**PROTOCOL TITLE:**

*Family Systems Approaches to Infant Mental Health Treatment.*

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**REVISION HISTORY**

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| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
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# Study Summary

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| **Study Title** | Family Systems Approaches to Infant Mental Health Treatment |
| **Study Design** | Randomized trial methodology with PRE-POST assessments |
| **Primary Objective/Purpose** | The objective of this study is to assess the feasibility of offering a family-centered (coparenting) intervention to families where children have experienced trauma and early adversity |
| **Secondary Objective(s)/Purpose** | To assess response burden of standardized interview and observational intake and discharge procedures |
| **Research Intervention(s)** | Dyadic child-parent psychotherapy with Focused Coparenting Consultation framework |
| **ClinicalTrials.gov NCT #** | N/A |
| **Study Population** | Children ages 12 to 36 months and their families |
| **Sample Size** | 30 |
| **Study Duration for individual subjects** | 12 months |
| **Study Specific Abbreviations/ Definitions** | IFC = Infant-Family Center; CPP = Child-Parent Psychotherapy; FCC = Focused Coparenting Consultation |

# Objectives

2.1 Most therapeutic encounters with children under the age of 3 include the child and a single parent or primary caregiver. Additional attachment figures are seldom integrated systematically in the course of such treatments, though ancillary consults are sometimes offered to involve such individuals. Our own infant-family mental health clinic experiences suggest that infants’ and toddlers’ coparents can be more meaningfully recruited into treatment programs to receive therapeutic support for the coparent-coparent-child triad and the broader family system. To date, there are no systematized data regarding the potential of a coparenting-framed approach to the treatment of infants and young children who have been exposed to trauma and adversity. Prior to embarking on gathering such evidence, it is necessary to determine the acceptability and feasibility of such a treatment approach to families themselves. Herein, we propose to investigate in a small randomized controlled trial the acceptability of substantive coparenting programming to families served through our clinic. The study’s Specific Aims are:

**Specific Aim 1**: To track, among families of infants and toddlers who have been referred for clinical care secondary to having experiencing trauma and early adversity, whether randomization at the point of intake is a barrier to enrollment in the proposed trial.

**Specific Aim 2**: To investigate whether a coparenting (triadic) focused intervention versus conventional relationship-based (dyadic) intervention can be implemented with a comparable degree of methodological rigor and acceptability (execution, treatment fidelity, clinician adherence to protocols, participant satisfaction, participant adherence to treatment).

**Specific Aim 3**: To investigate the feasibility of employing both dyadic and triadic observational assessment procedures and outcome measures with this population, and the necessary time and resources required to conduct such observational assessments as part of standardized intake and discharge protocols.

These results will provide needed preliminary information regarding the practicability of offering coparenting-focused interventions to families in which very young children have been exposed to trauma and psychosocial adversity.

2.2 We hypothesize that substantive coparenting programming is equivalent to or better than standard of care.

# Background

3.1Effective relationship repair in the caregiving environments of infants and young children exposed to trauma and toxic stress is essential if children are to move back onto healthy longer-term developmental trajectories. Historically, treatment for infants and toddlers who have been exposed to early trauma and adversity has been delivered within a dyadic, relationship-based framework, in which relationship repair between the child and one primary caregiver is targeted. Though only a small number of dyad-based treatments with very young children have been studied scientifically, evidence for their efficacy is good (Cicchetti et al., 2000; Cicchetti et al., 1999; Lieberman, Van Horn & Ghosh Ippen, 2005; 2006; Toth et al., 2008), and hence where feasible, evidence-based dyadic treatments are recommended as standard of practice (National Child Traumatic Stress Network, 2019). There is a problem, however, in that even when communities are able to offer such relationship-based therapies to higher risk populations, parents who take part in the dyadic therapies typically do so alone, without the active engagement and participation of other family members (who are themselves coparents and attachment figures for the infant or toddler) in the case conceptualization and treatment delivery. Because an inordinate number of parents whose young children are referred for infant mental health services are struggling themselves with mental health, substance abuse or other related problems, many later go on to re-experience clinical difficulties including occasional return of symptomatology and relapse. In such circumstances and without other family resources prepared to step in, the therapeutic gains of dyadic treatments are threatened, placing the child at recurrent risk.

Further, within-family strains in and of themselves often exacerbate matters, for parenting adults who are experiencing concurrent distress in other family relationships tend to be ineffective in cooperating and working as a team in child-rearing (McHale, 1995; Stroud, Durbin, Wilson, & Mendelsohn, 2011). Interventions with just a single parent and child do not mitigate these family-level challenges; there is little evidence that interventions at the level of child-parent dyads have positive reverberatory effects throughout family systems. Interventions targeted for mothers improve mother-child, but not father-child or coparenting outcomes; interventions for fathers improve father-child, but not mother-child or coparenting outcomes, and so forth (McHale, 2007a). And when therapeutic gains are not realized and child behavior problems continue, the family’s coparenting struggles themselves worsen (Zemp, Johnson & Bodenmann, 2018). Prospective longitudinal evidence indicates that children’s externalizing behavior problems drive child-related coparenting conflicts two years later (Jenkins, Simpson, Dunn, Rasbash, & O’Connor, 2005).

The promise of a coparenting approach for families experiencing adversity and risk has been engaged upon in work by the PI, who developed and field-tested a Focused Coparenting Consultation approach with unmarried uncoupled parents expecting a first child. Preliminary evidence for the promise of this approach in strengthening mother-father communication, collaboration, and cooperation showed benefits in dyadic mother-father conflict discussions and in triangular mother-father-baby play (McHale, Salman & Coovert, 2015). Though this work did not include the infant in the course of treatment, the focus of the work was explicitly on coparenting of the child and not on the couple’s own relationship. The rationale of a coparenting intervention and a treatment dedicated specifically to working to resolve child-related issues was acceptable to 100% of parents involved (Salman-Engin, McHale, Gaskin-Butler, Earle).

In the proposed study, the focus is on bringing coparents together for a family-focused intervention in the aftermath of early adverse experiences impacting the child, to work together to help recover or restore family level security. The coparenting intervention does not replace, but augments, the important dyadic repair efforts. Coparents can be the child’s residential or non-residential parents, but need not necessarily be those two individuals – any child’s coparents are those individuals responsible for the child’s everyday care and upbringing, with whom the child has developed close bonds (McHale & Irace, 2011). The investigative team’s well-grounded conceptual model and existing community base strengthens its preparedness for a future larger-scale RCT if feasibility study results substantiate treatment acceptability and document family and clinician adherence. This family-level intervention framework stands as a unique innovation in opening up a new line of study, for there exist no evidence-based coparenting interventions based on programming studies for families of infants and toddlers exposed to trauma and early adversity.

3.2 N/A

# Study Intervention

4.1 The experimental study intervention will combine dyadic therapy (Child Parent Psychotherapy) with a treatment plan framed by, and including, a 6-session family-focused intervention incorporating core elements of Focused Coparenting Consultation (McHale & Irace, 2010) and Interactive Guidance (Fivaz-Depeursinge & Philipp, 20014; McDonnough, 1993; Rusconi-Serpa et al., 2009). Families will be told from the outset that the treatment plan calls for both (or all, if more than two) coparents to take part in the coparenting intervention in combination with the dyadic work. Families in this group will be told that a key to helping the child improve will be the capacity of the adults to work together. The three stages of Focused Coparenting Consultation (McHale & Irace, 2010) will be followed in sequence. In Phase 1, consciousness-raising, the clinician builds trust and rapport while consulting with the parents about what they shared about the child and family during the intake. There is explicit focus on what parents had to report about both the child’s difficulties and about their coparenting habits and practices. The therapist both normalizes coparenting conflict and utilizes reflections on intergenerational experiences of having been coparented to discuss the impact of dissonance on children as young as infants and toddlers. Emerging evidence provides a conceptual basis for linking triadic interaction and insightfulness (Marcu, Oppenheim & Koren-Karie, 2016).

In the service of elevating conscious awareness, coparents also review their intake coparent-child interaction (during a coparent-coparent-child play procedure, the Lausanne Trilogue Play) with the clinician, setting a stage for increasing mindfulness about their own contributions to the family process. LTP videos are also utilized in Stage 2 (skill-building), where anger and conflict management and communication skills are covered, and active interaction guidance methods are employed. In Stage 3, guided enactments, coparents are supported as they discuss their most significant areas of disagreement about the child together with minimal therapist intervention. Also, during Stage 3, coparents develop together a shared plan for supporting the child and one another, and for engaging family member support and participation in the plan as appropriate. Per standard clinic procedure, videotaped recordings of both assessment and intervention sessions are obtained, and in the case of this second intervention condition the assessment videos will be used in the delivery of the intervention itself.

# Procedures Involved

5.1 The protocol for this project is designed to mirror that which would be employed in a subsequent larger-scale clinical trial that will benefit and make use of the procedures finalized in this study. Participants will enter the study through the customary manner in which they make contact with the USFSP Infant-Family Center and its services for families. Referrals come from all manner of health and human service agencies serving families of infants and toddlers and during initial screening procedures intake personnel will learn of the child's age, exposure to adverse childhood experiences (with score documented on ACES-Q instrument), and presence of an active coparent in child's life. Eligible families with 12-36 month old children with parents/coparents up to 65 years old who have experienced trauma and early adversity learn about the possibility of participating in a new intervention as part of a research study and are provided with details of the coparenting intervention, including that they will learn about the services being offered to them following the usual clinical intake. Consent is secured at the time of normal clinic consenting prior to assessment; assessment procedures are the same for all families whether participating in this study or not. Families are seen over the course of multiple sessions involving two coparents and child; 2 sessions are customary but a third is scheduled if a coparent's schedule makes attending common sessions a challenge.

5.2

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| Audio/Video Recording | Psychophysiological Recording |
| Behavioral Interventions | Record Review - Educational |
| Behavioral Observations and Experimentations | Record Review - Employee |
| Deception | Record Review- Medical |
| Focus Groups | Record Review - Other |
| Interviews | Specimen Collection or Analysis |
| Investigational Device – Non-Significant Risk (e.g. Mobile Applications) | Surveys and/or Questionnaires |
| Psychometric Testing | Other Social-Behavioral Procedures |

The Center for Youth Wellness Adverse Childhood Experiences Questionnaire (CYW ACE-Q), Child Version is presented as part of an initial screening, and ACE scores will be used to establish the family’s eligibility for the study. The CYW ACE-Q is an informant-report instrument appropriate for children of the ages enrolled in this study. Following determination of eligibility and family expression of interest in the treatment evaluation study, the two coparents and child will complete the standardized clinic intakes prior to randomization. They will complete the same battery of assessments again at discharge. Aims of the intake assessments are to obtain evaluations of individual, dyadic, and triadic functioning (a) to inform the individualized interventions delivered post-randomization, and (b) to provide a baseline against which levels of functioning at discharge can be contrasted.

Regarding the specific procedures and instruments administered at both intake and discharge (see Summary in Local Site Documents), both coparenting adults will complete (a) the Center for Epidimiological Studies Depression Scale (CES-D); (b) the Parenting Stress Inventory (PSI); (c) the Coparenting Scale (McHale) and Coparenting Relationship Scale (Feinberg) and (d) the Infant-Toddler Socioemotional Assessment (ITSEA).  The intake assessment is typically conducted over a span of 2 sessions, with the interview and self-report obtained by the clinic’s intake coordinator, and observational assessments and follow-up consultation and case planning completed by the clinician assigned to the case. Clinicians will not know which condition the family has been assigned to at the time of the intake observations but will learn of the condition to which the client has been assigned from their clinical supervisor after completion of the observational session and prior to the treatment planning session.

Both interview and observational data are obtained and video records are made for all families for later clinical and research usage. Randomization will occur following the last assessment session and the family learns of which condition (the clinic’s typical standard of care - dyadic CPP intervention with collateral coparenting consults or the experimental dyadic CPP with Focused Coparenting Consultation (FCC) intervention) at the subsequent treatment planning session. Study participation demands for this Dyadic Condition with Collateral Coparenting Consults are identical to those typical for clinic clients. Study participation demands for the Triangular group (CPP + FCC) include an additional 6 manualized sessions beyond that which would be standard in the IFC’s work with families. For those in the FCC condition, LTP videos obtained during intake will be utilized during all 3 stages of the FCC intervention. Fidelity checks for both dyadic and family work will be maintained continuously and (3) independent formal checks per family from video records will be made for FCC families by the study team.

Local Site Documents (See Uploads):

1. Data Capture Sheet
2. Instruments
3. Personnel Justification
4. Coparenting Consultation Framework
5. Infant Family Center Referral form
6. Focused Coparenting Consultation Manual

5.3 The standard of care procedure for children seen clinically at the Infant-Family Center is Child-Parent Psychotherapy (CPP), a dyadic (child-parent) treatment developed for children aged 0-5 who have experienced as least one traumatic event and/or are experiencing mental health, attachment, and/or behavioral problems including post-traumatic stress disorder. CPP is accredited as an evidence-based treatment by the Substance Abuse and Mental Health Services Association (SAMHSA) National Registry of Evidence-Based and Promising Practices. Standard of care practice at the Infant-Family Center is also that referred families be invited to take part in periodic parent-coparent consultations to review progress of dyadic treatment and discuss the importance of coparental support for gains made. These consults are described at the point of intake/treatment planning and are scheduled episodically as the work progresses as per the availability of the coparents. Control group participants will receive these services, which would have been delivered anyway even if the research was not occurring.

5.4 There are no additional foreseeable risks to the above procedures in need of further mitigation beyond those ordinarily incurred in working with a high risk population. Standard operational procedures of the clinic specify responsibilities for handling dangers to self and others, safety planning in the event of domestic violence, and reporting responsibilities in the event of a new episode of child abuse.

5.5 N/A

5.6 N/A

5.7 N/A

# Data and Specimen Storage for Future Research

N/A

# Sharing of Results with Subjects

7.1 Individual results of intake assessments are shared with families; indeed this is part of the clinic’s model and part of the process of raising families’ mindfulness about their family process and its impact on the child. Group findings will not be shared with individual families.

# Study Timelines

8.1 Participants will be seen for a minimum of two intake assessments and then up to 50 sessions of CPP over the course of the ensuing year, as determined by the family and clinician. The visits will be 60-90 minutes long. Those in the FCC experimental intervention group will also take part in 6 manualized sessions in addition to the CPP. The control group will receive episodic coparenting consultations, as indicated.

# Inclusion and Exclusion Criteria

9.1 Participants are to be 30 families (minimum of two adults and one child) who have been referred for clinical treatment services at USFSP’s Infant-Family Center. Families will be evaluated for eligibility at the point of initial contact when background information is gathered. Applicants will be considered eligible if the family has been referred to the IFC for treatment, the child is between the ages of 12 and 36 months at the point of intake, and the child’s adversity exposure score on the Center for Youth Wellness ACE Questionnaire (CYW ACE-Q), Child Version is two or greater.

9.2 Exclusion criteria: Absence of a coparent in the child’s life.

9.3 N/A

9.4 N/A

# Vulnerable Populations

10.1 By definition, children served by the clinic are a multi-risk and vulnerable population given their exposure to trauma and/or early adversity, and clinic staff take exceptional pains to deliver all interventions safely and ethically. When notifying families of the treatment they have been randomized to receive, they will assure that participants and their families feel no coercion to take part in the intervention if they do not wish. They will make certain that parents understand that they have a choice to accept the treatment modality offered to them, or elect to have a different course of treatment, without penalty. The intake team is experienced and accustomed to supporting higher-risk families and respecting their preferences and sensibilities. Staff will also assure that participation in the study is a safe, positive and affirming experience for those taking part. As part of standard operating procedure at the Infant-Family Center, exceptional measures are taken to protect both children and families including provision of evidenced-based therapies by seasoned clinicians and close and careful supervision of all casework.

# Local Number of Subjects

11.1 30 families for the feasibility trial is projected (30 children and 60 adults). To account for withdrawals, we will enroll up to 45 families (45 children and 90 adults).

# Recruitment Methods

12.1 Families will be identified in the Infant Family Center. Flyers will be posted in the waiting rooms.

12.2

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| Email | Online/Social Media Advertisement |
| Flyer | Record Review |
| Letter | SONA |
| News Advertisement | Other |

12.3 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 the same quality of clinic treatment.

# Withdrawal of Subjects

13.1 Withdrawals are not anticipated, but participants would be withdrawn from the study in the unusual circumstance where provision of the experimental treatment increased levels of risk, such as heightening the occurrence of intra-family violence. We have not encountered this situation in the clinic’s three years of operation but it is always a possibility and hence participants would be withdrawn from the feasibility trial if they could not be maintained safely in the study.

13.2 Their care at the clinic will continue.

# Risks to Subjects

14.1 Potential adverse effects resulting from participation in study assessments are no different from those associated with all clinical care provided. These include:

1. Possible violation of confidentiality;

2. Possible discomfort due to assessment procedures;

3. Possible embarrassment in disclosing sensitive personal information;

4. Possible discomfort or increased conflict in response to the assessment/ intervention procedures;

5. Possible disclosure of information about abuse or about neglect of children that would need to be reported by law and an investigation of the allegations(s) and further action, as indicated, that could ensue; or

6. Possible disclosure of homicidality or suicidality requiring mandatory reporting if participants are at imminent risk of endangering themselves or others. The likelihood of the first of these risks is low. Assurance of protection of confidentiality is a clinical responsibility and duty of the staff of the Infant-Family Center and will be emphasized and monitored regularly by the PI and Clinical Supervisor/Safety Officer. Risks 2 through 4 are possible, and perhaps likely, for many participants in the study, men in particular. Knowing this has assisted us in preparing clinical staff to pursue the establishment of strong rapport with families during outreach, recruitment, intake, and intervention, and to emphasize their ongoing availability to and support of study families throughout the course of the therapeutic work and the project. Risks 5-6, while small, can occur and will be treated with the utmost care and concern. Because all study assessments and interventions are delivered by, and closely overseen by, licensed clinicians, the project is positioned to promptly respond should emergency aid and referrals be necessary. Specific steps to be taken in response to any adverse circumstances that may arise are detailed in clinic’s operating procedures manual. If a parent acknowledges current suicidal ideation, the clinician would help the parent with the process of entry into the Pinellas Emergency Mental Health service system. The clinical supervisor/safety officer is available for emergency consultation if clinical concerns with high depression or suicidality arise. Upon report of suicidal intentions or the threat of harm to others, the participant will be secured to the needed level of treatment (e.g. hospital setting). If the threat is against an intimate partner, the partner participant will be notified for his/her safety (e.g., as in a Tarisoff report, if his/her safety is threatened). Our clinical team has expertise in dealing with high risk behaviors and abides by all state and federal regulations. If a clinician, or any staff member learns of homicidal or suicidal ideation or intent, they will immediately contact the supervisor who will assist in assessing the participant and facilitating a higher level of care if needed. Pinellas County maintains a mobile crisis unit funded by the Bureau of Primary Health Care that is a Federally Qualified Community Health Center (FQCHC) and can respond to urgent needs for mental health referral.

Child Abuse and Neglect: Child abuse concerns may arise if an adult states that abuse has occurred or is occurring, if during a clinical session the baby or toddler is observed being treated abusively, if the baby is observed with bodily injury (e.g. bruises, burns, black-eyes) whose origin appears to differ from the explanation given of the injury, or if a child from a prior union who accompanies the parents to a treatment session is observed with bodily injury whose origin appears to differ from the explanation given of the injury. If any of the above conditions lead clinical staff to suspect abuse or neglect of children, the Project Coordinator will obtain additional information and contact Ms. Negrini, who will advise staff regarding communication to the family, appropriate further inquiry, follow-up, and reporting. If at any time during the intervention, any of the above conditions lead mentors to suspect abuse or child neglect, the interventionist will notify the supervisor who will review the information and determine next steps. If abuse is indicated, the clinician will develop a safety plan with the parents and make appropriate reports of abuse to protective services on behalf of the baby and parents.

14.2 N/A

14.3 N/A

# Potential Benefits to Subjects or Others

15.1 Participants will be aware from the outset that they are participating in a project that was designed to assess the benefits of different kinds of family relationship interventions for very young children who have experienced trauma and/or adversity, and that in addition to any therapeutic or other intervention-based benefits they accrue, the new information the study generates about families will be of help to program planners and to others in the position to develop services for families like theirs. All participants will share the potential to benefit from reflecting on the factors that promote their child’s adjustment (and from the coherence provided by the framework of the study) from their time of intake on through the time of discharge. Families often appreciate knowing that findings from the study will benefit other families facing similar circumstances.

15.2 If found to be effective, this coparenting programming could be implemented across family programs.

# Data Management and Confidentiality

16.1 Though the study is underpowered to pursue and formally test treatment effects or meaningful effect sizes, initial descriptive summations and student t-tests and chi-square tests will compare the comparability of the two randomly assigned treatment groups at point of intake. Pre- and post- levels of functioning on all individual, dyadic and triadic variables will be detailed in a final progress report principally to identify directionality of family progress in this feasibility study.

Primary Aims 1-3: The proportion of clients who accept randomization assignments to the two groups will be calculated along with 95% confidence interval. For aim 2, analyses will also examine mean levels of engagement of coparents (sessions attended) for each of the two conditions, as well as mean participant satisfaction and adherence to treatment. Utilizing procedures developed and reported to assess adherence and competence in delivering Focused Coparenting Consultation by Salman-Engin and colleagues (2016), analyses will also report mean levels of clinician adherence to protocols. Recognizing the pilot nature of this analysis, analysis of covariance (ANCOVA) will be used to compare measures of intervention implementation by random assignment. Statistical adjustment will be limited to no more than 2 baseline variables (based on small sample size) that show any unexpected imbalance between the intervention groups. To assess feasibility and burden of the assessments designed for measuring outcomes, success rates in full and valid completion of each observational and interview-based intake/discharge procedures will also be reported, along with 95% confidence interval. Finally, although exploratory, standardized effect sizes of the outcome variables of interest (e.g. depressive symptoms, parenting stress, etc.) will be calculated along with 95% confidence interval using the independent-group pretest-posttest design described by Becker (1988) and Kadel and Kip (2012). Of note, standardized effect size calculations are relatively invariant to sample size (although precision is directly related to sample size), and these results are expected to provide initial insight in the postulated benefit of the coparenting (triadic) focused intervention as compared to the conventional relationship-based (dyadic) intervention.

16.2Data collected in this study will be entered into the university’s REDCap web-based data collection and reporting tool, operated and maintained by USF Health Sciences. The data captured and subsequently exported from the REDCap Database Management System will be imported into SAS datasets and subjected to extensive checks for logical, chronological, and data accrual inconsistencies. Additionally, the Data Manager, the Statistician, Principal Investigator and Safety Officer/Clinical Supervisor will conduct periodic qualitative and quantitative analyses to check for data integrity. The Project Coordinator will also be responsible for notifying the PI if any source documents or case report forms are not completed in their entirety (i.e., if there are missing or incomplete data). To assess change in the primary and secondary outcomes over time, box plots of the interquartile range and 95% confidence intervals will be depicted at each study timepoint. For analysis of sustained effects, baseline to follow up changes in the outcome evaluation measures will be compared by use of linear mixed models.

Confidentiality will be an utmost consideration in the study. All paper-and-pen and video data will be kept separate from clinic file records. All will be marked only by code numbers and never names. Any paper-and-pencil or video/audio records collected during home visits with families are transported immediately back to the project's secure file room, in a lock box, after sessions. The staffer transporting the confidential records delivers them directly to the Project Coordinator or, if arriving after hours, stores them in a locked drawer accessible only to designated research staff. The Project Coordinator assures that pertinent records marked with family code numbers are stored separately in drawers and cabinets separate and apart from records marked with participant names. Data are entered into REDCap systems within 72 hours after data collection. Weekly progress updates are provided by the Project Coordinator at team meetings. Data and consent forms will be stored in separate locked file cabinets in a Family Study Center office accessible only to the PI and to authorized clinical project staff under his direct supervision. Access to the Family Study Center is restricted. Reception staff members supervise public entrances during normal operating hours. All space accessible to the public is separated from research offices by locked doors.

The Infant-Family Center computing system 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.

16.3Data will be monitored by the Project Coordinator on a monthly basis to ensure the quality and integrity of the data.

16.4 Names, emails, telephone numbers, and dates will be included in the data. The data will be stored for 5 years after the final report is submitted to the IRB, and destroyed by deletion and file shredding. The deleted file will be purged from the hard drive. Confidential data will be shared with the study sponsor as indicated in the consent.

16.5 N/A

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| --- | --- |
| Obtaining Signed Authorization | Waiver of HIPAA Authorization for Recruitment/Screening Purposes Only |
| Obtaining Online or Verbal Authorization (Alteration of HIPAA Authorization) | Waiver of HIPAA Authorization for Entire Study |
| Data Use Agreement | Business Associate Agreement |

# Provisions to Monitor the Data to Ensure the Safety of Subjects

17.1 Ensuring Safety of Participants. All potential participants will receive services whether consenting to the research or not. There are no anticipated risks, other than breach of confidentiality, to allowing intake and discharge data to be used for group analyses. The potential benefits to the field of knowing what treatments are most helpful, and for whom, are great. It is certainly anticipated that the interventions in which they have taken part will themselves affect desirable changes in child and family functioning. The research will, hence, help us to better understand how family relationships and infant well-being change as a function of treatment, information that can be expected to benefit children in the future.

The Principal Investigator will be responsible for ensuring compliance with the study protocol and will conduct weekly staff meetings to review all study-related matters including data collection and to implement solutions to unanticipated problems. He will also meet independently once weekly with the Safety Officer/Clinical Supervisor to review clinical adherence progress. The Safety Officer/Clinical Supervisor will herself meet weekly with project clinicians and will meet weekly with the Project Coordinator to review ongoing interventions and to discuss any challenges or difficulties encountered in working with clients in the study.

The assessments used at the Infant-Family Center are widely used and validated instruments in the child and family mental health fields, but can instigate discomfort among participants. Trained staff administer the procedures as points of entry to treatment services, and so are poised to provide direct follow-up themselves and referrals to more intensive levels of care in instances where parents may be a danger to self or others.

17.2 N/A

# Provisions to Protect the Privacy Interests of Subjects

18.1 All research activities will be conducted in a private room within the Infant Family Center.

18.2 Subjects will provide informed consent. We will not access any previously existing records.

# Compensation for Research-Related Injury

19.1 N/A

# Subject Costs and Compensation

20.1 N/A

20.2 Families will receive no payment or other compensation for taking part in this study.

# Consent Process

21.1

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| --- | --- |
| Obtaining Signed Consent (Subject or Legally Authorized Representative) | Obtaining Consent Online (Waiver of Written Documentation of Consent ) |
| Obtaining Signed Parental Permission | Obtaining Verbal Consent (Waiver of Written Documentation of Consent) |
| Obtaining Signed Assent for Children or Adults Unable to Consent | Waiving Consent and/or Parental Permission (Waiver of Consent Process) |
| Obtaining Verbal Assent for Children or Adults Unable to Consent | Waiving Assent/Assent is Not Appropriate |

21.2 The consent process will occur at the IFC during the intake session and will be completed by the intake coordinator, an IRB-approved study team member. To summarize the consent process: families referred to the IFC by community partners are notified by the intake coordinator, after a determination is made that their family is suitable for clinic services on the basis of age and presenting concerns. Interested parents are asked to notify their co-parent about the possibility of taking part in the study; interested families contact the intake coordinator to schedule an initial intake visit in the IFC.

At the initial intake, the intake coordinator provides specific details of the study and answers the parent's, co-parent’s (and if appropriate, the LAR's) questions about the study. Parents and co-parents will be given an opportunity to ask questions and will be offered the opportunity to take the consent document home and discuss participation with friends and other family members. When a family indicates that they are interested in participating, the intake coordinator will obtain informed consent from both adult c-parents.

21.3 N/A

21.4 N/A

21.5 Once the English consent document is approved by the IRB, the study team will submit an amendment to obtain approval for the Spanish consent document. The intake coordinator speaks fluent Spanish and will be responsible for obtaining consent from all participants, including Spanish-speaking participants.

21.6 The children to be enrolled are between 12-36 months of age, and cannot provide assent. Signed parental permission will be obtained from both parent participants.

# Setting

22.1 The site for this project is USFSP’s Infant-Family Center (IFC). As a matter of routine clinical practice, those families without the means to travel or who have other impediments preventing their traveling to the Infant-Family Center are seen for home visits.