

1 Supplement 1: RESEARCH STRATEGY

2 A. Significance

3 A1. SIDS and sleep-related infant deaths: the current challenge.

4 This grant application is designed to address the purpose of FOA PAR-11-242 “to improve
5 the design and implementation, and effectiveness of preventive interventions for Sudden Infant
6 Death Syndrome (SIDS) and unintentional injury infant deaths associated with the sleep
7 environment.” We believe that this large randomized controlled trial (RCT) will provide evidence
8 of effectiveness of innovative, practical to disseminate interventions that address many of the
9 barriers to adherence to safe sleep recommendations in populations that are high risk for both
10 non-adherence and infant mortality. The existence of the currently active SAFE Infant Care
11 Practices study provides a timely and unique environment for testing interventions, and the
12 proposed SMART project fully takes advantage of the opportunities that this infrastructure
13 provides.

14 While the national Back to Sleep public health campaign was very successful, there are
15 still many barriers to changing parent behavior and to creating safe sleep environments for
16 infants, thus decreasing infant mortality. Adherence to supine sleep recommendations has
17 plateaued since 2001¹, at a level well below targets, especially among Blacks. Further, US
18 public health efforts have been less successful in changing behaviors with regard to soft
19 bedding and bedsharing in high-risk groups.² SIDS and other sleep-related infant deaths most
20 commonly occur in the presence of multiple unsafe sleep practices (such as prone/side
21 positioning, use of soft bedding, bedsharing, and pacifier nonuse).^{3,4} In addition, there are racial
22 disparities in all of these sleep-related deaths. Black infants are twice as likely to die from SIDS,
23 accidental suffocation and strangulation in bed, and undetermined deaths, compared to White
24 and Hispanic infants.^{5,6} While the increased mortality rate in Blacks is disturbing, it is also
25 concerning that the rate of unsafe sleep practices may be increasing in other racial/ethnic
26 groups as well. Rates of prone positioning, parent-infant bedsharing, and use of soft bedding
27 are higher among Blacks,^{2,7-18} infants with younger parents,^{12,14,16} and those of lower
28 educational and socioeconomic status.^{9,11,14,16}

29 As a team of investigators that has done much of the work nationally to understand and to
30 change parent behavior related to safe sleep practices in the US, we are aware of the barriers
31 to change and of the significant racial disparity that exists both in adherence and infant
32 mortality. Collectively we have studied infant care practices related to SIDS since 1992 through
33 an annual national telephone survey interviewing >15,000 caregivers,^{13,19,20} focus groups²¹⁻²⁶
34 and face-to-face interviews with at-risk mothers,^{27,28} and >15,000 interviews with follow-up
35 surveys at hospitals in Ohio and Massachusetts.¹⁴ Additionally, we have conducted the largest
36 case-control study of SIDS in the US (Chicago Infant Mortality Study).^{10,29,30} Our research
37 shows that recommendations³¹ for supine positioning, avoidance of soft bedding, pacifier use,
38 and room sharing without bedsharing may not resonate with many people, often because of
39 misconceptions or perceived barriers.²⁴ Specifically, we have learned the following:

- 40 • Mothers want their sleeping infants to be comfortable (i.e., sleep longer with fewer
41 awakenings) and are concerned that infants will be less comfortable on the back^{21,25,27} or on
42 a hard surface.²² This concern for infant comfort often results in prone positioning^{21,25,27} and
43 use of soft bedding.²²
- 44 • Mothers want their infants to be safe when they sleep. Those who worry about the danger of
45 choking when the infant is supine are less likely to place their infant supine.^{21,25,27} Those
46 who worry about falls and injury are more likely to use soft bedding.²² Those who bedshare
47 with their infants often do so because they believe that bedsharing is the best way to keep
48 their infant safe from any danger.²³
- 49 • Mothers often have conflicting feelings about pacifiers. Those who do not want to give their
50 baby pacifiers worry about nipple confusion, attachment to the pacifier, dental problems, and

germs. Mothers are also skeptical about the data that demonstrate that pacifier use is protective against SIDS.²⁶

- Advice about sleep position is important, especially advice from healthcare providers and advice from respected family members such as grandmothers.²⁵ Yet advice is often not given and if it is given, the advice is not always to place the infant on the back to sleep.^{21, 27}

In fact, we have shown that some of these barriers explain, at least in part, the racial disparity in adherence to safe sleep practices.¹⁹ Therefore, addressing these barriers would be expected to improve adherence and reduce the racial disparity in adherence. For that reason, we propose innovative interventions that both build upon our prior research and address these misperceptions and barriers bringing what we have learned about barriers and behaviors into practice through education.

A2. Social marketing techniques and culturally competent approaches in health promotion.

Social marketing is the use of commercial marketing concepts to design and implement programs to effect social change and is guided by the following principles: 1) the ultimate objective is to influence action; 2) action occurs when the target population perceives the benefits to outweigh the costs of the action; 3) programs are more effective when based on an understanding of the target population's perceptions; 4) target populations are rarely uniform in perceptions and/or responses to social marketing efforts; 5) there are always behaviors that compete with recommended behaviors, and these must be understood and addressed; and 6) because of constant changes in the "marketplace," there must be frequent monitoring in order to rapidly alter strategies as needed.³² Many health campaigns, however, have a one-size-fits-all approach, and thus are not necessarily effective in reaching all targeted audiences. Our goal is to develop educational messages for nursery staff and mothers that maximize social marketing techniques.

Furthermore, culturally and linguistically competent health promotion approaches respect cultural values, beliefs and practices of the target population; therefore, health promotion messages should ideally reflect these health beliefs and practices. This is often a challenge, as some of those beliefs and practices may be inconsistent with emerging knowledge of behaviors that support healthy outcomes. Culturally competent health promotion supports and honors those practices and beliefs that are protective or benign, and respectfully helps to identify and change those beliefs and practices that have a negative health impact.³³ Our interventions will incorporate techniques to favorably influence infant care practices, while respecting parental beliefs.

A3. Rationale for interventions during the postpartum hospital stay.

Studies, including our own, have shown that the postpartum hospital stay provides a unique venue for intervention for several reasons.^{34, 35} First, the birth of a child results in a change in the family dynamic that makes parents and family members more receptive to new information. Second, the postpartum hospital stay is a time when information can be delivered over several days and through multiple sources. Third, role modeling is a powerful tool and mothers often model what they learn in the nurseries.^{36, 37} Fourth, since mothers often receive visitors, education can be directed to family and friends. Our research shows that family and friends can play a key role in influencing infant care practices at home^{27, 28} Finally, since virtually all newborns are born in the hospital, the newborn nursery provides access to mothers who might otherwise be inaccessible for intervention.

Surprisingly, although the Back to Sleep Campaign targeted newborn nurseries for dissemination of its messages, actual practice varies tremendously.^{27, 38} One study found that only 30% of infants are placed supine by nursery staff, and 66% of nursery staff do not advise

100 parents to place their infants supine, largely because nursery staff share parental concerns that
101 newborns will choke in the supine position.^{35, 39} Our data among low-income mothers show that
102 only 42% reported receiving advice from nurses to place infants supine.²⁷ In our survey of low-
103 income mothers in 2008, 29% reported that their infant was **not** placed to sleep on the back by
104 nursery staff (Colson, unpublished data). We have shown that an intervention, focused on
105 nursery staff, that addresses concerns and emphasizes the importance of role modeling on
106 parental behavior is effective; parents report a significant increase in infants being placed on
107 their back by nursery staff, healthcare provider advice to place infants supine, and most
108 importantly, parents using the supine position at home.³⁵ Thus, a well-designed, nursery-based
109 intervention utilizing what we have learned, which would be practical to implement in hospitals
110 nationwide, could have broad implications for infant health and has the potential to help
111 decrease the racial disparity in post-neonatal deaths.

112 **A4. Rationale for mHealth (mobile health) interventions in high-risk groups.**

113 Most Americans now have internet access. In 2010, 59% of all Americans used the internet
114 to search for health information.^{40, 41} Internet access has become more affordable recently,
115 largely through cellular telephones and smartphones,⁴² and these devices have become the
116 primary means of internet access for lower SES groups.⁴³ The highest usage rates for cell
117 phones are among Blacks, adolescents, younger adults, and adults with lower SES and
118 educational levels.⁴⁴⁻⁴⁶ Black cell phone owners utilize their phones more frequently and for
119 more applications than White owners; they are more likely to use their cell phones for Internet
120 access, emails and viewing videos.⁴⁷ Younger persons, persons with lower educational status,
121 Blacks and Hispanics are more receptive to receiving messages related to appointment or
122 medication reminders and health-related education.⁴⁸ In particular, parents and pregnant
123 women, regardless of race or SES, have been receptive to receiving health-related messages
124 about their children.⁴⁹⁻⁵² Of note, of the first 523 SAFE study participants, 390 (75%) provided an
125 email address; among women who have completed the follow-up survey to date, 85% did so
126 online. Email is thus very promising as a conduit for health information. Furthermore, use of
127 mobile health (mHealth) technologies, [those that use mobile communication devices (e.g., cell
128 phones) to provide health services and information], results in increased behavior change,^{44, 53-55}
129 including positive impacts on immunization rates⁵⁶ and diabetes self-management.⁴⁵ Thus,
130 mHealth strategies are likely to be well-accepted and effective, particularly among minority and
131 low-income populations.

132 Most interventions using mHealth technologies have focused on automated message
133 systems using voice messaging and SMS technology, and most of these have used “push”
134 technology, in which target patients receive automated SMS or voice mail messages tailored to
135 their specific health care needs and/or personal preferences without a user-initiated request.^{56, 57}
136 We have chosen to use email rather than SMS or voice mail technology for our interventions.
137 Email can be accessed by many devices, including cell phones. Parents often prefer email for
138 receiving health-related messages and videos, because some phone services charge extra for
139 SMS or video⁵⁸ via SMS, while email video access is free. One study found that some potential
140 participants declined study participation because of the associated cost of receiving SMS
141 messages.⁵⁸ Streaming video that is embedded in an email message is technically easier than
142 embedding video in SMS, as video in the latter must be mobile-enhanced, and different phone
143 companies may use different mobile-enabling platforms. In addition, email messages can be
144 accessed asynchronously (at any time convenient for that individual) and can be easily stored
145 for future reference. Patients may perceive emails as less invasive than a phone call. Parents,
146 particularly young and minority parents, may be more responsive to health messages when
147 delivered by email than in person or by phone. It is more cost-effective for both the patient and
148 provider than face-to-face interventions, as it takes less time (including travel time) than an in-
149 person appointment and may be more practical for busy clinical settings. Customized email

150 messages can be tailored; personally tailored messages are more effective in changing health
151 behaviors than untailored messages.^{45, 59} Email messaging may also allow for a more
152 interactive, participatory process, which in turn may be more effective in promoting health
153 behavior changes.⁶⁰ Finally, the messages can be mass distributed to target audiences at little
154 additional cost.

155 A few studies investigating the effectiveness of using videos in patient education have
156 shown that patients receiving video education have improved understanding, knowledge, and
157 self-efficacy,^{61, 62} and are more likely to change behavior.^{63, 64} In addition, videos are considered
158 significantly more appealing to patients than written pamphlets.^{61, 62} Video may also be a more
159 effective means of providing health information to low-literate families. Thus, video technology
160 shows promise as an effective and appealing means of delivering health education.

161 In summary, our mHealth strategy is likely to be highly effective, because of its accessibility
162 and appeal to our target population (young adults). Our innovative strategy will use mHealth to
163 build upon the success of video education by 1) providing short, targeted videos via a
164 personalized email that can be accessed at the mother's convenience, and 2) using social
165 marketing techniques to create interactive, tailored messages (e.g., if a mother expresses
166 concerns about choking, she will be sent a video addressing these concerns). If shown to be
167 effective in improving adherence to safe sleep recommendations, this technology could also be
168 readily applied to multiple other health care messages.

169 **A6. Summary.**

170 With the successful completion of the SMART study, we will have shown the effectiveness of
171 our interventions to improve adherence to safe sleep practices that would be practical to
172 disseminate nationally in multiple diverse settings. These interventions include the use of: 1)
173 social marketing techniques in developing educational interventions, 2) nursery staff education
174 to improve education of mothers, and 3) mHealth technologies to disseminate health
175 information. We anticipate that this study will have the following implications:

- 176 • Hospitals and health care providers nationally will adopt these strategies for safe sleep
177 education. This will lead to increased adherence to safe sleep practices, which in turn will
178 result in fewer sleep-related deaths.
- 179 • The value of these strategies will inform interventions for other health conditions, particularly
180 those with racial/ethnic, educational, and socioeconomic disparities.

181 **B. Innovation.**

182 The SMART study is innovative for the following reasons:

- 183 • *Unique collaboration of leaders in the field:* Collectively, the investigators have contributed
184 the majority of the research that support the rationale for this FOA and have assembled a
185 multidisciplinary team with expertise in social marketing, cultural competence, educational
186 theory, curriculum development, and media communication.
- 187 • *Leverage of an existing infrastructure:* The availability of the infrastructure developed for the
188 NICHD-funded SAFE project will make it feasible to efficiently collect the data needed to
189 both define the prevalence of the relevant infant care practices and to assess the factors
190 that influence these practices. The timing of this proposal is unique because it coincides
191 perfectly with the completion of the final year of the planned SAFE survey. Such an
192 opportunity is unlikely to be available in the future.
- 193 • *Two complementary interventions:* The 2 interventions selected have the advantage of not
194 being mutually exclusive. Because they use different approaches, they have the potential
195 for having additive or synergistic impact.
- 196 • *Use of social marketing strategies and expertise in all interventions:* We will engage social
197 marketing and advertising expertise that will inform and strengthen the content and
198 strategies used in our messaging. This type of expertise is seldom brought to bear in health

199 interventions. We plan to develop positive messages and use techniques, such as humor,
 200 that appeal to our target audience and lead to a recognizable “branding” so that they look
 201 forward to each new message and share them with family and friends.

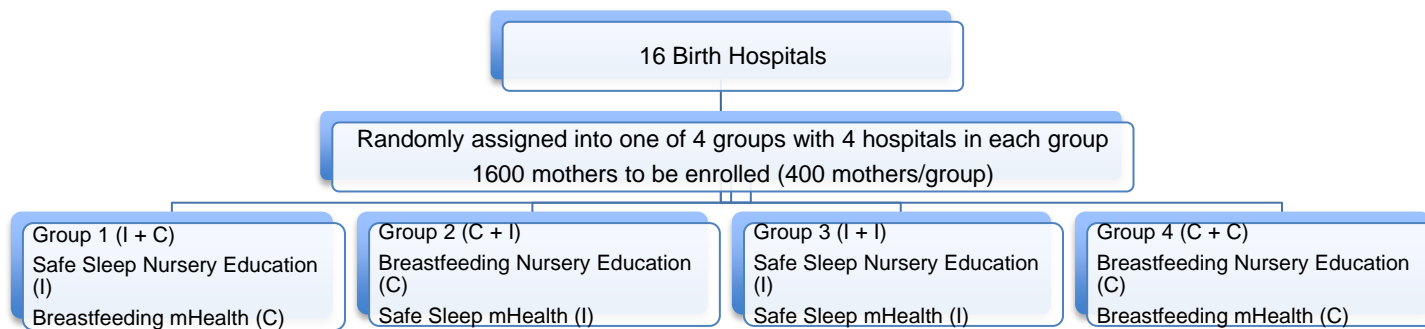
- 202 • *Use of mobile technology to deliver messages.* The mHealth intervention is a novel
 203 approach to delivering health messages to high-risk target audiences. This technique has
 204 enormous potential to have an impact in changing unsafe infant sleep practices that have
 205 been stubbornly stagnant. Use of personalized and interactive video messaging is a
 206 particularly unique approach in this setting.
- 207 • *Use of community resources and expertise.* The videos will be developed through an
 208 innovative collaboration with Duke Ellington School of the Arts (DESAP) in Washington DC,
 209 a magnet public high school. There are ~500 students at DESAP, 85% of whom are Black.
 210 We will be working with the Literary Media & Communications (LMC) Department, whose
 211 faculty is comprised of playwrights, authors, poets, digital media artists, and social
 212 media/internet marketing experts. LMC trains students in the different strands of
 213 communication, including written (dramatic writing, journalism), oral (public speaking,
 214 speech), and new media (online, film, documentary journalism, social media), and works
 215 collaboratively with other DESAP departments, including Theater, Visual Arts, and TDP
 216 (recording studio). Working with DESAP students, many of whom have similar
 217 demographics as families at highest risk for experiencing a sudden infant death, will provide
 218 a community context and increase credibility of the video content.

219 **C. Approach**

220 **C1. Overall strategy.**

221 We propose to utilize an already existing and operational infrastructure of 32 hospitals
 222 nationwide that are currently part of the SAFE infant care practices study. We will select 16 of
 223 the 32 hospitals to serve as sites in a 4-arm randomized clinical trial to assess 2 different safe
 224 sleep education strategies (Nursery Education and mHealth) compared to 2 control
 225 breastfeeding education strategies (Nursery Education and mHealth) (See **Figure 1**). The 16
 226 hospitals will be divided into sets of 4 similar hospitals, which will then be randomly assigned to
 227 one of 4 study groups: Group 1 will receive Safe Sleep Nursery Education and Breastfeeding
 228 mHealth messaging; Group 2 will receive Breastfeeding Nursery Education and Safe Sleep
 229 mHealth messaging; Group 3 will receive Safe Sleep Nursery Education and Safe Sleep
 230 mHealth messaging; and Group 4 will receive Breastfeeding Nursery Education and
 231 Breastfeeding mHealth messaging. A total of 1600 mothers will be recruited (100/hospital), with
 232 400 in each study group and an estimated response rate for the follow-up survey of 80%,
 233 resulting in mothers 320 per group.

234 **Figure 1: Four-armed Randomization by Hospital (I = Intervention; C= Control)**



235 There are 3 theoretical principles that inform our study design. First, the Theory of Planned
 236 Behavior is our framework for understanding the factors that are important in influencing the
 237

238 health-related behaviors of interest. (This theory informed the development of the SAFE
239 survey). Second, to develop the educational curricula designed to impact these factors, we will
240 use Kern's Six-Step approach. Finally, to inform the details of effective communication, we will
241 employ the principles of social marketing.

242 According to the Theory of Planned Behavior,⁶⁵ intention to perform a certain behavior is
243 influenced by 3 main factors: 1) attitudes and beliefs (e.g., baby might choke if he's on his
244 back); 2) perceived social norms (e.g., my friends don't put their babies on the back to sleep, so
245 I won't, either); and 3) perceived control (e.g., I would put my baby on the back, but my mother
246 takes care of her and likes the stomach).

247 In all of the education (Nursery Education and mHealth) components, we will be using
248 Kern's Six-Step approach to curriculum development.⁶⁶ These are:

249 1) Problem identification: Our previous studies have identified problems with accepting the safe
250 sleep recommendations, including but not limited to concerns about choking, safety, and
251 comfort.^{21, 22, 25, 27}

252 2) Needs assessment of targeted learners: Our previous qualitative studies^{21-23, 25-27} and the
253 data currently being collected in the SAFE study lay the groundwork for the needs assessment.
254 We will be conducting additional needs assessments of nursery staff through focus groups.

255 3) Goals/objectives: Our overall goal is to improve infant sleep safety. Specifically, we will
256 address misconceptions and barriers to adherence with safe sleep recommendations.

257 4) Educational strategies: We will accomplish this through education of nursery staff (which will,
258 in turn, improve education of mothers) and direct education of mothers using mHealth
259 technologies. We will utilize social marketing techniques. Before finalizing the educational
260 strategies, we will conduct focus groups of nurses and mothers, and adjust the strategies and
261 content accordingly.

262 5) Implementation: The educational strategies will be put into place.

263 6) Evaluation and feedback: We will evaluate the Nursery Education and mHealth components
264 through initial and follow-up surveys assessing knowledge, attitudes, and practice regarding
265 sleep and feeding practices.

266 Based on our findings about attitudes and perceptions, we will then use social marketing
267 techniques (as described previously in section A2) to develop targeted strategies to change
268 behavior and assess their effectiveness. To accomplish this, we will utilize our social marketing
269 experts to review the relevant information, based on the Theory of Planned Behavior, from the
270 SAFE surveys and the focus groups conducted in year 1, to understand what the important
271 messages need to be. We will then work with our experts to develop optimal messaging
272 strategies to formulate and deliver the messages. Our cultural competency expert will review all
273 of the messages to assure that they are sensitive and appropriate for each target audience.

274 **C2. Development of nursery-based education components.**

275 Using the principles above, we will develop 2 nursery-based education curricula: Safe Sleep
276 and Breastfeeding. The Safe Sleep Nursery Education curriculum will be developed by Dr.
277 Colson and Mary McClain, RN, MS (nursing education consultant), modeled after Dr. Colson's
278 successful nursery intervention in New Haven, CT,³⁵ using the NIH nursing curriculum⁶⁷ as a
279 guide, and incorporating findings from our collective research about barriers to adherence to
280 safe sleep practices.^{21-23, 25-27} Development of the New Haven intervention included qualitative
281 assessment of nursery staff's concerns about back sleeping, followed by curriculum
282 development and implementation targeting staff behavior change. Following implementation of
283 the curriculum, we found that nursery staff practices changed as desired and that maternal
284 adherence to back sleep recommendations improved from 42% to 75%.³⁵ We will follow a
285 similar process in the current study, including qualitative assessment of nursery staff concerns
286 and feedback on the curriculum.

287 The Breastfeeding Nursery Education curriculum will be developed by Dr. Kellams in
288 collaboration with Kathryn Heck, RN, IBCLC (breastfeeding education consultant) and modeled
289 after the online Breastfeeding Training course,⁶⁸ for which Dr. Kellams is a scientific advisor. It
290 will also be based on Dr. Kellams' successful efforts in the UVA Newborn Nursery (UVA was
291 designated as a 2010 University Hospital Consortium Top Ten Performer for exclusive
292 breastfeeding rates in the hospital). Additionally, the curriculum will draw from the evidence-
293 based WHO/UNICEF Ten Steps and the AAP and the Academy of Breastfeeding Medicine
294 protocols to support breastfeeding in the hospital.

295 Key components of both Nursery Education curricula will include:

- 296 1) Enlisting a nurse educator to coordinate the intervention. For each site, Mary McClain and Dr.
297 Kellams or Dr. Colson will contact the physician nursery director and the unit nurse manager.
298 With their help, we will identify an appropriate nurse educator to oversee educational activities.
- 299 2) Ensuring uniform actions in the nursery (putting the intervention in place). The nurse
300 educator will ensure that nursery staff receives educational material about either recommended
301 infant sleep techniques or breastfeeding that they will be required to read and to watch. The
302 materials will be based on established and tested curricula^{68, 69} and will emphasize
303 understanding of parental misconceptions and barriers that interfere with sleep safety
304 behaviors^{21-23, 25-27} and breastfeeding⁷⁰⁻⁷⁴, so that these can proactively be addressed.
- 305 3) Emphasizing the importance of role modeling. Nurses will learn about the powerful influence
306 their actions have on parental behavior at home. The importance of role modeling best practices
307 will be emphasized.
- 308 4) Emphasizing the importance of providing up-to-date guidance to parents and family
309 members. The nurses will deliver appropriate anticipatory guidance to mothers before
310 discharge. In addition, nurses will provide information to family and friends who visit the infant
311 in the hospital whenever possible. They will also provide, to mothers when available, language-
312 appropriate written materials that have been developed by NICHD,^{68, 69} AAP,⁷⁵ and HHS.⁷⁶
- 313 5) Ensuring that the intervention itself is effectively in place (process evaluation). We will track
314 that the appropriate advice is being uniformly offered to mothers by: a) observation of the
315 placement of infants; b) observation of the delivery of anticipatory guidance about safe sleep or
316 breastfeeding; c) pre and post-test scores; and d) information about nursery practice, provided
317 by mothers in the 2-5 month follow-up surveys.

318 **C3. Development of mHealth education components.**

319 C3a. Development of videos. Through pilot funding from the Clinical and Translational Science
320 Institute at Children's National Medical Center, DESAP students have begun developing
321 concepts for safe sleep videos [led by Sundance award-winning director Adetoro Makinde
322 (backdoorfilms.com)]. Each video will be ~2 minutes long and will discuss one aspect of infant
323 safe sleep. Drs. Hauck, Kellams, and Moon will work with the students and with our social
324 marketing consultants to develop the messages that will be in the videos. Letters of support
325 from DESAP and Watermark Design are attached. Our goal is to create a clearly identified
326 "brand" so that subsequent videos will be anticipated, recognized and viewed. Potential topics
327 include but are not restricted to 1) rationale for supine sleep positioning, 2) how to encourage
328 supine sleeping when the infant is fussy, 3) discussion of choking/aspiration and sleep position,
329 4) rationale for roomsharing without bedsharing, and 5) rationale for eliminating bedding from
330 the infant crib area. We anticipate that 5-7 videos will be developed. In weekly team conference
331 calls, ideas for videos will be discussed, scripts will be reviewed, and edited videos will be
332 viewed. A variety of videos will be created, some that are multicultural (>1 racial/ethnic group)
333 and others that are culturally specific (1 racial/ethnic group). Two sample video clips (not
334 educational videos) created by DESAP students can be viewed at
335 <http://www.youtube.com/watch?v=NM4rQXi9uLA> and <http://gallery.me.com/sojournals#100077>.
336 Videos about breastfeeding will be developed in a similar fashion under the direction of Dr.

337 Kellams, Kathryn Heck, RN, IBCLC and the social marketing consultants. Focus groups will be
 338 used to test and refine the video messaging (see section C4 for focus group methods).
 339 **C3b. mHealth Intervention.** Recruited mothers will receive routine postpartum care, including
 340 safe sleep education from the nursery staff (who have received either the Safe Sleep or
 341 Breastfeeding Nursery Education). Within 72 hours of enrollment, participants will begin to
 342 receive email messages on safe sleep or breastfeeding, determined by the group assignment,
 343 which will continue on a twice-weekly basis until the infant is 2 months of age. We will be using
 344 an email platform developed by our mHealth consultant David Mathison, MD, MBA (letter of
 345 support attached), pediatric emergency physician and CEO of healthEworks, who has received
 346 NIH funding to create and evaluate mobile Video Prescriptions™ sent via email to pediatric
 347 emergency department patients. A sample algorithm for sleep position messages for the Safe
 348 Sleep mHealth groups is in Table 1. The messages will be interactive and tailored to participant
 349 responses. Similar algorithms have been developed for roomsharing, soft bedding, pacifier use,
 350 and for the Breastfeeding mHealth education.

351 **Table 1: Sample Algorithm for Sleep Position Messages**

Intervention Component	Sample Message/Content
Introduction to program	<ul style="list-style-type: none"> Welcome to SMART As part of this study, we will send you messages twice a week for 2 months. What time of day would you like your message? (interactive)
Encouragement of supine sleep position	<ul style="list-style-type: none"> Check out this video here! It will help you keep (Baby's Name) safe while s/he sleeps! (Personalized) Video: rationale for supine sleep position Did you have a chance to see the video that we sent you? If NO- provide link for video again If YES: Did you like the video?
Addressing barriers to supine sleep position (choking/aspiration)	<ul style="list-style-type: none"> Do you worry that (Baby's Name) might choke if s/he is sleeping on the back? If YES: Look at this video here. It talks about why you don't have to worry about (Baby's name) choking while on the back Did you have a chance to see the video about choking that we recommended? If NO – provide link for video again If YES: Did you like the video?
Addressing barriers to supine sleep position (infant comfort)	<ul style="list-style-type: none"> Does (Baby's Name) ever have trouble falling or staying asleep on the back? If YES: This video here talks about ways to help your baby sleep on the back. Did you have a chance to see the video about helping your baby sleep? If NO – provide link for video again If YES: Did you like the video?

352 **C4. Focus group methodology.**

353 Focus groups will be conducted with nursery staff to obtain qualitative data to inform the
 354 Safe Sleep and Breastfeeding Nursery Education curricula. In addition, in focus groups, we will
 355 test all videos with members of the target audience for content validity, effectiveness, and
 356 cultural sensitivity. Drs. Colson, Hauck, and Kellams will coordinate the focus groups, and our
 357 social marketing and cultural competence consultants will advise us in this process. Mothers
 358 eligible for focus groups will be English-speaking, have infants <6 months of age (as young
 359 infants are at highest risk for sleep-related death), and have regular (at least weekly) email
 360 access. Participants for each maternal focus group will be fairly homogeneous with regard to
 361 SES and race/ethnicity, as homogeneity increases the comfort level of the participants, resulting
 362 in increased willingness to share thoughts and opinions.⁷⁷ Nursery focus groups will be
 363 comprised of newborn nursery nursing staff. Based on past experience, we believe that 3-5
 364 focus groups per subgroup will be sufficient for analysis of themes and patterns. If new themes
 365 are still emerging at the end of these focus groups, more will be conducted until thematic
 366 saturation is reached. Each focus group will have 6-8 participants. To aid in recruitment, \$50

367 and \$25 store gift cards, respectively, will be provided to each mother and nursery staff
 368 member.

369 A trained facilitator will lead the focus groups, using a general interview guide, with topics to
 370 be discussed. However, the flow of the conversation will be largely framed and structured by
 371 the respondents. Nursing focus groups will discuss common concerns about and barriers to
 372 providing safe sleep recommendations to mothers, sample messaging for mothers, and the
 373 nursing curriculum as a whole. Maternal focus groups will be shown videos of varying length
 374 (including those made by DESAP and those available publicly that have been prescreened by
 375 research staff for appropriateness) and asked questions about the videos.

376 All focus groups will be recorded and transcribed. Qualitative analysis software (NVivo8)⁷⁸
 377 will be used to organize, sort, and code the data. Using grounded theory methodology, we will
 378 analyze the interviews for thematic content. Themes will be developed and revised in an
 379 iterative manner as patterns within the data become more apparent⁷⁹ and until no new themes
 380 are emerging (thematic saturation).

381 **C5. Identification of sites and training of hospital-based study staff.**

382 *C5a. Site Recruitment.* As stated above, the 16 SMART sites will be selected from sites
 383 currently participating in the SAFE study. Using probability sampling of all US hospitals that
 384 deliver ≥100 newborns per year, SAFE has recruited a nationally representative sample of 32
 385 hospitals. Table 2 provides a list of these 32 hospitals, along with the number of births per year,
 386 and the calendar quarter during each year that the hospital is targeted to perform maternal
 387 recruitment.

388 **Table 2: SAFE hospitals**

Quarter 1		Quarter 2		Quarter 3		Quarter 4	
Riverside Reg Med Ctr VA	3,168	Brookdale Hosp Med Ctr NYC	1,900	Johns Hopkins Hosp MD	1,926	St Joseph Hospital CA	5,152
Baylor U Med Ctr TX	4,835	Genesys Reg Med Ctr MI	2,428	Natchitoches Med Ctr LA	450	Pomerado Hospital CA	1,211
Riverside Co Med Ctr CA	2,886	St Mary's Health Ctr MO	3,433	Hamilton Med Ctr GA	1,966	Rex Healthcare NC	6,757
Delaware Co Mem Hosp PA	1,688	Bethesda Mem Hosp FL	1,862	Moreno Valley Hosp CA	1,599	St Francis Hospital CT	2,966
Lake Charles Mem Hosp LA	1,689	Med Ctr of Arlington TX	4,058	Kaweah Delta Hlth Care CA	4,500	Sutter Roseville Med Ctr CA	2,046
Mount Carmel OH	4,559	Tacoma General Hosp WA	3,251	Methodist Hospital TX	5,500	Texas Hlth Presb Hosp TX	3,433
Rush-Copley Med Ctr IL	3244	Camden-Clark Mem Hosp WV	1,426	Nashville General Hosp TN	719	Baystate Med Ctr MA	4,200
Saint Mary's Health Care MI	2,836	Geisinger Wyoming Med Ctr PA	1,140	Northcrest Med Ctr TN	612	Jersey Shore U Med Ctr NJ	1,684

389 In the current SAFE study, each hospital recruits ~40 mothers per year in their assigned
 390 calendar quarter to achieve a total of ~1250 mothers in each survey year (2011, 2012 and
 391 2013). Therefore, prior to the start of the SMART study, each site will have 2 years of
 392 recruitment experience and data that can be used as a basis to select 16 SMART sites. Sites
 393 will be selected based on 1) their successful performance in the SAFE study, and 2) our ability
 394 to match sites into similar groups of 4, with regard to racial/ethnic mix, size of hospital, and
 395 baseline adherence to infant care practice recommendations (prioritizing sites with lower
 396 adherence). Within each hospital, we will use the same mother sampling strategy as has been
 397 used for the SAFE study, which was designed to ensure that 25% of the enrolled mothers were
 398 Black. To date, all of the hospitals currently in the SAFE study have been able to successfully
 399 meet their recruitment goals. To verify that current SAFE hospitals will be willing to participate in
 400 the SMART trial, we have received letters of support for this new project from all 8 of the
 401 Quarter 1 hospitals who have completed their work for the 2011 survey. Therefore, we are
 402 confident that almost all of the 32 current SAFE sites will be available as a pool from which we
 403 will be able to identify the proposed 16 SMART sites.

404 *C5b. Identification and Training of Site Interviewers.* Following the same approach as in the
 405 SAFE study, once a site agrees to participate in the SMART study, the site primary contact, with
 406 the assistance of central study staff, will identify one or more site interviewers to enroll and

407 interview subjects. Depending on the nature and resources of the hospital, interviewers may be
408 research assistants; research nurses; staff pediatric or obstetric nurses; research fellows; or
409 medical, nursing, or public health students. The central study staff will train each interviewer in
410 the study policies and procedures. The training will be based on a manual of procedures
411 specifically developed by the PIs. Each interviewer will receive and read the manual of
412 procedures prior to training. Training sessions will consist of detailed review of study
413 procedures, practice interviews, and several pilot interviews observed by the visiting central
414 study staff member. At no time will a site begin recruitment until the PIs are confident that the
415 site primary contact and interviewer understand and are capable of carrying out the study
416 procedures correctly and local IRB approval has been obtained. Site hospitals will receive a
417 reimbursement of \$120 per subject enrolled to defray the costs of the study.

418 C5c. Local Institutional Review Board (IRB) Approval. At each participating hospital, the
419 protocol will be submitted to the local IRB along with a letter from the Boston University Medical
420 Campus IRB stating that it has reviewed and approved the protocol. Central study staff, who
421 have extensive experience in this regard, will provide the site primary contact with support to
422 facilitate obtaining local IRB approval. We do not anticipate any difficulty because all of these
423 sites have active IRB approval for the SAFE study.

424 **C6. Recruitment procedures.**

425 C6a. Rationale and Eligibility/Exclusion Criteria. Since randomization is at the hospital level, all
426 mothers who deliver at a given hospital will be exposed to the educational practices resulting
427 from the assigned Nursery Education (Safe Sleep or Breastfeeding). At each hospital, 100
428 mothers will be recruited who agree to receive the mHealth curriculum (randomization to Safe
429 Sleep or Breastfeeding at the hospital level) and to provide survey information at baseline and
430 at 2-5 months after delivery.

431 To be eligible for the study, the mother must live in the US, deliver a healthy infant in one of
432 the study hospitals, plan to take her baby home with her, and be able to receive email
433 messages. The infant must be admitted to the well newborn nursery. Excluded are mothers who
434 are not English-speaking, whose infant is deceased, those who do not have custody of the
435 infant, and those whose infants require hospitalization for more than 1 week, or have ongoing
436 medical problems requiring subspecialty care. For multiple births, one infant will be randomly
437 selected. (Please refer to section C11 for the rationale for exclusion criteria.)

438 C6b. Recruitment and Informed Consent. Recruitment will begin within one month following the
439 completion of the Nursery Education training at each hospital and will use the same recruitment
440 strategy as has been used in the SAFE study. We estimate that 85% of mothers will be eligible,
441 and 75% of the eligible mothers will agree to participate. We thus project that each hospital will
442 need to approach ~160 mothers about the study, resulting in 100 mothers recruited per hospital
443 who complete the initial interview. Each hospital will be provided with written guidelines for
444 sampling new mothers and the employee(s) designated for this task will be trained in their use.
445 The hospital will be asked to enumerate all births happening within their specified data collection
446 period and then to select a systematic sample of mothers using pre-assigned “start with” and
447 “take every” numbers.

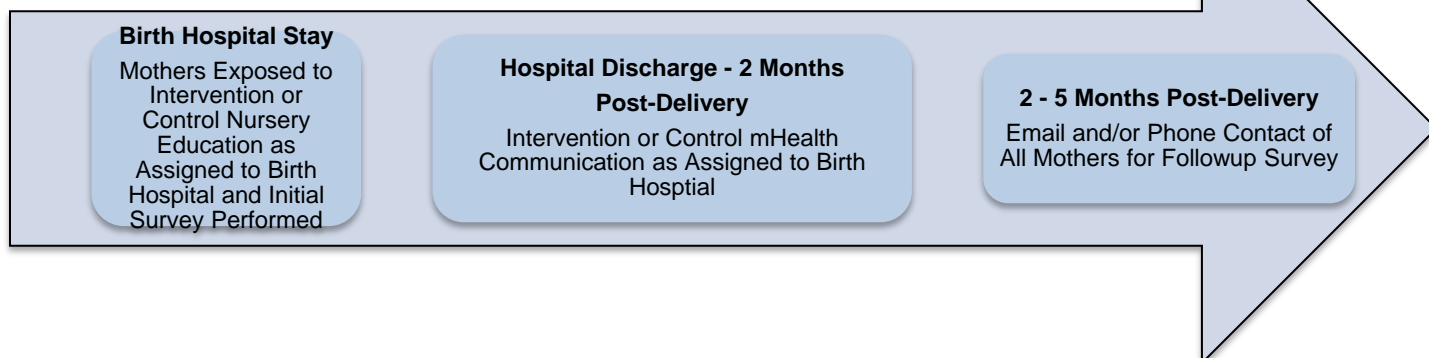
448 During the period of a given site’s subject recruitment, the interviewer will review each day’s
449 hospital birth log and apply the subject-sampling scheme as described above. For each
450 potentially eligible mother selected, the interviewer will approach a member of the mother’s care
451 team to verify that a live birth occurred, that the infant and mother will receive care in that
452 postpartum unit and that the mother’s medical condition does not prohibit approaching her. If
453 these conditions are met, the interviewer will approach the potentially eligible mother and obtain
454 verbal consent to verify the mother’s eligibility for the study. If the subject is deemed eligible,
455 the interviewer will obtain written informed consent as required by their IRB. The interviewer will
456 keep a log listing all potentially eligible subjects and the outcome for each (i.e., not approached;

457 approached but refused screening interview; screened but determined to be ineligible, screened
458 as eligible but refused further participation; enrolled). The interviewer will, in a secure fashion,
459 electronically send each day's log, including email addresses, to the mHealth center so that
460 mHealth messages can begin in a timely fashion. If a given site's performance does not meet
461 these expectations, we will provide further training to the interviewer(s) and help them identify
462 and correct any impediments to successful subject recruitment.

463 **C7. Performance of surveys.**

464 The procedures established for the SAFE study will be used to perform an initial interview of
465 mothers during the postpartum hospital stay to obtain demographic and tracking information and
466 then to perform a follow-up survey when the infant is 2-5 months of age about infant care
467 practices including sleep position, bed sharing, soft bedding, pacifier use, and feeding practices.

Figure 2: Individual Subject Timeline



468 **C7a. Initial Interview.** Once consent is obtained, the interviewer will conduct the initial interview
470 and record the subject's responses on an optically-scannable duplicate Teleform (Cardiff; Vista,
471 CA). This interview will collect contact information (including home address, any alternate
472 addresses, home and cell phone numbers, phone number of at least one close relative/friend,
473 and email address), maternal demographic information, brief obstetrical history, data about the
474 infant's birth, and home environment. Each mother will also be asked if she would prefer to
475 respond to the follow-up survey online or by telephone. The interviewer will fax a copy of each
476 completed initial interview to the study coordinator at the Slone Epidemiology Center at Boston
477 University (SEC) within 24 hours of completion, mail the original with a weekly batch of
478 enrollments for verification, and keep a duplicate copy in their site study files as an additional
479 backup. Each subject who completes the initial interview will receive a \$10 gift card and a
480 refrigerator magnet with the study logo and contact information.

481 **C7b. Follow-up Surveys.** The follow-up surveys will be the responsibility of SEC staff
482 (supervised by Dr. Corwin), who have decades of experience in survey design and computer-
483 assisted telephone interviews. Follow-up will consist of a single survey performed 2-5 months
484 after enrollment. The timing of the survey coincides with the period when the infant is at highest
485 risk for SIDS and sleep-related deaths^{6, 80-82} and when the mother is most likely to change infant
486 sleep position or location,^{13, 83, 84} so the survey will also ask about any potential changes in
487 practice during this period. The survey may be performed online or by telephone, depending on
488 subject preference and responsiveness. For online surveys, the SEC has developed proprietary
489 techniques to design and implement customized surveys (e.g., ASP.Net [C# and VB.Net,
490 Framework 2.0], PHP 4.x/5.x, Microsoft SQL server 2000/2005 database, Access 2000/2003
491 Database, IIS 6, Apache 1.3x and 2.x). Our online survey technology allows subjects to log into
492 a secure internet study portal at their convenience 24 hours/day, 7 days/week. Surveys can be

493 completed at one or multiple sittings. Data flow directly into the study's main Microsoft Access
494 database, eliminating the costs and errors inherent in secondary data entry.

495 For telephone surveys, we will employ a computer-assisted telephone interview (CATI)
496 technique. The CATI technique is the primary means of data collection in numerous SEC
497 studies as it facilitates accurate and efficient data collection. With CATI, interviewers can
498 conduct interviews from any location via the study's secure internet portal, facilitating the
499 completion of evening and weekend interviews.

500 Mail surveys (used as a backup to online and telephone surveys as described below) will be
501 formatted as Teleform documents. Teleform's customized optically-scannable surveys can
502 capture multiple-choice or free text responses. These surveys can be returned to the SEC by
503 mail or fax and scanned into the study's main Microsoft Access database.

504 C7c. Follow-up Procedures. Approximately 2 months after enrollment, each subject will be
505 contacted either by email or telephone, according to subject's preference, to complete the
506 follow-up survey. For those subjects who stated a preference to complete the survey online, an
507 email containing a link to the study internet portal and instructions will be sent. If the online
508 survey is not completed within one week, a second email will be sent. If the online survey is not
509 completed by one week after the second email, the subject will be contacted by telephone, as
510 described below. Subjects who express a preference for telephone interview will be contacted
511 by telephone. If a subject does not respond to the initial telephone interview attempt, a
512 minimum of 10 call attempts will be made on different days of the week and at different times of
513 day, utilizing all alternative telephone numbers collected at the time of enrollment. Subjects who
514 do not respond to a minimum of 10 call attempts will be sent an abbreviated survey by mail
515 covering the core infant sleep practice questions (see Survey Content below), along with a
516 cover letter and pre-addressed postage-paid envelope. If the mailed survey is not returned
517 within 2 weeks, a second identical survey will be mailed to the subject. Mothers who complete
518 the follow-up survey will receive a \$10 store gift card. We are successfully using this step-wise
519 follow-up strategy in the SAFE study (80% response rate).

520 C7d. Survey Content. We will be using the 2 survey instruments being currently used for the
521 SAFE study, with modifications to include questions about soft bedding and feeding practices.
522 The initial interview (current SAFE initial interview is provided in Appendix 1) is performed
523 during the newborn hospital stay and includes general demographics (maternal age, race,
524 ethnicity, marital status, education, income, employment), obstetrical history (gravidity, parity,
525 smoking), infant history (gestational age at birth, birthweight), home environment (rent vs. own
526 home, size of home, number of occupants, expected primary and secondary infant caretakers),
527 and follow-up tracking information (addresses, phone numbers, email). The follow-up survey
528 (current SAFE follow-up survey is provided in Appendix 2) is performed at 2-5 months of age
529 and asks about past, current, and anticipated future behavior in relation to infant care practices
530 (including feeding and sleep practices).

531 **C8. Data management.**

532 All study data will be managed at the SEC. Each subject will be assigned a unique study
533 identifier code. Data from completed online surveys and CATIs will flow directly into the main
534 study Microsoft Access database. Data from initial interviews and follow-up surveys received by
535 mail will be optically scanned into the study database. Standard quality control and cleaning
536 procedures will be applied to ensure that accurate data entry has occurred with each completed
537 survey. All study data will be stored on secure password-protected computer servers, which are
538 backed up automatically on a daily basis and maintained by the SEC's full-time Information
539 Systems staff. The database will be programmed to produce weekly reports tracking enrollment
540 and follow-up completion and other periodic reports as required by study staff.

541 **C9. Data analysis.**

542 Our study follows a 2x2 factorial design testing the effectiveness of the Safe Sleep Nursery
543 Education and Safe Sleep mHealth interventions. Randomization will occur at the hospital level,
544 and so analyses will account for within-hospital clustering through generalized estimating
545 equation (GEE) logistic regression models, which also allow for both individual-level and
546 hospital-level covariates.

547 Preliminary analyses will examine loss to follow-up from in-hospital enrollment to follow-up,
548 both examining demographic characteristics related to drop out and comparing rates of follow-
549 up across the 4 study groups. Based on our experience with the SAFE study, we do not
550 anticipate problems related to follow-up; however, if there are problems, multiple imputation
551 procedures will be used to account for potential drop out-related bias. Preliminary analyses will
552 also compare demographic characteristics of mothers and infants across the 4 study groups, to
553 identify demographic characteristics to be examined as potential confounders in our primary
554 analyses. Since randomization occurs at the hospital level rather than the individual level,
555 randomization will provide less protection against patient-level differences between study
556 groups.

557 For our primary analyses, separate analyses will examine intervention effects on each of the
558 safe sleep outcomes (supine sleep position, not bed sharing, pacifier use, and avoiding soft
559 bedding). For each outcome, we will first fit a multiplicative interaction model through GEE
560 multiple logistic regression, with indicator variables representing the Nursery Education
561 intervention, the mHealth intervention, and their interaction. We will also include as a hospital-
562 level variable the pre-intervention prevalence for the outcome based on SAFE data, to control
563 for pre-intervention hospital differences, and an individual-level variable for child age to account
564 for differences in age at follow-up (from 2 to 5 months). The effectiveness of the combined
565 interventions vs. each individual intervention (Hypothesis 1c) will be tested through two
566 contrasts based on the model parameters for the intervention and interaction terms in this
567 model. If the interaction term is significant, this model will be used to describe the effects of
568 each intervention alone (Hypotheses 1a and 1b) and in combination (Hypothesis 1c). If the
569 interaction term is not significant, we will fit a main effect model to test and describe the
570 separate effects of the Nursery Education (Hypothesis 1a) and the mHealth (Hypothesis 1b)
571 interventions. The GEE logistic regression modeling approach allows us to control for potential
572 confounding due either to individual-level demographic factors found in preliminary analyses to
573 differ between the 4 study groups, as well as hospital-level factors such as the pre-intervention
574 rates of safe sleep practices. To acknowledge the multiple comparisons issue in evaluating the
575 effectiveness of intervention on 4 safe sleep outcomes, we will use a Bonferroni adjustment for
576 an overall 2-tailed alpha level of 0.05 (using a comparison-wise alpha level of 0.0125) when
577 testing for intervention effects.

578 Analyses for our secondary aim will follow the approach of Baron and Kenny to evaluate the
579 3 domains of the Theory of Planned Behavior (attitudes/beliefs, social norms, perceived control)
580 as mediators of any intervention effects. To establish that social norms is a mediator of the
581 Nursery Education intervention effect of sleep position, for example, we would 1) show that the
582 Nursery Education has a significant effect on social norms (through a GEE linear regression
583 model); 2) show that social norms have a significant effect on sleep position (through GEE
584 logistic regression); and 3) show that the effect of the Nursery Education intervention on sleep
585 position is attenuated after controlling for social norms.

586 While our focus is on safe sleep outcomes, we will also be able to test the effect of the
587 breastfeeding interventions on breastfeeding behavior (treating the safe sleep interventions as
588 controls). Breastfeeding behavior will be captured through 4 outcome measures: exclusively
589 breastfeeding (yes or no) and any breastfeeding (yes or no), both over the 2 weeks prior to the
590 follow-up survey and at the time of discharge from the hospital. The effect of the 2 breastfeeding
591 interventions on these outcomes will be evaluated through GEE logistic regression models, as
592 described above.

593
594 Sample size and power considerations. We will enroll 100 mothers from each of 16 study
595 hospitals, yielding enrollment samples of 400 mothers in each study group. Based on our SAFE
596 experience, we anticipate 80% follow-up at 2-5 months, giving an analysis sample of 320 per
597 study group or 1280 overall.

598 Given that this is a group-randomized design focusing on categorical outcome measures,
599 intervention effects will be evaluated through generalized estimating equation (GEE) multiple
600 logistic regression models to account for the within-hospital correlation structure of the sample,
601 and sample size and power considerations depend on this within-hospital correlation as well as
602 the intervention effects. We evaluated statistical power through simulation for the following
603 scenario: the baseline prevalence of the outcome measure ranged from 0.50 to 0.60 across the
604 study hospitals; hospitals were stratified by baseline prevalence and baseline prevalence was
605 balanced across the 4 study groups; both the Nursery Education and mHealth interventions
606 increased prevalence of the outcome by 10 percentage points and so those receiving both
607 interventions would experience a 20 percentage point improvement in outcome. To
608 acknowledge the multiple testing issue in examining intervention effects on four outcomes we
609 used a Bonferroni adjustment for an overall two-tailed alpha level of 0.05 (comparison-wise
610 alpha level of 0.0125). Under this scenario the average intra cluster correlation was 0.002 and
611 the proposed study has 96% power of detecting a main effect of either the Nursery Education or
612 mHealth intervention, and 80% power of showing that receiving both interventions is more
613 effective than receiving one intervention alone.

614 **C10. Benchmarks for success.**

615 Study implementation: Completion of study manual, site recruitment and IRB approvals by end
616 of year 1.

617 Development of the interventions: Piloting and finalizing of intervention, including focus group
618 testing of videos, by end of year 1.

619 Enrollment: Subject enrollment rate will be monitored on a weekly basis. If a given site is not
620 meeting enrollment goals, a telephone conference between study investigators and the site staff
621 will be convened to discuss enrollment procedures and difficulties encountered and a site visit
622 may be arranged if the need for further site training is identified.

623 Retention: Strategies for retention are described in section C7c. In the SAFE study, these
624 strategies have resulted in an 80% response rate in the follow-up survey. Response rates will
625 be monitored on a weekly basis. If response rates fall below 80%, we will undertake additional
626 procedures to improve response rate.

627 **C11. Potential problems and alternative approaches.**

629 Randomization: We have several reasons for randomization by hospital instead of by individual
630 participant. First, it is impractical to randomize nursery staff at a single hospital to receive
631 different training. For the mHealth intervention, it is more feasible to randomize at an individual
632 level, but we felt that the possibility of mothers at the same hospital sharing information would
633 contaminate the results.

634 Eligibility criteria: Although we acknowledge the important role that fathers and other family
635 members may play in making infant care decisions and while these family members will be
636 encouraged to participate in the intervention, we will be studying the behavioral choices of
637 mothers of newborn infants in this protocol. In addition, although it would be ideal to assess the
638 intervention in non-English-speaking mothers, due to cost and time constraints in developing
639 language-specific curricula, videos, and surveys, and most importantly, because the infants of
640 recent immigrants have lower rates of SIDS and unintentional injury deaths related to the sleep
641 environment than US-born infants, eligibility in this study will be limited to English-speaking
642 mothers.

643 Validity of maternal report: It is possible that mothers might tell interviewers what they think

644 researchers want to hear rather than what they actually do at home. This type of reporting bias
 645 is always a possibility when there is reliance on self-report of behavior, especially when there
 646 may be a perceived negative connotation to a particular response. Ideally one would directly
 647 observe the behavior in the home, however, this is not a practical approach for this study.
 648 Objective data from the CHIME study demonstrated high correlation between maternal report of
 649 infant positioning and positioning detected by sensors.⁸⁵ Nonetheless, to address this issue, we
 650 designed our survey instruments in a manner such that: 1) particular responses do not seem
 651 more "correct" than others; 2) items surveyed include more than just the "recommended
 652 practices"; 3) information is not provided to participants that might influence their subsequent
 653 behavior, until after key information is collected regarding the behaviors of interest.

654 Variation in baseline practice by hospital: All hospitals have policies regarding breastfeeding
 655 and safe sleep promotion. We will be aware of these baseline practices at the beginning of this
 656 study from the data obtained in SAFE. In addition, our interventions will be much more
 657 comprehensive than any of the baseline hospital practices. Our statistical analyses will account
 658 for variations in baseline practice.

659 Unforeseen changes in recommended infant care practices: The possibility that new
 660 recommendations will arise is completely unpredictable. We have specifically selected as our
 661 outcome measures infant care practices that are soundly based in evidence, such that it is
 662 unlikely that recommendations will change drastically. In addition, Drs. Moon and Hauck are
 663 members of the AAP Task Force on SIDS, which is the body that determines safe sleep
 664 recommendations. Therefore, if changes are anticipated, we will be able to make the necessary
 665 adjustments in the study design.

667 **C12. Study timeline.**

668 Each hospital will have had 2 years of data collected during the SAFE study, which will
 669 provide the baseline data used to match hospitals in randomization groups and to serve as the
 670 pre-intervention infant care practice survey data. The overall timeline for the key study tasks
 671 are provided below.

Grant Year	Year 1				Year 2				Year 3				Year 4				Year 5			
	2012		2013		2014		2015		2016		2017		2018		2019		2020			
	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4		
Calendar Quarter																				
Site recruitment	x	x	x	x																
Piloting and finalizing interventions	x	x	x	x																
Focus groups		x	x	x																
Analysis of focus groups			x	x																
Training related to survey and nursery based educational interventions at sites 1-16				1, 2	3, 4	5, 6	7, 8	9, 10	11, 12	13, 14	15, 16									
Projected # mothers recruited					200	200	200	200	200	200	200									
Projected # maternal f/up surveys					80	160	80	80	160	80	80	160	80	80	160	80				
mHealth intervention distribution					x	x	x	x	x	x	x	x	x	x	x					
Data analysis															x	x	x	x		
Ms prep, dissemination of findings																	x	x		

672 The proposed timeline was chosen to spread recruitment and survey activities as smoothly as
 673 possible over the 5 year period, which provides the most cost efficient strategy to accomplish
 674 recruit subjects and perform surveys on 1600 mothers.
 675
 676

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