

1 **Supplement 1**

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3 Effect of addition of an intimate partner violence intervention to a nurse home visitation program on
4 maternal quality of life: a randomized clinical trial

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6 **This protocol supplement contains the following items:**

- 7 • eTable 1 Summary of protocol changes and approved amendments
8 • Original IRB-approved protocol (approved November 23rd, 2010)

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10

11 eTable1: Summary of protocol changes and approved amendments

Date	Description of change
20 December 2010	<p>Revised study instruments, questionnaire</p> <ul style="list-style-type: none"> ▪ Added Survey for nurse home visitors ▪ Added Semi-structured interview guides for focus groups with nurses and supervisors ▪ Revised consent forms for nurses and supervisors <p>Listed 10 study participating sites</p>
28 January 2011	Refined Permission to contact form with minor edits.
8 February 2011	Revised Consent form/participant information sheet for clients (minors) with the correct honorarium.
29 March 2011	<p>Revised consent form/participant information sheet for clients and the assent form.</p> <ul style="list-style-type: none"> ▪ The funding sources under the title of the study. The additional follow-up data collections (3, 18-, 24 months), to current follow-ups at 6 and 12 months. Requested permission to access information about participants and their babies that are collected by nurses. Refined wording in the confidentiality and risks/benefits sections. The additional details about the compensation. <p>Revised study design or methods</p> <ul style="list-style-type: none"> ▪ Revised data collection methods to be face-to-face, rather than telephone interview, as we determined this is the safer way to obtain information. ▪ Change in number of participating sites from 10 to 15 (7 intervention and 8 control) ▪ Increase in sample size. Document on Sep 25, 2012 stated increase in sample size through recruitment of additional sites approved by HIREB. ▪ Revised study instruments, questionnaires ▪ Added secondary outcomes: Childhood maltreatment measured at six months follow-up; women’s violence-specific service use in the past six weeks at six months and subsequent follow-ups. We update clients’ demographic information at each follow-up. ▪ Revised measurement: Degree of nurse’s readiness to treat IPV is assessed by the Public Health Nurses’ Responses to Women Who Are Abused (PHNR), instead of The Domestic Violence Health Care Provider Survey (DVHCPS), as we determined this to be a better instrument to measure nurses’ and supervisors’ comfort with the topic of IPV. <p>Revised eligibility criteria</p> <ul style="list-style-type: none"> ▪ We approached all clients enrolled in the nurse home visitation program in the last 30 days to seek their permission for participation, rather than to determine the eligibility by the indication of IPV. The decision was made based on our recent pilot study demonstrated that some women might not feel comfortable disclosing exposure to IPV right away. <p>Revised data collection and follow-ups and study end date:</p> <ul style="list-style-type: none"> ▪ We dropped the 36-week gestation follow-up (some women deliver before 36 weeks, which makes interview shortly after delivery difficult) and added 3- and 24-months follow ups to examine the changes in various aspects of health outcomes of mothers and babies to the extended period.

Date	Description of Change
14 April 2011	Added Project 3: Implementation Study - a knowledge translation study of this project. <ul style="list-style-type: none"> Added a new participation information sheets/consent forms for nurse consultants and site supervisors and directors for the Project 3.
14 November 2011	Revised Permission to contact form for nurse home visitation program clients.
16 February 2012	Revised follow-up protocol: <ul style="list-style-type: none"> Allowed study participants who relocate out of the service area for the NFP program to be interviewed by phone to conduct study follow-up. We determined this method can be helpful in retaining participants over the 2.5 years course of the study.
5 March 2012	Refined compensation for the clients <ul style="list-style-type: none"> Increase the compensation, starting at the 3 months interview from the current \$25 gift card to a \$50 card for all subsequent interviews to retain clients.
15 March 2012	Revised method of baseline interview administration <ul style="list-style-type: none"> At the Baseline Visit, participants have a consent discussion with the research assistant and complete a questionnaire package. In certain urgent cases, where a research assistant is unavailable, research assistant from another site could conduct the consent discussion and baseline interview via phone. In such a case, the initial signed consent will be obtained by fax, followed by an in-person visit and signed consent as soon as possible.
26 March 2012	Revised Permission to contact form to reflect changes in the honoraria offered to participants, previously approved by the research ethics board
25 September 2012	Revised sample size <ul style="list-style-type: none"> Project secured additional funding that allowed for an estimated sample size increase of 450 across the 15 sites. Documented through project renewal. Revised method of follow-up interview: <ul style="list-style-type: none"> The interviews at 3 months and onward will be conducted by telephone with many advantages with this method, including convenience, safety, confidence in the research assistant that was established because of the baseline in-person interview, reduced burden of time and organization, and fewer accidental missing of answering questions.
7 October 2013	Revised interview questionnaire <ul style="list-style-type: none"> Additional questions to the 24 months interview, including injury-related questions for the client's child and for the client; open-ended question about experience participating in the study; and client's permission to be contacted in the future.
29 October 2013	Revised questioner <ul style="list-style-type: none"> Additional two questions to the nurse home visitor and supervisor survey at 24 months. One of which reflects a change in the US Federal Legislation mandating agencies to include questions about IPV during encounters with female adult clients, as a result of the Affordable Care Act. Another is to assess nurses' attitude and impression about the training.
10 February 2014	Administrative change: New funding source (Public Health Agency of Canada)
23 September 2014	Administrative change: incoming and an outgoing co-investigator
12 September 2016	Administrative change: the increase in funding from Public Health Agency of Canada to cover added KT study
30 October 2017	Administrative change: incoming co-investigator

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15 Protocol

16 Development and Evaluation of an Intervention for Intimate Partner Violence in the Context 17 of Nurse Home Visits

18 The goal of this research is to develop and evaluate an intervention for reducing intimate partner violence (IPV)
19 among low-income women during pregnancy and in the first two years postpartum. IPV is a widespread problem with
20 significant adverse consequences for women and children. The long-term and as yet unmet goal of IPV intervention
21 research is to develop effective ways to reduce the prevalence and consequences of family violence.

22 Families at risk for IPV share many characteristics with families at risk for poor child health outcomes. For these
23 families, the Nurse-Family Partnership (NFP) has been shown to improve maternal, child, and family outcomes in three
24 separate randomized controlled trials (RCTs) over the past 29 years. The NFP is a program of home visiting in which
25 nurses visit first-time mothers from pregnancy through to the child's second birthday. Its success has led to widespread
26 program implementation with sites now serving over 62,000 families in over 270 counties nationwide.

27 The self-reported prevalence of moderate to severe IPV in families served by the NFP is higher than IPV in the
28 general population and the presence of IPV attenuates the program's effectiveness. Furthermore, many NFP nurses
29 feel inadequately prepared to manage IPV and are seeking intervention strategies. Unfortunately, there is a lack of
30 good evidence regarding effectiveness of approaches to reducing IPV, and none have been rigorously evaluated in the
31 context of a home visiting program such as the NFP. This knowledge gap is an important problem. As noted in the
32 Centers for Disease Control and Prevention's (CDC's) *Injury Research Agenda*, evaluating the effectiveness of
33 interventions for preventing IPV is a priority. Further, IPV and child maltreatment often overlap in families, so
34 evaluating the effectiveness of interventions that address two or more of these behaviors simultaneously is of high
35 priority. Identifying programs that can effectively address multiple types of victimization at once will facilitate a more
36 efficient allocation of prevention resources. The NFP is an example of such a program. An intervention that
37 effectively reduces IPV in this program also has the potential to reduce exposure of children to IPV, as well as other
38 types of child maltreatment.

39 The proposed research would occur in two phases: 1) Project 1 develops a model of in-home IPV intervention to
40 include in the current NFP protocol. Qualitative interviews will be conducted with NFP program nurses, clients,
41 program administrators, and community partners working on domestic violence; this will play an important role in
42 guiding the development of the intervention, which will be piloted. 2) Project 2 tests the intervention in NFP sites and
43 evaluates its effectiveness in improving quality of life and reducing violence for women using a RCT design.
44 Additionally, regular evaluations and feedback from NFP nurses will measure self-efficacy in their management of IPV.
45 While not a full-scale trial powered to determine effectiveness of all primary and secondary outcomes, this RCT will
46 provide information over the course of three years to determine whether the intervention shows promise and warrants
47 expanding to a large RCT. The specific aims of the proposed research are to:

- 48 1) Develop a model of in-home intervention for NFP mothers exposed to IPV ("NFP + IPVI") (Project 1).
- 49 2) Determine whether the intervention is feasible and acceptable in a small sample of NFP clients and nurses
50 (Project 1).
- 51 3) Determine whether the NFP+IPVI intervention improves women's quality of life and reduces violence
52 relative to the NFP alone using a cluster randomized controlled trial (Project 2).

53
54 Based on findings from NFP research and the NFP replication program, preliminary studies of program
55 participants and nurses, and experience implementing and evaluating IPV interventions, our central hypothesis is that
56 an IPV intervention can be designed that is acceptable to participants in the NFP, feasible to implement, and that this
57 intervention will improve quality of life for women and reduce exposure to violence. The research team, which
58 includes Dr. David Olds, the founder of the NFP program, has developed extensive collaborations, and is well-prepared
59 to undertake the proposed investigation. Collectively the investigators have expertise in family violence research, and

60 more generally, studies of vulnerable families, IPV interventions, mixed methods research, and multi-site
61 investigations.

62 The proposed research is innovative because it takes advantage of an existing program with proven effectiveness
63 to develop and evaluate a new IPV intervention in a high-risk population. Achieving our three aims will improve our
64 understanding of IPV interventions and address a critical need of home visitation programs. They will significantly
65 advance knowledge in the field of family violence.

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67 **B. BACKGROUND AND SIGNIFICANCE**

68 The team has adopted the CDC definition of IPV against women (1): any behavior purposely inflicted by a male
69 or female partner against a woman within an intimate relationship that causes physical, psychological or sexual harm.
70 Such behavior includes acts of physical aggression, psychological or emotional abuse, as well as forced intercourse and
71 other forms of sexual coercion. This proposal uses the term “intimate partner violence” (IPV), but adopts the language
72 used by the authors of individual studies cited below.

73 **Prevalence of IPV**

74 National violence surveys generally place annual prevalence of IPV against women at between 2% and 12%,
75 and lifetime prevalence at 25-30% (2,3). The CDC’s National Center for Injury Prevention and Control’s Fact Sheet
76 on Intimate Partner Violence (1) indicates that:

- 77 • nearly 5.3 million incidents of IPV occur each year among U.S. women
- 78 • about 1.5 million women are raped or physically assaulted by an intimate partner
- 79 • IPV results in nearly 2 million injuries and 1,300 deaths nationwide every year
- 80 • women who separate from abusive partners often remain at risk of violence: more than 1 million women are
- 81 stalked by intimate partners each year
- 82 • from 1976 to 2002, about 11% of homicide victims were killed by an intimate partner.

83 In a synthesis of studies examining abuse during pregnancy, Gazmararian and colleagues (4) found rates of IPV
84 ranging from 0.9% to 20.1%, with the most stable estimates falling in the range of 4 to 8% (5-7). While unintended
85 pregnancy has been linked to abuse (8), most studies find either no significant difference in rates during the pre-, peri-
86 and post-natal periods, or a trend towards a decrease in abuse once a woman is pregnant (6,9,10). Abuse during an
87 earlier period is by far the strongest predictor of abuse during a later period (6). Abuse during pregnancy is
88 significantly associated with femicide (11).

89 **Adverse Effects of IPV**

90 Women exposed to partner violence are at increased risk of injury and death, as well as a range of physical,
91 emotional and social problems (12). These include increased rates of mood and eating disorders (13,14) substance
92 dependence and antisocial personality disorders, nonaffective psychosis, depression, suicidality, posttraumatic stress
93 disorder (PTSD); alcohol and drug abuse/dependence (14,15). When violence decreases or is eliminated, physical and
94 mental health improve (16,17).

95 The effect of IPV on children has been well documented. Abuse during pregnancy can cause direct harm to the
96 child, such as pre-term birth or injury, low birth weight (18), as well as indirect harm (19,20). Adverse outcomes in
97 childhood include an increased risk of psychological, social, emotional and behavioral problems including mood and
98 anxiety disorders, drug abuse and school-related problems (14,21-23). These negative effects can often continue into
99 adulthood and become part of an intergenerational cycle of violence (24,25). Between 13% and 27% of adults report
100 having witnessed IPV during childhood (25-27). Children who witness violence in the home are more likely to become
101 poor parents, including perpetrating maltreatment on their own children (28,29); they are also more likely to have
102 violent dating and intimate relationships in adulthood (30-32).

103 **IPV and Child Maltreatment**

104 The co-occurrence of witnessing violence and exposure to other types of maltreatment among children is very
105 high; approximately 60-75% of families with battered women have children that are also battered (25,33-35). Children
106 exposed to IPV are at increased risk of experiencing other forms of abuse such as physical and sexual abuse (36,37).
107 As well, the frequency and severity of physical aggression towards children is directly related to the levels of IPV

108 found in the home (33,38-41). Results of the Adverse Childhood Experiences Study (42), a survey of adult members of
109 the Kaiser Health Plan in the region of San Diego, California, show that adults who were exposed to IPV in childhood
110 experience increased odds of sexual abuse (odds ratio (OR) 2.5), physical abuse (OR 4.7) and emotional abuse (5.9) as
111 well as neglect (both emotional (OR 4.0) and physical (OR 4.6) subtypes).

112 **Interventions for IPV**

113 In a recent systematic review examining the effectiveness of interventions for IPV, Wathen and MacMillan (43)
114 concluded that evidence-based approaches for primary prevention of IPV are “seriously lacking.” Evidence is also
115 lacking about the effectiveness of interventions to reduce risk of repeat violence, including counseling and referral. To
116 summarize this review and more recent studies:

- 117 • Limitations in study designs and methods preclude drawing conclusions about effectiveness of personal and
118 vocational counseling, and prenatal counseling in reducing IPV or its associated consequences (44).
- 119 • The evidence regarding treatment of male batterers is mixed, with the highest quality studies showing no
120 effect or small effects (45,46).
- 121 • Educational, community and policy-oriented interventions have not been adequately evaluated to assess their
122 effectiveness in preventing or reducing IPV and its associated consequences, although a recent study suggests
123 that permanent civil protection orders may be effective (47).
- 124 • No evidence of suitable quality exists to evaluate the effectiveness of woman abuse shelters as a means of
125 decreasing the incidence of violence (43).
- 126 • There is some evidence that an advocacy framework might lead to improved outcomes but the framework and
127 path to these kinds of interventions are unclear (48).

129 The most promising intervention for which rigorous evidence exists is the post-shelter advocacy counseling
130 program of Sullivan and colleagues, which was evaluated using an RCT design in a pilot study (49,50), a six-month
131 follow-up involving 146 participants (51-53), a two-year follow-up with 284 women (54), and a three-year follow-up
132 with 124 women (a sub sample of those followed to two years) (55). Women who had spent at least one night in a
133 shelter were randomly assigned to receive either advocacy services four to six hours a week for ten weeks following
134 shelter exit, or no contact other than for interviews. The focus of the intervention was on providing women with
135 practical support to help them access community resources such as housing, employment, and social support, while
136 teaching them how to “navigate the system”. Women in the experimental group reported significantly less re-abuse
137 over two years compared to those in the control group (76% and 89% respectively). Quality of life and access to social
138 support was also significantly better for women in the experimental group and improved across time. Of note, by the
139 time of the three-year follow-up, the effect of the intervention on re-abuse had been lost; however, the intervention
140 group women remained significantly better off with respect to quality of life and access to social support and use of
141 resources. The sustained positive impact of this counseling and advocacy intervention is a highlight of the IPV
142 literature. Further research is needed to determine whether these effects will generalize to women outside of shelters.

143 **Background of the Nurse-Family Partnership (NFP)**

144 The NFP was developed as an intervention in a research context. It has been tested in three large RCTs in Elmira,
145 New York; Memphis, Tennessee; and Denver, Colorado, with different racial and ethnic groups, in different contexts,
146 spanning three decades (56-65; see Appendix A for selected citations). The NFP was identified by the Surgeon
147 General as a model program in preventing violence (66). It received an “A” recommendation for the prevention of
148 child maltreatment by the Canadian Task Force on Preventive Health Care (67). The Prevention Research Center for
149 Family and Child Health at the University of Colorado directed by Dr. Olds, in collaboration with Dr. Ruth O’Brien,
150 Director of Evaluation of the National Center for Children, Families and Communities continues to conduct research
151 on NFP program implementation and improvement (“NFP Research”) with colleagues Pilar Baca, MN, (Director, NFP
152 Program Development); Maureen McClatchey, PhD, (Biostatistician); and Francesca Pinto, MPH, (Replication Project
153 Manager). The NFP’s success led to funding for a national replication of the program, including creating a new
154 organizational structure, NFP National Office (“NFP Replication”). It now serves over 62,000 families in over 270
155 counties nationwide.

156 The NFP is a program of prenatal and infancy home visiting by nurses for low-income mothers having their first
157 child; 92% of the mothers are under the age of 26 at registration. The goals of the NFP are to: 1) help women improve

158 the outcomes of pregnancy by promoting healthy prenatal behaviors; 2) improve child health and development by
159 promoting parents' competent care of their children; and 3) enhance parents' life-course development by encouraging
160 pregnancy planning and parents' education and work. The nurses help families make use of needed health and human
161 services and attempt to involve other family members and friends in the pregnancy, birth, and early care of the child.
162 Nurses follow detailed visit-by-visit guidelines in their efforts to assist families. The program guidelines are grounded
163 in research on risk and protective factors predictive of maternal and child health (56) and in theories of human ecology
164 (68,69), attachment (70,71), and self-efficacy (72); details of the NFP's design, theoretical foundation and
165 implementation are provided in the publications (56-65) including key articles cited in Appendix A (56,60-62).

166 The NFP follows a standardized protocol with a set schedule of visits beginning before the end of the second
167 trimester in pregnancy, as follows: weekly for the first four visits, every other week for the remainder of the pregnancy
168 (total of 14 prenatal visits); every week for six weeks in the postpartum period, every other week until the infant is 21
169 months old, then once a month for the last three months, ending when the child is two years old (total of 50 postnatal
170 visits). Women are recruited through NFP sites administered by state health departments and not-for-profit hospital
171 settings. NFP clients are routinely asked about exposure to IPV between intake and the third visit, at 36 weeks
172 gestation and 12 months postpartum. IPV is addressed during visits 17 and 36, when the infant is 28 weeks and 15 ½
173 months of age. There is no standardized approach to IPV training for the NFP; the need for and extent of training are
174 determined on a site-specific basis. Given that women often do not disclose IPV until trust has been developed after
175 multiple encounters with a health care provider (73,74) the long-term nature of the relationship between NFP clients
176 and nurses make this intervention an optimal vehicle for broaching this sensitive topic.

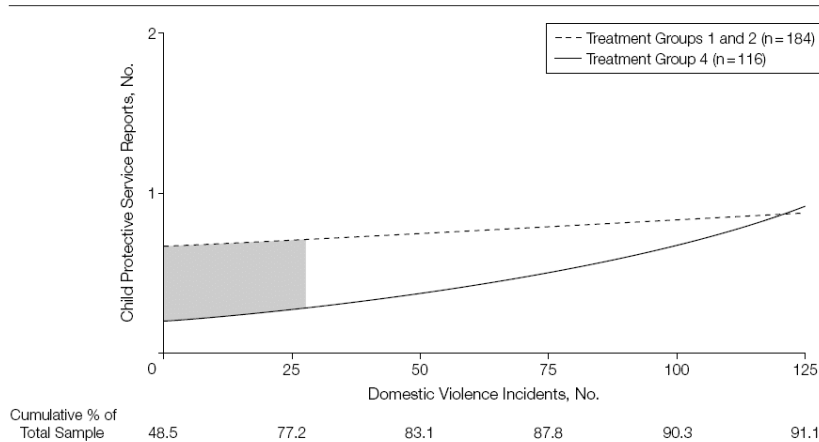
177 **NFP program effects on child maltreatment and associated outcomes**

178 The program has been shown to improve the quality and safety of the home environment (58,59); nurse-visited
179 children had fewer health-care encounters in which injuries and ingestions were detected and were hospitalized for
180 fewer days with injuries and/or ingestions than children in the comparison group. The intervention reduced rates of
181 state-verified reports of child abuse and neglect – an effect which increased over 15 years (60). However, *this*
182 *reduction was not found among mothers reporting moderate to severe levels of IPV* (61). As indicated in Figure 1
183 below, the program effect on child abuse and neglect found in the Elmira trial was reduced in those households in
184 which IPV was higher during the 15-year period following the birth of the first child. Treatment Groups 1 and 2 served
185 as the comparison group; Treatment Group 4 was the pregnancy and infancy nurse-visited group. The program effect
186 on child maltreatment decreased as the level of IPV increased, although the program had no impact on the incidence of
187 IPV in this trial. The moderating effect of IPV was specific to child maltreatment, and did not attenuate program
188 effects on any other outcomes (61).

189 It is of note, then, that nurse-visited women in the Denver trial reported significantly less IPV during the six-
190 month interval prior to the four-year interview than those in the control group (6.9% vs. 13.6%, $p=.05$) (62). IPV was
191 measured by the Conflict Tactics Scales' (75) physical violence items (e.g. being slapped, kicked, choked or threatened
192 with a knife or gun). However, nurse-visited mothers in the Memphis trial did not report less domestic violence at the
193 six-year follow-up interview relative to those in the control group (65). This strongly suggests that the standard NFP
194 curriculum requires enhancement in order to consistently reduce this adverse outcome.

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Figure. Adjusted Number of Maltreatment Reports Involving Study Children by Treatment Group and Level of Domestic Violence



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Figure 1

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Further, data indicate that IPV among NFP clients is common at the time of registration during pregnancy (see Preliminary Studies below). Finally, NFP nurses have expressed the need for a specific intervention to assist women exposed to IPV (see Preliminary Studies).

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SIGNIFICANCE

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This innovative project, which builds on the existing scientific and theoretical evidence for how best to assist high-risk families, has the potential to be highly significant. It will develop and test a new IPV intervention that, if effective, will improve the quality of life of these young mothers, reduce IPV, and in turn, reduce their children’s exposure to violence. There is little evidence that existing programs to reduce violence against women are actually effective. If the intervention developed for the NFP is shown to be effective, it may have wider applicability beyond this home visitation program, including the potential to influence the development of interventions for women beyond the perinatal period, and with other populations of women. The combined NFP+IPV intervention has the potential to launch young families on a violence-free path and break the inter-generational cycle of violence.

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C. PRELIMINARY STUDIES

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NFP Research Studies

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NFP article citations summarizing the results from the three trials conducted by Dr. David Olds, co-principal Investigator can be found in Appendix A.

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216

Studies from the NFP Replication

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In preparation for this proposal, two preliminary studies were undertaken. The first was an analysis of data collected from NFP participants in the replication programs. Process data as well as maternal, child, and family outcomes are gathered by every nurse for every family in the national replication sites of the NFP. Data are entered into the Clinical Information System (CIS). Every site implements the CIS, which is now located on the Worldwide Web.

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Table 1 summarizes the sociodemographic characteristics of women (N=57,017) enrolled in NFP National replication sites through December 2005.

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Table 1. Sociodemographic characteristics of participants

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Median Age	Median Education	Unmarried	Hispanic	Native American	Black	Non-Hispanic White	Asian	Mixed Race/	Median Annual Income	WIC	Medicaid	Food Stamps	TANF
19 yrs	11 yrs	80%	21%	5%	19%	49%	1%	5%	\$13,500	75%	65%	17%	5%

226
227 These characteristics (younger age, low socioeconomic status, lower education) are significantly correlated with
228 IPV risk (76).

229 All women enrolled in the NFP are asked about exposure to IPV, using a slightly modified version of the Abuse
230 Assessment Screen (77; see Measures below) shortly after enrollment (between intake and the third visit), at 36 weeks
231 gestation and when the infant is 12 months of age (see Appendix B). At intake, 30% of participants endorsed having
232 “ever been emotionally or physically abused by your partner or someone close to you”. In addition to the lifetime
233 question, four questions asked about experiences of violence in the last 12 months: 1) “have you been hit, slapped,
234 kicked or otherwise physically hurt by someone”; 2) “within the last year, has anyone forced you to have sexual
235 relations”; 3) “since your pregnancy began have you been hit, slapped, kicked or otherwise physically hurt by
236 someone”; and 4) “are you afraid of any current or previous male partner or someone else important to you”. These
237 behaviors reflect moderate to severe abuse. Responses were tabulated where the respondent indicated that the
238 perpetrator was one or more of husband, ex-husband, boyfriend, ex-boyfriend. One or more yes responses were
239 deemed “IPV”. Overall, 9.9% of women were experiencing this moderate to severe IPV at intake. Secondary analysis
240 of data from a separate study of community women (N=2461) presenting at a health care setting (78) showed a
241 prevalence of 6.6% when measured on equivalent abuse items. The prevalence in the NFP population, then, is 50%
242 higher than in that community sample. Only 0.5% of NFP women were receiving “domestic violence services” at
243 intake.

244 The second preliminary study targeted nurses delivering the program. A web-based survey was sent to all NFP
245 nurses (N=512) and supervisors (N=134). Appendix B contains the survey. The response rate was 283/646 (44%).
246 About 72% of those responding reported that IPV in the home made delivering the NFP program somewhat or very
247 difficult; 38% felt that they did not have enough knowledge and 43% that they did not have enough skills relevant to
248 IPV; 61% reported not enough formal training to address IPV in NFP families. Given the expertise and background of
249 NFP nurses, they are in a unique position as health care providers to assist women experiencing IPV. Clearly there is a
250 need to help nurses feel adequately prepared to deal with this issue.

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252 **D. RESEARCH DESIGN AND METHODS**

253 **Overview of Research Design**

254 The overall program of research will use a sequential mixed methods design; this involves collecting, analyzing
255 and integrating both quantitative and qualitative data for the purpose of developing a holistic understanding of the
256 phenomenon under study (79). The proposed research would occur in two phases: 1) Project 1 develops a model of in-
257 home IPV intervention to include in the current NFP protocol. Qualitative interviews will be conducted with NFP
258 program nurses, clients, program administrators, and community partners working on domestic violence to guide the
259 formative development of the intervention, which then will be piloted. 2) Project 2 tests the intervention in NFP sites
260 and evaluates its effectiveness in improving quality of life and reducing violence for women as well as mothers’ reports
261 of their children’s exposure to IPV. Additionally, regular evaluations and feedback from NFP nurses will measure self-
262 efficacy in their management of IPV.

263 The specific aims of the proposed research are to:

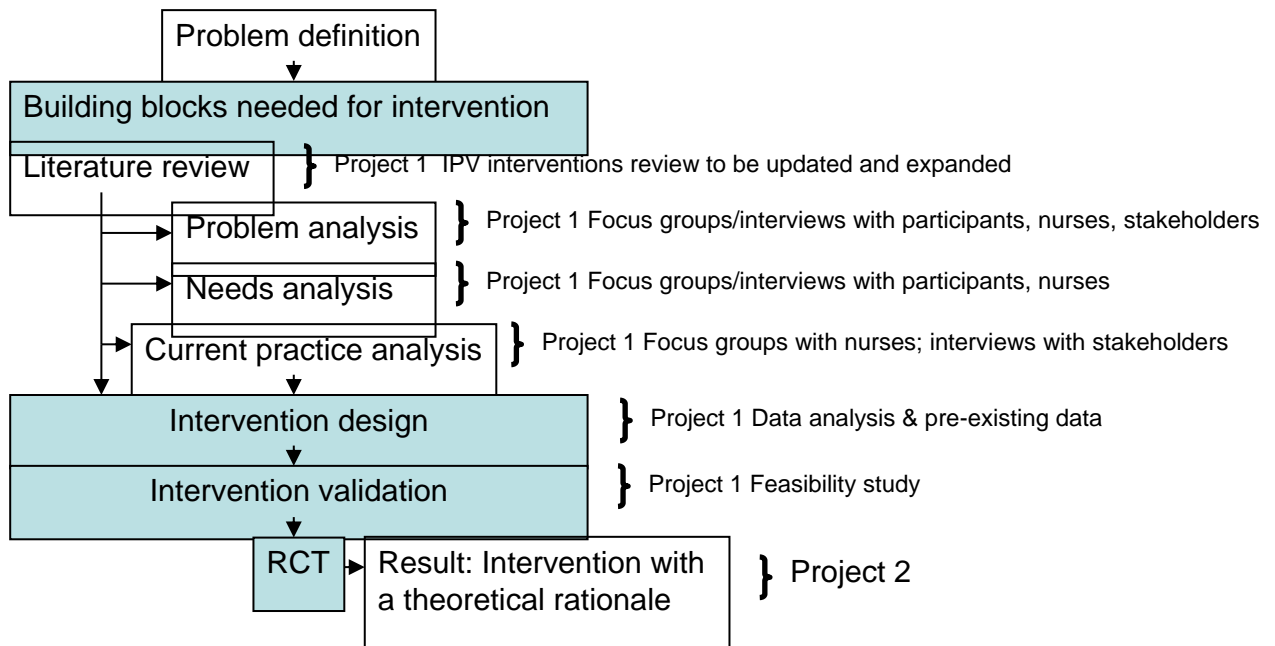
- 264 1) Develop a model of in-home IPV intervention for NFP mothers exposed to intimate partner violence (“NFP +
265 IPV”) (Project 1).
266 2) Determine whether the intervention is feasible and acceptable in a small sample of NFP clients and nurses
267 (Project 1).

268 3) Determine whether the NFP+IPVI intervention improves women’s quality of life and reduces violence relative
 269 to the NFP alone using a cluster randomized controlled trial. (Project 2)
 270 We have adopted the framework for the development of nursing interventions from vanMeijel and colleagues
 271 (80) (Figure 2).

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281 **Figure 2.** Framework for development of a nursing intervention from vanMeijel and
 282 colleagues (80) and projects that accomplish each component

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285 **Problem definition**

286 As outlined above, only one intervention (54,55) has proven effective for women experiencing IPV, and it may
 287 not generalize to women outside shelters. The linkage of the proposed intervention with the NFP is driven by the four
 288 issues detailed above: attenuated reduction in child maltreatment in homes experiencing IPV; the prevalence of IPV
 289 among NFP participants; some indication that NFP as delivered may have positive effects on IPV; and NFP nurses’
 290 desire for IPV strategies. As well, the NFP has many of the important characteristics (49-55) to support the
 291 development and implementation of a potentially effective intervention.

292 **Literature review**

293 In the model above, the literature review informs the problem analysis, needs analysis, current practice analysis
294 and intervention design. Since the intervention to be developed will be specific to the NFP program (thus limiting the
295 usefulness of a more general review), the literature review will focus on intervention design, and will expand upon the
296 work done in the preparation of this proposal (details in Intervention Design section below).

297 **PROJECT 1: Develop an intervention for NFP mothers exposed to IPV (“NFP + IPV1”)**

298 A qualitative study using case study methodology (81) will analyze the problem as defined by all stakeholders,
299 client needs and current practice of NFP nurses. A case study approach provides the structure for collecting the data
300 that will inform the development of the intervention (82). Data triangulation, or the use of multiple data sources and
301 data types, is a key characteristic of case study research (83) and is used to gain understanding, to ensure completeness,
302 and to confirm the credibility of findings (84). Data will be collected from NFP clients, nurses, administrators and
303 community stakeholders in four NFP sites to ensure that individual, organizational, and social factors influencing the
304 phenomenon of supporting mothers exposed to IPV are identified.

305 **Design and site selection**

306 We propose an embedded, multiple-case approach; this contributes to the transferability (generalizability) of
307 study findings (81). Cases are purposefully selected based on predictions that findings will be similar in nature (literal
308 replication) or contrasting (theoretical replication) (81). Multiple NFP sites will be recruited in this development phase
309 so that a broad understanding of how different organizational and social factors and characteristics of sub-groups of
310 participants may influence an IPV intervention. The inclusion criteria are as follows: 1) a NFP site that has graduated
311 at least one cohort of program clients; 2) evidence from the NFP Client Information System (CIS) that nurses are
312 providing services to women exposed to IPV; 3) low levels of nurse attrition; and 4) a high percentage of nurses who
313 have worked in providing home visitation services for more than two years. We will select four sites from which to
314 recruit clients and nurses, based on ensuring limited simultaneous involvement in other research studies as well as
315 reasonable proximity for travel and cost considerations. As outlined in attached letters of support, the following NFP
316 sites have indicated their willingness to participate in Project 1 and have provided details of their client populations:

317

318 Baby Steps Nurse Family Partnership Program, Cass County, (Fargo), North Dakota

319 Brighter Futures Nurse Family Partnership, Montgomery County, (Dayton), Ohio

320 Center for Child and Family Advocacy Nurse Family Partnership, Franklin County, (Columbus), Ohio

321 Clay County Public Health Nurse Partnership (Moorhead), Minnesota

322 Guilford Child Development Nurse Family Partnership, Guilford County, (Greensboro), North Carolina

323 Kane Kares / Nurse Family Partnership, Kane County, Illinois

324 Pontiac Nurse Family Partnership Program, Oakland County, Pontiac, Michigan

325 Trenton Nurse Family Partnership Program, Mercer County (Trenton), New Jersey

326 **Problem Analysis, Needs Analysis & Current Practice Analysis**

327 The case study will explore the problem of IPV as it is reported by mothers enrolled in the NFP and as it is
328 identified by the NFP nurses (80,85). These data sources will also elucidate the range of mothers’ needs and requests
329 for intervention (80,85). Finally, we will analyze current strategies nurses use to address the needs of women exposed
330 to IPV. Interviews with NFP administrators and key NFP community partners will further identify current practices
331 and organizational policies.

332 **Case study propositions**

333 Using concepts from the theoretical literature and building upon the expertise of NFP researchers, our *a priori*
334 propositions (similar to hypotheses in quantitative work) guiding and limiting the case study (81) are:

- 335 1. Women experiencing IPV are central to defining the problem of IPV and are the best source of information
336 regarding their needs.
- 337 2. The needs of women will be influenced by (a) the type and severity of violence being experienced; (b) the
338 meanings the woman attributes to her experiences of violence and relationships (86); (c) her readiness to
339 respond to the violence in her life (86); (d) her definition of a positive outcome; “success” may range from her
340 identifying strategies for coping with the abusive behavior to the perpetrator leaving the household.
- 341 3. Nurses who intervene with women exposed to IPV must be non-judgmental, compassionate, sensitive and
342 committed to keeping information confidential (87).
- 343 4. The relationship that develops between a woman and her nurse within the home visiting context is an important
344 facilitator of change (88).
- 345 5. Several facilitators as well as barriers to the implementation and effectiveness of an intervention exist. Some
346 of these may be specific to the site and to the organization or environment in which it is situated, e.g. workload,
347 availability of services. Others are not; for example, the presence of partner in home (89), or developing a
348 trusting relationship (88,90).
- 349 6. Nurse training about IPV-related issues and the development of skills for identifying and responding to IPV
350 will reduce some barriers to the implementation and success of the IPV intervention (91).
351

352 **Interviews with NFP Mothers**

353 We will conduct an in-depth exploration of mothers’ experiences of living, parenting and receiving support
354 through the NFP while exposed to IPV. Women are enrolled in the NFP when less than 29 weeks pregnant; they must
355 have no previous live births and low income (eligible for Medicaid). Women who 1) report exposure to IPV within the
356 past year on the Abuse Assessment Screen (44,77,92,93), which is routinely administered to women within the first 3
357 visits, 2) are age 16 years or older and 3) able to converse in English will be eligible. Informed consent (see Appendix
358 B) will be obtained from each study participant (and each parent for those subjects who are younger than 18 and not
359 emancipated according to state laws). Women will be asked to participate in one face-to-face interview (60- to 90-
360 minute) and a brief (30-minute) interview about six months later. Each participant will be given an honorarium of \$30
361 for each completed interview and reimbursed for costs incurred (e.g. child care).

362 We will continue to sample to the point of saturation – i.e., no new variation in the data. We estimate recruiting
363 about 20 NFP mothers (five women per site) (94). Maximum variation sampling will be used to recruit women who
364 differ in their length of involvement with NFP and their household composition.

365 A training and safety protocol for interviewing women exposed to IPV, based on that used extensively by
366 members of this research team in similar work, has been developed to minimize safety risks to the client and to ensure
367 that all contacts are conducted in a safe manner (95); it is included in Appendix B.

368 With the permission of the participant, all interviews will be audiotaped. A semi-structured interview guide
369 (Appendix B) with sample questions and probes to use during the first interview has been developed. The interview
370 guide may be adapted during data collection to promote exploration of emerging themes (96). In the second interview,
371 the researcher will describe the emergent key themes from the interviews and ask the participant to comment on the
372 accuracy of the interpretation.

373 At the end of each interview, the participant will also be asked to complete the Composite Abuse Scale (CAS)
374 (97) and the Domestic Violence Survivor Assessment tool (DVSA) (see description in Measures below) (86).
375 Quantitative data from these tools will be used to enrich the analysis of the interview data.

376 To facilitate immersion in the data and to enhance the analytic process, 25% of the interviews will be conducted
377 by Dr. Susan Jack (SJ). The remaining interviews will be conducted by the local research assistant.

378

379 **Focus groups with NFP Nurses**

380 NFP nurses who report having worked with abused NFP women will be invited to participate in focus groups
381 conducted to further the problem analysis, including knowledge about the factors that impact the effectiveness of the
382 NFP protocol with women exposed to IPV. As part of the current practice analysis, we will explore nursing strategies
383 currently used to resolve client issues related to IPV and to meet client identified needs. Two 90- to 120-minute focus
384 groups will occur over the course of six months. Four to six nurses will participate in each focus group.

385 Audiotaped focus groups will be facilitated by SJ and the local research assistant will attend to record field notes
386 of observations of group and individual behaviors and interactions (98). The first focus group will involve: 1) a
387 reflection on NFP mothers' experience of the problem and their needs; 2) nurses' experiences in working with women
388 and children exposed to IPV; 3) identification of current strategies used to identify and respond to IPV; 4) nurse
389 recommendations for strategies to enhance management of IPV within the NFP program; and 5) client, organizational,
390 cultural and systemic factors influencing the nurses' abilities to respond to IPV. The second focus group will explore:
391 1) the knowledge and skills required for nurses to address IPV during home visits; 2) issues regarding nurses'
392 perceived self-efficacy and capacity to respond to IPV; and 3) the feasibility of using motivational interviewing (MI)
393 techniques to enhance client self-efficacy and stimulate behavior change (99). The semi-structured interview guide for
394 each focus group is included in Appendix B. A summary of key themes emerging from each group will be distributed
395 to participating nurses for comments on the accuracy of the interpretation of the data (84).

396

397 **Interviews with Key Informants**

398 To identify facilitators and barriers to augmenting the NFP program to address IPV and to discuss the feasibility of
399 intervention components suggested by NFP mothers and nurses, interviews will be conducted with consenting NFP
400 program stakeholders. Informants will be identified by NFP nurses, program administrators and study investigators.
401 These may include NFP supervisors and personnel from domestic violence service agencies, local child welfare
402 agencies, mental health services, or police departments. Approximately five key informant interviews will be
403 conducted per case study site. The purpose of the first interview (60 to 90 minutes) is to understand the stakeholder's
404 current role in supporting women exposed to IPV and to identify organizational, system and cultural influences on
405 developing enhanced NFP interventions to support this population. Appendix B includes the semi-structured interview
406 guide. Within two months, a second interview (30 minutes) will explore whether the researchers' interpretation of the
407 data is congruent with the stakeholder's experiences. At the end of the first interview, each key informant will receive
408 an honorarium of a \$25 gift certificate. Across all data collection procedures, SJ and local research assistants will
409 maintain field notes and reflective journals (100-102).

410 **Data analysis**

411 Data analysis will be conducted concurrent with data collection in order to identify emerging themes requiring
412 further exploration. All data will be transcribed and stored in password-protected files. NVivo 7.0 will be used for
413 indexing, searching, and coding. Principles of conventional content analysis (103,104) and constant comparison (103)
414 will guide the coding and analysis. SJ, Dr. Marilyn Ford-Gilboe, co-investigator, and the research coordinator will
415 participate in the first, second and third level coding of the data (103). Then we will compare and contrast findings
416 across sites to identify core themes related to managing IPV within the NFP and to identify factors that facilitate or
417 inhibit the implementation of a nurse intervention (105). A case narrative (multiple-case report) will be written to
418 inform intervention design and the training program for nurses delivering the intervention.

419 **Intervention design**

420 Two primary sources of information will be used: the results of the case study above and literature reviews.
421 Much review work has been done in preparation for this proposal; it will be expanded to include a recent meta-analysis
422 of qualitative studies identifying what women want from health care providers in response to disclosures of abuse (87),
423 preliminary results from the Women's Health Effects Study (WHES; Dr. Ford-Gilboe, principal investigator), a
424 longitudinal investigation of women's health and resources in the early years after leaving an abusive partner (106), as
425 well as reviews of MI outcome studies, and the relationship of MI to stages of change, especially as it pertains to IPV.

426 Once the qualitative analysis and the expanded literature review are complete, the research team will develop a
427 first draft to describe the intervention's 1) goals/outcomes, 2) principles, 3) processes, 4) structure, and 5) content. For
428 example, findings from the meta-analysis can be used to create a draft set of principles that guide interactions between
429 nurses and clients (87); studies by Bybee and Sullivan (49-55) and the WHES can determine the specific content of the

430 intervention (e.g., safety planning and use of community resources); women’s perceptions of the “success” of the
431 intervention will contribute to defining goals.

432 We anticipate that MI will be an important component of the intervention, as it is designed to address participants’
433 ambivalence about behavioral change (a critical challenge facing women who are in abusive relationships), but this will
434 be explored through the qualitative study. Developed by Miller and Rollnick (107), MI involves the client and health
435 care provider working together to facilitate the client’s movement through stages of change in achieving health benefits
436 (108). MI includes two main elements: 1) building a therapeutic rapport with clients, especially those who are
437 ambivalent about change; and 2) facilitating progression through decision-making and behavioral change. NFP nurses
438 currently use MI in the NFP model; the focus groups will better clarify MI’s role in current practice. We expect that
439 the intervention, in its broadest outline, will use MI techniques to assist women in moving through the stages of change
440 outlined by Prochaska (109) and made specific to IPV by Dienemann and colleagues (86).

441 Several aspects of MI make it an appealing initial technique for consideration in developing the NFP-IPV
442 intervention. First, it has demonstrated efficacy for improving health-related behaviors in other domains, such as
443 reducing substance use and increasing exercise (110). Second, MI experts have successfully trained non-mental health
444 providers, including nurses, in this psychosocial approach (111,112). Third, a MI coding system already exists so that
445 we can assess treatment fidelity.

446 **Intervention validation**

447 A training program and structure for integrating the intervention within the existing NFP will be developed and
448 then tested with nurses and their clients prior to the preliminary trial. The current core training for the NFP includes a
449 combination of core training in Denver (three separate three-day sessions for nurses and five three-day sessions for
450 supervisors), on-site training at the individual NFP sites and distance learning for follow-up and reinforcement of
451 concepts. Once the intervention is developed, it will be integrated into the core training for those sites participating as
452 NFP-IPVI sites in the RCT. Each site will have at least one session of face-to-face training for the NFP-IPV
453 intervention with further distance learning through use of web-based instruction and teleconferencing. The training will
454 be developed in consultation with Ms. Baca, Director of Program Development for NFP, who has advised us on this
455 proposed strategy. Further development of the training program will await creation of the intervention.

456 Development of the training program will only occur after the acceptability of the intervention has been
457 determined as outlined below. Please refer to Appendix C for examples of the current training program.

458 The intervention will be implemented over a two-month period with 10 clients and 10 nurses (5 clients and 5
459 nurses each in two sites) and interviews conducted at the end of the first and second months to determine its
460 acceptability among nurses and clients. The two NFP+IPVI sites will be selected from among the sites that participated
461 in the development of the intervention. How the client experiences the intervention and the effects of the intervention
462 as observed by both nurse and client will also be explored. This process will continue with revision of the intervention
463 until eight of the ten nurses and clients (80%) each find the intervention acceptable based on an instrument that will be
464 developed using Likert scaling.

465 We hypothesize that:

- 466 1. The intervention developed in Project 1 (NFP+IPVI) will be acceptable to clients for delivery within the NFP.
- 467 2. NFP+IPVI will be acceptable to nurses and feasible to administer within the NFP.
- 468 3. Nurses participating in training and administering the NFP+IPVI will develop an enhanced knowledge base
469 and increased self-efficacy in the management of IPV.

470

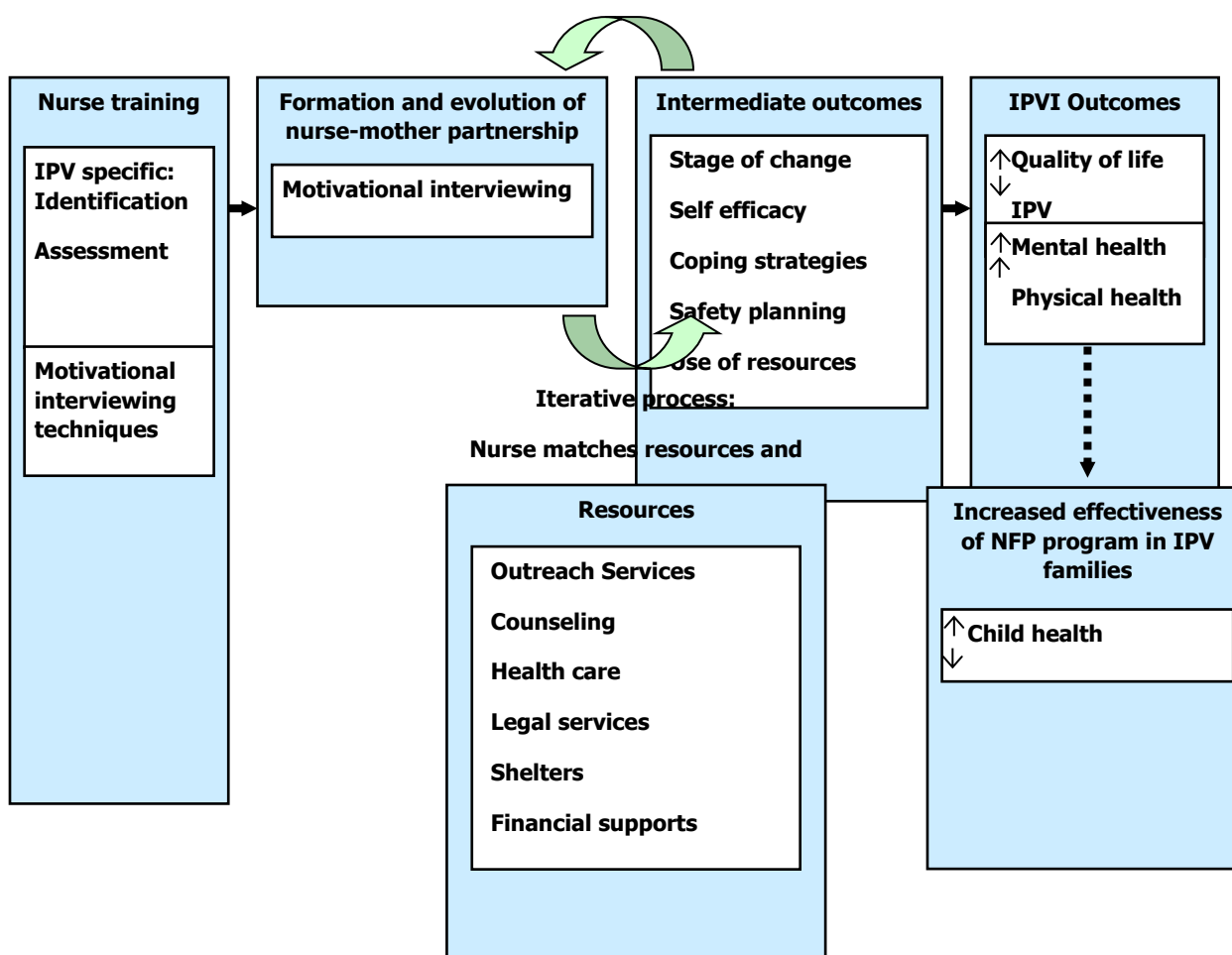
471 **PROJECT 2: RCT Testing the NFP+IPVI in a sample of NFP sites**

472

473 We will test the NFP+IPVI in a RCT with a selection of NFP sites. The IPV intervention will extend from intake
474 until two years postpartum, to match the NFP intervention period. Quality of life is the primary outcome of interest.
475 Results from a large sample of women recruited for a cluster randomized controlled IPV trial underway in Canada

476 show a strong correlation between IPV and quality of life scores, but quality of life shows greater responsiveness to
477 change (MacMillan, unpublished data). However, we will also examine reductions in IPV and intermediate measures
478 of effectiveness that provide information about the likelihood of long-term benefit for women (54,55). These include
479 self-efficacy (113), access to and use of available community resources (54), and use of protective strategies (114).
480 Figure 2 shows the proposed processes and outcomes of this intervention.

481

Figure 2. Conceptual Model of IPV Intervention processes and outcomes

483

Hypotheses

Primary hypothesis: Women receiving the NFP+IPVI, compared with those receiving the NFP alone, will experience an improvement in quality of life. Other measures will be administered in the RCT to test their feasibility and acceptability and will be reported for descriptive purposes. Depending on the study's power, once the data are collected, preliminary estimates of intervention effects on victimized women will be calculated for IPV exposure as measured by the score on the Composite Abuse Scale, self-efficacy in dealing with IPV, use of community resources, and use of protective strategies. For nurse outcomes, this will include knowledge/skills and self-efficacy in the management of IPV. For child outcomes, this will include birth weight, gestational age, injuries, emergency room visits, hospitalizations, immunizations, and developmental delay.

Design and site selection

Randomization will take place at the level of sites among 10 NFP sites. We understand that working with only 10 sites in this preliminary trial is a limitation in the design and that statistical power is likely to be limited with the number of sites to be included, but it would be impossible to prevent contamination of the groups if individuals were randomized within sites. As well, logistical issues such as nurse training and the possibility of strengthening NFP linkages with community resources have influenced this decision. The site sampling frame includes sites which have 1) no previous involvement in development or pilot-testing of the NFP+IPVI; and 2) no ongoing participation in other NFP research. We anticipate recruiting sites from a broad range of states. Five sites will receive NFP+IPVI and five will receive NFP as usual. We plan to enroll women soon after they register in the NFP program; enrollment is anticipated to extend over a six-month period. The intervention will continue until the child is two years of age. Given that the length of the grant funding period is five years, we will conduct analyses regarding effectiveness of the intervention when the child is 18 months. We would expect to see some indication of positive effects at that stage based on the literature (49-55), and the majority of the NFP visits will have been completed (55 of 64; 86%). This will provide us with the opportunity to make decisions about the need to extend the follow-up, including application for further grant support to do so, beyond the two-year intervention period, if warranted.

506 **Population and sample size considerations**

507 Sample size is based on the primary outcome: quality of life, as measured by the WHO-Bref. Based on data from our in-
508 progress RCT of screening for IPV (MacMillan, personal communication) and the findings of Sullivan and Bybee regarding the
509 magnitude of improvements in quality of life over time in both treatment and control groups (54,55) we hypothesize the following:

510

Quality of life WHO-Bref	NFP + IPV	NFP
Baseline score (sd)	230 (45)	230 (45)
18 month follow up score (sd)	271 (45)	251 (45)

511

512 We set alpha at 0.05 two-sided and power at 80%, with equal numbers in each group. A recent analysis of the data from the
513 NFP replication program showed an intra-cluster correlation (ICC) of 0.005 (115) among all NFP sites for moderate to severe IPV
514 based on the Abuse Assessment Screen (M. McClatchey, personal communication). There are no data available regarding the ICC
515 for quality of life scores from the NFP because such measures have not been administered to date; however, as noted above, measures
516 of IPV and quality of life are strongly correlated. We therefore conservatively estimate an ICC of 0.01. We assume 10 sites. Using
517 the formula given by Donner for estimating cluster randomized sample size (116), a sample of 90 per group is needed to detect a
518 small-to-moderate effect size of .45 standard deviation units on a continuously distributed measure. We allow for a refusal rate of
519 15% for the trial, and losses to follow-up of 20%: 133 women per group to be recruited.

520 **Client eligibility**

521 Women, aged 16 and older, who enroll in the NFP according to the criteria outlined above (first live birth and living in poverty)
522 and speak English, will be eligible for the study. Women who cannot communicate in English will be excluded because of the
523 specific problems of confidentiality and safety when using interpreters to discuss IPV.

524 All NFP clients are administered the Abuse Assessment Screen (77) (see Measures, below) during one of the first three visits.
525 Women positive on the screen (yes to any of the 4 questions about IPV in the last 12 months) will be invited to participate. Clients
526 will be advised that they are under no obligation to participate in the trial itself, but that specific sites have been designated as sites
527 where an IPV intervention is being evaluated.

528 **Intervention (NFP+IPVI)**

529 As outlined above, the content and implementation of the NFP+IPVI will be determined in Project 1. The availability and
530 accessibility of community resources and services, as well as community agency interventions for women exposed to IPV will also be
531 identified in the qualitative study. Strategies for overcoming barriers to using and accessing these services will be built into the
532 NFP+IPVI. We expect that the protocol for number and timing of visits will be the same for both NFP+IPVI and Standard Care, as
533 follows: weekly for the first four visits (while establishing a relationship), every other week for the remainder of the pregnancy, every
534 week for six weeks in the postpartum and every other week until the infant is 21 months old after which it is once a month for the last
535 three months. However, we also recognize that the intervention might prompt the nurse and mother to alter the regular visit schedule
536 if IPV is present.

537 **Standard Care**

538 The NFP nurses currently receive some training regarding IPV, but it is minimal. Between intake and the third visit, at 36
539 weeks of pregnancy, and when the child is 12 months old, there is a brief instruction that the nurse assess for IPV; if the client
540 acknowledges current abuse when completing the Abuse Assessment Screen, the nurse should “assist her to evaluate threats to
541 personal safety and make referrals as needed”. There is a prompt to be mindful of client safety, and to make referrals as needed.
542 Supervisors at sites are advised that IPV is a topic about which they should provide training if the nurses express lack of confidence
543 in their knowledge. No additional materials about IPV are provided at this point.

544 The existing Visit Guidelines first introduce materials for the nurse to discuss IPV in more depth with the client at Visit 17
545 when the infant is 28 weeks old. Assessment of the client’s risk for IPV is recommended again at Visit 36, when the child is 15½
546 months of age. The nurse uses educational materials, “Dealing with Domestic Violence in the Home” and the facilitator, “Preventing
547 and Dealing with Domestic Violence in the Home”, to raise the issue of IPV with the client. There is also information provided on
548 the effects of IPV on children. Copies of the IPV materials currently used in the NFP are included in Appendix C. We will not limit
549 in any way nurses assisting abused women in the usual care sites. As outlined below, we will collect information from the nurses
550 using web-based questions to determine specific information about any activities involving IPV intervention prior to the start of the
551 trial, and this will be monitored throughout the course of the trial.

552 Measures

553 Table 2 summarizes all constructs and instruments that are detailed in the text below. To introduce efficiencies, we use some
554 measures collected routinely by nurses as part of the NFP program where constructs overlap. Built to assess many of the outcomes
555 and background variables examined in trials of the NFP, the CIS provides extensive data relevant to this study (Table 2). Copies of
556 CIS questionnaires can be found in Appendix B.

557 Data Collection

558 Study assessments will be implemented following intake at baseline, 36 weeks gestation (near the end of pregnancy) and
559 every six months postpartum until the child is 18 months of age (with plans to extend follow-up to two years and beyond, if results of
560 the analysis at 18 months suggest positive effects). NFP nurses will collect the CIS data required by the NFP program. However, the
561 main outcome measure and most secondary measures will be collected in telephone interviews conducted with each participant by a
562 research assistant masked to group allocation. As well, study research assistants will collect (by telephone interview) *all* measures
563 listed in Table 2 from participants who drop from the program, since NFP nurses would not be visiting those who have left the
564 program.

565 Quality of Life

566 The World Health Organization Quality of Life instrument (WHOQoL-Bref) (117,118) consists of 26 items using a five-point
567 Likert-type scale. These items are organized into four domains of physical health (7 items), psychological health (6 items), social
568 relationships (3 items), and environment (8 items). The remaining two items measure overall quality of life and general health. This
569 test shows good internal consistency (Cronbach alpha: physical health, 0.80, psychological health, 0.76, social relationships, 0.66, and
570 environment, 0.80) and test-retest reliability (0.66 for physical health, 0.72 for psychological, 0.76 for social relationships and 0.87
571 for environment) (117,118). The WHOQoL-Bref is currently being used as a primary outcome measure in the McMaster VAW
572 Screening Effectiveness Trial, allowing us to validate the tool in a sample of abused women.

573 Exposure to IPV

574 As noted above, a modified Abuse Assessment Screen (77) is used by NFP nurses to probe for IPV. The scale was designed for
575 clinical use among pregnant women and has shown test-retest reliability of .97 and criteria-related validity established against
576 national survey instruments (92). It focuses on physical and sexual abuse. This screen determines eligibility for the study; the longer,
577 more comprehensive instrument below is used to measure more precisely the severity and frequency of abuse.

578 The Composite Abuse Scale (CAS) is a validated 30-item research instrument that assesses exposure to physical, sexual and
579 emotional abuse, harassment and combined severe abuse (97,119). The CAS has a total possible score of 150; each of the 30 items is
580 measured according to frequency, from 0 = “never” to 5 = “daily.” A CAS score of ≥ 7 is considered positive for exposure to IPV.
581 The internal consistency (reliability) of the CAS is high with Cronbach alpha for each scale of > 0.85 and all item-total correlations of
582 > 0.5 (119).

583 Stage/state in process of taking action to reduce violence

584 The Domestic Violence Survivor Assessment (DVSA) is based on Prochaska’s Transtheoretical Model of Behaviour Change
585 (109) (also known as “stages of change”) and was developed by Dienemann and colleagues (86) to gain a better understanding of
586 battered women’s cognitive states during counseling. The goal of the DVSA, which used Landenberger’s theory of entrapment and
587 recovery as a guiding framework, is to assist battered women to effectively resolve the dilemma of their abusive relationships while
588 experiencing personal growth. There are two versions of the test – Clinician and Woman’s Self Report. The Clinician form has
589 shown good inter-rater reliability with agreement varying from 44 to 81% (86). However, a modified version is currently being tested
590 and will be used in this study. The DVSA is currently being used as a secondary outcome measure in the McMaster VAW Screening
591 Effectiveness Trial.

592 Maternal health and behavioral outcomes related to violence exposure.

593 A number of mental health and behavioral outcomes are highly correlated with abuse status (14). The following measures,
594 some of which are routinely collected in the NFP with the CIS, will be included in the present study:

595
596 Depression –Depression will be assessed using the self-report version of the nine-item depression sub-scale from the PRIME-
597 MD Patient Health Questionnaire (PHQ-9) (120). The PHQ-9 items range in frequency from 0 = not at all to 3 = nearly every day
598 (range 0-27). The test-retest reliability of the PHQ-9 was 0.84 (two tests were within 48 hours of each other). For PHQ-9 criterion
599 validity, scores that were greater than or equal to 10 had a sensitivity of 88% and a specificity of 88% for major depression. For

construct validity, associations between the PHQ-9 and the Medical Outcomes Study Short-Form General Health Survey (SF-20) scales ranged from .27 to .73 (121).

Post-Traumatic Stress Disorder - SPAN (Startle, Physiological arousal, Anger and Numbness): The SPAN is a four-item derivation of the longer Davidson Trauma Scale (122), an established measure of PTSD validated, in part, on a sample of battered women. The SPAN had an efficiency of 0.88, sensitivity of 0.84, specificity of 0.91 and positive likelihood ratio of 0.90 in a sample of mainly Caucasian women (123).

Physical Health - The SF-12 (v. 2) is a valid and reliable short-form of the widely used SF-36, which measures global mental and physical health and well-being. The instrument was designed to measure the effectiveness of interventions, and is very sensitive to change (124).

Alcohol Use - The TWEAK is a five-item screening tool for alcohol abuse/dependency. TWEAK is an acronym for Tolerance (number of drinks to feel high), Worry about drinking, Eye-opener (morning drinking), Amnnesia (blackouts), and Cut down on drinking (K/C). The TWEAK has been found to be “the optimal screening questionnaire for identifying women with heavy drinking or alcohol abuse and dependence in racially mixed populations” (125).

Prescription and Street Drug Use - The drug use questions will be based on two questions from the Drug Abuse Screening Tool (DAST) being tested in the McMaster VAW Screening Trial, and in Dr. Ford-Gilboe’s studies.

Specific actions women take to cope with violence

The Intimate Partner Violence Strategies Index (IPV Strategies) asks women about the nature and extent of specific strategies, across a number of instrumental domains, that they have used to deal with an abusive relationship (114). The 39-item instrument asks women whether or not they have taken a specific action, and if so how helpful it was. Dr. Ford-Gilboe has added an additional question that asks, globally, how helpful all of the actions were in dealing with the violence. This instrument (with the added global question) is being used in both the McMaster VAW Screening Effectiveness Trial, as well as Dr. Ford-Gilboe’s studies with women who have left an abusive relationship.

Child health outcomes

Data regarding the following child health outcomes are gathered through the CIS by maternal interview: 1) birth weight; 2) length of gestation; 3) injuries; 4) emergency department visits (including those that are injury-related); 5) hospitalizations; 6) immunizations; and 6) developmental delay. Outcomes #3 to #6 will be assessed at 6, 12 and 18 months postpartum. We also will abstract the children’s Child Protection Service records to assess the number of reports made, cases of confirmed child maltreatment, the type of maltreatment, the duration that cases were open, and whether children were placed in foster care or in custody of another family member.

Nurses’ readiness to treat IPV

The Domestic Violence Health Care Provider Survey (DVHCPS), developed by Maiuro and colleagues (126), provides a method to measure health care providers’ domestic violence-related knowledge, attitudes, and beliefs, and their perceived ability and readiness to act and use this information with their patients. The items are distributed over six domains which include perceived self sufficiency, system support, tendency to blame the victim, professional role resistance/fear of offending the patient, concerns about victim and provider safety, system support and self-reported frequency of domestic violence inquiry. This instrument has good internal consistency with an overall Cronbach alpha of 0.88. Maiuro et al. (126) suggest this tool may be useful in evaluating the success of an intervention for IPV.

Nurse characteristics, including age, years in the NFP program, and professional and personal experience with IPV will be gathered at the same time as the DVHCPS for inclusion in the statistical analysis models.

Additional sources assessing IPV

If possible, data will be gathered from state administrative records documenting any restraining orders issued by the mothers against their partners, as well as data from Child Protective Service records as outlined above under Child health outcomes. We have

646 good cooperation from the major states involved in supporting the NFP, and are confident that, given appropriate informed consent,
 647 we will be given permission to review CPS records and state administrative records on IPV. Dr. Olds has received permission to
 648 review such records in previous NFP research.

649 **Adherence to the NFP protocol**

650 CIS tracks percentage of time spent on “Friends and Family” (including a violence component) on each Home Visit Encounter
 651 and Telephone Encounter with the Family Form. This information combined with the number of visits will measure adherence. Prior
 652 to the trial, we will review the information from the CIS about the involvement of NFP nurses in addressing IPV. It is not expected
 653 that the standard care outlined above will vary substantially before the RCT is underway; however, it will be important to monitor any
 654 changes. Supervisors accompany nurses at regular intervals and observe qualities of the home visit, using a Visit Implementation
 655 Scale (VIS). The VIS captures multiple dimensions of nurse performance, including plans developed prior to the visit, assessment of
 656 family needs and teaching and guidance provided during the visit, and negotiation with the family on goals to be addressed during the
 657 next visit. This will also be used in the trial.

658 **Adherence to the NFP+IPVI protocol**

659 Once the NFP-IPV intervention is developed, a specific form will be created for use by nurses in the NFP-IPV intervention sites
 660 to provide details of their encounter with clients when IPV is identified and addressed. For the current IPV screening RCT at
 661 McMaster, we have developed a Health Care Provider Checklist (see Appendix B) that asks about the encounter between a clinician
 662 (either nurse or physician) and client in addressing IPV. This will be modified for inclusion in this trial.
 663

664 **Table 2. Constructs, instruments and timing**

665

Construct	Instrument or Form	Baseline	36 Weeks Gestation	Follow up (months)		
				6	12	18
CIS Measures*						
CIS IPV Screen	Abuse Assessment Screen (Family and Friends Form)	X	X		X	
Socio-demographics		X				
Maternal Health Behaviors	Health Habits Form	X	X		X	
Psychosocial Characteristics	Maternal Health Assessment	X				
Infant NICU & Hospital Visits	Infant Birth Form			X	X	X
Child Health Outcomes & Emergency Department Visits	Infant Health Care Update Form			X	X	X
Patterns of Welfare Use	Infant Birth Form			X	X	X
Adherence to NFP protocol	Home Visit Encounter Form Telephone Encounter Form	X	X	X	X	X
Nurse Performance	Visit Implementation Scale	X	X	X	X	X

666

667

Additional Measures**						
Exposure to IPV	Composite Abuse Scale	X	X	X	X	X
Quality of Life	WHOQoL-Bref	X	X	X	X	X
Stages of Change	DVSA	X	X	X	X	X
Depression	PHQ-9	X	X	X	X	X
PTSD	SPAN	X	X	X	X	X
Physical Health	SF-12	X	X	X	X	X
Alcohol Use	TWEAK	X	X	X	X	X
Drug Use	DAST	X	X	X	X	X
Coping with IPV	IPV Strategies	X	X	X	X	X
Nurses readiness to treat IPV	Domestic Violence Health Care Provider Survey	X	X	X	X	X
Adherence to NFP+IPVI protocol	Health Care Provider Checklist will be modified	X	X	X	X	X
Additional Sources Assessing IPV	Child Protective Services Reports Restraining Orders					X

*CIS measures are currently routinely collected by nurses as part of the NFP program

** Additional measures will be collected by phone with research assistants hired specifically for this study

Data analysis

We will estimate intent-to-treat program effects on quality of life using multilevel growth curve analysis (127). In this study, growth curve analysis will model the baseline (starting point) and trajectory (shape of the curve) formed by consecutive assessments of the same woman. We will then investigate whether or not differences in these estimates exist between women (127). The first step is achieved by regressing the repeated assessments collected over time (the dependent variable) on time itself (the independent variable); this provides modeled estimates of the baseline and trajectory of response for each woman. Next we regress the growth parameters in step one (i.e., baseline and trajectory estimates) on the characteristics of women selected for study (the independent variables).

To evaluate program effects, we will develop two different growth curve models: (a) an unconditional model to characterize growth overall (model 1) and (b) a model to compare the growth trajectories of women exposed to NFP + IPVI versus Standard Care (model 2). Model 1 provides the basis to identify statistically significant residual variation or random effects so that growth trajectories can be modeled appropriately. Model 2 provides the basis to test whether or not there are statistically significant differences (fixed effects) between women participating in NFP + IPVI versus Standard Care. In addition to comparing trajectories of response among women assigned to NFP + IPVI versus Standard Care, we will estimate net differences in response at the end of the trial (128). This will allow a formal test of outcome differences.

The use of cluster randomization is likely to result in between-site heterogeneity and within-site homogeneity of response. Although there are relatively few sites, we will include them in the analysis as a random effect.

Growth curve analysis is very flexible: it does not require equally spaced observations among respondents and easily accommodates missing data points. The moderating influence of other characteristics which prove to have a significant effect on response (age of the mother, age of youngest child, abuse severity at baseline, among others) can be examined by modeling their influence on growth trajectories. This involves testing interactions between the characteristics of women, their response pattern, and intervention status.

Intent-to-treat program effects in reductions in IPV will be estimated using logistic regression techniques within a mixed model framework (129). Repeated measurements of IPV status will be the outcome and fixed effects will include characteristics of women, their response pattern and intervention status, as well as any interaction terms warranted. In addition random effects due to randomization by cluster will be incorporated into the mixed model.

697 Intermediate measures of effectiveness will be modeled using mixed model methods also. The distribution of outcome
698 measures will determine whether a linear mixed model or a generalized linear mixed model will be utilized for data analytic purposes.
699 Nurse outcomes as well as child outcomes will be explored similarly. In the case of nurse outcomes, characteristics of nurses will be
700 incorporated into the mixed model.

702 **Strengths and limitations of the research design**

703 The proposed research will contribute significantly to knowledge about IPV intervention using a unique combination of
704 qualitative and quantitative data collection. It makes efficient use of the NFP, an existing program, already shown to improve health
705 outcomes for women and children, to develop an approach to delivering an IPV intervention to women at increased risk of IPV. As
706 outlined in the budget justification, the NFP National Office and the research team are contributing in-kind support to supplement the
707 funds sought through this application. Although the timeline is ambitious, the research team has already recruited the sites for Project
708 1, and is able to begin Project 1 as soon as funds are received.

709 Randomization by site rather than at the individual level creates challenges in the sample size requirement and data analysis,
710 however it is essential, given the strong potential for NFP-IPV group contamination, that cluster randomization is the approach used.
711 As recommended by Donner (116), when selecting sites for Project 2, we will establish cluster-level eligibility criteria so as to reduce
712 between-cluster variability and will obtain baseline measurements on potentially important prognostic variables. The research design
713 includes taking repeated assessments over time from the same clusters.

714 The current NFP intervention does include MI strategies as well as some information about IPV so it is important to consider
715 the potential for how the existing content might dilute program effects. While this is possible, the nurses currently receive minimal
716 training regarding IPV, and have expressed through web-based surveys that they see an urgent need for the development of an IPV
717 intervention. This is strong indication that existing IPV content is quite limited; clearly the intervention developed must be
718 comprehensive, must meet the clients' and nurses' needs, and include sufficient training.

719 The RCT outlined in this proposal will not provide definitive information regarding the effectiveness of the NFP-IPV
720 intervention on decreasing the recurrence of IPV; however, it is powered to detect changes in quality of life. We are limited by time
721 and budget, but most importantly, undertaking this smaller RCT will give us the information needed to make the decision to extend
722 the follow-up and/or conduct a larger scale RCT. If the NFP-IPV intervention is shown effective with English-speaking women, a
723 larger trial should also take into account the generalizability of such findings to non-English-speaking women as well.
724

725 **Follow-up protocol and safety procedures**

726 The follow-up interviews for the RCT will take place in locations selected by the participants, based on safety and comfort
727 level. We plan to:
728 Compensate participants \$25 for each interview during the prenatal period (baseline and 36 weeks gestation or the corresponding
729 gestational age of the infant should the mother deliver prior to 36 weeks), and for surveys at six, 12, and 18 months postpartum. These
730 amounts of compensation are based on the length of interviews planned.
731 Study participants will be asked for contact phone numbers and addresses where they can safely be reached. Special consideration will
732 be taken to ensure that it is safe for the participant to be contacted by phone and under what circumstances.
733 Study participants will be asked for contact numbers and addresses of two friends and two family members not living with the
734 participant. The information will be requested at each evaluation and a database developed.

735 **Safety Protocols**

736 **Participant and Staff Safety**

737 The techniques outlined in Appendix B have been used by McMaster/West Virginia University/University of Western Ontario
738 members of the research team in IPV-related studies and will undergo review with NFP colleagues prior to beginning Project 1.
739 Members of the research team have a combination of in-depth clinical and research experience in addressing issues of safety within
740 the context of family violence research.

741 For Projects 1 and 2, the study researchers and research assistants will be trained to help women who choose to participate to
742 decide the best time and date for the interviews; they will work with the woman to develop a study-specific safety plan regarding
743 where she would like to keep the letter of information (i.e. take home or keep on file at research office), how best to leave messages
744 for her; what the researchers should do if a phone call is suddenly terminated (e.g. call back, wait for woman to call the toll-free
745 number, call a neighbor or friend to check on her, call police); the best time to conduct a face-to-face interview (Project 1) or a
746 telephone interview (Project 2) and what the woman will do if she decides on the day of the interview that the situation is unsafe (e.g.
747 someone comes to her home at the scheduled interview time, she is followed to the assessment interview or seen by someone whom
748 she perceives is a threat). For the face-to-face interviews in Project 1, the interviewer will encourage the woman to consider her
749 visibility, particularly in small communities, and will have alternate locations to offer such as a shelter, or conference room in a health
750 care facility. They will also plan for care of children while participating in the study.

751 During each subsequent contact with the woman, interviewers will: determine if it is safe to talk at the beginning of the
752 conversation; update how to safely contact the participant, the safety plan, and the contact information, recording it on the contact
753 sheet; obtain or reaffirm informed consent; confirm when the next contact will be and obtain permission to make a reminder call; and
754 in Project 1, avoid leaving the interview location with the participant. The interviewer may provide money for transportation as
755 necessary.

756 **Research Assistant Safety**

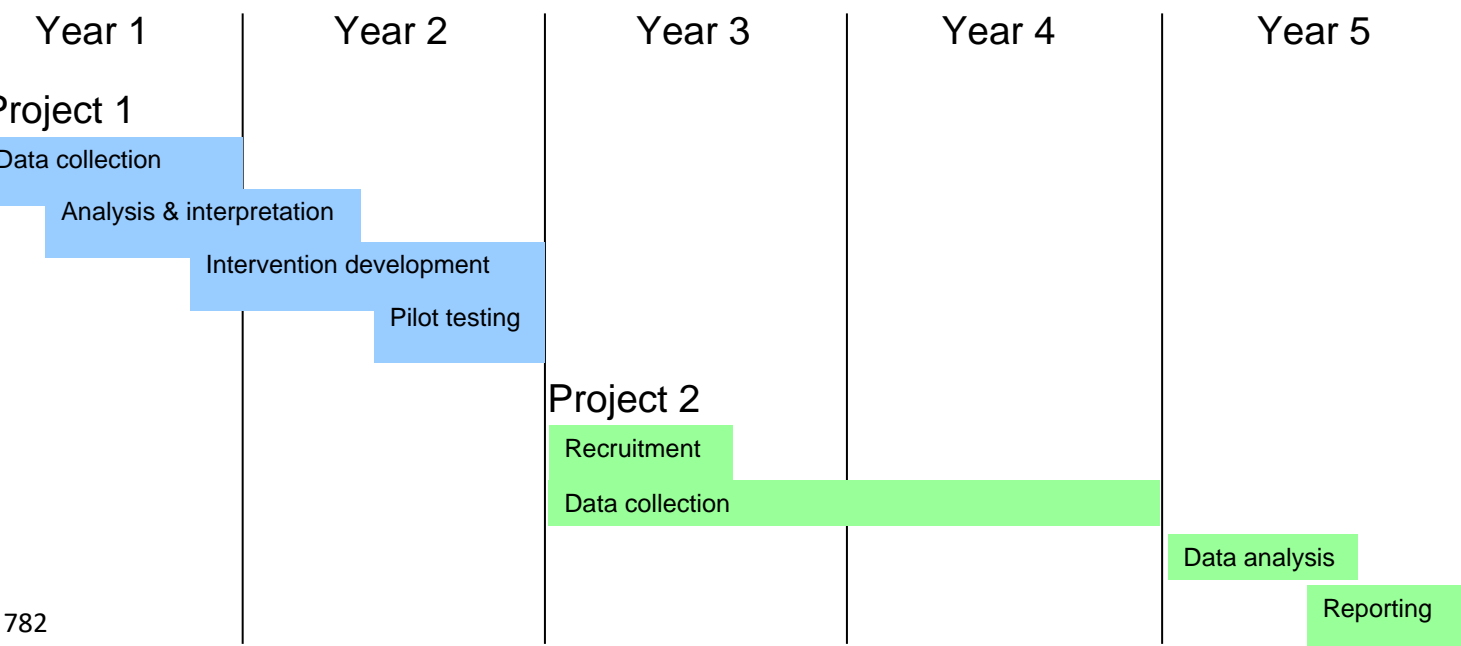
757 At each site, there will be a protocol for researcher safety; further information about this protocol is outlined in Appendix B.

758 Research assistants will participate in a training session regarding safety of participants and staff in this study. General
759 guidelines for research assistant safety, particularly in Project 1, include such aspects as knowing the interview location, approaching
760 the interview confidently, organizing necessary materials and bringing only essentials to the interview, among others.

761 **Personnel and Responsibilities**

762 As principal investigator, Dr. MacMillan from McMaster University will work closely with co-principal investigators, Drs.
763 Coben from West Virginia University (WVU) and Olds from University of Colorado in overseeing the five-year research plan.
764 Project 1 will be led by Dr. Jack; she will oversee the qualitative work, in consultation with Drs. Ford-Gilboe, Stevens and Wathen.
765 Dr. Jack will work closely with Ms. Baca in all aspects of recruiting nurses and participants for involvement in Project 1. Drs. Jack
766 and Coben will hire and supervise the research coordinator and research assistants involved in Project 1. Dr. Scribano will assist with
767 the identification and recruitment of relevant stakeholders/providers for the collection of qualitative data. He will also help to
768 develop the intervention protocol. Ms. Jamieson and Dr. McClatchey, who oversees the CIS, will be responsible for development of
769 the data management system for the studies; along with Dr. Boyle, they will be responsible for the data analysis. Development of the
770 intervention will occur in consultation with Dr. Coben, the University of Colorado/NFP team of Drs. Olds, O'Brien, McClatchey and
771 Mss. Baca and Pinto, the McMaster team of Drs. MacMillan, Jack, Wathen, Boyle and Ms. Jamieson, Dr. Ford-Gilboe from the
772 University of Western Ontario (UWO) and Drs. Stevens and Scribano from Ohio State University. Dr. MacMillan will supervise the
773 pilot work and consult with co-investigators and staff to identify potential problems and make necessary alterations before the RCT is
774 initiated. Drs. MacMillan, Jack, Coben, Wathen and Ms. Jamieson will be responsible for overseeing Project 2. One of these
775 investigators will meet with staff members to provide information about the study; contact with NFP nurses and supervisors will be
776 coordinated through the University of Colorado/NFP team of Mss. Baca, Pinto and Dr. Olds. The three teams in addition to Drs.
777 Stevens and Scribano will collaborate on data analysis, interpretation and disseminating results. Dr. Jack will serve as a liaison for
778 the WVU, University of Colorado/NFP, McMaster/UWO and Ohio State University personnel.

780 **Figure 3. Timeline**



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783
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Project Timeline

Figure 3 shows the time-line for the completion of Projects 1 and 2. The initial development of the intervention as outlined in Project 1 will take 18 months. We expect that pilot-testing of the intervention developed following the qualitative methods outlined will take approximately six months. We will continue to revise the intervention until it is acceptable and ready for evaluation in the RCT. We expect that enrollment in the RCT will take place over six months; all participants will be followed through the NFP intervention to the child reaching 18 months – a period of approximately 22 to 24 months, depending on the time of enrollment. Once the RCT is underway, we will conduct analyses of data from the CIS and interviews of the participants at six-month intervals. We will also conduct web-based surveys of nurses in the intervention sites every six months to assess their attitudes toward the intervention. We will analyze the survey data and use that information to refine the intervention as we proceed. Finally, at the end of Year 5, we will synthesize the data and determine whether the findings indicate that we should undertake a larger multi-site RCT to determine effectiveness and external validity of the NFP+IPVI intervention.

Dissemination Plans

Our audiences for the results of this research will include a broad range of health care providers, supervisors and policy makers working in the area of family violence including those involved with the NFP as well as providers of other interventions that serve this population. We plan to communicate directly with the providers of the NFP through email and the NFP website. Assuming that the results of the study produce the expected positive results, we will embark on a multi-site RCT adequately powered to evaluate the effectiveness of the NFP-IPVI on the primary outcomes of recurrence of IPV and quality of life. The proposed intervention study will help establish effect size estimates for this later research and will result in a refined IPV protocol that can be embedded within the NFP curriculum.

The NFP is a member of an organization known as the Home Visit Forum, a group of national home visiting programs (e.g., Healthy Families America, Parents as Teachers, Early Head Start, the Parent-Child Home program) that come together to support one another on issues of common interest. We will make a formal presentation to this group and send all of the participants a written report. We will consult with CDC regarding opportunities for knowledge dissemination, including such conferences as the Family Violence Prevention Fund. Two of the investigators (NW and SJ) have expertise in knowledge translation, and will take the lead in determining approaches to disseminate the information broadly. In addition, we will submit the results of this study for publication in a professional journal, such as the *American Journal of Public Health*, and we will submit abstracts for presentation of the findings at professional meetings, such as the American Public Health Association.

Experience and Qualifications of the Research Team

Here we highlight the direct experience of team members in conducting research specific to IPV and nurse home visitation, using the research methods proposed for the current projects. We also include citations to relevant articles by team members in Appendix A.

815 **Experience with family violence research**

816 This research team has extensive experience conducting research on a broad range of issues related to IPV in particular, and
817 family violence more broadly. This includes epidemiological studies assessing the distribution and determinants of IPV child
818 maltreatment and abuse of older persons; development and evaluation of interventions in various health and community settings;
819 development and evaluation of educational approaches for professionals interacting with women and children exposed to violence;
820 qualitative studies addressing mothers' efforts to move on after leaving and the ways in which public policy influences these
821 activities; a longitudinal study of the health effects of IPV after leaving an abusive partner; and systematic evidence reviews to assess
822 the state of knowledge in these areas. The following are some key studies we have in this area.

823

824 **McMaster University Violence Against Women Research Program** (*MacMillan, Wathen, Jamieson, Jack, Ford-Gilboe,*
825 *Coben, Boyle*) was funded in 2003 (to 2007) by the Ontario Women's Health Council to carry out ten research projects in the area of
826 IPV, including a multi-site RCT evaluating the effectiveness of IPV screening for women in health care settings (RCT underway
827 since May 2005 involving 26 health care settings).

828 **McMaster University IPV Knowledge Translation Project** (*Wathen, Jack, MacMillan*) is funded (2006-2007) by the
829 Canadian Institutes of Health Research (CIHR).

830 **McMaster University New Emerging Team: Health Impacts of Violence Across the Lifespan** (*MacMillan, Boyle,*
831 *Jamieson, Jack, Wathen*) is funded by the Canadian Institutes of Health Research (2002-2007), and involves multiple projects with a
832 major focus on child maltreatment, IPV and abuse of older persons.

833 **McMaster University – Interval House of Hamilton Domestic Violence Education Project** (*Wathen, MacMillan, Ford-*
834 *Gilboe, Jack, Coben*) funded (2005-2006) by the Ontario Women's Directorate is an environmental scan of universities, colleges and
835 professional organizations to determine educational opportunities available to health care providers regarding IPV.

836 **Ontario Shelter Effectiveness Evaluation Study** (*Wathen, Ford-Gilboe*) is under review by the Ontario Trillium Foundation,
837 and is an evaluation of the effects of shelter stays on women experiencing IPV.

838 **McMaster University-Parenting by Women Exposed to Childhood Maltreatment** (*Jack, MacMillan*) is a qualitative study
839 to examine risk and resiliency funded (2006-2007) by the Hamilton Health Sciences Foundation.

840 **University of Western Ontario Women's Health Effect Study** (*Ford-Gilboe*) funded by CIHR (2002-2007) is a five-year
841 longitudinal study of women who have recently left abusive partners.

842 **University of Western Ontario Health Promotion Study** (*Ford-Gilboe*) funded by CIHR is a three-year study of 40 single
843 mothers and their children that generated a theoretical description of the ways in which families reconstruct their lives after abuse.

844 **University of Western Ontario Public Policy & Health Promotion Study** (*Ford-Gilboe*) funded by CIHR (2005-2008)
845 examines the processes of single mothers and their children after leaving abusive partners.

846 **West Virginia University** (*Coben*) has been involved in numerous investigations of IPV interventions including ongoing
847 studies of co-occurring IPV and child maltreatment and collaborative projects with the McMaster team. The primary focus of his
848 IPV-related research has been examining the impact of healthcare provider interventions for abused women. He has worked closely
849 with nurses and social workers in a variety of settings. He has also conducted several investigations examining the interactions and
850 collaborations between healthcare providers, domestic violence service organizations, and child welfare agencies. These have
851 included multi-site investigations, using both qualitative and quantitative designs, employing all of the procedures (i.e., interviews,
852 focus groups, RCT's,) included in the proposed investigations. Finally, through his involvement in the National Resource Center for
853 Domestic Violence and his linkages with the IPV advocacy community, he has established a track record of trust and cooperation
854 with the service community that will facilitate their engagement in the research and the broadest possible dissemination of project
855 results.

856 **Experience with research in the context of nurse home visits**

857 David Olds, PhD, Director of the Prevention Research Center for Family and Child Health, University of Colorado, and
858 colleagues, Pilar Baca, MN, (Director of Program Development at the Prevention Center); Ruth O'Brien, RN, PhD (Professor of
859 Nursing and Director of Evaluation at the National Center for Children, Families and Communities (NCCFC), School of Nursing at the
860 University of Colorado Health Sciences Center), Maureen McClatchey, PhD, (biostatistician at the NCCFC), and Francesca Pinto,
861 MPH (Replications Program Manager at the Center) at the Center bring to this project their extensive expertise conducting research and
862 implementing the internationally recognized NFP as described above and in the relevant attachments related to the RCT.

863 Harriet MacMillan, MD headed a RCT aimed at reducing the recurrence of child physical abuse and neglect (Michael Boyle, PhD
864 and Ellen Jamieson, MEd also had key roles in this trial). Based on evidence from the NFP, the intervention consisted of two years of
865 nurse home visiting which augmented usual care from Child Protective Services (130). Dr. Susan Jack is currently analyzing the
866 qualitative data collected during the trial from both nurse home visitors and primary caregivers in the home. Dr. Jack has also
867 designed and completed two qualitative studies of home visitation (88,90).

868 Jack Stevens, PhD, and colleagues recently conducted a series of focus groups of home visitor supervisors, home visitors, and mothers to
869 identify both facilitators and barriers to retention in these prevention services. Dr. Stevens has also published scientific articles on the topics of
870 maternal depression and trauma for home-visited mothers.

871 **Experience using sequential mixed methods**

872 As indicated in the description of relevant projects above, team members have extensive experience using a variety of
873 methods, both qualitative and quantitative, including: surveys of various types, qualitative interviews and focus groups, instrument
874 development and validation studies, prospective and retrospective observational (cohort) studies, longitudinal studies, case studies,
875 multi-site clinical trials, including RCTs, and secondary data analyses, including systematic reviews and meta-analyses.

876 Philip Scribano, DO, MSCE, is co-principal Investigator on an award from the Administration of Children and Families which
877 evaluates the feasibility of an electronic health record for foster youth in the medical environment. This project's first phase includes
878 qualitative (semi-structured) interviews, and focus group methods to determine optimal strategies for implementation. His prior work
879 has included use of quantitative and qualitative survey measures and validation to evaluate asthma health outcomes in the emergency
880 department setting.

881 **Experience with Motivational Interviewing**

882 Dr. Stevens is co-principal Investigator on a R01 currently funded by the National Institute of Drug Abuse. This grant
883 examines the combination of information technology and MI to identify adolescents at risk for substance abuse problems and to
884 facilitate their participation in ongoing treatment services.
885

886 **Prior collaboration**

887 This team has an established record of collaboration on IPV-specific projects, including a number of longitudinal, multi-site
888 studies. For example, Jeff Coben, MD is a consultant to the McMaster VAW Research Program, and a co-investigator on several
889 related studies, including the meta-analysis of risk indicators for IPV (with Wathen, Jack and MacMillan) and the domestic violence
890 education study (Wathen, Jamieson, Dodd, Jack, MacMillan). Marilyn Ford-Gilboe, PhD works closely with Wathen, PhD and
891 MacMillan, MD on projects based at McMaster, and leads projects at UWO in which Wathen and MacMillan participate. Olds has
892 provided consultation to MacMillan and colleagues over the past 10 years regarding their RCT of home visitation conducted in the
893 child welfare setting. In 2004, Olds invited MacMillan to take the lead in developing IPV strategies to be evaluated within the NFP.
894 In summary, the team has much expertise and many years of experience in IPV and home visitation research, as well as established
895 collaborative relationships.
896
897

E. HUMAN SUBJECTS RESEARCH

1. Risk to subjects

Protection of Human Subjects

In Project 1, approximately 20 first-time mothers, 24 nurses and 20 NFP administrators and community stakeholders will be asked to describe the phenomenon of delivering the NFP or receiving support from the NFP for women exposed to IPV. The NFP-IPVI will then be pilot-tested with 10 clients and 10 nurses for acceptability. In Project 2, 266 pregnant women will be approached to participate in a study where they may receive an IPV intervention that augments the NFP or they will receive NFP as usual. Women are likely to be in reasonably good health at the time of recruitment.

Age 16 was set as the lower limit to address consent issues of younger participants. Although those 16 years of age up to 18 years may require parental consent, they still will generally be of an age where they can provide informed assent. Non-English speaking women are excluded because the validity of the measurement instruments has not been established in other languages. The time frame and resources provided by the grant do not provide sufficient time or funds to translate and back-translate and validate the instruments required for use in the study. If the NFP-IPVI is shown effective however, it will be essential to develop approaches to measuring its effectiveness among non-English-speaking women.

Sources of Materials

Study data are gathered specifically for research purposes from interviews, focus groups, and questionnaires within the RCT with mothers, nurses and agency personnel. For Project 1 of the study, either Dr. Jack or a research assistant will take notes and tape record the interviews or focus group sessions. Any identifying information will be deleted from the tapes and transcripts made from the tapes. For Project 2, mothers will be asked to fill out questionnaires in the presence of the research assistant. In Project 2, surveys will be completed by telephone interviews. We will seek permission to access data that is routinely collected from NFP participants by NFP nurses using the CIS. The participants' names will not appear on any of the questionnaires with their answers. Confidentiality will be protected further by storing all research data, including tapes, in a locked file or on a password-protected computer.

Potential Risks

There is the potential risk that there may be a breach of confidentiality and the data may be divulged to individuals not involved in the data collection or analysis. Also, some women who are experiencing violence have found that they might be at risk for further violence when they decide to leave an abusive relationship.

Recruitment and Informed Consent

In Project 1, NFP nurses working with women exposed to IPV will be invited by either Dr. Jack or the local research assistant to consent to participate in two focus groups. For mothers who self-report exposure to IPV administered within the NFP, their NFP nurse will, using a script developed by the study investigators, inform the mothers of the study and ask for permission to share the client's name and contact information. Interested women will then be contacted by the research assistant to obtain informed consent to participate in two face-to-face interviews and to retrieve basic demographic data from the CIS. In situations where the client is between the ages of 16 and 18 in those states where informed consent is required from a parent unless the client is emancipated, parental consent will be sought as well. Agency personnel will be contacted by telephone by either Dr. Jack or the research assistant and invited to participate in two interviews. For Project 2, women who are positive on the Abuse Assessment Screen, administered within the NFP, will be invited to consent to participate in the RCT by the research assistant.

Consent forms for Projects 1 and 2 can be found in Appendix B. All participants will be provided with a written consent that will be read by participants and summarized verbally by the trained research assistant. The consent forms contain a written description of the study which includes the purpose, the assessments, the time required and the compensation. The research assistant will ask whether the participant understands what the study consists of and whether they have any questions. The participant will then be asked to sign and date the form. The research assistant co-signs the consent form, places one in the record, and gives the other to the participant. Data collected exclusively for research purposes from the interviews and focus groups in Project 1 and the telephone surveys in Project 2 will not be shared with anyone, including the client's NFP nurse.

2. Protection Against Risk

Minimization of Potential Risk of Breach of Confidentiality

Proper safeguarding techniques to protect the confidentiality of data will be employed. All research staff will sign confidentiality agreements. In addition, only the necessary contact information required to follow up with participants for further data collection will be collected. There will also be a controlled level of data access. Personal contact information will only be accessible to a minimum number of persons necessary on the research team to follow up with participants. Data use will be limited to compiling aggregate statistics. The key linking the code back to direct identifiers will be available only to investigators and the research assistant.

All data will be stored in locked file cabinets in the research office or under password-protected computer files. All study-related material will be destroyed after the normal retention interval necessary to satisfy publication requirements and University research protocol (seven years after publication).

Minimization of Potential Risks Related to Abuse Disclosure

One of the documented potential risks of intervention in cases of IPV is the threat of retaliatory violence by the abusive partner when a woman seeks external help for abuse, or decides to leave an abusive relationship. To address this, all NFP nurses receive IPV training within the NFP. As well, a specific safety protocol will be followed by NFP nurses and research personnel to ensure the safety of all women participating in the trial.

Safety Protocol

In order to promote safety of participants and researchers, a safety protocol will be used for all contacts between the research team and participating women (Appendix B). This protocol is based on the national Violence Against Women Survey (131), existing protocols for research with abused women (95,132-134), and the experience of the research team in successfully carrying out studies of women and families who have experienced violence without compromising safety of participants or researchers. We will take as many safety precautions as possible, including conducting those interviews that are face-to-face in a safe location and referring to the study generically as the "Mothers' Health Study."

All research assistants will take part in a training session focused on using strategies to promote their safety and the safety of study participants, as described in Appendix B. Each participant will also be assessed for any changes in the risk of violence, in particular as related to participation in the study, using the protocol presented in Appendix B. If women become distressed during data collection, the interviews will be stopped and women will be offered contact information for local agencies providing support to abused women. For the qualitative phase of this study, the participants will be de-briefed by one of the clinically trained researchers at the end of the interview or focus group meeting and offered a list of community resources.

Participants will also be told throughout the study that they may refuse to participate, refuse to answer any questions, or withdraw from the study at any time with no effect on them or any services they may wish to access (now or in future). They are told that refusing participation in this study will in no way affect their status as a participant in the NFP.

Minimization of Potential Risks Related to Mandatory Reporting

Although confidentiality will be maintained, there are some circumstances where information may need to be shared. If the participant provides information that suggests that a child is at risk of harm or has experienced harm, the study will need to report these concerns and the information upon which it is based to the local Department of Social Services. IPV has been recognized as having a significant emotional impact on children in addition to the physical risks to children. Thus, Child Protective Agencies in some states view children exposed to IPV as potentially children in need of protection. In order to ensure that the study meets the reporting obligations while also maintaining participant confidentiality, a protocol will be established with the local Child Protective Agencies outlining the circumstances under which concerns should be reported, how to report these concerns and the person most responsible for reporting. These issues regarding the duty to report are covered in the participant information and consent forms.

3. Potential Benefits to Subjects and Others

In the qualitative interviews, benefits of participating may include increased feelings of empowerment and opportunities for catharsis, self-acknowledgment, identification of a sense of purpose, increased self-awareness and a chance to provide a voice to marginalized individuals (135). For women who disclose abuse, participation may prove empowering, as they seek to contribute to a definitive understanding of how best to help women who, like themselves, are abused. These women will also benefit from receiving care from the NFP nurses who by virtue of their participation in this study may have received enhanced training regarding appropriate responses and referrals for abused women. They will also receive, as part of the study's safety protocol, information regarding community resources to assist women exposed to violence.

994 In Project 1, discussion of sensitive and personal issues in the interviews with the participant may create an emotional response.
995 Interviewers will be clinically trained (e.g. Dr. Jack is a registered nurse) and will possess the knowledge and skills to respond
996 empathetically and appropriately if a participant experiences distressing emotions. At the end of each interview, the interviewer will
997 debrief with each participant about the interview and offer a list of community resources (the participant will be asked if she can
998 safely take the list). The interviewing will be shared by Dr. Jack and the local research assistants. The individual(s) hired as research
999 assistants will have a clinical background working with high-risk women and children, and they will receive training on the conduct
000 of qualitative interviews and the process of debriefing. At the end of the interview, the interviewer will de-brief with the participant
001 and offer a list of community resources.

002 **4. Importance of the knowledge to be gained**

003 Few interventions have shown promise in reducing IPV and none have been rigorously tested within the context of the NFP.
004 The self-reported prevalence of moderate to severe IPV in families served by the NFP is higher than the general population and the
005 presence of IPV has been found to attenuate the program's effectiveness. Furthermore, based on results of a web-based survey, as
006 outlined in the Preliminary Studies section, NFP nurses feel inadequately prepared to manage IPV and are seeking management
007 strategies.

008 This knowledge gap is an important problem. As noted in the CDC's *Injury Research Agenda*, evaluating the effectiveness of
009 interventions for preventing IPV is a priority. Further, IPV, sexual violence, and child maltreatment often overlap in families, so
010 evaluating the effectiveness of programs that address two or more of these behaviors simultaneously are of high priority. Identifying
011 programs that can effectively address multiple types of victimization at once will facilitate a more efficient allocation of prevention
012 resources.

013 Expected outcomes of this investigation include the development of an IPV intervention that is theoretically grounded and the
014 production of evidence of its effectiveness, which may enable the translation of these findings to other settings. These results will be
015 important, as they will improve our understanding of IPV interventions and address a critical need of home visitation programs.
016 These outcomes would significantly advance the field of family violence.

017 **5. Data and Safety Monitoring Plan**

018 The data monitoring committee will be based on the template provided by the DAMOCLES study group (136), which sets out
019 guidelines for the composition of the committee, the roles of members, the content considered by the group, trial documentation, the
020 decision-making process, and reporting. The committee will consist of academic and clinical professionals as well as a biostatistician.
021 They will monitor the progress of the study for any negative side effects. These will be discussed with the investigators. Appropriate
022 CDC staff or other appropriate institutions will receive the results of the meetings concerning possible negative side effects depending
023 upon the nature of risk identified. Options available to the data monitoring committee regarding stopping any aspect of the research,
024 including the RCT as outlined by the DAMOCLES study group (136) will be determined once the committee is organized, prior to
025 beginning Project 1.

026 **INCLUSION OF WOMEN AND MINORITIES**

027 Only women will be recruited for Projects 1 and 2 since we are testing an intervention of IPV within the NFP that has only
028 mothers as participants. Project 1 might include male NFP nurses; the overall proportion of males participating in the NFP is 1%.
029 They might report experiences of working with women exposed to IPV or male agency personnel who are knowledgeable about the
030 delivery of supports or services to women exposed to IPV. The ethnic and racial composition of the clients enrolled in the NFP up to
031 December 2005 are as follows: Hispanic – 21%; Native American – 5%; Black – 19%, Non-Hispanic White – 49%; Asian – 1%;
032 Mixed-race/Other – 5%. The precise composition of the samples to be included in Projects 1 and 2 may differ somewhat from the
033 table below, depending on the sites selected for inclusion in the projects.

035 **Inclusion of Children**

036 The proposed study will follow the first-born children of women participating in the RCT. Women will provide information
037 about their first-born children in the self-report CIS questionnaires. These CIS instruments are regularly administered in the NFP
038 program. Three of the investigators (Olds, MacMillan, Boyle) have extensive experience conducting developmentally-sensitive
039 research with children. One of the investigators (MacMillan) is a pediatrician and child psychiatrist with extensive training and
040 experience with children in clinical settings, and was director of a hospital-based child abuse program for 12 years.

043

Principal Investigator/Program Director (Last, First, Middle):

MacMillan, Harriet Louise

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study **An Intervention for Intimate Partner Violence in the Context of Nurse Home Visits**

Title:

Total Planned **372**

Enrollment:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	78	0	78
Not Hispanic or Latino	294	0	294
Ethnic Category: Total of All Subjects	372	0	372
Racial Categories			
American Indian/Alaska Native	18	0	18
Asian	4	0	4
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	71	0	71
White	279	0	279
Racial Categories: Total of All Subjects	372	0	372

044

045

F. VERTEBRATE ANIMALS – NOT APPLICABLE

047

G. SELECT AGENT RESEARCH – NOT APPLICABLE

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H. LITERATURE CITED

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312

313 **I. MULTIPLE PI LEADERSHIP PLAN - NOT APPLICABLE**

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315 **J. CONSORTIUM/ CONTRACTUAL ARRANGEMENTS - NOT APPLICABLE**

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317 **K. RESOURCE SHARING - NOT APPLICABLE**

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320 **L. LETTERS OF SUPPORT**

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322 We have attached letters from eight NFP sites expressing their willingness to participate in Project 1, as
323 well as a letter of support from the NFP National Office. Additional letters are from Drs. Scribano and Stevens
324 at Ohio State University indicating their agreement to work with us as a consultant and co-investigator,
325 respectively through in-kind support. Dr. Ford-Gilboe from the University of Western Ontario has provided a
326 letter outlining her agreement to participate as a co-investigator, also through in-kind support.

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