113 of the assessment
- 9114 iii. UR: PC will mail gift cards or other site determined method.

- 9115 iv. NCH: PP will be credited the money to the ClinCard within 2-3 days of the  
9116 assessment.
- 9117 b. 6 month measurements:
- 9118 i. At the end of the measurement, assure the participating parent that they  
9119 earned \$25
- 9120 ii. Inform family that they have earned the chance to be entered for a \$50 raffle at  
9121 the end of the study.
- 9122 c. 12 and 18 month measurements:
- 9123 i. At the end of the measurement assure the participating parent that they earned  
9124 \$50
- 9125 ii. Inform family that they have earned the chance to be entered for a \$50 raffle at  
9126 the end of the study.
- 9127 d. 24 month measurements:
- 9128 i. At the end of the measurement assure the participating parent that they earned  
9129 \$100
- 9130 ii. There will be a receipt mailed with the check, please have the family sign this  
9131 receipt and text the PLAN or measurement coach a picture of their signature.
- 9132 1. Follow-up with the family 1 week from the mailing date if a receipt  
9133 picture has not been submitted.
- 9134 iii. Measurement coach will need to contact site PC immediately following session  
9135 to notify them if family has won lottery or not so that check can be prepared if  
9136 needed
- 9137 e. Height quality control measurement:
- 9138 i. Families that participate in the second measurement will receive \$10.00  
9139 payment as specified above.
- 9140 4. 24 Month-specific procedures
- 9141 a. Inform family that they have earned the chance to be entered for a \$50 raffle.
- 9142 i. The blinded assessor will pull from the ticket bag via video conference for the  
9143 family.
- 9144 ii. If the family wins the raffle, notify the Coach and the PC so they can adjust the  
9145 payment.
- 9146 b. PLAN Coach sends the family the link to 24-month video to describe PLAN website and  
9147 handouts.
- 9148 i. Sent during the assessment, but after the blinded assessor leaves the call  
9149 ii. Sent via email
- 9150 iii. Include the PC's contact information
- 9151 Thank the family for their participation.

9152 **Step 3: Measurement Coach Instructions for HEIGHT MEASUREMENTS**

- 9153 1. Confirm with family and/or coach that measurement is set for the scheduled date

- 9154 2. Contact family at the day and time of assessment  
9155 a. If the family has a Webcam and Internet Access: use WebEx and/or Zoom  
9156 b. If they do not have a WebCam and Internet access: use phone to call the family and  
9157 ensure they have a camera  
9158 3. Guide family through height and weight procedure, giving them feedback, answering any  
9159 questions, making notes, and voicing corrections if they are needed  
9160 a. Assume the family has NOT read the instruction sheet and will need to be walked  
9161 through the steps  
9162 b. Have them e-sign consent forms if they need to (see previous section)  
9163 c. Remind the family about which members need to be measured  
9164 d. Reference “Measurement Coach Checklist” with all the necessary information  
9165 4. Have family report their measurements aloud, and write them on a blank paper  
9166 5. Measurement coach will confirm accurate values and write them down on “Height and Weight  
9167 form”  
9168 6. After the assessment, enter these values into REDCap as per normal protocol

9169 **Family Instructions for HEIGHT MEASUREMENTS**

9170 NOTE: Only children who enrolled in PLAN as participants need to have their heights measured. Parents  
9171 or legal guardians enrolled in PLAN should measure the children’s heights.

9172 Location: On a level, non-carpeted, flat surface (e.g. wood, concrete floor, tile) against a door

9173 Materials Needed:

- 9174 1. Carpenter’s square <https://www.homedepot.com/p/Empire-7-in-Polycast-Rafter-Square-296/100154430>  
9175  
9176 2. Metal measuring tape  
9177 3. Tape  
9178 4. Object of known height (ie participating parent, adult, yardstick)  
9179 5. Pencil or Pen  
9180 6. Piece of paper  
9181 7. Stool (especially if your child is taller than you)  
9182 8. Computer or phone with a web cam and internet access  
9183 1. If you do not have a web cam and/or internet access, have a camera present

9184 Procedure:

- 9185 1. First, you will practice taking a height measurement with the carpenter’s square and foldable  
9186 yardstick.  
9187 a. Tape the foldable yardstick against a door with the bottom on a level, flat floor and it  
9188 standing straight.  
9189 b. Place an object of known height against the foldable yardstick  
9190 c. Place the carpenter’s square on top of the person’s head or object,  
9191 i. Make sure one of the square’s flat edges is directly touching the door



- 9192                   ii. Make sure the object is standing straight up and not leaning, compare to edge  
9193                   of door.
- 9194           d. Check the height of the object with the bottom edge of the carpenter square  
9195           e. Remove the person or object  
9196           f. Tell your measurement coach the height of the object  
9197           g. Did your measurement match the known height of the object? if it did not to make  
9198           some adjustments and recheck.
- 9199   2. Now, you will measure your child. Make sure:  
9200       a. Your child's hair is let down (if possible)  
9201       b. Your child is not wearing shoes
- 9202   3. Have your child stand with their back against the door.  
9203   4. Tape a piece of paper on the door behind the foldable yardstick, around the center of the top of  
9204   their head.  
9205   5. Have them put their heels as close to the door as possible  
9206   6. Have them touch their heels together so they are standing in a V-shape  
9207   7. Have your child look straight ahead at you  
9208   8. Find your child's **mastoid process** (a bony knob behind their ears – see picture)  
9209   9. Place your pointer and middle fingers of both hands on your child's mastoid processes  
9210   10. Tell them, "On the count of three, take a deep breath, and I will lift your head up"  
9211   11. Count to three, and as they breath in, gently lift their head slightly upwards.  
9212   12. While they are holding their breath:  
9213       a. Make sure they are NOT on their tiptoes  
9214       b. Make sure their head is NOT tilted up or down  
9215       c. Place the carpenter's speed square on top of your child's head with the right angle  
9216       facing the wall and one flat side directly touching the wall  
9217       d. Make a mark of their height on the paper
- 9218   13. Tell your child they can let go of their breath and step away from the wall  
9219   14. Write the number "1" and your child's initials next to the mark  
9220   15. Report the height to the measurement coach  
9221   16. Repeat steps 2-15 to complete a second measurement  
9222       a. Mark the line on the piece of paper with a "2" and the child's initials to differentiate  
9223       from the first mark  
9224       b. If measurements 1 and 2 differ by more than 0.3 centimeters, the measurement coach  
9225       will ask you to take two more measurements.  
9226   17. Repeat steps 2-16 for additional siblings enrolled using a new piece of paper.

9227                   **Family Instructions for WEIGHT MEASUREMENTS**

9228   NOTE: All participants who are enrolled in PLAN—parents and children—should measure their weight.

9229   Location: On a level, non-carpeted, flat surface (e.g. wood, concrete floor)

9230   Materials Needed:

9231 1. PLAN weight scale

9232 Procedure:

9233 1. Before stepping on the scale, make sure:

9234 a. You remove shoes, any items in your pockets, and any heavy pieces of clothing or  
9235 jewelry, such as belts, hoodies, etc.

9236 b. You use the restroom beforehand

9237 2. Step on the scale

9238 a. Stand straight, in the middle of the scale, with feet shoulder-width apart, looking  
9239 straight ahead

9240 b. Make sure your child does not move on the scale, as that can affect the accuracy of the  
9241 measurement

9242 3. Once the weight has stabilized, step off the scale and write down the weight.

9243 4. Report the measurement to the measurement coach .

9244 5. Repeat steps 2-5 to get a second weight

9245 6. If measurements 1 and 2 differ by more than 0.25 pounds, your measurement coach will tell you  
9246 to take two more weights.

9247 7. Repeat steps 2-7 for every PLAN participant

9248

9249 **Step 4: Wrapping up Assessment**

9250 1. PLAN Coach:

9251 a. Thank the family and praise their efforts.

9252 b. Identify families that will participate in the quality measurement of height to take a  
9253 second measurement at a later date, confirm date and time. Follow protocol for remote  
9254 height.

9255 c. Instruct family to make confirm they received payment

9256 d. Contact PC with payment amount and family address

9257 e. Update site-specific tracking forms

9258 2. Measurement Coach:

9259 a. Enter data into REDCap

9260 i. Check email to see if you received the pictures of the measurements

9261 b. Contact PLAN Coach to notify that assessment was completed (or not completed)

9262

9263

9264

9265

9266

9267

9268

9269

9270

### Participant Instructions on Opening and Signing Consent Form

9271 **Steps:**

- 9272 1. Coach and participant will discuss how the consent form will be sent.
  - 9273 a. I.e. Email
    - 9274 i. Confirm email is correct and working
- 9275 2. Coach will send the consent form to the participant and confirm that the participant has indeed  
9276 received it.
- 9277 3. Participant will open the email and download the document.
  - 9278 a. Once the form is downloaded, participant will open the form
  - 9279 b. The document will open up as a tab
  - 9280 c. This tab CANNOT be used to sign the form
    - 9281 i. Steps on how to sign the form will be below
- 9282 4. Participant will close the tab and instead open the consent form manually from the 'Downloads'  
9283 folder on the computer
- 9284 5. To access the 'Downloads' folder:
  - 9285 a. Open up 'Start' menu option
  - 9286 b. Search for 'File Explorer'
    - 9287 i. This icon looks like a vanilla folder
  - 9288 c. Open the 'File Explorer'
  - 9289 d. On the left hand side should be a tab labeled as 'Quick access'
    - 9290 i. A drop down menu should be below 'Quick access'
  - 9291 e. Select the 'Downloads' option
  - 9292 f. You are now in the 'Downloads' folder
- 9293 6. Once in the 'Downloads' folder
  - 9294 a. Find the name of the consent form, labeled as '(INSERT CONSENT FORM NAME HERE)'
  - 9295 b. Open the consent form, it should automatically open up with 'Adobe'
- 9296 7. To complete the consent form:
  - 9297 a. There will be blue squares and rectangles which are interactive
  - 9298 b. Participant will click on the blue rectangle below 'Participant Name' and type their name
  - 9299 c. Participant will then select a box on whether they consent or do not consent
    - 9300 i. These boxes will pop-up a check mark when clicked on
  - 9301 d. Participant will then 'Date' the form before signing it
    - 9302 i. Just like the 'Name' section of the form, click the box and write the date in

- 9303                   ii.    Format the date in as MM/DD/YYYY
- 9304                         1.   Click the 'Enter' key on your keyboard
- 9305                         2.   The program will then change the format of the date, this is fine
- 9306                   e.   Participant will then sign the document by clicking on the blue box below 'Signature'
- 9307   8.   To sign the document is a little complicated to be sure to follow the steps below:
- 9308                   a.   Click on the blue box below 'Signature'
- 9309                   b.   Another window will appear on the form asking about a Digital ID
- 9310                         i.   If you already have one preset with your correct name, you may use it and and
- 9311                                 click the 'Continue' button
- 9312                                 1.   Then click 'Sign' and move on to step 9
- 9313                   ii.   If you need to create a Digital ID, the steps are:
- 9314                         1.   There may be a button which says 'Configure New Digital ID' at the
- 9315                                 bottom of the window Click this button to go to a screen which asks you
- 9316                                 to 'Select the type of Digital ID'
- 9317                                 a.   If there is no 'Configure New Digital ID' button, but instead asks
- 9318   you to 'Select the type of Digital ID' then this is the screen which
- 9319   you need to be on
- 9320                         2.   'Select the type of Digital ID' window is what you want to see
- 9321                                 a.   There should be a list of options
- 9322                                 b.   Select the option which says 'Create a new Digital ID'
- 9323                                 c.   Then click 'Continue'
- 9324                         3.   A new window will appear labeled 'Select the Destination of the New
- 9325                                 Digital ID'
- 9326                                 a.   Two options will be there
- 9327   i.   First option will be to save your Digital ID to your
- 9328   computer
- 9329   ii.   Second option will be to save your Digital ID to the
- 9330   Windows Certificate Store
- 9331                                 b.   Either option is fine, which ever the participant prefers
- 9332   i.   PLAN Recommends to save the Digital ID to a file on
- 9333   your computer
- 9334   ii.   However, it is up to the participant to decide which
- 9335   option is best for them
- 9336                                 c.   Once the destination is selected, click 'Continue'
- 9337                         d.   'Create a self-signed Digital ID' window will appear
- 9338                                 i.   This window will ask for your name
- 9339   1.   First and Last is preferred
- 9340                                 ii.   The window will also ask for your email address
- 9341   1.   Preferably the email address you have
- 9342   registered with PLAN
- 9343                         iii.   These two pieces of information are the only ones that
- 9344   you need to provide, all else can be ignored

- 9345 iv. Click 'Continue' once you have filled this window out
- 9346 e. 'Save the self-signed Digital ID to a file' window will appear
- 9347 i. Here is where you would select a file on your computer
- 9348 where the Digital ID should be stored
- 9349 ii. Select the 'Browse Button'
- 9350 iii. And select a file
- 9351 iv. PLAN Recommends that you should select the
- 9352 'Documents' file as for convenience purposes
- 9353 1. However, it is up to the participant to decide
- 9354 where the Digital ID should be stored
- 9355 v. Once you have selected the location of the file, you will
- 9356 have to give a password for security purposes of your
- 9357 Digital ID
- 9358 1. The participant is responsible for choosing the
- 9359 password and remembering this password
- 9360 2. PLAN recommends you choose a password that
- 9361 only the participant knows and keeps the
- 9362 password a secret
- 9363 vi. Once the password is written and rewritten on the
- 9364 second box, click 'Save'
- 9365 4. You have now created your Digital ID and should see your Name on the
- 9366 window that pops up
- 9367 c. Select the option which has your name on it
- 9368 d. Then click 'Continue'
- 9369 e. A new window will appear asking you for your password that you have previously made
- 9370 i. First review that all the information is correct on this screen
- 9371 ii. Then type the password in
- 9372 iii. Click 'Sign'
- 9373 f. Once you have clicked the 'Sign' button a new window will appear asking you where the
- 9374 Consent Form should be saved to
- 9375 i. PLAN Recommends for the document to be saved in the 'Documents' tab which
- 9376 can be located on the left hand side of the window that pops up, for easy access
- 9377 ii. However, the participant is responsible to decide where the best location to
- 9378 save this document is
- 9379 g. Once you have decide the location, click the 'Enter' key on your keyboard
- 9380 h. Once you have done this, your signature should appear on the document and the
- 9381 document is complete
- 9382 9. The participant will now review the consent form to make sure everything is correct
- 9383 10. The participant will then save the entire file once more by:
- 9384 a. Click the 'File' tab in the top left of the window
- 9385 b. A drop menu will appear
- 9386 c. Select the 'Save' option

9387 d. Your document is not saved once again  
9388 11. The participant will now email the consent form to their coach

9389 If any problems arise during this process that the participant cannot solve, please contact your coach,  
9390 who will then proceed to help and fix the issue. The coach can also reach out to the tech specialist if  
9391 more assistance is needed. This process can be done through email or a phone call.

9392

9393 NEED TO ASSESS COSTS AND BUDGET

<b>EQUIPMENT</b>	<b>Equipment Cost</b>	<b>Shipping Cost</b>
Scale	25.00	TBD
Carpenters 90 degree Angle	8.00	TBD
Tape measure	5.00	TBD
Yard stick	10.00	TBD
Total	48.00	TBD

9394

9395  
9396  
9397  
9398  
9399  
9400

9401 **Delay of Gratification.** (Delay Discounting: Secondary Aim 2)

9402

9403 The following items are representative of the type of questions a participant may be asked to  
9404 answer in the delay of gratification computer task. The task is adaptive and adjusts the questions  
9405 based on participant responses, thus each participant will receive different questions.

9406

9407 Instructions: For each of the following choices, please **choose** which reward you would prefer: the  
9408 smaller reward at the time point listed, or the larger reward in the specified number of days. Please  
9409 carefully consider each of the choices.

9410

9411

1. Would you prefer	<b>\$49 today</b>	<input type="radio"/>	<b>\$60 in 89 days?</b>
2. Would you prefer	<b>\$47 today</b>	<input type="radio"/>	<b>\$50 in 160 days?</b>
3. Would you prefer	<b>\$54 today</b>	<input type="radio"/>	<b>\$80 in 30 days?</b>
4. Would you prefer	<b>\$27 today</b>	<input type="radio"/>	<b>\$50 in 21 days?</b>
5. Would you prefer	<b>\$41 today</b>	<input type="radio"/>	<b>\$75 in 20 days?</b>

9412

9413

9414

9415

9416

9417 **Parental Survey – Child Report.** (Secondary Aim 3)

9418

9419 *Instructions:* Please circle the best answer for the questions below.

9420

9421 1. It happens that my parent/caregiver promises me a reward and then forgets about it.

9422

9423 **Never or Very Rarely**                      **Sometimes**                      **Often**                      **Always or Almost Always**

9424

9425

9426 2. My parent/caregiver promises to get something for me, but then [s]he doesn't do it.

9427

9428 **Never or Very Rarely**                      **Sometimes**                      **Often**                      **Always or Almost Always**

9429

9430

9431 3. It happens that my parent/caregiver announces something (e.g., a family excursion, a visit at the  
9432 zoo), and then it falls through.

9433

9434 **Never or Very Rarely**                      **Sometimes**                      **Often**                      **Always or Almost Always**

9435

9436

9437

9438

9439 *Scoring:* Items are scored from 1 (never or very rarely) to 4 (always or almost always) and summed to  
9440 create a total score.

9441

9442



9443  
 9444  
 9445  
 9446  
 9447  
 9448

**FAMILY NUTRITION & PHYSICAL ACTIVITY (FNPA)**

Administered at Baseline, 12 month, and 24 month assessments (*DSMB approved protocol addenda, 9.29.19*).

For Each Question, please select the answer that best represents your child/family

Question	Almost Never	Sometimes	Usually	Almost Always
1. My child eats breakfast...				
2. Our family eats meals together.....				
3. Our family eats while watching TV...				
4. Our family eats fast food...				
5. Our family uses microwave or ready to eat foods...				
6. My child eats fruits and vegetables at meals or snacks...				
7. My child drinks soda pop or sugary drinks...				
8. My child drinks low fat milk at meals or snacks...				
9. Our family limits eating of chips, cookies, and candy...				
10. Our family uses candy as reward for good behavior...				
11. My child spends 2 hours on TV/games/computer per day or less...				

12. Our family limits the amount of TV our child watches...				
13. Our family allows our child to watch TV in their bedroom...				
14. Our family provides opportunities for physical activity...				
15. Our family encourages our child to be active every day...				
16. Our family finds ways to be physically active together...				
17. My child does physical activity during his/her free time...				
18. My child is enrolled in sports or activities with a coach or leader...				
19. Our family has a daily routine for our child's bedtime...				
20. My child gets 9 hours of sleep a night...				

9449

9450 Scoring: Add up scores for each scale (items should be scored 1, 2, 3, 4 from left to right except  
 9451 for items that are reverse coded (3, 4, 5, 7, 10, and 13), These should be scored 4, 3, 2, 1 from  
 9452 left to right. See back for Feedback.

9453	Family Meal Patterns	Item 1	_____	+	Item 2	_____	=	_____
9454	Family Eating Habits	Item 3	_____	+	Item 4	_____	=	_____
9455	Food Choices	Item 5	_____	+	Item 6	_____	=	_____
9456	Beverage Choices	Item 7	_____	+	Item 8	_____	=	_____
9457	Restriction / Reward	Item 9	_____	+	Item 10	_____	=	_____
9458	Screen time behavior and monitoring	Item 11	_____	+	Item 12	_____	=	_____
9459	Healthy Environment	Item 13	_____	+	Item 14	_____	=	_____
9460	Family Activity Involvement	Item 15	_____	+	Item 16	_____	=	_____
9461	Child Activity Involvement	Item 17	_____	+	Item 18	_____	=	_____
9462	Family Routine	Item 19	_____	+	Item 20	_____	=	_____

9463 Total Score: \_\_\_\_\_

9464

9465 The FNPA Tool was developed at Iowa State University by Michelle Ihmels  
9466 (mihmels@iastate.edu) and Greg Welk (gwelk@iastate.edu) in partnership with the American  
9467 Dietetic Association.

9468

9469

9470 **Environmental Enrichment – Parent Report.** (Secondary Aim 3)

9471

9472 *Instructions:* The following questions ask you about your home environment and the surrounding areas.

9473 Please read the instructions for each section and answer the corresponding questions.

9474

9475 *About how long would it take to get from your home to the nearest businesses or facilities listed below if*

9476 *you walked to them? Please put only one check mark (v) for each business or facility.*

9477

	1–5 min	6-10 min	11-20 min	20-30 min	30+ min	Don't Know
<b>Example:</b> gas station			v			
<i>Environment</i>						
1. convenience/small grocery store						
2. supermarket						
3. hardware store						
4. fruit/vegetable market						
5. laundry/dry cleaners						
6. clothing store						
7. post office						
8. library						
9. elementary school						
10. other schools						
11. book store						
12. fast food restaurant						
13. coffee place						
14. bank/credit union						
15. non-fast food restaurant						
16. video store						
17. pharmacy/drug store						
18. salon/barber shop						
19. your job or school [check here _____ if not applicable]						
20. bus or train stop						
21. park						
22. recreation center						
23. gym or fitness facility						

9478

9479

9480 For each of the following food types, please tell us whether they are RIGHT NOW in your home,  
9481 immediately eatable, and about how much is there. (Answer yes if any of the items listed for each  
9482 question is in your home.)

9483

- 9484 • *In home* = the food can be in the kitchen, pantry, bedrooms, basement, garage, or other rooms

- 9485 ● Child can immediately eat = Is the food in a package/container that the child is able to open,
- 9486 and/or does it require preparation that the child can do on her/his own? (Regardless of whether
- 9487 or what rules may be about your child accessing food by himself/herself)
- 9488 ● How much = *A little* (enough for up to 2 people to eat at a snack/meal), *Some* (enough for 3-8
- 9489 people to eat at a snack/meal), *A lot* (more than a little or some)
- 9490

FOOD	In home?	Child can immedi
24. fresh bananas, oranges, pineapple, melons	Yes No	Yes No
25. fresh apples, grapes, celery, lettuce	Yes No	Yes No
26. potatoes, corn on the cob, whole tomato, frozen vegetables	Yes No	Yes No
27. "100% fruit juice"	Yes No	Yes No

9491 *For the following electronic devices, please write down the total number in each room that work, regardless*

If an electronic device has multiple functions, please list each function in the appropriate spot UNLESS it is a DVD/CD player under DVD. However, if you have a stereo that plays CDs, tapes, and the radio, count all three of

General room categories are listed at the end for you to add rooms that are specific to your home that may have the additional bedrooms, dining room, etc.). BR stands for Bedroom.

Electronics	Kitchen	Living Room	Parent's BR	Child's BR	BR #3:	BR #4:	Other Room: _____
28. TVs							
29. VCR (not portable)							
30. DVD player (not portable)							
31. Digital TV recorders (e.g., TiVo, ReplayTV)							
32. Radio (not portable) can include alarm clock							
33. CD player (not portable)							
34. Tape Player (not portable)							
35. Desktop computer <u>with</u> internet access							
36. Desktop computer <u>without</u> internet access							
37. Video game player (e.g., Playstation, xbox)							
38. Telephone (non-cell phone)							
39. Portable CD player							
40. Portable Tape Player							
41. Portable Radio Player							
42. Portable MP3 player (ex: iPod)							
43. Portable DVD player							
44. Hand held videogame player (e.g., Game boy, Sony PSP etc.)							
45. Laptop or portable computer							
<b>Total number of electronics in each room:</b>							

Which of the following things are **available and in useable condition** in your home or yard/common area? Do not include things that are buried in boxes (except toy boxes), buried in a closet, or in storage. **Please circle either “Not Available” or “Available,” and then indicate whether your child commonly uses the item(s)** If any of the items listed for each question is available, circle *available*.

Activities	Not Available	Available	If available, does your child commonly use this item?
46. bike	0	1	Yes No N/A
47. basketball hoop (includes child size or adult size)	0	1	Yes No N/A
48. jump rope	0	1	Yes No N/A
49. sports equipment (e.g., balls, racquets, bats, sticks)	0	1	Yes No N/A
50. swimming pool (including kiddie pool)	0	1	Yes No N/A
51. roller skates, skateboard, scooter	0	1	Yes No N/A
52. fixed play equipment (e.g., swing set, play house, jungle gym)	0	1	Yes No N/A
53. home aerobic equipment (e.g., treadmill, cycle, cross trainer, stepper, rower, workout video or audiotapes)	0	1	Yes No N/A
54. weight lifting equipment, toning devices (e.g., free weights, pull up bars, exercise balls, ankle weights, etc.)	0	1	Yes No N/A
55. water or snow equipment (e.g., skis, skates, canoe, row boat, surf board, boogie board, windsurf board, slip-n-slide, etc.)	0	1	Yes No N/A
56. yoga/exercise mats	0	1	Yes No N/A
57. exercise, play, or recreation room	0	1	Yes No N/A

58. trampoline	0	1	Yes No N/A
----------------	---	---	------------------

9492

59. How many books are in the home that are approximately at your child's reading level and that he/she has access to? (please check one)			
<input type="checkbox"/> 0 books <input type="checkbox"/> 1 - 10 books <input type="checkbox"/> 11 - 20 books <input type="checkbox"/> 21 - 30 books <input type="checkbox"/> 31 - 40 books <input type="checkbox"/> 41+			
Books	Never	Rarely	Sometimes
60. How often does a parent or caregiver in the home read to your child?			
61. How often does your child read for pleasure?			
62. How often does your family receive magazines and/or newspapers?			
63. How often does a parent or caregiver take your child to a museum?			
64. How often does a parent or caregiver take your child to a show or performance?			
65. Are there any musical instruments in the home that your child has access to?		Yes	No
66. Does your child receive lessons for singing or playing a musical instrument?		Yes	No
67. Does your child engage in any other regular hobbies or activities? If YES, please specify: _____		Yes	No

9493  
9494  
9495  
9496  
9497  
9498  
9499  
9500  
9501  
9502  
9503  
9504  
9505  
9506  
9507  
9508  
9509  
9510  
9511  
9512  
9513  
9514  
9515  
9516  
9517  
9518  
9519

*Scoring for Environmental Enrichment:*

**1-23: Land-Use Mix Diversity**

*Responses (item scoring):*

1-5 min (5)    6-10 min (4)    11-20 min (3)    20-30 min (2)    30+ min (1)    don't know (1)

*Additional scoring:* Tally the number of items ≤20-minute walk (either a '3', '4' or '5' response) and call this 'tally of close facilities')

**24-27: Fruit and Vegetable**

Each food item can be given a total of up to 5 points (range: 0-5). Points are given – then summed to get the total points for that food item – based on (a) presence in the home, (b) the child being able to immediately eat the food, and (c) amount present:

"In home?" – Yes=1, No=0

"Child can immediately eat?" – Yes=1, No=0

"How much is there?" – A little=1, Some=2, A lot=3

**28-45: Electronic Equipment**

OVERALL TOTAL = The total number of electronics in the household: Sum the "total" row for all rooms (i.e., kitchen, living room, etc.), including the total for "in house (not always in 1 room)." If "total" for a given room is blank, code that room as 0.

**46-58: Physical Activity**

Each physical activity item can be given a total of 0, 1, or 2 points. Points are given – then summed to get the total points for that physical activity equipment item – based on availability and whether the child uses the item:



9520  
 9521 “Which of the following things are available and in usable condition in your home or yard/common area?”  
 9522 Not available = 0, Available = 1  
 9523  
 9524 “If available, does your child commonly use this item?”  
 9525 Yes = 1  
 9526 No = 0  
 9527 N/A = 0  
 9528 **Total score** = sum of physical activity item points (items 41-53)  
 9529  
 9530 **59-67: Cognitive Stimulation**  
 9531 A total of 0-28 points may be awarded based on the presence of cognitively-stimulating items in the child’s home.  
 9532 These questions are scored on different scales, as follows:  
 9533  
 9534 **Item 59 (“How many books...”)**  
 9535 0 books = 0  
 9536 1-10 books = 1  
 9537 11-20 books = 2  
 9538 21-30 books = 3  
 9539 31-40 books = 4  
 9540 41 or more books = 5  
 9541  
 9542 **Items 60 – 64 (“How often does a parent...”)**  
 9543 Never = 0  
 9544 Rarely = 1  
 9545 Sometimes = 2  
 9546 Often = 3  
 9547 Very Often = 4  
 9548  
 9549 **Items 65 – 67**  
 9550 Yes = 1  
 9551 No = 0  
 9552 **Total score** = sum of points awarded for items 59-67  
 9553  
 9554 *Summary Score for Environmental Enrichment Questionnaire:* Sum all subscales to create a global score of non-  
 9555 snack food reinforcers available to the child.  
 9556  
 9557

9558 **Attitudes toward Evidence-Based Treatment.** (Exploratory Aim)

9559

9560 The following questions ask about your feelings about using new types of therapy, interventions, or  
 9561 treatments. Manualized therapy, treatment, or intervention refers to any intervention that has specific  
 9562 guidelines and/or components that are outlined in a manual and/or that are to be followed in a  
 9563 structured or predetermined way. **Indicate the extent to which you agree with each item using the**  
 9564 **scale shown below.**

9565

	0 Not at all	1 To a slight extent	3 To a moderate extent	4 To a great extent	5 To a very great extent
1. I like to use new types of therapy/interventions to help my clients.					
2. I am willing to try new types of therapy/interventions, even if I have to follow a treatment manual.					
3. I know better than academic researchers how to care for my clients.					
4. I am willing to use new and different types of therapy/interventions developed by researchers.					
5. Research-based treatments/interventions are not clinically useful.					
6. Clinical experience is more important than using manualized therapy/interventions.					
7. I would not use manualized therapy/interventions.					
8. I would try a new therapy/intervention, even if it were very different from what I am used to doing.					

For the following questions if you received training in a new therapy or intervention how likely would you be to adopt it if:

	0 Not at all	1 To a slight extent	3 To a moderate extent	4 To a great extent	5 To a very great extent
9. It was intuitively appealing?					
10. It made sense to you?					
11. It was required by your supervisor?					
12. It was required by the counseling center director?					
13. It was a state requirement?					
14. It was being used by colleagues who were happy with it?					
15. You felt you had enough training to use it correctly?					

9566

9567

9568

9569  
9570  
9571  
9572  
9573  
9574  
9575  
9576  
9577  
9578  
9579  
9580  
9581  
9582  
9583  
9584  
9585  
9586  
9587  
9588  
9589  
9590  
9591  
9592  
9593  
9594  
9595  
9596  
9597  
9598  
9599  
9600

*Scoring guide for Attitudes Towards Evidence-Based Treatment*

**Scoring the Subscales**

The score for each subscale is created by computing a total or mean score for the items that load on a given subscale. For example, Items 11, 12, and 13 constitute subscale 1.

**Subscales**

**Requirements**

Items: 11, 12, 13

**Appeal**

Items: 9, 10, 14, 15

**Openness**

Items: 1, 2, 4, 7

**Divergence**

Items: 3, 5, 6, 7

**Computing the Total Scale Score**

For the total score, all items from the Divergence subscale (Sub-scale 4) must be reverse scored before being used in computing the EBPAS total score.

9601 **Attributes of FBT.** (Exploratory Aim)

9602

9603 Given your knowledge and understanding of FBT, please respond to the following questions.

9604

9605 1. Using FBT in the clinic was more effective than the clinic's existing treatment method.

9606

9607 *Strongly Agree*

9608

9609

9610 2. The content of FBT is compatible with my personal beliefs and values.

9611

9612 *Strongly Agree*

9613

9614

9615 3. FBT is useful.

9616

9617 *Strongly Agree*

9618

9619

9620 4. FBT is credible.

9621

9622 *Strongly Agree*

9623

9624

9625 5. FBT is easy to administer in the practice setting.

9626

9627 *Strongly Agree*

9628

9629

9630 6. The content of FBT is clear.

9631

9632 *Strongly Agree*

9633

9634

9635 7. The content of FBT is relevant to my work as a medical treatment provider.

9636

9637 *Strongly Agree*

9638

9639

9640 8. FBT can be experimented without requiring an extensive involvement.

9641

9642 *Strongly Agree*

9643

9644

9645 9. FBT can be adapted or modified to suit the needs of the interventionist.

9646

9647 *Strongly Agree*

9648  
9649  
9650  
9651  
9652  
9653  
9654  
9655  
9656  
9657  
9658  
9659  
9660  
9661  
9662  
9663  
9664  
9665  
9666  
9667

10. The benefits of using FBT with my patients are obvious/visible.

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<i>Strongly Agree</i>				<i>Strongly Disagree</i>

11. The evidence regarding the impact of FBT is available.

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<i>Strongly Agree</i>				<i>Strongly Disagree</i>

*Scoring for Attributes of FBT:*

The scale is composed of five subscales: Relative advantage (1), compatibility (2-4), complexity (5-7), trialability (e.g., the potential to experiment with an innovation before implementing; 8-9), and observability (10-11). If the subscale has more than one item, the subscale score is created by computing a total or mean score for the items that load on a given subscale.

9668 **Intended Adoption.** (Exploratory Aim)

9669

9670 How likely is it that you will use this model of having a co-located interventionist to treat children who  
9671 are overweight/obese as a result of your experiences with an FBT interventionist within your practice?

9672

9673 0% \_\_\_\_\_ 100%

9674

9675

9676 *Scoring:* Physicians will place an X on the electronic line to signal their percentage likelihood.

9677

9678

9679

9680 **Family Demographics.** (Descriptor)

9681  
 9682 Please put an X in the appropriate box for your mother’s, your father’s, your spouse / partner’s, and  
 9683 your level of school completed and occupation. If the exact occupation is not listed, please put an X by  
 9684 the category that most closely matches the individual’s occupation, and if a parent is retired, please  
 9685 indicate their most recent occupation. If you grew up in a single parent home, mark only your one  
 9686 parent, and mark “N/A” for the other parent. If you are neither married nor partnered, mark “N/A” for  
 9687 Spouse/Partner.  
 9688

A. Level of School completed	Mother	Father	Spouse/Partner	You
(N/A)				
Less than 7 <sup>th</sup> grade				
Junior high / Middle school (up to 9 <sup>th</sup> grade)				
Partial high school (10 <sup>th</sup> or 11 <sup>th</sup> grade)				
High school graduate				
Partial college (at least one year)				
College education				
Graduate degree				

9689

B. Occupation	Mother	Father	Spouse/Partner	You
(N/A or stay-at-home parent)				
Day laborer, janitor, house cleaner, farm worker, food counter sales, food preparation worker, busboy.				
Garbage collector, short-order cook, cab driver, shoe sales, assembly line workers, masons, baggage porter.				
Painter, skilled construction trade, sales clerk, truck driver, cook, sales counter, or general office clerk.				
Automobile mechanic, typist, locksmith, farmer, carpenter, receptionist, construction laborer, hairdresser.				
Machinist, musician, bookkeeper, secretary, insurance sales, cabinet maker, personnel specialist, welder.				
Supervisor, librarian, aircraft mechanic, artist or artisan, electrician, administrator, military enlisted personnel, buyer.				
Nurse, skilled technician, medical technician, counselor, manager, police or fire personnel, financial manager, physical/occupational/speech therapist.				
Mechanical/nuclear/electrical engineer, educational administrator, veterinarian, military officer, elementary/high school/special education teacher.				
Physician, attorney, professor, chemical/aerospace engineer, judge, CEO, senior manager, public official, psychologist, pharmacist, accountant.				

9690

9691 **C. Please indicate whether your current household income is derived from: (circle all that apply)**

- 9692  
 9693 1. One income  
 9694 2. Two incomes  
 9695 3. Unemployment  
 9696 4. Public assistance  
 9697 5. Child support / alimony  
 9698 6. Other: \_\_\_\_\_

9699  
9700  
9701  
9702  
9703  
9704  
9705  
9706  
9707  
9708  
9709  
9710  
9711  
9712  
9713  
9714  
9715  
9716  
9717  
9718  
9719  
9720  
9721  
9722  
9723  
9724  
9725  
9726  
9727  
9728  
9729  
9730  
9731  
9732  
9733  
9734  
9735  
9736  
9737  
9738  
9739  
9740  
9741

**D. Please circle your current annual household income:**

- |                        |                           |                           |
|------------------------|---------------------------|---------------------------|
| 1. Under \$9,999       | 9. \$80,000 - \$89,999    | 17. \$170,000 - \$179,999 |
| 2. \$10,000 - \$19,999 | 10. \$90,000 - \$99,999   | 18. \$180,000 - \$189,999 |
| 3. \$20,000 - \$29,999 | 11. \$100,000 - \$119,999 | 19. \$190,000 - \$199,000 |
| 4. \$30,000 - \$39,999 | 12. \$120,000 - \$129,999 | 20. Over \$200,000        |
| 5. \$40,000 - \$49,999 | 13. \$130,000 - \$139,999 |                           |
| 6. \$50,000 - \$59,999 | 14. \$140,000 - \$149,999 |                           |
| 7. \$60,000 - \$69,999 | 15. \$150,000 - \$159,999 |                           |
| 8. \$70,000 - \$79,999 | 16. \$160,000 - \$169,999 |                           |

**E. Please circle the ethnic group(s) that YOU identify with (please circle all that apply):**

1. American Indian or Alaskan Native
2. Asian
3. Native Hawaiian or Other Pacific Islander
4. Black or African American, not of Hispanic origin
5. White or Caucasian, not of Hispanic origin
6. Hispanic or Latino
7. Other (please specify): \_\_\_\_\_

**F. Please circle the ethnic group(s) that your CHILD most identifies with (please circle all that apply):**

1. American Indian or Alaskan Native
2. Asian
3. Native Hawaiian or Other Pacific Islander
4. Black or African American, not of Hispanic origin
5. White or Caucasian, not of Hispanic origin
6. Hispanic or Latino
7. Other (please specify): \_\_\_\_\_

**G. Think of this ladder as representing where people stand in the United States.**

At the **top** of the ladder are the people who are the best off—those who have the most money, the most education, and the most respected jobs. At the **bottom** are the people who are the worst off—who have the least money, least education, and the least respected jobs or no job. The higher up you are on this ladder, the closer you are to the people at the very top; the lower you are, the closer you are to the people at the very bottom.

**Where would you place yourself on this ladder?**

Please place a large "X" on the rung where you think you stand at this time in your life, relative to other people in the United States.



9742 *Scoring guide for Participant Demographics:*

9743

9744 **Parts A and B:**

9745 The parent indicates level of school completed by their Mother, their Father, their Spouse / Partner, and  
 9746 themselves. If the parent grew up in a single-parent home, they only provide information for their one parent. If  
 9747 the parent is not married and does not have a partner, they do not provide information on a spouse. If they are a  
 9748 full-time student, they only circle scores for their parents. Point values are assigned depending on the level of  
 9749 school completed for each person:

9750

Level of School Completed	Mother	Father	Spouse	You
Less than 7 <sup>th</sup> grade	3	3	3	3
Junior high / Middle school (9 <sup>th</sup> grade)	6	6	6	6
Partial high school (10 <sup>th</sup> or 11 <sup>th</sup> grade)	9	9	9	9
High school graduate	12	12	12	12
Partial college (at least one year)	15	15	15	15
College education	18	18	18	18
Graduate degree	21	21	21	21

9751

9752 The parent indicates the occupation for their Mother, their Father, their Spouse / Partner, and themselves. If the  
 9753 parent grew up in a single-parent home, they only provide information for their one parent. If the parent is not  
 9754 married and does not have a partner, they do not provide information on a spouse. If they were a full-time  
 9755 student, they only circle scores for their parents. If a parent is retired, they use their most recent occupation. Point  
 9756 values are assigned depending on the occupation for each person:

9757

Occupation	Mother	Father	Spouse	You
Day laborer, janitor, house cleaner, farm worker, food counter sales, food preparation worker, busboy.	5	5	5	5
Garbage collector, short-order cook, cab driver, shoe sales, assembly line workers, masons, baggage porter.	10	10	10	10
Painter, skilled construction trade, sales clerk, truck driver, cook, sales counter or general office clerk.	15	15	15	15
Automobile mechanic, typist, locksmith, farmer, carpenter, receptionist, construction laborer, hairdresser.	20	20	20	20
Machinist, musician, bookkeeper, secretary, insurance sales, cabinet maker, personnel specialist, welder.	25	25	25	25
Supervisor, librarian, aircraft mechanic, artist and artisan, electrician, administrator, military enlisted personnel, buyer.	30	30	30	30
Nurse, skilled technician, medical technician, counselor, manager, police and fire personnel, financial manager, physical, occupational, speech therapist.	35	35	35	35
Mechanical, nuclear, and electrical engineer, educational administrator, veterinarian, military officer, elementary, high school and special education teacher.	40	40	40	40
Physician, attorney, professor, chemical and aerospace engineer, judge, CEO, senior manager, public official, psychologist, pharmacist, accountant.	45	45	45	45

9758  
9759

**Level of School Completed**

1	Parents' score: If they grew up with both parents, add "Mother" + "Father" and divide by 2. If they grew up with one parent, enter that score to the right.	
2	If they are married or partnered, add "Spouse" + "You" and divide by 2. If they live alone/are not married/do not have a partner, enter the "You" score to the right. If they are a full-time student, leave this blank.	
3	Double the score from line 2. If they are a full-time student, leave this blank.	
4	If they are a full-time student, enter only their parents' score. Otherwise, add line 1 and line 3, then divide by 3 (three) for a <b>TOTAL EDUCATION</b> . <i>Note: Score should be between 3 and 21</i>	

9760  
9761

**Occupation Scoring**

1	If they grew up with both parents, add "Mother" + "Father" and divide by 2. If they grew up with one parent, enter that score to the right.	
2	If they are married or partnered, add "Spouse" + "You" and divide by 2. If they live alone/are not married/do not have a partner, enter the "You" score to the right. If they are a full-time student, leave this blank.	
3	Double the score from line 2. If they are a full-time student, leave this blank.	
4	If they are a full-time student, enter only their parents' score. Otherwise, add line 1 and line 3, then divide by 3 (three) for <b>TOTAL OCCUPATION</b> . <i>Note: Score should be between 5 and 45</i>	

9762  
9763

**TOTAL SES Score (A & B)**

9764 Add **TOTAL EDUCATION + TOTAL OCCUPATION**. *Note: Score should be between 8 and 66*

9765

**Parts C-F:**

9766 Individual stand-alone items

9767

9768

**Part G:**

9770 The ladder contains 10 rungs and responses will be scored based on location of the "X." The bottom rung is given the score of 1 and each subsequent rung progresses in numerical order until the top rung, which is given the score of 10.

9771

9772

9773

9774

9775

9776 **Participant Acceptability: Parent.** (Descriptor)

9777

9778 We are interested in your honest opinions regarding the services you have received through the study,  
9779 whether they are positive or negative. Please answer all questions.

9780

9781

9782 1. How would you rate the quality of service you received?

9783 4 3 2 1  
9784 Excellent Good Fair Poor

9785

9786

9787 2. Did you get the kind of service you wanted?

9788 1 2 3 4  
9789 No, definitely not No, not really Yes, generally Yes, definitely

9790

9791

9792 3. To what extent has our program met your needs?

9793 4 3 2 1  
9794 Almost all of my Most of my needs Only a few of my None of my needs  
9795 needs have been met have been met needs have been me have been met

9796

9797

9798 4. If a friend were in need of similar help, would you recommend the treatment to him/her?

9799 1 2 3 4  
9800 No, definitely not No, not really Yes, generally Yes, definitely

9801

9802

9803 5. How satisfied are you with the amount of help you received?

9804 1 2 3 4  
9805 Quite dissatisfied Indifferent or Mostly satisfied Very satisfied  
9806 Mildly dissatisfied

9807

9808

9809 6. Have the services you received helped you deal more effectively with your problems?

9810 4 3 2 1  
9811 Yes, they helped Yes, they helped No, they really No, they seemed to  
9812 a great deal somewhat didn't help make things worse

9813

9814

9815 7. In an overall, general sense, how satisfied are you with the service you received?

9816 1 2 3 4  
9817 Very satisfied Mostly satisfied Indifferent or Quite dissatisfied  
9818 Mildly dissatisfied

9819

9820 8. If you were to seek help again, would you use the treatment you received again?

9821 1 2 3 4  
9822 No, definitely not No, not really Yes, generally Yes, definitely

9823

9824

9825 9. I would follow through if my child was referred outside this clinic for childhood obesity

9826 treatment.

9827 1 2 3 4 5

9828 Strongly Agree Strongly Disagree

9829

9830

9831 10. I am comfortable having my child receive obesity treatment at the clinic.

9832 1 2 3 4 5

9833 Strongly Agree Strongly Disagree

9834

9835

9836 11. My child was treated the same as other people who get care at the clinic.

9837 1 2 3 4 5

9838 Strongly Agree Strongly Disagree

9839

9840

9841 12. I prefer my child to receive obesity treatment services at the location where he/she receives

9842 medical care.

9843 1 2 3 4 5

9844 Strongly Agree Strongly Disagree

9845

9846

9847 **Participant Acceptability: Child.** (Descriptor)

9848

9849 What do you think about the care we gave you? Was it good or bad? Tell us by answering all of the  
9850 questions below. Please be honest!

9851

9852 1. Did you like the care we gave you?

9853

9854 4 3 2 1  
9855 Very Good Good Bad Very Bad

9856

9857 2. Did you get the kind of care you wanted?

9858

9859 1 2 3 4  
9860 No, not at all No, not really Yes, sort of Yes, I really did

9861

9862 3. Did we help with all the things you wanted?

9863

9864 4 3 2 1  
9865 All of the things Most of the things Some of the things None of the things  
9866 I wanted I wanted I wanted I wanted

9867

9868 4. If a friend needed care like you did, would you tell them to see us?

9869

9870 1 2 3 4  
9871 No, not at all No, not really Yes, sort of Yes, I would

9872

9873 5. Were you happy with all of the kinds of help we gave you?

9874

9875 1 2 3 4  
9876 Very Happy Happy Kind of happy Kind of unhappy

9877

9878 6. Has the care we gave you helped with your problems?

9879

9880 4 3 2 1  
9881 Yes, it helped a lot Yes, it helped a little No, it didn't help No, it made it worse

9882

9883 7. How happy are you with the care we gave you?

9884

9885 1 2 3 4  
9886 Very Happy Happy Kind of happy Kind of unhappy

9887

9888 8. Would you want us to help you again if you needed it?

9889

9890 1 2 3 4  
9891 No, not at all No, not really Yes, sort of Yes, I would

9892

9893 **Provider Demographics.** (Descriptor)

9894  
9895 Please respond to the following questions. For the questions with space to mark your answer (e.g., place  
9896 an “X”), please mark all that apply. For any responses that you mark as “Other,” please write in your  
9897 response.

9898  
9899 1. What is your age? \_\_\_\_\_ years

9900  
9901 2. What is your race? (Check all that apply.)

9902  American Indian or Alaskan

9903  Asian or Asian American

9904  African American or Black

9905  Caucasian or White

9906  Native Hawaiian or Pacific Islander

9907  Other: \_\_\_\_\_

9908

9909 3. What is your ethnicity?

9910  Hispanic

9911  Non-Hispanic

9912

9913 4. What is your gender?

9914  Male

9915  Female

9916  Other: \_\_\_\_\_

9917

9918 5. What is your highest degree?

9919  MD

9920  NP

9921  PA

9922  DO

9923  Other: \_\_\_\_\_

9924

9925 6. What is your job title? \_\_\_\_\_

9926

9927 7. How many years have you worked at the clinic? \_\_\_\_\_

9928

9929 8. How many years have you been in practice? \_\_\_\_\_

9930

9931 9. What is your specialty? \_\_\_\_\_

9932

9933 10. Before your enrollment in this study:

9934

9935 a) Were you aware of the American Academy of Pediatrics Guidelines for Assessing Obesity?

9936 Yes

No

9937

9938 If yes, how did you learn about these guidelines?

9939

9940 b) Were you aware of Family-based Behavioral Weight Loss Treatment for Children with Obesity?

9941 Yes No

9942

9943 If yes, how did you learn about this treatment?

9944

9945 11. Have you had experience(s) with **weight-related counseling for obesity or behavioral intervention**  
9946 **for obesity (including weight control/weight management)**? If yes, what type of experience(s)?  
9947 (Check all that apply.)

9948

9949 \_\_\_ I have not had any experience with weight-related counseling or behavioral interventions for  
9950 obesity

9951

9952 \_\_\_ Yes, I have observed weight-related counseling or behavioral interventions for obesity

9953

9954 \_\_\_ Yes, I have delivered weight-related counseling or behavioral interventions for obesity

9955

9956 \_\_\_ Yes, I have received weight-related counseling or behavioral interventions for obesity

9957

9958 \_\_\_ Yes, other: \_\_\_\_\_

9959

9960

9961

9962 12. Have you had experience(s) with **other counseling or behavioral interventions (i.e., not related to**  
9963 **weight or obesity)**? If yes, what type of experience(s)? (Check all that apply.)

9964

9965 \_\_\_ I have not had any experience with counseling interventions or behavioral interventions

9966

9967 \_\_\_ Yes, I have observed counseling interventions or behavioral interventions for: \_\_\_\_\_

9968

9969

\_\_\_\_\_

9970

9971 \_\_\_ Yes, I have delivered counseling interventions or behavioral interventions for: \_\_\_\_\_

9972

9973

9974 \_\_\_ Yes, I have received counseling interventions or behavioral interventions for: \_\_\_\_\_

9975

9976

9977

9978 \_\_\_ Yes, other: \_\_\_\_\_

9979

9980

9981

9982

9983

9984

	<b>At well child visits, I (check all that apply):</b>
	Accurately measure height and weight of child
	<ul style="list-style-type: none"> <li>○ Calculate BMI</li> <li>○ Plot BMI on BMI growth chart</li> <li>○ Make a weight category diagnosis using BMI percentile</li> </ul>
	Define BMI and explain consequences of high BMI to families
	Perform a thorough physical examination
	<ul style="list-style-type: none"> <li>○ Measure blood pressure</li> <li>○ Order lab tests</li> </ul>
	Take a family history, including:
	<ul style="list-style-type: none"> <li>○ Obesity</li> <li>○ Type 2 diabetes</li> <li>○ Cardiovascular disease</li> <li>○ Early deaths from heart disease or stroke</li> </ul>
	Assess diet and physical activity behaviors
	<ul style="list-style-type: none"> <li>○ Sugar-sweetened beverages</li> <li>○ Servings of fruits and vegetables per day</li> <li>○ Daily eating patterns (e.g., consumption of breakfast, portion sizes, family meals)</li> <li>○ Frequency of fast food or restaurant eating</li> <li>○ Amount of moderate to vigorous physical activity per day</li> <li>○ Screen time</li> </ul>
	Provide positive feedback for behavior(s) in optimal range
	<ul style="list-style-type: none"> <li>○ Elicit response to feedback</li> <li>○ Reflect/probe</li> </ul>
	Provide neutral feedback for behavior(s) not in optimal range
	<ul style="list-style-type: none"> <li>○ Elicit response to feedback</li> <li>○ Reflect/probe</li> </ul>
	Query which, if any, of the behaviors the family may be interested in changing or which might be easiest to change
	Agree on a target behavior
	Assess readiness to change
	Assess self-efficacy to change
	Collaborate possible next steps to change
	Develop and write a plan for change
	Summarize change plan and provide positive feedback
	Offer referral to a more intensive behavioral weight management intervention if necessary



	Agree to follow up within a certain amount of time (e.g., 6 months from today)
--	--

987  
988  
989

24 Month Survey – Parent (DSMB approved protocol addenda, 9.29.19).

Date: \_\_\_\_\_

1. Which site are you at? *\*this is required for branching logic for the next question\**
  - a. Buffalo
  - b. Rochester
  - c. Columbus
  - d. St. Louis
2. Who was your most recent Coach? *\* list of each site’s Coaches will appear with a “Don’t Know” option \**
3. Were you ever assigned another Coach?
  - a. Yes
  - b. No
4. Who else was your Coach? *\* list of each site’s Coaches will appear with a “Don’t Know” option \**

For the following questions, please CIRCLE the number that matches how much you agree with each statement.

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
5. This program changed the healthy habits of my family members who were not enrolled.	1	2	3	4	5
6. If a friend were in need of similar help, I would recommend this program to him/her.	1	2	3	4	5
7. This program has met my needs.	1	2	3	4	5

Some people have made the following statements about their food situation. Please answer whether the statements were OFTEN, SOMETIMES, or NEVER true for you and your household in the last 12 months.

8. Within the past 12 months, you worried that your food would run out before you got money to buy more.
  - Often true
  - Sometimes true
  - Never true
  - Don’t know, Refuse
9. Within the past 12 months, the food you bought just didn't last and you didn't have money to get more.
  - Often true
  - Sometimes true
  - Never true
  - Don’t know, Refuse

The following are behaviors that people may or may not use to support their healthy lifestyle. For each of the following behaviors:

Please choose how often YOU use them on a scale from Never to Daily:

Never	Yearly	Monthly	Weekly	Daily
0	1	2	3	4

Please choose how helpful YOU find them on a scale from Slightly Helpful to Very Helpful:

N/A	Slightly Helpful	Somewhat Helpful	Moderately Helpful	Very Helpful
-----	------------------	------------------	--------------------	--------------



- 0054 d. All of the above
- 0055 34. Aerobic exercises (moderate to intense physical activity) does not burn a lot of calories and is not good for weight  
0056 loss.
- 0057 a. True
- 0058 b. False
- 0059 35. Once your child has learned a new behavior, you can slowly decrease the amount of praise for that behavior.
- 0060 a. True
- 0061 b. False
- 0062 36. Which of the following methods can be used to remove distractions when eating?
- 0063 a. Eat when sitting down
- 0064 b. Eat in the same place
- 0065 c. Turn the television and laptop off
- 0066 d. All of the above
- 0067 37. When you give children a choice about an activity, they are more likely to enjoy that activity.
- 0068 a. True
- 0069 b. False
- 0070 38. Which of the following is a way to shop healthy on a budget?
- 0071 a. Meal planning
- 0072 b. Making a grocery list
- 0073 c. Using leftovers
- 0074 d. All of the above
- 0075 39. Which of the following are examples of activities that only burn limited calories (RED activities)?
- 0076 a. Sending text messages
- 0077 b. Watching a movie on your tablet
- 0078 c. Sitting and playing a video game
- 0079 d. All of the above
- 0080 40. A good sleeping area includes all of the following EXCEPT:
- 0081 a. Comfort
- 0082 b. Low noise level
- 0083 c. Bright room lights
- 0084 d. No distractions
- 0085 41. The portion sizes in many restaurants will make up two or more meals.
- 0086 a. True
- 0087 b. False
- 0088 42. How can you decrease the chance of relatives giving your child high-calorie, low-nutrient foods like candy (RED  
0089 foods)?
- 0090 a. Give your child high-calorie, low-nutrient foods before they go over to a relative's house
- 0091 b. Threaten to ground your child if they accept any high-calorie, low-nutrient foods
- 0092 c. Give your relatives examples of non-food items that they can give your child
- 0093 d. Tell your child it's okay for them to eat high-calorie, low-nutrient foods because it is like they're on  
0094 vacation
- 0095 43. Which of the following will increase the chance of a person staying committed to a physical activity?
- 0096 a. Paying for an exercise class
- 0097 b. Buying new exercise clothes
- 0098 c. Buying new workout music
- 0099 d. Doing it with a buddy
- 0100 44. Parents can increase their child's concern about body shape by doing which of the following?
- 0101 a. Talking about their own concerns about their body shape in front of their children.
- 0102 b. Ignoring any concerns about their body shape they might have in front of their children.
- 0103 c. Downplaying their own concerns about their body shape in front of their children.

d. All of the above.

Is there anything about the program that you really liked or you thought worked really well for your family?

---

---

---

---

---

---

---

---

---

---

Is there anything about the program that you would change or would recommend for future programs that would make it work better for your family?

---

---

---

---

---

---

---

---

---

---

121

---

122

---

123

0124 24 Month Survey – Child (DSMB approved protocol addenda, 9.29.19).

0125 **Date:** \_\_\_\_\_

0126

0127 For these questions, please CIRCLE how much you agree with the sentence:

0128

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
45. This program helped my family members (like your other parent or your brother or sister) who were not a part of the program.	1	2	3	4	5
46. If a friend needed the same help as me, I would tell them to try the PLAN program.	1	2	3	4	5
47. This program helped me.	1	2	3	4	5

0129

For each of the following questions, please circle the best answer.

0130

- 0131 48. Avocados, marshmallows, and black olives are a part of which food group? 10158 52. Aerobic exercises (medium to intense activity) do not burn a lot of calories and are not good for weight loss. 10159
- 0132 a. Proteins. 10160 a. True
- 0133 b. Fats, Oils, and Sweets. 10161 b. False
- 0134 c. Condiments and Dressings. 10162
- 0135 49. Which of the following are examples of the lowest calorie foods with the most nutrition (GREEN foods)? 10163 53. The best rewards or reinforcers are:
- 0136 a. Green (non-starchy) vegetables. 10164 a. Something you want.
- 0137 b. Fruit. 10165 b. Not food, money, or sitting activities.
- 0138 c. Dairy. 10166 c. Special.
- 0139 d. Beans/legumes. 10167 54. All of the above. When you are eating, you should:
- 0140 50. Why is a food journal (Habit Book) important for weight loss and making healthy food choices? 10168 a. Watch television.
- 0141 a. It helps you really think about what you are eating. 10169 b. Play on your tablet.
- 0142 b. It helps you to track the foods you are having throughout the day. 10170 c. Just eat.
- 0143 c. It is not really that important for weight loss or healthy food choices. 10171 d. None of the above.
- 0144 d. A and B. 10172 e. All of the above.
- 0145 51. A good thing about planning ahead for meals is: 10173 55. You want to eat foods that are low in:
- 0146 a. Allowing time for you and your parent to prepare food. 10174 a. Fat.
- 0147 b. Having healthy meals already chosen. 10175 b. Fiber.
- 0148 c. Knowing the calorie content of meals. 10176 c. Protein.
- 0149 d. All of the above. 10177 d. Color.
- 0150 56. Instead of drinking soda, a healthier option is:
- 0151 a. Diet soda. 10178
- 0152 b. Water with fruit. 10179
- 0153 c. Juice. 10180
- 0154 d. Iced tea. 10181
- 0155 57. Which of the following are examples of activities that only burn limited calories (RED activities)? 10182
- 0156 a. Watching television. 10183
- 0157 10184 10185

- 10186 b. Watching a movie on your tablet. 10208
- 10187 c. Playing a video game while sitting. 10209
- 10188 d. All of the above 10210
- 10189 58. Why might fast food restaurants be unhealthy? 10211
- 10190 a. Fast food is high in calories. 10212
- 10191 b. Fast food is high in fat. 10213
- 10192 c. Fast food restaurants usually do not 10214
- 10193 offer a lot of healthy options. 10215
- 10194 d. All of the above. 10216
- 10195 10217
- 10196 10218
- 10197 59. A bedtime routine could include which of the 10219
- 10198 following? 10220
- 10199 a. A bath. 10221
- 10200 b. Reading a book. 10222
- 10201 c. Brushing teeth. 10223
- 10202 d. All of the above. 10224
- 10203 60. How could you tell your friends about your healthy 10225
- 10204 habits? 10226
- 10205 a. Give your friends examples of medium 10227
- 10206 to intense activity (GREEN physical 10228
- 10207 activity) that they can do with you. 10229
- 10230
- 10231
- b. Give your friends examples of low-  
calorie foods (GREEN foods) that they  
can eat every day.
- c. Tell them that you can only eat high-  
calorie foods (RED foods) when you are  
playing at their houses.
- d. Both A and B.
61. Which of the following is a benefit of planning  
physical activities to do with your friends during  
get-togethers?
- a. You can strengthen friendships with  
your healthy friends.
- b. It helps you and your friend to feel  
good.
- c. It makes it easier to make healthy  
activity choices.
- d. All of the above.
62. If you have a positive body image, you think which  
of the following?
- a. That your body is good.
- b. That your body is valuable.
- c. That you feel proud of what your body  
can do.
- d. All of the above.

10232  
10233  
10234  
10235  
10236  
10237  
10238  
10239  
10240  
10241  
10242  
10243  
10244  
10245  
10246  
10247  
10248  
10249  
10250  
10251  
10252

The following are behaviors that people may or may not use to support their healthy lifestyle. For each of the following behaviors:

**Please choose how often YOU use them on a scale from Never to Daily:**

<b>Never</b>	<b>Yearly</b>	<b>Monthly</b>	<b>Weekly</b>	<b>Daily</b>
0	1	2	3	4

**Please choose how helpful YOU find them on a scale from Slightly Helpful to Very Helpful:**

<b>N/A</b>	<b>Slightly Helpful</b>	<b>Somewhat Helpful</b>	<b>Moderately Helpful</b>	<b>Very Helpful</b>
0	1	2	3	4

If you do not use the behavior, you may write "0" for N/A in the helpfulness column.

	<b>How Often?</b>	<b>How</b>
--	-------------------	------------



63. Using a food journal where you write down what you ate every day (Habit Book)		
64. Writing down the number of Calories you eat		
65. Increasing the number of low-calorie, green, leafy foods you eat like spinach or kale (GREEN foods)		
66. Decreasing the number of high-calorie, low-nutrient foods you eat like candy or pizza (RED foods)		
67. Decreasing the number of high-calorie, low-nutrient drinks you drink like soda (RED drinks)		
68. Increasing your medium to intense physical activity like walking or biking (GREEN physical activite)		
69. Weighing yourself		
70. Getting praise from your parent		
71. Having a Daily Check-In with your parent about what you are eating		
72. Decreasing screen time		
73. Sleeping for 9-11 hours a night		
74. Getting rewards or points (reinforcers) for doing healthy behaviors		
75. Doing physical activity with your family		
76. Eating healthy with your friends		
77. Doing physical activity with your friends		
78. How helpful were the PLAN sessions for you?		
79. How helpful was the PLAN program for you?		

10253

10254

10255 Is there anything about the program that you really liked or you thought worked really well for your

10256 family?

10257 \_\_\_\_\_

10258 \_\_\_\_\_

10259 \_\_\_\_\_

10260 \_\_\_\_\_

10261 \_\_\_\_\_

10262 \_\_\_\_\_

10263 \_\_\_\_\_

10264

10265 Is there anything about the program that you would change, or would recommend for future programs

10266 that would make it work better for your family?

10267

---

10268

---

10269

---

10270

10271 **Coach Demographics Survey** *(This change was made on 7.25.19 prior to review and approval by the*  
10272 *DSMB, DSMB approved protocol addenda on 9.29.19).*

10273

10274 Please complete the survey below. Thank you!

10275

10276 Which Site are you from?

- 10277 ● Buffalo
- 10278 ● Columbus
- 10279 ● Rochester
- 10280 ● St Louis

10281

10282 Which Coach are you, A,B,C?

- 10283 ● A
- 10284 ● B
- 10285 ● C

10286

10287 What is your age? \_\_\_\_\_

10288

10289 How would you describe your race?

- 10290 ● Native American Indian or Alaskan
- 10291 ● Asian or Asian American
- 10292 ● African American or Black
- 10293 ● Caucasian or White
- 10294 ● Native Hawaiian or Pacific Islander
- 10295 ● Other or Multi-racial:
- 10296 ● Refused

10297 Please describe: \_\_\_\_\_

10298

10299 What is your ethnicity?

- 10300 ● Hispanic or Latina/o
- 10301 ● Non-Hispanic or Latina/o

10302

10303 What is your sex:

- 10304 ● Female
- 10305 ● Male
- 10306 ● Other
- 10307 ● Refused

10308

10309 What is your job title? \_\_\_\_\_

10310

10311

10312 **BEFORE YOUR ENROLLMENT AND PARTICIPATION IN THIS STUDY:**

10313

10314 Were you aware of the American Academy of Pediatrics Guidelines for Assessing Obesity?

10315       **A.** Yes

10316       **B.** No

10317

10318 If yes, how did you learn about these guidelines? \_\_\_\_\_

10319

10320 Were you aware of Family-Based Behavioral Weight Loss Treatment for Children with Obesity?

10321       • Yes

10322       • No

10323

10324 If yes, how did you learn about this treatment? \_\_\_\_\_

10325

10326 Have you had experience(s) with weight-related counseling or behavioral intervention for  
10327 obesity (including weight control or weight management)?

10328       • Yes

10329       • No

10330

10331 If yes, what type of experience(s)? Check all that apply.

10332       • Yes, I have observed weight-related counseling or behavioral interventions for obesity.

10333       • Yes, I have delivered weight-related counseling or behavioral interventions for obesity.

10334       • Yes, I have received weight-related counseling or behavioral interventions for obesity.

10335       • Yes, other, please describe:

10336 Other, please describe:

10337 \_\_\_\_\_

10338 Have you had experience(s) with other counseling or behavioral interventions (i.e., not related  
10339 to weight gain or obesity)?

10340       • Yes

10341       • No

10342

10343 What type of experience(s) have you had with other counseling or behavioral interventions  
10344 (i.e., not related to weight gain or obesity)? Check all that apply:

10345       • Yes, I have observed counseling interventions or behavioral interventions.

10346       • Yes, I have delivered counseling interventions or behavioral interventions.

10347       • Yes, I have received counseling interventions or behavioral interventions.

10348       • Yes, Other, please describe.

10349

10350 Please describe the type of experience you have:

10351 \_\_\_\_\_

10352

10353

10354 **Coach Treatment Knowledge** (This change was made on 7.25.19 prior to review and approval by the  
10355 DSMB, DSMB approved protocol addenda on 9.29.19).

10356

10357 Please complete the survey below. Thank you!

10358

10359 For a child, overweight is defined as \_\_\_\_ for age and sex.

10360 A. Weight-for-height ratio >85th percentile

10361 B. Weight-for-height ratio >99th percentile

10362 C. Body mass index (BMI) percentile of 85th to 94th

10363 D. BMI > 90th percentile

10364

10365 For a child, obesity is defined as \_\_\_\_\_ for age and sex.

10366 A. Weight-for-height ratio >95th percentile

10367 B. Weight-for-height ratio >99th percentile

10368 C. BMI >99th percentile

10369 D. BMI > 95th percentile

10370

10371 At what age should BMI begin being calculated, and how often should BMI be calculated?

10372 A. At age 2, every year

10373 B. At age 2, every well-child visit

10374 C. Overweight or obese children, every other year

10375 D. All children every other year

10376

10377 What are the maximum recommended weight loss targets for obese children and adolescents?

10378 A. Weight loss should not exceed 1 lb. per month in children 2-11 years or 3 lbs. per  
10379 week in older children and adolescents.

10380 B. Weight loss not to exceed .5 lb. per month in children 2-11 years or 1 lb. per week in  
10381 older children and adolescents

10382 C. Weight loss not to exceed 1 lb. per month in children 2-11 years or 2 lbs. per week in  
10383 older children and adolescents.

10384 D. Weight loss not to exceed .5 lb. per month in children 2-11 or 2 lbs. per month in  
10385 older children and adolescents.

10386

10387 23) There are several recommendations for assessing obesity. Calculating and plotting BMI is  
10388 one of them. Which of the following are the other recommendations for assessing obesity?

10389 I. Assess medical risk, including patient history, parental obesity, family history, and  
10390 physical exam and review of systems.

10391 II. Assess psychological risk, including depression, anxiety, and eating disorders

10392 III. Assess behavior risk, including sedentary time, eating, physical activity, and home  
10393 environment

10394 IV. Assess attitudes, including family and patient concern, and motivation.

10395 A. I, III, and IV

10396 B. All four

10397 C. I and III

10398 D. I, II, and III

10399

10400 24) For children 2 and older, which of the following are appropriate recommendations for what  
10401 children should be eating, drinking, and doing each day?

10402 A. 5 or more fruits and vegetables, 1 hour or less of recreational screen time, 30  
10403 minutes or more of physical activity

10404 B. 6 or more fruits and vegetables, 2 hours or less of recreational screen time, 90  
10405 minutes or more of physical activity, 0 sugary drinks

10406 C. 5 or more fruits and vegetables, 2 hours or less of recreational screen time, 60  
10407 minutes or more of physical activity, 1 sugary drink or less

10408 D. 6 or more fruits and vegetables, 1 hour or less of recreational screen time, 60  
10409 minutes or more of physical activity, 1 sugary drink or less.

10410

10411 25) Imagine you that you are working with a family of an overweight child and have  
10412 recommended that the child lose a small amount of weight in the next few months (e.g., 4  
10413 pounds). If you only have time to set one goal, which of the following is the most likely to help  
10414 the child to lose weight and establish healthy habits?

10415 A. Identify healthy options the child can choose for lunch at school by discussing the  
10416 menu (i.e., reviewing what is posted online by the child's school).

10417 B. Determine which healthy foods the parents(s) will have available at home so that the  
10418 home is a "healthy zone" and increase the amount of foods consumed from home.

10419 C. Discuss physical activity options and increase walking to and from school or the bus  
10420 stop.

10421 D. Reduce the child's time spent watching movies or playing video games by  
10422 determining an appropriate amount of time and having the parent(s) set a timer.

10423

10424 26) If you are setting a goal with the parent(s) and child about increasing exercise to 3 times in  
10425 the next week, but they seem resistant to the goal (i.e., they are not "getting it"), what would  
10426 you do?

10427 A. Patiently describe the exercise goal and its importance in their larger goals for health,  
10428 focusing on the goal you have defined (3 times in the next week).

10429 B. Ask them what they are interested in setting as a goal for exercise, then encourage  
10430 them to follow through with their identified goal.

10431 C. Discuss their perceived barriers and collaboratively identify an appropriate goal that  
10432 will address their exercise behaviors.

10433 D. If they seem more willing to focus on a goal related to the child's eating patterns  
10434 instead, identify a goal for the family that will address eating behaviors rather than  
10435 activity behaviors.

10436

10437

10438

10439

10440

10441 **Coach Attributes of Evidence Based Treatment** *(This change was made on 7.25.19 prior to review*  
10442 *and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).*

10443

10444 Please complete the survey below. Thank you!

10445 The following questions ask about your feelings about using new types of therapy,  
10446 interventions or treatments. Manualized therapy, treatment, or intervention refers to any  
10447 intervention that has specific guidelines and/or components that are outlined in a manual  
10448 and/or that are to be followed in a structured or predetermined way.

10449

10450 **Indicate to the extent to which you agree with each item using the scale shown below.**

- 10451 1. Not at all  
10452 2. To a slight extent  
10453 3. To a moderate extent  
10454 4. To a great extent  
10455 5. To a very great extent

10456

10457 I like to use new types of therapy or interventions to help my clients.

- 10458 1. Not at all  
10459 2. To a slight extent  
10460 3. To a moderate extent  
10461 4. To a great extent  
10462 5. To a very great extent

10463

10464 I am willing to try new types of therapy or interventions, even if I have to follow a treatment  
10465 manual.

- 10466 1. Not at all  
10467 2. To a slight extent  
10468 3. To a moderate extent  
10469 4. To a great extent  
10470 5. To a very great extent

10471

10472 I know better than academic researchers how to care for my clients.

- 10473 1. Not at all  
10474 2. To a slight extent  
10475 3. To a moderate extent  
10476 4. To a great extent  
10477 5. To a very great extent

10478

10479 I am willing to use new and different types of therapy or interventions developed by  
10480 researchers.

- 10481 1. Not at all  
10482 2. To a slight extent  
10483 3. To a moderate extent  
10484 4. To a great extent

10485 5. To a very great extent

10486

10487 Research-based treatments/interventions are not clinically useful.

10488 1. Not at all

10489 2. To a slight extent

10490 3. To a moderate extent

10491 4. To a great extent

10492 5. To a very great extent

10493

10494 Clinical experience is more important than using manualized interventions.

10495 1. Not at all

10496 2. To a slight extent

10497 3. To a moderate extent

10498 4. To a great extent

10499 5. To a very great extent

10500

10501 I would not use manualized therapy/interventions.

10502 1. Not at all

10503 2. To a slight extent

10504 3. To a moderate extent

10505 4. To a great extent

10506 5. To a very great extent

10507

10508 I would try a new therapy or intervention, even if it were very different from what I am used to  
10509 doing.

10510 1. Not at all

10511 2. To a slight extent

10512 3. To a moderate extent

10513 4. To a great extent

10514 5. To a very great extent

10515

10516 **For the following questions if you received training in a new therapy or intervention how**

10517 **likely would you be to adopt it if:**

10518

10519 It was intuitively appealing?

10520 1. Not at all

10521 2. To a slight extent

10522 3. To a moderate extent

10523 4. To a great extent

10524 5. To a very great extent

10525

10526 It made sense to you?

10527 1. Not at all

10528 2. To a slight extent



- 10529 3. To a moderate extent
- 10530 4. To a great extent
- 10531 5. To a very great extent

10532

10533 It was required by your supervisor?

- 10534 1. Not at all
- 10535 2. To a slight extent
- 10536 3. To a moderate extent
- 10537 4. To a great extent
- 10538 5. To a very great extent

10539

10540 It was a state requirement?

- 10541 1. Not at all
- 10542 2. To a slight extent
- 10543 3. To a moderate extent
- 10544 4. To a great extent
- 10545 5. To a very great extent

10546

10547 It was being used by colleagues who were happy with it?

- 10548 1. Not at all
- 10549 2. To a slight extent
- 10550 3. To a moderate extent
- 10551 4. To a great extent
- 10552 5. To a very great extent

10553

10554 You felt you had enough training to use it correctly?

- 10555 1. Not at all
- 10556 2. To a slight extent
- 10557 3. To a moderate extent
- 10558 4. To a great extent
- 10559 5. To a very great extent

10560

10561

10562 **Coach Attributes Family Based Treatment (FBT)** *(This change was made on 7.25.19 prior to review*  
10563 *and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).*

10564

10565 Please complete the survey below. Thank you!

10566

10567 1. Strongly Agree

10568 2. Agree

10569 3. Neither Agree or Disagree

10570 4. Disagree

10571 5. Strongly Disagree

10572

10573 The content of FBT is compatible with my personal beliefs and values.

10574 1. Strongly Agree

10575 2. Agree

10576 3. Neither Agree or Disagree

10577 4. Disagree

10578 5. Strongly Disagree

10579

10580 FBT is useful.

10581 1. Strongly Agree

10582 2. Agree

10583 3. Neither Agree or Disagree

10584 4. Disagree

10585 5. Strongly Disagree

10586

10587 FBT is credible.

10588 1. Strongly Agree

10589 2. Agree

10590 3. Neither Agree or Disagree

10591 4. Disagree

10592 5. Strongly Disagree

10593

10594 FBT is easy to administer in the practice setting.

10595 1. Strongly Agree

10596 2. Agree

10597 3. Neither Agree or Disagree

10598 4. Disagree

10599 5. Strongly Disagree

10600

10601 The content of FBT is clear.

10602 1. Strongly Agree

10603 2. Agree

10604 3. Neither Agree or Disagree

10605 4. Disagree

- 10606 5. Strongly Disagree
- 10607
- 10608 FBT can be implemented without requiring an extensive training.
- 10609 1. Strongly Agree
- 10610 2. Agree
- 10611 3. Neither Agree or Disagree
- 10612 4. Disagree
- 10613 5. Strongly Disagree
- 10614
- 10615 FBT can be adapted or modified to suit the needs of the interventionist.
- 10616 1. Strongly Agree
- 10617 2. Agree
- 10618 3. Neither Agree or Disagree
- 10619 4. Disagree
- 10620 5. Strongly Disagree
- 10621
- 10622 The benefits of using FBT with my clients are obvious/visible.
- 10623 1. Strongly Agree
- 10624 2. Agree
- 10625 3. Neither Agree or Disagree
- 10626 4. Disagree
- 10627 5. Strongly Disagree
- 10628
- 10629 The evidence regarding the impact of FBT is available.
- 10630 1. Strongly Agree
- 10631 2. Agree
- 10632 3. Neither Agree or Disagree
- 10633 4. Disagree
- 10634 5. Strongly Disagree
- 10635
- 10636 The content of FBT is relevant to my work as a clinical treatment provider.
- 10637 1. Strongly Agree
- 10638 2. Agree
- 10639 3. Neither Agree or Disagree
- 10640 4. Disagree
- 10641 5. Strongly Disagree
- 10642
- 10643 **Coach consent**
- 10644 Please upload the .pdf file of the signed Coach consent.
- 10645
- 10646 Indicate yes or no that Coach consent is uploaded.
- 10647 • No
- 10648 • Yes
- 10649

10650 Why is the coach consent not uploaded? \_\_\_\_\_

10651

10652  
10653  
10654  
10655  
10656

**D. Additional Forms**

**Figure 1. Study Flow Chart**

**PLAN Adverse Event Questionnaire**

10657  
10658  
10659  
10660  
10661  
10662  
10663  
10664  
10665  
10666  
10667  
10668  
10669  
10670  
10671  
10672  
10673  
10674  
10675  
10676  
10677  
10678  
10679  
10680  
10681  
10682  
10683  
10684  
10685  
10686  
10687  
10688  
10689  
10690  
10691  
10692  
10693  
10694  
10695  
10696  
10697  
10698  
10699  
10700  
10701

During the time since your last visit on *(insert date of last major assessment)*, have you or your child:

1. Been hospitalized overnight?  
YES NO
2. Been to the emergency room or an urgent care clinic?  
YES NO
3. Been treated by a medical provider for illness or injury?  
YES NO
4. Had any injuries (e.g., sprained ankle or broken bone)?  
YES NO
5. Started any new medications or receive a change in dosage of a current medication?  
YES NO
6. Experience increased symptoms of a current illness or injury (If applicable)?  
YES NO
7. Seen a new counselor, psychologist, or psychiatrist?  
YES NO
8. Gone long periods (8 waking hours or more) without eating to control your weight?  
YES NO
9. Felt like you have lost control over your eating?  
YES NO
10. Thrown up after eating?  
YES NO
11. Taken laxatives or diet pills?  
YES NO
12. Felt particularly nervous, worried, or anxious?  
YES NO
13. Felt very sad or down? Or lost interest in things that you normally enjoy doing?  
YES NO

*(This change was made on 5.23.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18)*

10702  
10703

**ADVERSE EVENT FORM**

**The Effectiveness of Family-based Weight Loss Treatment Implemented in Primary Care**

Site: \_\_\_\_\_

Participant ID: \_\_\_\_\_

Has the participant had any adverse event?

Yes (Please list all AEs below)

No

10704

Severity	Relationship to Study Intervention	Action Taken Regarding Study Intervention			Outcome of AE		
1. Mild 2. Moderate 3. Severe	1. Definitely related 2. Possibly related 3. Not related	1. None 2. Discontinued			1. Resolved 2. AE still present – no treatment 3. AE still present – being treated 4. Residual effects present – not treated 5. Residual effects present – treated 6. Death (complete SAE form) 7. Unknown		
Adverse Event	Start Date	Stop Date	Severity	Relationship to Study Intervention	Action Taken	Outcome of AE	

10705  
10706  
10707

Signature of Clinical Site PI: \_\_\_\_\_

Date: \_\_\_\_\_

**SERIOUS ADVERSE EVENT FORM**

**The Effectiveness of Family-based Weight Loss Treatment Implemented in Primary Care**

Site: \_\_\_\_\_

Participant ID: \_\_\_\_\_

10708  
10709

1. SAE Onset Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

10710  
10711  
10712  
10713  
10714  
10715  
10716  
10717  
10718  
10719  
10720  
10721  
10722  
10723  
10724  
10725  
10726  
10727  
10728  
10729  
10730  
10731  
10732  
10733  
10734  
10735  
10736  
10737  
10738  
10739  
10740  
10741  
10742  
10743  
10744  
10745  
10746  
10747  
10748  
10749  
10750  
10751  
10752  
10753  
10754

2. SAE Stop Date: \_\_\_\_/\_\_\_\_/\_\_\_\_\_

3. Location of SAE:

4. Was this an unexpected adverse event?  Yes  No

5. Brief description of participant with no personal identifiers:  Male  Female  
Age\_\_\_\_\_

6. Brief description of SAE (attach description if more space needed):

\_\_\_\_\_

---

\_\_\_\_\_

---

\_\_\_\_\_

---

- Death  Congenital anomaly/birth defect  
 Life-threatening impairment  Required intervention to prevent permanent  
 Hospitalization – initial or prolonged  Other:  
\_\_\_\_\_
- Disability/incapacity

7. Intervention type:

- Medication or nutritional supplement  
 Behavioral/lifestyle  
 Device  
 Surgery

8. Relationship of SAE to intervention:

- Unrelated (clearly not related to intervention)  
 Possible (may be related to intervention)  
 Definite (clearly related to intervention)

9. Was study intervention discontinued due to event?  Yes  No

10. What other steps were taken to treat SAE?

\_\_\_\_\_

---

\_\_\_\_\_

---

\_\_\_\_\_

---

**Signature of Clinical Site PI:**

**Date:**