

Project Protocol: Revision 17 – March 5, 2019
Randomized Controlled Trial of Prenatal Coparenting Intervention for African American Fragile Families (Alternative Title: Figuring it Out for the Child)
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1. General Information

Strategies for addressing intractable disparities in the early development of African American infants must involve meaningful and sustained father engagement. Poor African American infants born to unmarried uncoupled parents are more likely to have such a presence by fathers if their parents create a positive coparenting alliance early on. No empirically-validated prenatal interventions that successfully encourage unmarried fathers and mothers to intentionally create enduring alliances in their babies' best interest currently exist. The original IRB proposal for this project was submitted in April, 2015 in anticipation of funding ultimately secured on July 31, 2015 from the National Institute of Child Health and Development. In the study, we are testing -- using randomized controlled trial (RCT) methodology -- the efficacy of the "Figuring It Out for the Child" (FIOC) intervention originally piloted as Pro00004412, and further studied in Pro00019385, New Applications for Promoting Coparenting Alliances in Unmarried Couples.

FIOC was designed specifically to aid development of positive coparenting alliances between at-risk (unmarried, uncoupled, low income) African American mothers and fathers having a first baby together. In the RCT, 75 randomly-assigned control group families (referred by already-known referral agents and partners who worked closely with our team on the pilot projects) will receive Pinellas County services as-usual for pregnant parents and assistance of a Resource and Referral Navigator for referrals to desired community services ("Treatment as Usual", or TAU). Another 75 (experimental group) families will receive the same services and aid, plus the 6-session FIOC prenatal intervention with a post-natal booster session. The FIOC intervention addresses the importance of safe, healthy families for early infant development, the impact a cooperative and sustained coparenting alliance can have in promoting positive infant development, challenges unmarried parents face cultivating a coparenting alliance together when their commitment to one another as romantic or married partners is in doubt, and ways to surmount these obstacles, maintain rapport, and sustain a strong alliance.

All 150 participating families, both at intake (prior to the intervention) and then again at 3 and 12 months post-partum, will report beliefs about fatherhood; extent of depressive symptomatology; and quality of the mother-father partnership. State-of-the-field coparenting observations will be conducted at each follow-up, along with measures of parental stress, intimate partner violence (IPV), perceived coparenting support, father engagement, and infant socioemotional adjustment. Analyses will examine impact of the intervention on promoting more supportive, coordinated post-partum coparenting alliances and more positive adult and infant outcomes. Exploratory analyses will examine links between father involvement and child adjustment and whether this coparenting intervention also stands to prevent IPV.

2. Background information

Strong, positive coparenting alliances play adaptive functions in a wide variety of family systems. Positive alliances foster competence in the parenting role, helping parents feel less distressed and more capable of handling challenges, protecting against abuse, and promoting healthy infant and toddler development (Fagan et al., 2007; Florsheim et al., 2003; McHale, 2009; McHale & Lindahl, 2011, Minuchin, Colapinto & Minuchin, 2007). For unmarried parents in non-romantic relationships, the impediments to developing a positive coparenting alliance are formidable -- but must be overcome if fathers are to stay engaged and coparent their child (Carlson et al. 2008; Fagan et al., 2003; Fagan & Palkovitz, 2007). Most relationship enhancement efforts with higher-risk unmarried parents miss their mark. Dion and colleagues' (2006) report on recruitment for the federally-funded Building Strong Families pilot study estimated that less than 1 in 10 families served by Healthy Start programs even qualified for BSF interventions based on project inclusion criteria (mother and father romantically involved, not living together). Hence despite its fine work, the HMI missed important opportunities to strengthen adaptations of many of the nation's highest risk families. Problems connecting with and supporting high-risk families -- including, and especially families of unmarried African American parents with young infants -- are deeply concerning. African American children experience significant health disparities that begin before birth and follow them throughout their lives (CDC Healthy People 2010 Database). Black infants remain over twice as likely as white infants to die before age one, to be born low birthweight, a core risk factor for infant mortality and childhood developmental disorders, and to continue to suffer childhood illnesses. A federally-sponsored African American Healthy Marriage Initiative (AAHMI) offered an intensive coupling focus that turned out to be in poor synch with the lived realities of many African American men and women in the underclass, where non marriage often owes to poverty and economic instability.

Formidable relationship obstacles (gender mistrust; concerns about immaturity and readiness to commit, fear of or anger about sexual infidelity; children from prior unions) also influence strategic relational choices (Carlson et al., 2004; Edin, 2000; Furstenberg, 2001; McLanahan, et al., 2003; Ooms & Wilson, 2004). Low income young African American men encounter multiple barriers in their efforts to synchronize work and family participation (Roy, 2005), and many low income young African American women deliberately choose not to marry the fathers of their children if they believe the fathers will not be breadwinners (Wilson, 1987).

This said, choosing to forego a committed marital relationship does not mean that expectant African American mothers in lower socioeconomic families exclude fathers from the lives of their children (Crosbie-Burnett & Lewis, 1993) or that expectant African American fathers abandon interests in their children. Though no published study has examined prenatal gatekeeping expectancies of primigravida African American women, Fragile Families and Well-Being (FFWB) data indicate that 93% of expectant mothers surveyed reported wanting the child's father involved in the baby's life -- including two-thirds of mothers no longer even in relationships with children's fathers when the child was born (McLanahan & Carlson, 2002). 99% of expectant fathers surveyed reported a wish to help rear their child, and over 80% of FFWB fathers saw mothers episodically during her pregnancy. Hence at least during the pregnancy, most first-time African American mothers are not harboring identifiable exclusionary beliefs about their baby's father.

For African American men, prenatal engagement is an important prognosticator of things to come. Early Head Start Research and Evaluation Project data indicate that in contrast to White and Hispanic fathers, whose non-residential status at birth is the best predictor of the timing of eventual inaccessibility to their children, the best predictor for African American fathers is whether they were involved during the pregnancy, not non-residential status at birth (Lamb et al, 2009). Although African-American children are far more likely than Asian, Hispanic, or White children to know non-co-resident biological fathers (Avenilla et al., 2006), the nature of the coparenting alliance unmarried parents create (or fail to create) is a critical determinant of whether fathers stay involved. Coparenting between non-co-resident FFWB parents during infancy strongly predicted later father involvement, but early father involvement only weakly predicted later coparenting (Carlson et al., 2008). Prenatal fatherhood programs that promote father involvement without also helping mothers and fathers coordinate as coparents hence may also miss their mark (McHale, 2007; 2009); unwelcome father involvement triggers more, not less, coparenting conflict (Talbot et al., 2009). In the lone fatherhood intervention study examining both father involvement and coparenting as distinct outcomes, Doherty (2005) found desired intervention effects on early father engagement -- but no effect on coparenting.

In Pro00004412 (supported by funding from the Brady Education Foundation), we established that the FIOC intervention successfully promoted improvements in unmarried African American parents' rapport, problem-solving and communication. In Pro00019385, New Applications for Promoting Coparenting Alliances in Unmarried Couples, we established the feasibility of successfully delivering the intervention with positive outcomes to parents positive for minimal (or situational) intimate partner violence (IPV). The NIH study protocol (assessment, intervention, safety plan) diverges very little from the prior studies. The main difference is more extensive pre- and post- assessments and, of course, random selection for participation in the experimental group to receive the FIOC intervention. Any referred families with more significant and serious IPV are ineligible for participation in the study, as they were in the prior projects.

3. Research questions, objectives and purpose:

- Aim 1: To determine the efficacy of FIOC in positively affecting first-year coparenting of unmarried African American parents, relative to early coparenting of comparison families
Hypothesis 1: Families who participate in FIOC will demonstrate more cooperation and better communication in their post-natal coparenting systems at 3 and 12 months post-partum than families receiving TAU
- Aim 2: To determine the efficacy of FIOC in affecting early child outcomes
Hypothesis 2: Infants whose coparents participate in FIOC will show a more advanced triangular capacity at 3 and 12 months
Hypothesis 3: Infants whose coparents participate in FIOC will show better regulatory and socioemotional competence at 12 months than control group children.
- Aim 3: To determine the efficacy of FIOC in affecting father involvement
Hypothesis 4: Fathers who participate in FIOC will show greater involvement at 3 and 12 months post-partum
- Aim 4: To determine whether increased father involvement is associated with better socioemotional adjustment by the baby

Hypothesis 5: Children of more involved fathers will show greater regulatory and socioemotional competence at 12 months post-partum

- Aim 5: To explore whether the FIOC intervention has an impact on the emergence of intimate partner violence (IPV)

Hypothesis 6: IPV will be more likely to emerge during the child's first year among TAU families than among families who complete the FIOC intervention

4. Study design including information needed to answer the research questions:

This is a prospective longitudinal study using a pre-post randomized controlled treatment design that will allow comparisons of the extent to which study participants in experimental and control groups show pre-to-post changes in family functioning.

All families are seen initially for a PRE Intake assessment (Time 1), during which mothers are screened for prior or active IPV using valid, standardized instruments, an IPV Screen and the Revised-Conflict Tactics Scale (CTS2). If mothers report a history of IPV, they may under specified circumstances still be eligible to participate depending upon results of an assessment performed by trained project staff using the Danger Assessment Scale (DAS; Campbell 2003) as a screening instrument (see inclusion and exclusion criteria). If certain indicators are present in the mother's IPV screen/CTS2 assessments at baseline, the father will not be given the IPV screen/CTS2. If the father is not be given the IPV screen/CTS2 at pre-assessment, he will not be given the IPV screen/CTS2 at either post assessment time-point. The decision about whether to enroll a family reporting IPV is made in consultation with Co-PI Stover after the session concludes. Families are notified that they will receive a phone call within 48 hours appraising them of whether or not they have been chosen to take part in the study and, if they are chosen, which group (treatment or control) they will be assigned to. All families for whom levels of IPV are NOT of substantive concern and who are not found ineligible for other valid exclusion factors are randomized to one of the 2 groups and notified of their assignment. Those for whom IPV is a concern or who are ineligible for other reasons are notified that they were not selected.

For those to be enrolled (projected to be the overwhelming majority of all screened families who complete the intake process), subjects are assigned to treatment conditions through urn randomization, to maximize the likelihood that treatment groups will be balanced with respect to demographic variables (presence of children from prior unions) and prognostic variables (frequency of IPV). We will use a Microsoft Access-based program previously developed for the Yale Department of Psychiatry NIDA-funded Psychotherapy Development Center and used in prior studies by Co-PI Stover. In urn randomization, an algorithm modifies ongoing randomization probabilities based on prior composition of treatment groups, and maximizes multivariate equivalence of treatment groups (Stout et al., 1994). Thus, urn randomization offers the benefits of balancing allocation of important prognostic variables in treatment groups, while still retaining other benefits of random assignment (Wei, 1978).

Once enrolled, parents assigned to the treatment group are contacted by the Intake Coordinator or Resource and Referral Navigator who introduces their mentors and delivers the participants' gift cards for completing the intake assessment. Mentors arrange two initial 1-on-1 mentorship sessions with the parents, as per the FIOC protocol, after which the FIOC intervention

commences. Families randomized to the control group are contacted by the Intake Coordinator or Resource and Referral Navigator, who schedules a meeting to deliver gift cards for completing the intake assessment. The R&R Navigator also provides a listing of existing Pinellas County Services and offers parents the opportunity to contact her at any time for assistance with referrals to Pinellas County services for pregnant or parenting families. All families, regardless of assignment, are also reminded about the follow-up assessments that will be completed at 3 months post-partum; and at 12 months post-partum. A formal check-in will be completed at 1-month post-partum (Congratulations on the birth card sent), and episodic newsletters and reminder texts (for families consented after January 30, 2017) will be sent at staged intervals to help keep in touch. Texts or phone calls to keep in touch will be sent to female participants by female staff only to ensure comfort of research participants. The project timeline and work plan are projected as follows:

Work Plan Timeline

Major Activities per 6 Month (Years 1-5)	1-6	7-12	13-18	19-24	25-30	31-36	37-42	43-48	49-54	55-60
Recruitment/Baseline Assessments (T1)										
Prenatal FIOC Intervention										
3 Month Assessments (T2)										
12 Month Assessments (T3)										
Analysis, Reports										

The table below summarizes major constructs of interest and timeline of administration. This is followed by summary descriptions of all measures. Individual scales and measures are embedded within an interview protocol. Response keys accommodate parents with poor reading levels. In terms of participant burden, demographic and risk interviews (with surveys) average 45 minutes; mother-father coparenting discussions (with debriefing) average 20 minutes, and post-natal LTP assessments average 10 minutes inclusive of directions.

Data Collection Measures, Schedule, and Respondent

Measure	Mother			Father			Baby	
	B	3P	12P	B	3P	12P	B	3P
Risk History	X			X				
IPV (Conflict Tactics Scale)	X	X	X	X*	X*	X*		
Beliefs about Fathering	X	X	X	X	X	X		
The Role of the Father Questionnaire	X	X	X	X	X	X		
Depressive Symptoms	X	X	X	X	X	X		
Positive and Negative Quality Relationships Scale	X	X	X	X	X	X		
Collaboration/conflict (Coparenting Discussions)	X	X	X	X	X	X		
Parenting Stress Index		X	X		X	X		
Parenting Alliance Measure		X	X		X	X		
Coparenting during the LTP		X	X		X	X		
Father Engagement		X	X		X	X		

Infant Triangular Capacities (LTP)								X
Infant Socioemotional Development (BITSEA)			X			X		
Child Health Background Questionnaire			X					

Note. B=Baseline; 3P=Post-Partum, 12P=12 months Post-Partum

*Father is only administered the IPV screen/CTS2 at baseline if mother does not report certain levels/traits of violence, as specified in the IPV manual, on her IPV screen at baseline. Father is only administered the IPV screen/CTS2 at post assessment time points if he was administered the IPV screen/CTS2 at baseline.

Measures

Client Demographics – Detailed demographic and risk characteristics include age at intake, race/ethnicity, family composition, housing arrangements, employment status, relationship status, and prior substance, mental health and IPV issues. Demographic data are collected only once, at the pre-assessment prior to randomization. Data are continuously reviewed and updated throughout the study to identify and record any changes occurring in participant status.

Psychiatric Symptomatology. Evaluated using select items from the Brief Symptom Inventory (BSI; Pearson, 2001) to determine if participants have concerning psychological symptoms that would prevent them from benefitting from study participation. The BSI helps make an assessment regarding inclusion vs exclusion at the pre-assessment prior to randomization, and is administered at subsequent assessments to establish whether any changes to client mental state have occurred since intake.

Predictor Variables: Measures Taken at Time 1 Only

1. Risk History reported by mother and by father: A scale assessing background degree of family risk is administered as a subset of the Time 1 protocol only.
2. Early Childhood Adversity Risk Factors- are assessed using the standardized ACE screener, a validated demographic indicator of participant risk that is used nationally and allows comparison to other populations. The ACE is given once only at pre assessment.

Outcome Variables: Changes in Measures Taken at Times 1, 2 and 3

1. Intimate Partner Violence. IPV is estimated using the Revised-Conflict Tactics Scale CTS2; (Straus, Hamby, Boney-McCoy, & Sugarman, 1996). Mothers and fathers report their own and their partners behaviors both over the preceding 12 months and over the lifetime of their relationship. Per the project’s Safety Protocol, fathers only receive the CTS2 if mothers’ screen does not reveal concern with serious IPV or dangerousness. The 66-item CTS2 scale (33 behaviors or experiences, each asked once for respondent and once for partner) contains psychological aggression, physical assault, injury, and sexual coercion subscales (Straus et al., 2003). Response categories gauge the frequency with which acts were used during conflict with a partner in the past year, and include options of “Never in the last year, but it did happen before that,” and “This has never happened.” It has consistently been shown to have good reliability and validity. The CTS2 is the most widely used measure in the research literature on IPV.
2. Beliefs about Fathering. Positive beliefs about importance of father involvement rated by mother and by father will be assessed using a 6 item set for which national data exist.

3. The Role of the Father Questionnaire. The Role of the Father Questionnaire (ROFQ) measures the extent that a parent believes the father's role is important to child development (Palkovitz, 1984). The ROFQ contains 15 items. Subjects indicate their level of agreement or disagreement with each item on a 5-point scale. Total scores on the ROFQ can range from 15 to 75. Higher scores reflect attitudes that fathers are capable and should be involved with and sensitive to their children.
4. Depressive Symptoms of mother and of father. The Edinburgh Depression Scale (Cox, Holden, & Sagovsky, 1987) consists of ten statements assessed on a 4-point scale (never to always). Reference is how the parent has felt over the past week. Each item is scored from 0 to 3, yielding a total range of 0–30.
5. Overall Quality of Relationships as reported by mother and by father. Positive and Negative Quality in Relationships Scale (PANQIRS; Fincham & Linfield, 1997), a 6-item global assessment of positive and negative relationship quality valid for use with unmarried partners (Mattson, Paldino & Johnson, 2007).
6. Mother-Father Conflict and Collaboration during Coparenting Discussions. Evaluated using a paradigm validated in the PI's prior coparenting studies. Father and mother discuss areas of current child-related disagreement or uncertainty (e.g., overnights; paternal support; childcare; child temperament concerns; involvement of other kin caregivers; complications of children from prior unions). Raters observe and rate videotaped discussions using Lindahl and Malik's (2000) System for Coding Interactions in Dyads (SCID). In the feasibility study, statistically-significant improvements were seen in SCID ratings of (increased) problem-solving communication; (increased) mother-father cohesion; and (decreased) coerciveness

Outcome Variables: Family and Child Measures Taken at Times 2 and 3 Only

1. Parenting and Coparenting Adjustment. Two sets of coparenting indicators and one parenting measure not yet possible to evaluate at Time 1 will be obtained as Time 2 and 3 outcome measures:
 - a) Coparenting: Felt Coparenting Support: Reported by both mothers and fathers, and assessed using Abidin and Konold's (1999) 20-item Parenting Alliance Measure (PAM). The PAM is a five-point self-report scale (1 = strongly disagree; 5 = strongly agree), which evaluates how cooperative, communicative and mutually respectful parents are with regard to caring for the baby.
 - b) Coparenting: Observed Coparenting Behavior during Trilogue Interaction. All families are assessed at 3-months and at 12-months post-partum in Fivaz-Depeursinge and Corboz-Warnery's Lausanne Trilogue Play. The LTP has 4 parts: (a) first one parent plays with baby, other parent just present; (b) parents switch roles; (c) all 3 family members play together; (d) parents active and baby placed in the third party position. Coparenting during the LTP at 3 months postpartum is to be evaluated using the 3-month version of the Coparenting and Family Rating System (McHale & Coates, 2015). The standard CFRS is to be used to evaluate 12-month coparenting during the LTP.
 - c) Degree of Parenting Stress: Reported by both mothers and fathers, and assessed using a 36-item Parenting Stress Index-Short Form, validated in a low-income, African American population (Reitman et al. 2002). The PSI-SF has 36 items from the original 120-item PSI. Items are identical to those in the original version and yields scores on the

following subscales: 1) Parental Distress, 2) Parent-Child Dysfunctional Interaction, and 3) Difficult Child

2. Father Engagement:

- a) Father engagement is assessed using relevant items from the HAPPI (Cabrera et al., 2004). The HAPPI father-child engagement activities scale consists of 34 items on which the respondent reports the frequency with which various activities by the father with the child (socialization, management, didactic, physical play/warmth, and caregiving) took place over the past month. Questions are answered on a Likert-type scale from 1 (more than once a day) to 6 (not at all).
- b) Multiple measures introduced by the Fatherhood Research and Practice Network (FRPN) are also being used to estimate father engagement, coparenting decision making, and barriers to involvement at 3 and 12 months post assessment. Scales include the Fatherhood Research and Practice Network's Father Engagement Scale (FRPN-ES, completed by fathers only), Maternal Gatekeeping Scale (completed by mothers only), Measure of Father's Challenges (completed by fathers only) and Decision Making Responsibilities Scale (completed by both parents). Besides frequency of engagement, items from the HAPPI completed by both parents will be used to estimate father accessibility at both 3 and 12 month post assessment.
- c) The Father Involvement Scale (Hernandez & Coley, 2007) is comprised of a series of queries assessing fathers' accessibility, responsibility, and involvement with the child.

3. Infants' Triangular Capacities. Infants' deployment of attention and affect during the LTP interactions with their parents at 3 and at 12 months will be rated as follows:

- a. Gaze: Gaze frequency and duration (at mother's face, at father's face, elsewhere) will be coded.
- b. Affective configurations: Coding of affective configurations during periods of gaze at either parent, coded as social engagement, social monitoring, tense monitoring, active protest or non-engagement.
- c. Triangular bids: The term 'bid' covers infant response to parental solicitations as well as initiative by the infant. Four categories are coded: triangular engagement, triangular monitoring, triangular tension, and triangular protest.

4. Child Health Background. Child's health history during the first year of life will be assessed via a short self-report questionnaire.

Child Outcome Measures at Time 3: An adapted version of the Infant Toddler Social Emotional Assessment (ITSEA; Carter & Briggs-Gowan, 2006), comprised of the full Brief Infant Toddler Social Emotional Assessment (BITSEA) and select additional scale items from the longer ITSEA instrument, was developed in consultation with the scale's author. The instrument measures both social-emotional/ behavioral problems and delays in competency for children ages 12-36 months. It is a 71-item parent-report index constituting of six sub-scales: Problem behavior, competence, compliance, negative emotionality, aggression, and sleep.

5. Sample size justification:

We employed a computer program provided by Murphy et al. (2009; the same information is available from the tables in Cohen, 1988) to compute the significance level required for a projected sample size, incorporating attrition estimates, of $N=120$ (60 each in the treatment and control groups, respectively). Assuming the null effect hypothesis and alpha set at .05 and power of .8, an $F(1, 117)$ of 7.74 with a $d = .514$ is required for significance. Keeping the null hypothesis test, alpha .05 and lowering power to .5, an $F(1, 117) = 4.03$ with a $d = .37$ is required for significance. Drawing on effect size estimates from the feasibility study, even with low power (.5) resulting in a $d=.37$ we would be positioned to establish the effect of the FIOC treatment for 10 of the 12 FIOC variables (10 of the 12 SCID-evaluated couple problem-solving and communication variables summarized earlier had a d greater than .33).

6. Sample type or inclusion and exclusion criteria for participating in the research:

Inclusion criteria: Low-income, unmarried mothers and fathers, for whom the child will be the parents' first baby together. The target population is African American, but mixed race parents may also enroll so long as at least one parent is African American. Underage parents (i.e., 16 and 17-year olds) who are able to give consent for their own health care but may not be able to obtain parental consent for research because they are estranged from their parents/caregivers, would be offered the opportunity to take part in the project. For potential participants who wish to participate but are under 18 and not emancipated, we will assign a special advocate in situations where the participants' parents cannot be contacted and/or parents refuse to talk to study staff. The advocate's role will be to make certain that the minor parents understand the study fully before providing their informed consent to participate. The advocate will also sign the informed consent. This is an extra measure of protection for minor parents in fragile families and will allow them to participate and derive the benefits study participation offers. This exception to the normal consent process would be offered only to 16 and 17 year olds who are referred to and/or contact the study themselves and who expressly desire to take part in the project to derive benefit from its opportunity to receive support in pursuing resources for their child and family -- but who have indicated when describing their circumstances that although not legally emancipated, they cannot connect project staff to their parent or caregiver in order to obtain parental consent because they are estranged from and living apart from their parents or legal caregivers. All other minor parents will be recruited in the manner previously outlined to and approved by the IRB, taking part in the study only if they are legally emancipated or if written consent has been obtained from their parent or guardian.

Exclusion Criteria: Families will be excluded if they: 1) demonstrate evidence of psychotic symptoms or suicidal ideation on the Brief Symptom Inventory; 2) either partner has recently (over the past 12 months) been arrested and convicted for violence (assault) perpetrated against someone other than a current or former partner who is the co-parent of one of their children; or 3) are deemed high risk or in need of more intensive intervention. Risk determination is made by weighing the parent's report on the Danger Assessment Scale (DAS). As a rule of thumb, a DAS score of 9 or higher will result in automatic exclusion from the study. However, it is also possible that even with a score below 9, the parent may disclose one or more of the following issues during administration of the DAS, any of which would result in exclusion from the study: 1) parent reports she has required medical care because of significant injuries due to his violence, 2) parent says she fears for her life, 3) parent reports that the partner has threatened with a weapon and owns a gun or has a gun in the household; 4) parent reports that the partner has

threatened to kill her; 5) parent reports that violence has escalated recently; 6) parent reports the partner's use of illicit drugs such as cocaine, methamphetamines, hallucinogens, or opiates .

7. Expected results of the research (reports, materials, discussion papers, contributions to theory):

Results will equip the research team with answers to study objectives and determine whether there would be value in studying the curriculum in a future multi-site implementation trial.

8. Description of the roles of study staff including whether or not the research is being conducted at other sites and the roles of investigators at those sites:

Study Staff

1. **James McHale, Ph.D., P.I.** Will provide all project oversight; serve as IRB officer; ensure research integrity and compliance; chair senior staff and other relevant team meetings; supervise fidelity-monitoring efforts; oversee proper implementation of all protocols, data collection, evaluation of videotaped infant and family data, data management and entry, analyses, report writing, and dissemination of findings.
2. **Carla Stover, Ph.D., Co-P.I.** Provide oversight of all clinical aspects of project related to IPV assessment and safety planning, including training of assessment staff and Mentors and oversight of randomization of cases with IPV or other mental health issues; monitoring of clinical operations, clinical consultation, filing for mandatory reporting, direction of safety monitoring team, and compliance of all staff with clinical protocols. Attend senior staffings and other relevant meetings.
3. **Chad Dube, Ph.D., Lead Statistician,** Responsible for ongoing senior oversight of all data functions. Will take the lead on interim and final data analysis and interpretation; assist with report writing; and attend relevant research team meetings.
4. **Yana Sirotkin, Ph.D., Research/Study Coordinator/Primary Regulatory Specialist.** Working closely with the PI, Co-PI, and Project Coordination, responsible for research database management, project documentation and randomization of cases, assistance with retention efforts (congratulations cards, newsletter content), training and oversight of research assistants, assistance with data analyses, report preparation, writing and dissemination, filing of reports and amendments for IRB compliance. Communicates with study's data safety monitoring board and attends relevant trainings and team meetings.
5. **Caylen Holmes, QA Coordinator:** Communicates with lead clinical supervisor to provide reports of mentor fidelity and adherence to FIOC curriculum; trains and oversees research assistants who contribute to Quality Assurance efforts; coordinates with Research Coordinator; attends all relevant trainings and team meetings.
6. **Mari Kittle, Recruiter/Intake Coordinator/Resource and Referral Navigator:** Works closely with Project Assistant to support recruitment and retention of study participants, liaises with community referral agents in recruitment efforts, conducts initial screening for eligibility, provides home and community-based project orientations to eligible parents and any legal guardians, and obtains participant and parental informed consent, conduct prenatal and postnatal assessment, records and reports post-intake gift card disbursements, assists families with resource and referral navigation, and attends all relevant trainings and team meetings.
7. **Serina Lewis, Project Assistant/Mentor:** Works closely with Study/Research Coordinator to assure smooth project operations, triages calls and inquiries, oversees and tracks

scheduling of appointments and cancellations, assists with consenting and with prenatal and postnatal assessments, liaises with research personnel and community referral agents, manages the distribution and the bookkeeping of participant incentives, participates in weekly clinical supervision meetings and intervenes with families following curriculum guidelines, and attends all relevant trainings and team meetings

8. Teresa Gerard, Assessor/Mentor: participates in weekly supervision meetings, intervenes with families following curriculum guidelines, conducts prenatal and postnatal assessments, assists with consenting, and attends all relevant trainings and team meetings.

9. Florence Guillet, Intake Assessor/Mentor/Resource and Referral Navigator. Participates in weekly supervision meetings, and intervenes with families following curriculum guidelines; assists in the training of less experienced mentors; assists with consenting, prenatal and postnatal assessments; assists families with resource and referral navigation; attends all relevant trainings and team meeting.

10. Rashid Mizell, Mentor/Assessor/Recruiter and Obtains Informed Consent. Participates in weekly supervision meetings, intervenes with families following curriculum guidelines, assists in the training of less experienced mentors, assists with consenting, prenatal and postnatal assessments, and attends relevant trainings and team meetings.

11. Pierre Guillet (Mentor/Assessor/Recruiter). Participates in weekly supervision meetings, intervenes with families following curriculum guidelines, assists in the training of less experienced mentors, assists with prenatal and postnatal assessments, and attends relevant trainings and team meetings.

12. Christopher Davis (Mentor/Assessor/Recruiter) Participates in weekly supervision meetings, intervenes with families following curriculum guidelines, assists in the training of less experienced mentors, assists with prenatal and postnatal assessments, and attends relevant trainings and team meetings.

13. Katherine McKay, Ph.D., Lead Clinical Supervisor: Supervises clinical casework, assists in monitoring project Mentor fidelity to curriculum and compliance with clinical protocols, and attends relevant trainings and clinical team meetings.

14. Lisa Negrini, LCSW, Supervisor: Supervises clinical casework, participates in bi-monthly clinical team meetings, Serves as accountable officer for recordkeeping and reporting to funder for family meals fund and attends other meetings as relevant.

Besides these key project personnel, the project also calls upon both paid OPS and student volunteer research assistants. Current research assistants involved include:

15. Erica Coates

16. Nicholas D'Souza

17. Kendall Barrios

18. Corell Kimer

19. Michael Nickas

20. Eric Umlah

21. Jessica Lassiter

22. Tori Jansen

23. Christopher Ellison (Research Assistant/Assessor), assists with data quality assurance and study scheduled postnatal assessments.

The project also utilizes the services of a group of experienced community professionals who contribute clinically to the project. Unlike the Mentors named above who sometimes serve the project by assisting with assessments and consenting of participants, the Mentors listed below are involved exclusively with the clinical side of the project, and do not interface with human subjects research data. All project Mentors train in the FIOC curriculum model, participate in weekly supervision meetings, intervene with families following curriculum guidelines, and attend relevant trainings and in-services. These Mentors include:

24. LaVerne Feaster Johnson (Mentor)

Other experienced community professionals serve families as Resource and Referral Navigators and provide information and connections to existing community resources, when parents ask for these. Unlike the Resource and Referral Navigators named above who also serve the project in other capacities, one research and referral navigator works exclusively in this role, and does not interface with human subjects data.

Finally, the project calls upon the unique expertise of several internal and external consultants who advise on different aspects of the work:

Internal

Linda Kraus, Ph.D., Senior Grants Specialist/Consultant who brings specialized expertise and experience from earlier feasibility study as primary editor for original and revised FIOC curricula, parent materials and Fidelity Manual. Contributes to project trainings and in-services involving revised FIOC curricula and supplementary materials, assists with annual sponsor reports, and attends relevant team meetings.

External

Selin Salman-Engin, Ph.D. Independent Contractor who brings specialized expertise from prior work on the feasibility study that was completed as seedwork for this project. She will be available to consult on fidelity monitoring; assist with coding of videotapes, and assist with manuscript preparation and report writing.

Anne Menard, Expert Family Violence & Safety Consultant, advises on curricular changes, Mentor safety training, and other issues relevant to enhancing the safety of implementation of project assessments and interventions, provides both ongoing and as-needed consultation to PI and Co-PI to formally review progress and developments so as to help maximize project safety.

Ronald Seifer, Ph.D. Expert Research Consultant, Consult with team on project's research operations, details relevant to proper conduct and reporting of a Randomized Controlled Trial, and issues relevant to data analysis.

9. The risks to the subjects:

While this is considered to be a minimal risk study, there is always the possibility of adverse effects resulting from participation. These include:

1. possible violation of confidentiality,

2. possible discomfort due to assessment procedures,
3. possible embarrassment in disclosing sensitive personal information,
4. possible disclosure of information about intended physical harm to victims or abuse/neglect of children that would need to be reported to the child welfare agency and an investigation of the allegations(s) and further action, as indicated, that could ensue,
5. possible disclosure of homicidal or suicidal thoughts, threats, ideation, attempts, or plans requiring mandatory reporting if participants are at imminent risk of endangering themselves or others.
6. possible dissatisfaction with the assessment/intervention procedures

Procedures for managing risks are described below.

10. Any experimental procedures including the use procedures already being performed on subjects for diagnostic or treatment purposes.

All participants will take part in the curriculum (6- pre-natal sessions and 1 post-natal session) designed to support families and strengthen coparenting relationships across the transition to new parenthood. Participation in the intervention is the only experimental procedure used in this project. The assessments families will complete have all been previously used by the PI and other family researchers in studies with similar populations.

11. The potential benefits to subjects:

All participants will share the potential to benefit from reflecting on the factors that promote their baby's adjustment (and from the coherence provided by the framework of the study) from their time of enrollment through the post-intervention follow up. Analyses of data collected in Pro0004412 indicated that participant couples showed improvements in rapport, problem-solving and communication, reductions in coparenting conflict, reductions in maternal depression, and improvements in views of fathers' roles and responsibilities. Some families also voiced appreciation knowing that findings from the study might benefit other non-co-resident parents like them planning ahead for life of their baby. In addition to the anticipated educational and intervention-based benefits study participants accrue, information from the study about benefits of interventions for unmarried parents having their first baby together will be of further help to Pinellas County agencies providing services to at-risk parents, to parents, and most of all to infants, by significantly enhancing environmental supports during the baby's first months of life. Program planners and others in the position to develop services for families outside of Pinellas will also benefit.

12. Human subjects considerations including a description of the informed consent process:

Participants who indicate interest after learning of the study from community partners are contacted by project staff and given details of study participation. Mothers who continue to express interest in the study are asked by project staff to notify fathers and provide contact information if fathers express interest. When so requested, staff meet individually at either parent's residence or elsewhere agreed upon to provide specific details of the project and answer the parent's (and if appropriate, the LAR's) questions about the study. Female staffer will meet

with both parents and male staffer will join her for the visit of the father, if deemed beneficial and/or desired by the participants. Informed consent for the participating mother and father is obtained only later, at the time they appear for their intake assessment session.

If a parent who is aged 16 or 17 and who has self-identified as being interested in participating in the study advises the project staffer that they no longer live with the parent or guardian, the staffer asks whether the parent has gone through the legal proceedings to become an emancipated minor. If the minor parent has not, the staffer asks permission to speak with his or her parent or guardian to explain the study. If the minor parent does not think he or she would have any success in contacting his or her parent to ask the parent to meet the project staffer to learn about the project and to provide parental consent, the staffer will ask the minor parent to provide last known residence information for his or her parent or guardian. If the minor's parent or guardian is unreachable or refuses to speak with the project staffer, the staffer will ask the minor parent if he or she is interested in enrolling in the project and providing the same adult consent to participate as any 18-year-old. Assuming so, parental consent would be waived, and the minor parent would be consented in as an adult and would sign the adult consent form. At the time of consent signing, a mental health professional (holding a LMHC license or a license in a related clinical field) who is unaffiliated with the research study but who knows and understands the community and works with young people in the census areas served by this project will be on hand to serve as an advocate for the minor parent and to ask of answer any questions on the minor parent's behalf. This LHMC would be contacted by project staff in advance of the meeting where the minor parent is asked to give consent to assure that she is available to be at the appointment with the parent. The advocate will explain her role as advocate to the minor parent, and will sign the consent form below the minor parent's name. A note would be made in the family's chart documenting that this was an exception involving the waiver of parental consent as per stipulations established through IRB review.

At the intake and then subsequently at the time of each follow-up assessment, participants are reminded that they may discontinue any procedure at any time, or withdraw from the study altogether, without prejudice, and afforded opportunities to ask questions about any facet of the study.

We take great care to assure that neither participants nor their families feel any coercion to take part in the project, and that participation in the study is a positive and affirming experience for those who do take part. Study participants are assured that they are free to withdraw at any time without prejudice and will still receive payment for the segment of the research assessment in which they had been participating at the time of withdrawal. For participants with low literacy levels, consent materials are conveyed verbally and all surveys are administered as interviews.

(a) Confidentiality Safeguards. To protect confidentiality, all information is de-identified so it cannot be associated with any individual. No one except authorized USF administration and project staff will ever have access to study records identifying subjects' names. Once participants have contributed data to the study, the key linking participant identities to the code numbers they have been assigned is kept securely and confidentially, accessible only to designated project staff supervised by the PI, and maintained for the duration of consent form storage. All information gathered will be used only for scientific, educational, or instructional purposes.

13. Data and safety monitoring plan:

In the project, 150 families will be referred to take part in the investigation and will receive support from a Resource and Referral Navigator in connecting to existing support throughout Pinellas County.

The following descriptions are covered below:

1. Monitoring of the recruitment, enrollment and retention activities
2. Potential adverse events resulting from participation
3. Procedures to safeguard against adverse events
4. Response procedures for adverse events
5. Reporting procedures for adverse events
6. Oversight

1. Monitoring of the recruitment, enrollment and retention activities

An important aspect of this work is carefully monitoring the experiences of the enrolled families. The entire project team will be involved in this endeavor, but major responsibilities for connecting with families will be shouldered by the Recruiter/Intake Coordinator. Her role involves talking with parents who have signaled their interest and enrolling them in the study. Each week's recruitment, enrollment and retention activities are reviewed by the project operations team, and appropriate strategies for improvement are identified and implemented. Retention of parents who have been randomized to the control condition is always of special concern; in this project, retention of control group parents is promoted by episodic contacts with the assigned Resource and Referral Navigator, a Congratulations card after the baby is born, and episodic staged reminder texts and newsletters. Retention of parents who have been randomized to the intervention condition is likewise supported by a R&R Navigator, and Mentors are also important to retention efforts with intervention group families. All families will be contacted by female Resource and Referral Navigator and mentors throughout the study duration as is needed for scheduling, follow-ups on missed appointments, formal check-ins at 1 and 9 months postpartum, and planning for 3- and 12-month post-partum follow-up visits. When deemed necessary to ensure retention, fathers will be contacted for the above purposes by male staff members. Should challenging issues arise, Clinical Supervisors, kept informed of family situations by project Mentors during weekly supervision meetings, help guide Mentors in responding to clinical challenges and monitor potential adverse effects in an ongoing way during supervision meetings. Monitoring can also occur at any time and with any required frequency in the event a situation qualifying as an adverse event occurs in between weekly supervision meetings. If clinically concerning scenarios of any sort arise, the Mentors first attempt to resolve the situation through consultation with clinical supervisors, who in turn report weekly (and more often if needed) to the PI and Co-PI. If resolution of a clinically-concerning scenario cannot be reached through use of supervision and rises to the level of an adverse event, the clinical team (co-PI and clinical supervisor (informed by the Mentors) and PI coalesce to form a plan that is then reported to the project's Data and Safety Monitoring Board, who comment on the plan and provide guidance. Expert consultant Anne Menard can also be available to consult as needed on cases requiring additional expert input. Families will be retained in the project so long as they

continue to express interest in participation and can continue to be safely enrolled. If a family must be withdrawn from the project based on assessments of concerns around safety, unresolved trauma, or other level of psychological or medical need beyond that which the project can safely provide, appropriate community resources and referrals are provided to the parents..

Parents who before or after referral express no interest in coparenting, whether owing to a history of domestic violence or for other reasons, will not be pursued for this study.

2. Potential adverse events resulting from participation

As indicated in Question 9 above, potential adverse effects resulting from participation in study assessments include:

1. possible violation of confidentiality,
2. possible discomfort due to assessment procedures,
3. possible embarrassment in disclosing sensitive personal information,
4. possible disclosure of information about intended physical harm to victims or abuse/neglect of children that would need to be reported to the child welfare agency and an investigation of the allegations(s) and further action, as indicated, that could ensue,
5. possible disclosure of homicidal or suicidal thoughts, threats, ideation, attempts, or plans, requiring mandatory reporting if participants are at imminent risk of endangering themselves or others.
6. possible dissatisfaction with the assessment/intervention procedures

3. Procedures to safeguard against adverse events

Confidentiality Safeguards and Informed Consent

Consent will be obtained by approved study staff overseen by the PI, who is responsible for integrity monitoring of the informed consent process. Legally emancipated parents are eligible to take part in the study without parental consent if they elect to do so. LAR permission is obtained for under-aged mothers and fathers co-residing with parents or guardians; approved study staff travel to the caregiver's residence to explain the study and seek consent when teens express interest in participation. They will also provide the LAR with a Consent Form along with the Recruiter's number to call to talk about and discuss the study further if they wish additional time or information before making a decision about the teen's participation. A male mentor is available to travel to the residence to discuss the study and obtain consent if any parent or caregiver wishes. Ethical guidelines prohibit 14-17-year-olds who are not emancipated and not co-resident with legal guardians from participation in the study. In addition, ethical guidelines preclude from participation potential teen participants whose co-resident parents are not home during research member visits and do not coordinate with the USF research staff to discuss consent. Section 7.4.2 Waiver or Alternation of Informed Consent Process in the study dashboard describes circumstance where the need for parental consent for a participating minor may be waived. Consent documents describe the length of the study, benefits, risks, payment, confidentiality of records, and the voluntary nature of participation.

All Mentors and assessment specialists receive detailed pre-project and ongoing in-service training on Intimate Partner Violence screening and safety plans. All research staff are trained in

participant protections and maintain Human Subjects Research certification, renewed every three years. Certificates are kept on file.

Once participants do contribute survey, interview, or observational data to the study, the key linking participant identities to code numbers is kept securely and confidentially, accessible only to designated project staff supervised by the PI, and maintained for the duration of consent form storage. All data entered into REDCAP and analyzed using SPSS are identified by subject code number only.

The USFSP computing system used for this project is protected from outside access by a three-tiered firewall system: the VMware Cluster is protected by Symantec End Point, Cisco Security Agent and access control lists (ACL). The software allows us to define rules that block any attempt to compromise the system. Logs are maintained and generate reports of access attempts, which are reviewed by the System Administrator.

Prior to data analysis all identifying information except for participant IDs is removed from all data. No pictures or likenesses of study participants will ever be published or presented at scientific conferences without participants' explicit written permission. No names of participants will ever be disclosed in publications or presentations.

Discomfort Due to Assessment Procedures

USF research staff will place a premium on establishing rapport with project participants to mitigate any potential discomfort due to assessment procedures. In addition, the USF research staff will strive to diminish additional concerns about assessment procedures via the informed consent process and assurance of confidentiality. Participants will also be reminded at each stage of participation that they may terminate participation in the project should their level of discomfort outweigh the potential perceived benefits of participation.

Discomfort with Assessment/Intervention Procedures

Mild discomfort from tasks in the coparenting intervention is expected. For some parents a childhood or earlier relationship history involving domestic violence, infidelity in the current relationship, and having other children with one or more different partners may all present stresses as parents work to strengthen their coparenting alliance. These issues will be dealt with in a sensitive and forthright manner during intervention sessions, and debriefed after sessions during clinical supervision.

Mild discomfort may also be experienced by some participants during the prenatal or postpartum assessment visit, or any of the FIOC intervention sessions. One source of discomfort during the assessment procedures may be the problem-solving discussion about areas of difference between the mother and father. To address any residual distress or arousal parents may be experiencing, parents will be asked to rate their current level of anger after the assessment has ended. Relaxation debriefing will be used if a client rates their level of anger as a 4 (considerable) or 5 (very strong). The relaxation exercise is one that has been used successfully by the Co-PI in prior studies and is presented in a matter-of-fact manner if a parent ever rates themselves as a 4 or 5. Parents listen to a soothing relaxation audio called "Special Place", after which they re-rate their anger. Further debriefing instructions are scripted into the protocol

Assessors use with parents. A second source of discomfort can occur as parents consider and discuss unmet expectations of caregiving support. Third, there is always the possibility that high levels of depression and/or potential suicidal ideation even in this minimal risk setting could be disclosed by a parent during the assessment interviews and/or the intervention sessions. All assessors and mentors are experienced community-connected professionals who have also received training in the project's Suicidality Protocol. Additional guidance is provided in the interview protocols for Assessors directing them to inquire should a parent report a recent increase in significant symptomatology. Assessors report this occurrence in an Assessor note they complete for every participant at the conclusion of pre- and post-natal interview assessments. If the need arises, the project's Resource and Referral Navigator (following an assessment) or Mentors (following an intervention session), in consultation with the Co-PI and/or Clinical Supervisor, stand ready and are will be able to provide necessary referrals and/or access emergent care if ever needed..

Embarrassment in Disclosing Sensitive Personal Information

As part of establishing rapport, the Mentors and USF research staff will explain, both during outreach visits to families and again during the formal informed consent process, the study's concern with potentially sensitive personal information relevant to understanding family adjustment. Participants will be assured that all such information will be kept confidential and will not be disclosed to parties beyond the research team.

Mandatory Reporting Safeguards

Procedures to prevent violation of confidentiality in accordance with reporting requirements are limited by the mandatory nature of these requirements. Parents will be informed in the consent document that staff must report to authorities 1) physical injury to any child caused by other than accidental means, as required by Florida Statute 39.201; and 2) information from a study participant which leads staff to believe a person is in imminent danger of physical harm. To further assure participant understanding of safety, a Program Agreement will be signed by both parents and Mentors at the first FIOC intervention session with Mentors.

Disclosure of Domestic Violence

Following consultation with local and national experts, we designed best-practice means of responding to any significant problems with IPV that surface. A Safety Protocol, developed together and reviewed annually with the project's nationally-recognized IPV expert consultant Anne Menard, details steps in responding to any IPV issues that may be encountered. Assessment staff and mentors are trained on the Safety Protocol prior to commencing their work with participants. They are also trained on mandatory Baker Act reporting procedures should a study participant ever become actively homicidal, and on a Suicidality Protocol that was developed should a parent ever express active suicidality. Relevant staff are trained in the procedure for assisting a study participant in the event a dangerous level of IPV is revealed by a participant. Staff are regularly provided updated trainings and in-services covering the consenting process, reporting responsibilities; interview administration, and response recording.

Safety is our paramount concern. Any mother referred to the study who thought she would be in danger if she took part in a coparenting intervention with the father would not be recruited to the study, but instead would be referred to a community agency more properly situated to provide

needed support services. The same is true if a family is assessed and reports a level of trauma beyond the capacity of the project to safely accommodate. If after a family has been randomized to the study, high levels of conflict without violence are reported or witnessed during the course of the intervention -- but the participating mother does not express concern that she is in danger - - the female Mentor has been trained to work with the mother to identify a "mother-specific" mechanism for checking back in with her later, after the individual session ends, to ascertain (in an ongoing way, if indicated) whether all remains well. For higher-conflict couples randomized to the intervention, gender-specific individual preparatory sessions (part of the usual individual Mentorship meetings completed individually with mothers and fathers following the intake assessment and before the FIOC curriculum commences) addresses with the parent how violence is bad for both the parents and the baby. Parents are enjoined to form a plan for safe, supportive participation in coparenting. After the individual mentorship sessions parents and Mentors come together for FIOC session 1, and at the end of this session all four individuals sign a Project Agreement symbolizing their commitment to a safe and violence-free pregnancy..

Additional Staff Training Safeguards

In addition to the opportunity for weekly clinical supervision, project staff who work directly with the mothers and fathers) also are provided both initial and ongoing trainings and in-service workshops that regularly revisit work with pregnant women, safety issues, Intimate Partner Violence and procedures in handling high levels of depression and suicidality. These trainings are offered bi-annually or more frequently if needed.

Dissatisfaction Safeguards

Participants are encouraged to discuss with the project P.I. and/or relevant project staff any experiences of dissatisfaction with any assessment/intervention activity. Dissatisfaction disclosed by mothers or fathers will be shared among the PI, Co-PI and Clinical Supervisors. As appropriate, relevant issues will be discussed in supervision and/or at team conferences or trainings. If ever needed, amendments would be made to the project protocol to respond to any recurring issues raised by multiple participants, while taking care to assure that any accommodations do not materially influence the integrity of the research protocol.. Referrals to appropriate community services will always be made at time in cases where project staff and participants concur that such referrals could be of help to the family.

4. Response procedures for adverse events

Discomfort with disclosure

Participants will be reminded that their participation is voluntary and they may choose not to disclose any information that creates extreme discomfort for them.

Mandatory reporting

1. Suicidal thoughts, ideation, attempts, or plan

Staff who work with families have been trained in the project's Suicidality Protocol. In the event of disclosures of suicidal ideation or thoughts by participants, appropriate referrals for counseling will be provided by the interventionists. In addition, the interventionists will notify the /Co-PI and Clinical Supervisor of such revelations. Disclosures of suicide attempts or plans

will be handled by assisting the parent(s) with accessing services via the Pinellas Emergency Mental Health service system.

2. Abuse/neglect

In the event that child abuse or neglect is disclosed or observed (e.g., bruises, burns, or black-eyes) whose origin appears to differ from the explanation given of the injury during the assessments or intervention, the Mentor will further question the participant(s) and obtain additional information. If any of the above conditions lead the Mentor to suspect abuse or neglect of a child, the Mentor will compile a report from the collected information. Based on the information provided, the Co-P.I. and Clinical Supervisor will advise the Mentors regarding communication with parents, appropriate further inquiry, and proper reporting.

3. Threat of danger to others

Threats of danger to others include disclosure of potential physical harm by a participant to others, including members of the participant's family or other individuals in the community. Mentors will report such disclosures to the Co-PI and Clinical Supervisor. These disclosures will be handled in accordance with Florida law, requiring reporting to proper legal authorities by project staff.

4. Family crisis

Family crisis involves a range of situations that threaten the ability of subjects to provide essential supports for their children. Mentors will provide appropriate referrals to assist parents with relieving crisis situations.

5. Domestic Violence

A coordinated response to disclosures of domestic violence will be initiated, tailored to the particular issues disclosed during the intervention. All staff who work with families have been trained on the project's safety plans, and how to assist the mother in taking actions she has deemed appropriate to increase her safety. Plans can include, but not be limited to, project-specific safety planning, working with CASA (Community Action Stops Abuse, 1011 First Avenue North, St. Petersburg), the local certified domestic violence center, taking steps to go into shelter, contacting law enforcement, obtaining an Injunction for Protection, and/or terminating participation in the project. The project safety plan is included as a separate document.

5. Reporting procedures for adverse events

Potential adverse events during assessments/intervention are limited to those described above and will be addressed in a timely manner by the Mentors, Co-PI, Clinical Supervisor and P.I. *Reporting Procedure for Serious Unanticipated Adverse Events.* In the event of any unanticipated serious adverse event, the P.I. will ensure that the event is reported to the proper authorities within 24 hours by phone, fax, and/or email and will submit a written report to the

Program Official no more than two days later. The project staff will also utilize the following reporting procedures:

1. When project staff and/or the P.I. become aware of a serious adverse event, reporting requirements must be implemented in a timely manner.
2. The P.I. will complete an "Adverse Event Reporting Form" and submit the form to the University of South Florida IRB Officer.
3. The IRB Officer immediately distributes the form to USF IRB Officials.
4. The IRB Officer will convene an expedited meeting of the IRB either on site or via telephone. The IRB, with the input of the PI will review the study protocol and determine what further action to take based on the best interests of the participants and of the research.

6. Oversight

The Data and Safety Monitoring Board consists of 3 non-USF-affiliated field experts (Tricia Bent-Goodley, Bonnie Rosendale, Wendy Loomas) in randomized controlled trials and research and in working with fragile families and domestic violence. The Safety Officer, Stover, in consultation with supervisors and Mentors, will monitor potential adverse effects. When such occur she will be contacted immediately by supervisors who will be in position to ascertain in ongoing fashion whether any such events have occurred during the weekly supervision meetings (and more frequently, if adverse events occur between supervision meetings).

If an serious adverse event (SAE) occurs that may be study related, the safety officer, Stover, will send a report to the DSMB along with the IRB for their review and recommendations about modification and continuation of the study. Outside of SAEs, a quarterly DSM report will be prepared and sent to the board for review and their comment on continuation of the study will be attained.

USF's Human Research Protection Program (HRPP) is responsible for the general oversight for all grant activities at the university and will inform the P.I. about changes and requirements for the DSMP. The project will have a yearly review of its DSMP by the USF IRB during the continuing review process, outlining the following points:

Reassessment of the risks and benefits to study participants

Participant recruitment, accrual, and retention

Data quality and confidentiality

Consideration of external scientific or therapeutic developments with impact on the safety of participants or the ethics of the study

Review any adverse events

The HRPP will update the general DSMP procedures as needed.

14. Research references:

McHale, J. (2007) *Charting the Bumpy Road of Coparenthood*. Washington DC: Zero To Three Press.

McHale, J. & Lindahl, K. (2011). *Coparenting: A clinical and conceptual examination of family systems*. Washington DC: APA Press.

McHale, J., Salman., S. & Covert, M. (in press). Improvements in unmarried African American parents' rapport, communication and problem-solving following a prenatal coparenting intervention. Family Process.