

University of Miami - Miller School of Medicine

Set-Enhanced Aftercare for Mothers in Substance Abuse Recovery and Their Children

Version Date 6-7-2016

National Clinical Trial Number: NCT02702193

Victoria Mitrani

4. Description of Study

Study Protocol

4.1. * Abstract and Specific Aims

Include a brief summary of the significance, purpose or research question, specific aims, and risks/benefits. Specific aims include hypotheses you will investigate.

The study will conduct a translational randomized trial comparing an adaptation of Structural Ecosystems Therapy (SET), "Healthy Home", as an enhancement of substance abuse or mental health outpatient treatment, to outpatient treatment as usual (TAU) among approximately 172 Black, Hispanic and White non-Hispanic mothers enrolled in outpatient substance abuse, mental health or substance abuse as a co-occurring condition treatment. The study will be conducted with a community partner, Banyan Health Systems (also known as Miami Behavioral Health and Spectrum Programs), that delivers integrated substance abuse/mental health treatment and primary care. Agency staff will conduct data collection and agency nurses will deliver Healthy Home. Data will be collected at baseline and 4, 8, and 12 months post-randomization.

The Specific Aims of the proposed study are to:

- 1) test the effectiveness of SET for improving physical and mental health and reducing relapse of mothers in substance abuse/mental health recovery;
- 2) test the effectiveness of SET for improving health and mental health outcomes of children of mothers in recovery;
- 3) test mechanisms of action of SET (self care, environmental risk, family functioning and stigma);
- 4) assess SET implementation and sustainability factors and the relationship between fidelity and outcomes; and
- 5) examine the interactions of ethnicity and ethnicity-related factors on outcomes.

SET is a manualized, strength-based, directive and process-oriented family-ecosystemic intervention developed to address the needs of minority women. SET targets the woman's social environment by building on existing adaptive interactions and reducing maladaptive interactions within the family and between the woman, family and supportive resources. A recently completed randomized trial with minority women in drug recovery who were also HIV+ found that for women who were raising children, SET resulted in reduced relapse and psychological distress in the mothers, and reduced symptoms of depression, anxiety and behavioral problems in the children.

The proposed study will aim to demonstrate SET's effectiveness, acceptability and feasibility for implementation in a community setting. The partnership between El Centro and Banyan Health Systems, a substance abuse, mental health and primary care provider with considerable research experience, provides a unique opportunity to rigorously test substance abuse/mental health treatment enhanced by SET in a real-world setting.

4.2. * Research Background

Provide background and previous studies supporting the study rationale. Include a brief summary of existing knowledge relevant to the research. Explain how the research may contribute to the advancement of knowledge.

Substance abuse is a chronic condition, with high rates of relapse following treatment (Hser, Longshore, & Anglin, 2007; Moos, Moos, & Timko, 2006; Scott, Dennis, & Foss, 2005). The proportion of women in substance abuse treatment has increased over the last few decades. In 2002, according to the Treatment Episode Data Set (TEDS), about 30% (565,000) of admissions to substance abuse treatment facilities were females, up from 28% in 1992 (Brady et al., 2005). Women with substance abuse disorders are more likely than men to experience mood, anxiety, and eating disorders, as well as post-traumatic stress disorder (Greenfield et al., 2007). Women develop medical and social consequences of addiction faster than men, and are

more susceptible to relapse (Addiction in women, 2010). Major factors contributing to women's relapse include low self-worth, interpersonal conflicts which interfere with treatment, an inability to sever ties with her using network and environment, and a lack of knowledge and relapse prevention coping skills (Sun, 2007).

Women with substance use disorders are more likely than women without substance use disorders to suffer physical and mental health conditions such as hypertension (Kataoka et al., 2001; McCabe et al., 2002; Wechsberg, Craddock, & Hubbard, 1998), sexually transmitted infections (Binswanger et al., 2010), mood disorders (Kataoka et al., 2001), diabetes and other chronic medical disorders (Binswanger et al., 2010). They also experience higher morbidity from these conditions than their non-substance abusing counterparts (Wu et al., 2009) due to the effects of substance abuse (Albright & Rayburn, 2009; Greenfield et al., 2007) and suboptimal utilization of health care (Owens, 2008). Further, the stigma associated with substance abuse can lead to limited help-seeking behaviors and isolation, reducing access to support systems, a critical component for women in substance abuse recovery (Walker, 2002). The prevalence of health conditions upon entering or while in care among women at the substance abuse treatment agency in this proposal highlights the health vulnerability of this group: 68% with a mental health diagnosis, 50% with a sexually transmitted infection, 50% with dental problems, 15% with high cholesterol, 10% with hypertension, and 10% with diabetes.

Indicators of family functioning that predict substance abuse relapse include emotional distance, lack of open communication (Lavee & Altus, 2001), and lack of support from male partners (Laudet, Magura, Furst et al., 1999). Outcome studies have demonstrated that family support is associated with fewer depressive symptoms and lower alcohol consumption two years after treatment (Finney, Moos, & Newborn, 1980). As compared to men in recovery, women have greater involvement with family, and thus have the potential for more problematic relationships with family members and substance using partners that challenge sobriety (Boyd, Blow, & Orgain, 1993; Grella et al., 2003; Knight, Logan, & Simpson, 2001; Westermeyer & Boedicker, 2000), as well as greater potential for involvement in supportive family relationships that foster sobriety (Hunt & Seeman, 1990). Further, because psychosocial factors such as family stress, problematic romantic relationships, and psychological distress have been linked to substance abuse and dependence (Aneshensel, 1999), reducing these stressors may prevent relapse.

Substance abuse affects the entire family and is associated with disruptions in parenting (Boland, Czarniecki & Haiken, 1992; Smith, 1996; Williams & O'Connor, 1995) and violence in couples (e.g., Gondolf & Foster, 1991; O'Farrell & Murphy, 1995). The substance abuse of a mother can increase a range of risks to her children from environmental (such as unsafe living conditions), psychological, and physical causes (Johnson & Leff, 1999). Children of substance users are at high risk for developing substance use disorders, lives characterized by high parent and family conflict, frequent moves, household financial troubles, and family legal conflicts (Haggerty et al., 2008). When mothers experience mental health issues, substance use, or domestic violence, their children have greater risk of mental health issues, substance use, or domestic violence (Whitaker, Orzol, & Kahn, 2006). Despite these challenges, mothers with substance abuse disorders can be particularly motivated to receive and remain in substance abuse treatment as a means of regaining child custody and being better mothers (McComish et al. 2003; Scott-Lennox et al. 2000).

Given these reciprocal and intertwined effects between family functioning and substance abuse, mobilizing family protective factors and reducing family risk factors can be a promising approach for preventing relapse, and by extension, improving health for mothers in recovery and buffering children against the negative effects of maternal substance abuse.

Preliminary Data.

SET has been tested in three randomized trials funded by the NIH that focused either exclusively or predominantly on persons from minority groups (Hispanic or African American) with substance use disorders.

SET for substance-abusing African American and Hispanic adolescents (R01DA10574, José Szapocznik, PI). SET was originally developed for adolescents with substance abuse disorders and involved with the juvenile justice system. A randomized trial compared SET with family therapy as usual and community services control with 190 African American and Hispanic adolescents with substance use disorders. Follow-up assessments were conducted at 3, 6, 12, and 18 months post-randomization. SET was more efficacious than the other two conditions in reducing drug use among Hispanic adolescents, $B = 3.34$, $t(160) = 2.15$, $p < .05$, and in improving family interactions (conflict, cohesion, and parenting) in both ethnic groups (Robbins et al., 2008).

SET for HIV seropositive African American mothers (MH55796, José Szapocznik, PI). SET was adapted and tested in comparison to an individual person-centered intervention and to a community control group with 209 African American HIV seropositive mothers. Follow-up assessments were conducted at 3, 6, 9, and 18 months post-randomization. SET was superior to both of the other conditions in reducing family hassles, $F(6, 472) = 2.53$, $p < .05$, and psychological distress, $F(6, 472) = 2.19$, $p < .05$, (Szapocznik et al., 2004). Moreover, SET was superior to the person-centered intervention in reducing drug relapse, $\chi^2(1) = 5.35$, $p < .05$, among the 68% of the sample with drug use history. Relapse prevention was mediated by reductions in family hassles. $t(120) = 2.59$, $p < .01$ (Feaster, Burns, et al., 2010).

SET for HIV seropositive women in drug abuse recovery (R01DA15004, Daniel Feaster, PI; R01DA16543, Victoria Mitrani, PI). In response to the findings described above regarding the potential of SET for reducing drug relapse, the SET model was adapted to focus specifically on women in recovery. SET was compared with a supportive psychoeducational health group in a randomized trial with 126 predominantly African American HIV seropositive women in recovery. Follow-up assessments were conducted at 4, 8, and 12 months post-randomization. Women in SET showed improvement in CD4T-cell count, $B = 77.02$, $SE = 30.18$, $p < .05$, and in theoretical mechanisms of action on drug relapse including accessing substance abuse services in response to relapse, $B = -.74$, $SE = .25$, $p < .01$, and separating from drug-using household members, $B = -.35$, $SE = .12$, $p < .01$ (Feaster, Mitrani, et al, 2010). A companion study enrolled the women's family members to examine the family mechanisms SET; SET prevented the deterioration of family functioning, $B = -0.05$, $SE = 0.02$, $p < .01$, that was evident in the families of women in the health group and of those who did not participate in their respective interventions (Mitrani et al., under review). In a subgroup analysis of women ($n=25$) raising children ($n=42$) SET was more efficacious than the control in decreasing children's internalizing, $B = -1.94$, $SE = 0.73$, $p < .01$, and externalizing, $B = -2.17$, $SE = 0.58$, $p < .001$, behaviors, reducing mothers' psychological distress, $B = -0.25$, $SE = 0.09$, $p < .01$, and preventing mothers' relapse, $B = -.29$, $SE = 0.15$, $p < .05$. Children in SET reported improvements in parenting, $B = 0.15$, $SE = 0.07$, $p < .05$, compared to the children of mothers in the control (Mitrani, McCabe et al., 2010). Women raising children were more likely to engage in SET and the control condition $B = 1.25$, $SE = 0.58$, $p < .05$, (Mitrani, Feaster, Weiss-Laxer and McCabe, 2010) indicating that mothers in recovery are particularly motivated to participate in psychosocial interventions.

Mother's in recovery qualitative study. Thirteen mothers currently or recently discharged from substance abuse treatment at Banyan were interviewed regarding family influence on treatment, recovery and relapse, and attitudes/preferences regarding family aftercare. Preliminary review (formal content analysis is ongoing) suggests the following themes: 1) Children and family are the major motivation to remain substance-free; 2) Partner relationships, stress, family problems, shame/guilt, depression and environmental cues are the most challenging for abstinence; 3) Mothers want to involve supportive family members (especially children) in a home-based family aftercare intervention to address family healing, improve communication and support, establish family boundaries, re-establish maternal roles and repair parent-child relationships.

- 4.3. **If you have cited references above, please attach a bibliography, including title, full author list, journal, date and pages. This bibliography should include only those articles referenced above.**

Name	Description	Version
SET R Refs for IRB.docx		0.01

4a. Description of Study (cont'd)

Rationale and Methodology

- 4.4. *** In non-technical, lay language, describe the study design and all study procedures, in order of sequence and timing. Include length of subject participation, what tasks are involved in the study, what tests or procedures subjects will be asked to complete or undergo, specific measures to be used, etc. If applicable, include frequency of visits, duration of visits, and study procedure calendar.**

Study design: The study uses a mixed design in which mothers who are enrolled in outpatient substance abuse/mental health treatment (or treatment for substance abuse as a co-occurring condition) will be randomized to outpatient substance abuse/mental health (or co-occurring) treatment enhanced by Healthy Home (TAU + Healthy Home) or outpatient substance abuse/mental health (or co-occurring) treatment as usual (TAU). Mothers and their minor children enrolled in the study (ages 2-17) will be assessed 4 times at 4 month intervals: Baseline, 4 months, 8 months, and 12 months (with a window for final assessment up to 18 months). Randomization will take place after the baseline assessment.

Study Setting: Participant recruitment, outreach, consent and data collection, as well as the interventions, will be conducted by staff of the Banyan Health Systems (Banyan), a joint venture between Spectrum Programs, Inc. and Miami Behavioral Health Center, Inc. which joined forces 6 years ago to integrate mental health and substance abuse treatment services.

Screening, Recruitment and Retention: Study staff employed by Banyan will invite all women who are enrolled in outpatient substance abuse, mental health (or co-occurring) treatment or case management at Banyan and who have minor children to participate in the study. Study staff will also accept referrals from women receiving outpatient substance abuse, mental health (or co-occurring) treatment at other centers. Study staff will ask local agencies that serve women who receive mental health or substance abuse treatment to provide contact information for their clients who have consented to be called regarding the study. Those women will be called by study staff for recruitment to the study. The study will also be promoted via social media (e.g., Craigslist); potential participants will be instructed to call the study number - there will be no direct communication with individual study candidates via social media. For purposes of participant recruitment and retention, communication with participants includes email and text messages. The body of the messages will not include any mentions of private health information. Participants also receive greeting cards (e.g., mother's day, birthday, holiday) from the study team.

After the baseline assessment, the mother will be given a postcard indicating her treatment conditions (uploaded in section 6.2a). Staff will call enrolled women monthly to check in regarding plans to relocate, changes in contact information and to remind them of their next assessment appointment. Mothers who are unavailable for in-person assessments (e.g., if they have relocated out of town) may have their assessments by phone.

Pilot Phase: There will be a period used for piloting, refining and manualizing procedures, training the study team, translation of materials to Spanish as needed, and to apply for a Certificate of Confidentiality. The research procedures including recruiting, screening, consenting/assenting and data collection will be pilot tested with up to four sets of mothers and children at up to two time-points. [This portion of the study has been completed].

Measures:

A table listing each construct, instrument and translation information is attached. Most of the measures have Spanish versions – either published or used in previous protocols, if not they will be translated using translation/back-translation methods. The following measures are planned to be used with mothers and children. No additional instruments or measures will be used without seeking IRB approval.

Mother Outcome Measures

- Mental Health will be assessed using the Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983).
- Physical Health will be assessed using the PROMIS Global Health Scale (Hays, Bjorner, Revicki, Spritzer, & Cella, 2009). Clinical measurement of height and weight (i.e., body mass index) and waist circumference will be indicators of obesity.
- Dental Health will be assessed using the Oral Health Impact Profile short form (OHIP-14) (Slade, 1997).
- Substance Use will be assessed using the Addiction Severity Index Lite Alcohol and Drug Scale (McGahan, Griffith, Parente, McLellan, 1986), and a urine drug toxicology test.

Child Outcome Measures

- Mental health will be assessed using the Youth Self-Report (Achenbach & Rescorla, 2001) and Child Behavior Checklist (CBCL; Achenbach, 2009).
- Physical Health will be assessed with the Child Health Questionnaire (Landgraf & Abetz, 1997). Additionally, height and weight will be obtained to calculate BMI. No urine or blood samples will be taken from children.
- Dental Health will be assessed using the Oral Health Impact Profile-14 (Slade, 1997) and three items from the Florida Dental Health Survey (Gilbert & Litaker, 2007).

Child medical condition Measure. This measure combines items from the Caregiver Strain Questionnaire (Brannan, Heflinger, & Brickman, 1997) and modified items from the Early Childhood Longitudinal Survey-Birth Cohort questionnaires. The measure with Spanish and English items is attached in Supporting documents. For this study, 1 item will assess whether a child has any medical condition, and what condition, if one exists. 9 items will assess the strain associated with the condition on a 5-point Likert scale. 2 items will assess whether the child receives services for the condition (e.g., speech therapy), and where services are received (e.g., school, home). 1 item asks for the number of hours received on average per week. The Caregiver Strain measure was used, in Spanish and English, in a previous IRB-Approved study (20070334) and the other items were translated from English into Spanish using a translation-back translation process for this study (statements attached in supporting documents).

The measure will be administered at baseline. If enrolled mothers have already completed the baseline, they will complete the form at one of the follow-up assessments. If participants have already completed all of the assessments, then study staff will attempt to contact the participant to complete the measure by phone.

We are requesting a Waiver of Signed Consent for this measure for the only participants who have already completed their baseline and all other assessments. They will answer these questions by phone to complete this measure. The Waiver is requested to avoid burdening participants who have already signed consent forms for this study, and would have to schedule an additional meeting to complete the consent form for this measure.

Mediator variables.

- Mother Self-care: Health Care Use will be assessed using the Stanford Health Care Utilization (Lorig, Stewart, Ritter, Gonzalez, Laurent, & Lynch, 1996) plus items from El Centro Demographics Scale and using two questions about recency of physical check-up and Pap test. Dental Care Use will be assessed using the Florida Dental Health Survey (Gilbert & Litaker, 2007). Form 90 Treatment/Living Experiences subscale (Tonigan, Miller, & Brown, 1997) and substance abuse treatment attendance records from Banyan will assess use of substance abuse services and self-help groups.
- Family Functioning will be measured with the family cohesion subscale of the Family Environment Scale (Moos & Moos, 1981). Family Coping will be measured with two subscales from the Family-Crisis Oriented Evaluation Scales (F-COPES; McCubbin, Larsen, & Olsen, 1996).
- Social Support will be assessed using the Important People Interview (Clifford & Langabuagh, 1991).
- Stigma will be measured using a version of a Stigma scale (Ahern, Stuber, & Galea, 2007).
- Maternal Parenting Functioning will be assessed using the Parenting Practices Questionnaire (Gorman-Smith, Tolan, Zelli, & Huesmann, 1996) and Parenting Self Agency (Dumka, Stoerzinger, Jackson & Roosa; 1996) .

Moderator Measures

- Ethnicity (Black, Hispanic, White non-Hispanic), Socio-economic Status and general demographic information will be collected using demographics items from El Centro and other UM IRB-approved studies.
- Household Composition and Stability will be collected using a Household Composition Form.
- Mother's Stress will be assessed using the Hassles Scale (DeLongis, Folkman, & Lazarus, 1988)
- Mother's Abuse and History of Abuse will be measured using the Violence Scale (Peragallo, 2005).
- Mother's Sleep will be assessed with 4 items regarding sleep from the PROMIS-29 Health Scale.

We will be extracting some information from our intervention clinical forms to capture some of our research constructs. This information includes data related to health assessments, recommendations/referrals, treatment/services rendered, follow-up plan of care, and education. The data collection form has been created in RedCap (Research electronic data capture), an electronic data capture software. A table demonstrating items extracted from the clinical forms is uploaded to the eprost protocol. These clinical forms are kept in the locked research vault at the School of Nursing and Health Studies and will be protected at all times. RedCap data will be kept in password protected files.

Nurse Progress Notes. These measures take information from clinical progress notes completed by nurses in the Healthy Home condition. There are 2 parts of this measure. First, the nursing intake note will be transcribed into an electronic format. Second, clinical progress notes for each nurse visit will also be transcribed into an electronic format. The transcription is similar to a chart review process, and will be completed for each family member's health status using clinical forms based on the standard documents used as clinical progress notes by Banyan.

We are requesting a waiver of consent for this data extraction. All subjects involved sign consent for the parent study. This data will be analyzed using secondary analysis.

Follow-up for positive clinical indicators. Mothers or children who report suicidal thoughts or intention to hurt others will be interviewed by a licensed health professional on site or by

telephone, or staff will call the Crisis Stabilization Unit or 911 as indicated. Reports of child abuse or neglect will be reported to the authorities as per Florida law and to corresponding SET or TAU clinical supervisor for follow-up.

Contacts with mother/family participants will be conducted in the candidate/participants' preferred language (English or Spanish). Data will typically be obtained in interviewer format as follows. The data collector will meet with the participant in a private room, read the questions and the participant will have the items and responses to read along. The assessor will enter the participant's responses on a computer. Children will complete questionnaires appropriate to their age. Younger children will have the clinical measures only. Data will typically be collected at the sites where the mothers receive substance abuse treatment. Home-based assessments will be offered. It is estimated that data collection procedures will take 90 minutes for mothers (+30 minutes x number of children) and 50 minutes for children. Breaks will be offered and snacks may be offered.

Interventions. The study intervention period is scheduled for 4 months. Healthy Home and substance abuse treatment services received by mothers in both conditions will be tracked to compare intervention exposure across conditions. Mothers in both conditions will be free to access any health or substance abuse services offered in their communities.

- The Healthy Home intervention integrates a family therapy approach, Structural Ecosystems Therapy (SET), with health services for mothers in substance abuse treatment and their children. Healthy Home is delivered by nurses through family visits. The nurse sees the family all at once, so that nursing care strengthens family unity. Visits take place approximately once every two weeks for a period of four months in the mother's home or other sites that are private and convenient to the family. Visits are ordinarily planned to include the mother, her children and some person(s) from the family and/or ecosystem (e.g., neighbor, friend).

During family visits the nurse attends to the health of the mother, children and other family members who are present. The nurse assesses family members' health needs, provides recommendations and education, and assists with referrals and access to services. The referrals for services may be to the nurse's own facility or to other service agencies. In between visits the nurse interacts with other service providers – e.g., the substance abuse counselor and mother and children's health care providers – to help optimize the family's use of these services and to help coordinate care. The nurse incorporates SET techniques into the delivery of these nursing functions as a means of strengthening family functioning. The family functions we are particularly interested are those that support the mother's substance abuse recovery, the mother's health and the care of the children.

The three basic techniques in SET are joining, structural diagnosis, and restructuring. Joining refers to the process of establishing therapeutic alliances. Diagnosing refers to the identification of interactional patterns that contribute to the problems experienced by the mother, and thus need to be changed, as well as those that are sources of support and thus should be reinforced. Restructuring involves orchestrating opportunities for individuals to interact in ways that reinforce strengths and change maladaptive interactional patterns. Each Healthy Home case is tailored to the particular needs of the mother and her family. Healthy Home consists of three phases of treatment: initiation, treatment, and termination. Specific focus areas include: Substance abuse contexts, support and family status, couple relationships, parenting, and health/self-care. Healthy Home training will be conducted by Dr Mitrani and another trainer. Healthy Home supervision will be ongoing and conducted by Dr Mitrani and Banyan clinical supervisors.

-TAU consists of substance abuse outpatient treatment services normally offered by Banyan and other agencies where the women are receiving substance abuse or mental health services.

In addition to collecting measures from mothers and children, staff of the Banyan Health System will complete measures for assessment of study implementation factors. We do not believe that these measures constitute human subjects research and therefore do not consider

staff to be study participants. Measures are as follows:

- Healthy Home Treatment Fidelity. Healthy Home nurses will typically complete a fidelity checklist after each family visit.
- Implementation Costs will be obtained from invoices completed by agency administrators that cover the full range of costs involved in implementing Healthy Home, salaries (training, supervision, and delivery), materials, etc. Nurses will log all contacts with participants (phone calls, visits, time/location, purpose, etc.). Nurses will log the amount of time spent each week on cases that does not involve contact with participants, e.g., documentation, preparation, discussing cases with colleagues, training, etc.
- Satisfaction with Implementation will be assessed using a measure adapted from a previous substance use intervention study (Santisteban, 2008). Nurses, supervisors and agency administrators will rate their satisfaction with training, supervision, intervention, and impact on delivery of usual services.

4.4.A. Standard Measures: Click the "Add" button to open the search window, then click the "Find" button to browse and select measures.

Name of Measure	Brief Description	Type of Measure
There are no items to display		

NOTE: A copy of the first page of each standard measure is provided in the [Library of Standard Measures](#) for verification. Ensure that the version being used in this study is the same as the version that has been selected.

Upload any questionnaires and/or assessment tools to be used that are not listed above:

Name	Description Version
Child Behavior Checklist Preschool CBCP.040813.docx	0.01
Child Behavior Checklist Schoolage CBCS.040813.docx	0.01
CHILD DEMOGRAPHIC INTAKE FORM CDIM.docx	0.03
Child Health Questionnaire Physical and Fam Scales Child Report CHQC.041013.docx	0.01
Child Health Questionnaire Physical CG and Family Scales Mother Report CHQM. 041013.docx	0.01
Child's BMI BMIC.040913.docx	0.01
Family Environment Scale Cohesion FES.040913.docx	0.01
FCO FCOPES bilingual.docx	0.01
FI Dental Care Study Child Rating FDSC.040813.docx	0.01
FL Dental Care Study Mother Rating Child FDSM.040813.docx	0.01
FL Dental Care Study Mother rating herself FDSW.040813.docx	0.01
Healthy Home Hassles Scale (HHH).docx	0.01
Healthy Home Important People Interview (IPI) English.docx	0.01
Healthy Home Important People Interview (IPI) Spanish.docx	0.01
HLF Health Literacy Screener HLF.041513.docx	0.01
Household Composition Form HCF.040913.docx	0.01

MDIF Mother Demographic-Translation v2.doc	0.05
Measures_Table_for IRB protocol.04-16-2013.docx	0.01
Modified Stigma Scale with Alcohol MSS.040913.docx	0.02
MSF (Mother Screening Form) with mental health.010914.	0.01
Oral Health Impact Scale Mother rating self OHIP.040913.docx	0.01
Pap Smear Last Check Form LCF.040913.docx	0.01
Parenting Practices Child Report PPC.041013.docx	0.01
Parenting Practices Parent Report PPP.040813.docx	0.01
Parenting Self Agency PSA.040813.docx	0.01
PER--Parent Relationship With Peer Group-Parent (English).doc	0.01
PER--Parent Relationship With Peer Group-Parent (Espanol) (DD).doc	0.01
PROMIS SF v1.0 - ED-Anxiety-SF8a Spanish.pdf	0.01
PROMIS SF v1.0 - ED-Anxiety-SF8a.pdf	0.01
PROMIS SF v1.0 - ED-Depression-SF8a Spanish.pdf	0.01
PROMIS SF v1.0 - ED-Depression-SF8a.pdf	0.01
SET-R Addiction Severity Index LITE (ASI).RX accomodation.docx	0.01
SET-R Form 90 (F90).doc	0.01
SET-R PROMIS 29 Profile ENGLISH.docx	0.01
SET-R PROMIS 29 Profile SPANISH.docx	0.01
SET-R Stanford Health care Utilization (SHU).doc	0.02
SET-R Violence (VIL).doc	0.01
Urine Drug Screen UDS.041013.docx	0.01
Youth Self Report YSR.040813.docx	0.01

4.5. Identify and distinguish between those procedures that are standard treatment versus those that are experimental/research-specific.



Not applicable

The control condition, TAU, consists of the substance abuse/mental health outpatient treatment (or treatment for substance abuse as a co-occurring condition) routinely offered at the participants' treatment program. The Healthy Home condition consists of Healthy Home in addition to outpatient treatment routinely offered at the participants' treatment center. Therefore all participants are assigned to receive the standard of care, at minimum. The study intervention period is scheduled for 4 months. The outpatient program does not have a time limit.

4.6. Describe any therapeutic alternatives that may exist for the study population.



Not applicable

Participants who do not enroll in the study are offered the standard outpatient substance abuse/mental health services.

4b. Description of Study (cont'd)

Risk/Benefit Assessment

4.7. * Describe the nature, degree, and if available, expected frequency of all potential economic/financial, legal, physical, psychological, social or other risks to which research participants may be exposed as a result of their participation in this research. If applicable, please describe the risk of investigational agents or devices (side effects).

No side effects have been noted in the current literature in association with the behavioral

questionnaires or interviews used in this study, although as with many assessment batteries, some people may experience mild fatigue or momentary concern about their ability to do well. There is a minimal risk of distress or family strife and of family members learning about the mother's substance abuse/mental health problems associated with the family intervention, Healthy Home. We have extensive experience in delivering SET, the precursor of Healthy Home, and have not found it to induce lasting family stress. The control condition, TAU, consists of the substance abuse/mental health outpatient treatment routinely offered at the participants' substance abuse treatment program. Therefore all participants are assigned to receive the standard of care, at minimum.

4.8. *** Are there potential direct benefits of this research to the subjects?**

Yes No

4.8.A. **If yes, provide a description of the potential direct benefits and indicate if all, or only some, of the subject groups may derive this potential benefit.**

The potential for benefit for all participants include: 1) They may spend some pleasant family time (at assessments), 2) they may gain satisfaction in knowing that they are helping to advance the science of family health. The additional potential benefit for participants randomized to the Healthy Home condition is improved health and family relationships that can positively impact the women and their children as well as of other participating family members.

4.9. *** Are there potential benefits of this research to society?**

Yes No

4.9.A. *** Please explain:**

Women in substance abuse/mental health recovery and their children are at high risk for significant health consequences and there is a need for culturally-informed interventions tailored to address their unique needs. The proposed outpatient treatment enhancement approach is unique, innovative, and well suited to the needs of mothers in recovery. There are no existing substance abuse/mental health approaches that integrate family therapy with the entire family, parenting practices, and primary care in home-based and culturally tailored intervention. The information obtained in this project will aid in the development of strategies to serve women in recovery and their children.

4.10. *** Explain why the risk/benefit ratio supports conducting this research.**

We anticipate that this study poses a relatively low level of risk to participants. There are some potential benefits for participants as well as to society.

4c. Description of Study (cont'd)

Data

4.11. *** Describe follow-up, data storage methods, data security, authorized access to records and record retention, including site name and address.**

All data will be collected using Velos eResearch, paper-based questionnaires or lab reports. Hard-copy forms will also be used if the electronic systems are unavailable. All hard-copy data will be stored in locked facilities. Data will only be accessible by IRB approved protocol personnel or designated system administrators and only for studies and functions for which those individuals are specifically authorized. The database will be programmed with appropriate across form logic checks.

QA monitoring will be conducted by staff of El Centro according to the standard procedures which include a QA review prior to initiation, upon conducting baseline procedures with the

first few study participants, and then for interim reviews.

4.12. * Support the study validity by describing the statistical design, including quantitative and qualitative methods used to analyze data.

The following is the planned data analysis procedure as submitted in the grant application.

-Testing of data quality and distributional assumptions.

Distributions and frequencies of all measures will be examined for non-normality and transformed as needed. If transformation is not sufficient, other distributions (Poisson, Negative Binomial) or nonparametric analyses will be used. Internal consistency will be reported for all measures with Cronbach's alpha. If any scale alphas are below .70, item total correlations and/or factor analysis will be employed to diagnose the psychometric problems and new scales with higher internal consistency will be considered.

-Evaluating the effectiveness of randomization will be accomplished by use of ANOVA and Chi-square of baseline variables. Although not anticipated, if variables with theoretical importance to outcomes show baseline differences by condition, hypotheses tests will statistically control for (baseline) differences.

-Growth curve analysis. Latent growth modeling (LGM) in Mplus 6 (Muthén & Muthén, 2010) will examine change over time in the outcomes. LGM involves creating latent variables representing growth parameters (the baseline or intercept; the linear slope or rate of change, the quadratic slope, etc.). It allows for the simultaneous estimation of multiple growth functions with growth parameters of one function related to growth parameters of another. Mplus allows for outcome variables with distributions that are not continuous (e.g., Poisson for skewed variables or logistic for binary outcomes), which is particularly important with substance use and health outcomes. LGM can generate effect sizes for rate of change or the difference at a single time between the two conditions, i.e., Cohen's d (Cohen, 1992). Following Cohen's (1992) guidelines, we will interpret our effect sizes using the convention of "small" ($d = .2$), "medium" ($d = .5$), and "large" ($d = .8$).

-Testing hypothesized differences between experimental and control groups will use an intent-to-treat analysis that includes all participants randomized. LGM will examine the effect of treatment condition on trajectories of change separately for each of the outcomes over the one-year follow-up. To test Hypothesis 1, we will assess the trajectories of the mothers' outcomes (mental health, physical health, substance abuse, etc.) and predict of the trajectory of change by intervention condition (Healthy Home vs. TAU). Controlling for the effects of socio-demographic variables and pretest levels of the dependent variables is possible in LGM, if these variables are found to differ by randomization group. To test Hypothesis 2, a similar procedure will consider children's outcomes (mental health, physical health, behavior problems, etc.).

- Testing mechanisms of action. Using Mplus 6, this set of analyses will investigate links between trajectories of change (growth curves) for the hypothesized mechanism of action variables (mediators) and trajectories of mothers' outcomes or children's outcomes following MacKinnon, Lockwood, Hoffman, West and Sheets' (2002) procedures. This method is more powerful than the classic (Baron & Kenny, 1986) method, particularly for binary outcomes. LGM can also test multiple indirect paths or mediators (i.e., Hypothesis 3c) with this method.

- Clinically significant change procedures (Jacobson & Traux, 1991) can also investigate efficacy of an intervention. These procedures: 1) determining whether participants have made statistically reliable change and 2) categorizing subjects according to clinically meaningful cut-points, e.g., recovered (statistically reliable change that moves a client out of clinical range), improved (statistically reliable improvement, but still in the clinical range), and unimproved/deteriorated.

-Implementation analysis will be used to determine the feasibility of adapting Healthy Home for other agencies. Using cost logs for training and service delivery, the total cost of

implementing Healthy Home can be determined. Therapist and agency satisfaction as well as therapist fidelity to Healthy Home will be assessed to determine if changes to the Healthy Home implementation protocol are needed.

-Mothers will have additional data from baseline assessments administered by the treatment agency: a GAIN-I administered at treatment intake and a GAIN-M90 administered 90 days into treatment. As noted in the measures section, several variables (e.g., demographics, history of abuse) will be taken from the GAIN-I. There are a number of follow-up analyses that may provide greater understanding of the direct and interactive relationships between symptoms, intervention, and post-treatment substance use, including adding to growth models of mental or physical health and examining moderators of treatment effects. [The GAIN is no longer being used in the study]

- Proposed moderators will be used in two types of analyses. The variables might predict trajectories of change of the mothers' and children's outcomes, only. For example, does poor sleep contribute to early relapse for mothers in recovery? The moderators might also interact with treatment. For example, do mothers from different ethnic groups respond differently to Healthy Home? Effect sizes will be generated for future intervention development/refinement from the results of these exploratory analyses.

- Secondary data analysis will be used to examine data extracted from clinical intervention forms related to health assessments, recommendations/referrals, treatment/services rendered, follow-up plan of care, and education provided to individuals during home health visits.

- Missing data and attrition patterns will be examined. In research with samples of individuals in substance use recovery some loss to follow-up is expected. Our proposed methods allow the inclusion of cases with randomly missing data, we will test for non-randomness, i.e., a non-ignorable or informative missing data pattern (Little & Rubin, 1987). If there is differential attrition by condition, alternative models will be examined (in addition to the proposed) which account for or model the attrition mechanism (Angrist, 1997; Heckman, 1979; Idson & Feaster, 1990) to produce a more robust range of estimates.

Privacy/Confidentiality Agreements

4.13. **Describe any privacy agreements or certificates of confidentiality, if applicable.**
We have received a certificate of confidentiality from NIH.

4d. Description of Study (cont'd)

Deception

4.14. *** Is the use of deception part of the study design?**

Yes No

If yes, please answer the following 3 questions:

4.14.A. **Describe in detail the nature of the deception and explain why this is necessary for the research.**

4.14.B. **State how, when, and by whom the research subjects will be debriefed.**

4.14.C. **Upload a copy of the debriefing script.**

5. Study Participants

Per 45 CFR 46, human subjects (participants) means a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual; or
2. identifiable private information (i.e. pathological specimens, medical records, etc.)

5.1. * Participant Age:

Check all that apply	Notes
<input checked="" type="checkbox"/> 0-6	<i>Parent Permission/Consent required for each participant</i>
<input checked="" type="checkbox"/> 7-17	<i>Parent Permission/Consent & Child Assent required for each participant</i>
<input checked="" type="checkbox"/> 18-65	<i>Consent required for each participant unless a waiver of consent is approved by the IRB</i>
<input type="checkbox"/> 65+	<i>Consent required for each participant unless a waiver of consent is approved by the IRB</i>

5.2. For the following questions, please use integers for your responses. For any question that is not applicable, please enter the number 0. (Do not enter commas, decimal points or special characters)

5.2.A. * Maximum number of subjects in the Protocol to be *screened* at all sites (regardless of PI):
1000

5.2.B. * Total number of subjects in the Protocol to be *studied* at all sites (regardless of PI):
800

University of Miami

5.2.C. * Maximum number of subjects to be *screened* by this PI at UM:

0

* Maximum number of subjects to be *enrolled* by this PI at UM:

0

* From the above, how many are expected to *complete* this study (participate in the study beyond initial enrollment)?

0

Jackson Health Systems

5.2.D. * Maximum number of subjects to be *screened* by this PI at ***Jackson Health Systems (JHS)***:

0

* Maximum number of subjects to be *enrolled* by this PI at ***Jackson Health Systems (JHS)***:

0

* From the above, how many are expected to *complete* this study (participate in the study beyond initial enrollment)?

0

Miami VA Medical Center

5.2.E. * Maximum number of subjects to be *screened* by this PI at *Miami VA Medical Center*:

0

* Maximum number of subjects to be *enrolled* by this PI at *Miami VA Medical Center*:

0

* From the above, how many are expected to *complete* this study (participate in the study beyond initial enrollment)?

0

5a. Study Populations

5.3. * Study populations to be included in this study where PI will be conducting research and those sites where the UM IRB will have oversight responsibility:

Check all that apply Notes

Normal, healthy volunteers

Children/minors
(under 18 years of age)

Poor/uninsured

Pregnant women/fetuses Specific Florida statutes apply to prohibit the use of any live fetus or live, premature infant for any type of scientific, research, laboratory or other kind of experimentation except as necessary to protect or preserve the life and health of such fetus or premature infant.

Outpatients

Wards of the state Specific Florida statutes apply to prohibit the enrollment of a minor/adult, for whom a guardian has been appointed by the court, in a research study without first acquiring the approval of the court having jurisdiction of the ward.

5.3.A. If *other*, please specify:

5.3.B. **Describe below any additional safeguards that have been included to protect vulnerable subjects:**

Study candidates will be told that their participation is voluntary, that they may withdraw consent at any time, and that their decisions regarding participation will not affect their relationship with Banyan or UM.

This study population includes children. With IRB approval and following legally-established procedures, we plan to enroll children who are wards of the state.

We do not anticipate enrolling prisoners, and subjects who become incarcerated after the study begins will not be involved in human subjects activities during their

incarceration. Participants are also told that if they are on probation or parole there will be no special privileges given by the courts because of their participation in the study.

Pregnant women may be enrolled in the study. Interventions are behavioral with some minimal physical procedures for assessment, and data collection involves minor physical procedures the most invasive of which are collection of urine samples, which pose no foreseeable risks to pregnant women, fetuses or neonates. It is possible that some pregnant minors (children of the index women) may be enrolled. Children do not have any physical procedures in the assessment portion of the study and physical procedures in the intervention portion are limited to minimally invasive physical procedures. Children age 7 or above will be assented.

We have received a certificate of confidentiality.

5b. Inclusions/Exclusions

5.4. * Is the population being enrolled in this study at high risk for incarceration?

Yes No

5.4.A. If yes, will the subjects be withdrawn from the study once they are incarcerated?

Yes No

5.4.A.(i) If the above answer (question 5.4.A.) is no, describe how re-contacting/re-consenting, treatment, and/or follow-up will occur:

We will not conduct study procedures with participants while they are incarcerated but will not withdraw them from the study as they may be available to conduct study procedures upon release if they are still within the study timepoint windows. If a mother is incarcerated we will attempt to conduct follow-up assessments within the appropriate timepoint windows with children enrolled in the study if they can be accompanied by an adult family member.

NOTE: If a subject becomes incarcerated while enrolled in a study, all research interactions and interventions with that subject, and the obtaining of identifiable private information about the subject, must cease until the requirements of subpart C have been satisfied with respect to the relevant protocol.

If notified that a previously enrolled research subject has become a prisoner, the principal investigator must promptly seek IRB re-review of the protocol in accordance with the requirements of subpart C if the principal investigator wishes to have the prisoner-subject continue to participate in the research. In special circumstances in which the principal investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the IRB Chairperson may determine that the subject may continue to participate in the research until the requirements of subpart C are satisfied.

5.5. * What are the criteria for exclusion of participants from the research?

Persons who do not meet the inclusion criteria listed below will be excluded.

5.6. * Will any population be systematically excluded in this study?

Yes No

5.6.A. If yes, provide rationale/justification for this exclusion:

5.7. * What are the criteria for inclusion of participants in the research?

To be eligible for the study Mothers must meet all of the following criteria: (1) Enrolled in outpatient substance abuse or mental health treatment (or treatment for substance abuse as a co-occurring disorder) or case management for mental health or substance abuse problems, (2) have at least one child age 0-17 with whom she has at least monthly contact (3) be age 18 or above, (4) capable of giving informed consent and comprehending either English or Spanish, (5) willing and able to participate fully in the protocol (e.g., to accept assignment to either condition, to provide sufficient locator information for follow-up, to allow their treatment sessions to be monitored for fidelity/process assessment and supervision).

To be eligible for the study Children must meet all of the following criteria: (1) biological, step or adopted child of a mother enrolled in the study and with whom the mother has at least monthly contact (2) age 2-17, (3) has the signed permission of a legal guardian to enroll in the study, (4) gives assent to participate in the study if age 7 or above.

5.8. * Will only one group of individuals be systematically selected and recruited for this study (e.g., welfare patients, racial and/or ethnic minorities, persons confined to institutions or persons determined to be incapacitated)?

Yes No

5.8.A. If yes, please state how this participant group will benefit from the results of the research and provide the reasons and justifications to target this group:

This study focuses on women in substance abuse/mental health treatment and their children. These groups are at high risk for significant health consequences and there is a need for culturally-informed interventions tailored to address their unique needs.

5c. Research Involving Pregnant Women or Fetuses

Pregnant woman or fetuses may be involved in research if **ALL** of the following conditions are met (all items must be justified):

(a) **Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.**

*** Justification:**

Pregnant women may be enrolled in the study although the study does not specifically target pregnant women. Interventions are behavioral with some minimal physical procedures for assessment, and data collection involves minor physical procedures the most invasive of which are collection of urine samples, which pose no foreseeable risks to pregnant women, fetuses or neonates. It is possible that some pregnant minors (children of the index women) may be enrolled. Children do not have any physical procedures in the assessment portion of the study

and physical procedures in the intervention portion are limited to minimally invasive physical procedures.

- (b) **The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.**

*** Justification:**

Interventions are behavioral with some minimal physical procedures for assessment and data collection involves minor physical procedures the most invasive of which are collection of urine samples, which pose no foreseeable risks to pregnant women, fetuses or neonates.

- (c) **Any risk is the least possible for achieving the objectives of the research.**

*** Justification:**

Interventions are behavioral with some minimal physical procedures for assessment and data collection involves minor physical procedures the most invasive of which are collection of urine samples, which pose no foreseeable risks to pregnant women, fetuses or neonates.

- (d) **If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part.**

*** Justification:**

Interventions are behavioral with some minimal physical procedures for assessment and data collection involves minor physical procedures the most invasive of which are collection of urine samples, which pose no foreseeable risks to pregnant women, fetuses or neonates.

- (e) **If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.**

*** Justification:**

NA

- (f) **Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.**

*** Justification:**

NA. Interventions are behavioral with some minimal physical procedures for assessment and data collection involves minor physical procedures the most invasive of which are collection of urine samples, which pose no foreseeable risks to pregnant women, fetuses or neonates.

- (g) **For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part.**

*** Justification:**

Children who are pregnant may be enrolled if they are the child of the index mother. Children do not have any physical procedures in the assessment portion of the study and physical procedures in the intervention portion are limited to minimally invasive physical procedures. Assent and parental or guardian permission will be obtained.

- (h) **No inducements, monetary or otherwise, will be offered to terminate a pregnancy.**

*** Justification:**

No inducements whatsoever will be offered to terminate a pregnancy.

- (i) **Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.**

*** Justification:**

Research staff will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

- (j) **Individuals engaged in the research will have no part in determining the viability of a neonate.**

*** Justification:**

Research staff will have no part in determining the viability of a neonate.

5f. Research Involving Minors

- * Pick ONE category below:**

Select one

§46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than

- minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.**

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

- HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct**

benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

- a. The risk is justified by the anticipated benefit to the subjects;
- b. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches;
- c.

Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

- a. The risk represents a minor increase over minimal risk;
- b. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations;
- c. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition;
- d. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

*** Justify each criterion within the category chosen above:**

Children do not have any physical procedures in the assessment portion of the study and physical procedures in the intervention portion are limited to minimally invasive physical procedures which pose no foreseeable risks. Procedures with children do not constitute risk above and beyond what children encounter in everyday life.

NOTE: HHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:

- A. The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
- B. The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:
 - 1. that the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or
 - 2. the following:

- i. *The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;*
- ii. *The research will be conducted in accordance with sound ethical principles;*
- iii. *Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.*

6. Subject Recruitment

6.1. * From what sources or by what methods will subjects be recruited?

Check all that apply

Flyers/newsletters

Internet (web postings)

Contact letters (physicians, teachers, etc.)

Outpatients/clinics

Medical records

Direct contact

Mass e-mail solicitation

Telephone

6.1.A. **If postings within hospital, please indicate name of facility:**

6.1.B. **If emergency room, please indicate name of facility:**

6.1.C. **If other, please specify:**

6a. Subject Recruitment (cont'd)

6.2. * Provide a step-by-step description of the recruitment procedures used to identify and/or contact prospective participants:

Mothers will be recruited from substance abuse/mental health treatment sites run by Banyan. Study staff employed by Banyan will invite all women who are enrolled in outpatient substance abuse, mental health (or co-occurring) treatment and who have children ages 0-17 to participate in the study. Study staff will contact candidates up to 4 times to offer study enrollment. Candidates who express interest in participating will be administered a screening interview by phone or in person. Study staff will explain the study and if the mother agrees to participate she will be read and asked to provide signed consent and permission for her children to participate.

In addition, study personnel will reach out to personnel from sites that refer women to Banyan for outpatient substance abuse or mental health treatment. This includes Banyan-affiliated residential substance abuse treatment sites, Family Intervention Services, the drug courts and other venues. The study team members will talk to personnel of those sites about the study and

provide them with IRB-approved study flyers and pamphlets and ask them to distribute these materials to mothers who might be referred to Banyan for outpatient substance abuse treatment. Study staff will ask local agencies that serve women who receive mental health or substance abuse treatment to provide contact information for their clients who have consented to be called regarding the study. Those women will be called by study staff for recruitment to the study. We will also use social media (e.g., Craigslist) to broadcast information about the study as a means of promoting recruitment. Potential participants will have to call the study number - there will be no direct communication with individual study candidates via social media.

In addition, the study will accept self-referrals from women who are receiving substance abuse, mental health (or co-occurring) treatment at other centers (besides Banyan). Study staff will inform staff at substance abuse/mental health treatment center about the study and will provide them with flyers and pamphlets. Staff from the substance abuse/mental health treatment center will post/distribute flyers/pamphlets and those clients who are interested will contact the study.

After obtaining the mother's informed consent to enroll in the study, study staff will administer the Child ID Form to identify children who are eligible to participate.

6.2.A. Please upload copies of scripts, recruiting materials, and advertisements:

Name	Description	Version
20111132_ADV_IRBApp_HealthyHomeFlyer_ENG		0.04
20111132_ADV_IRBApp_HealthyHomeFlyer_SPA		0.03
20111132_ADV_IRBApp_HHBrochure_ENG		0.05
20111132_ADV_IRBApp_HHBrochure_SPA		0.04
ChildID_translation.doc		0.02
Healthy Home Tear Off Flyer English.docx		0.03
Healthy Home Tear Off Flyer Spanish.docx		0.03
Mother's Screening Form_translation.doc		0.02
Treatment assignment Postcard with Translation.docx		0.01

NOTE: Any materials that will be given to or seen by potential subjects must be reviewed and approved by the IRB. This includes assessments, instruments, diaries, questionnaires, and all screening and recruitment materials, including advertisements, web postings, letters, and telephone scripts. Only IRB approved versions of these materials may be used during the course of the study.

6.3. * What measures will be taken during the recruitment process to safeguard against the potential coercion or the appearance of coercion of participants, particularly vulnerable populations?

Study candidates will be told (verbally and in writing) that their participation is voluntary, that they may withdraw consent at any time, and that their decisions regarding participation will not affect their relationship with Banyan.

6.4. * Are there specific criteria to prematurely end a particular subject's participation in the study (e.g., predetermined safety endpoints, unexpected clinically significant

findings, distress or serious adverse events, etc.)?

Select one

- Yes
- No
- Not Applicable

6.4.A. If yes, please describe:

6.5. * Will subjects be remunerated for their participation in the study in any way other than credit toward a course requirement?

- Yes No

6b. Remuneration

6.5.A. * List type, frequency, interval, and total value of remuneration:

Type of Remuneration	Frequency	Total Value
View Cash	4	Mothers will be paid \$50 per assessment interview. Mothers will receive a \$20 bonus if all of her enrolled children attend.
View Gift Certificates	4	Children will receive a \$10 (age 10-12) or \$20 (age 13-17) gift card. Mothers will receive a giftcard with a value of \$20. to encourage participation in the first intervention visit. Those mothers who are assigned to the Healthy Home condition will receive the gift card at their first home visit. Those who are assigned to TAU will receive the gift card at their next follow up assessment. For participants who enrolled in the study before the gift card procedure was approved, those in Healthy Home who have already been terminated from the intervention will receive the gift card at their next assessment.

6.5.B. * If a subject withdraws from the study early, will remuneration be prorated?

yes

6.5.B.(i) If yes, describe plan for prorating payments and ensure that this plan is defined in consent forms:

Participants will be remunerated for assessments that they attend and complete.

6.5.B.(ii) If no, justify why prorated payment is not being offered:

6c. Financial Liability

6.6. * Financial Liability for Study Participants:

Complete the table below, indicating the responsible party for payment of research activities and procedures.

Not applicable

Procedure or Activity	Frequency
There are no items to display	

6.7. * Select all categories indicating costs which participants or their insurance companies will be responsible for:

Check all that apply

- Participants will have no costs associated with this study
- Study-related procedures which would be done under standard care
- Study-related procedures not associated with standard care
- Administration of drugs/devices
- Study drugs
- Study devices

Other

6.7.A. If other, please specify:

The study does not cover costs to participants for the outpatient substance abuse treatment (they are already enrolled in substance abuse treatment when they enroll in the study) or costs associated with referrals made by the Healthy Home nurse.

6.8. * In the event of study-related subject injury, who will be responsible for compensation?

Not Applicable

6.8.A. If Other 3rd Party, please specify:

7. Informed Consent

7.1. * Is an alteration of the consent process being requested?

Yes No

NOTE: "Alteration of consent" is when the consent procedure does not include, or alters, some of the required elements of informed consent. This only applies to studies conducted by state or local government on public benefit or service programs. See <http://www.hhs.gov/ohrp/humansubjects/assurance/consentcls.htm>

7.2. * **Is a waiver of informed consent being requested?**

Yes No

NOTE: This indicates there is no consent process; waiver criteria need to be justified.

7.3. * **Is a waiver of signed consent being requested?**

Yes No

NOTE: This indicates that the consent process will occur, but there is no signed consent (i.e., verbal script or consent letter).

7b. Informed Consent (cont'd)

7.8. * **Under which of the following criteria does this research qualify for Waiver of Signed Consent?**

Check one	Description
<input type="radio"/> 45 CFR 46.117 (c) (1)	The only records linking the subject and the research would be the consent document, and the principal risk would be the potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
<input checked="" type="radio"/> 45 CFR 46.117 (c) (2)	This research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

7.8.A. * **Please state the justification for the criterion selected above:**

We are requesting a waiver of signed consent for screening. The questions asked for the mother's screening are innocuous - e.g., her age, whether she has minor children, whether she has monthly contact with any of those children.

7c. Informed Consent (cont'd)

7.9. * **Describe the specific steps for obtaining informed consent (e.g., by whom, his/her credentials, language, where, when, etc.):**

Not applicable

CITI certified study staff will explain the study to the mother and if she agrees to participate she will be asked to provide signed consent and permission for her eligible children to participate.

7.10. **Consent may be required from a parent, legal guardian, legal representative, court-appointed representative, or health care surrogate where research involves children/minors, wards of the state, cognitively or developmentally impaired individuals, comatose or traumatized or emergency subjects, as well as any other subjects lacking capacity to consent. Such surrogate/representative/guardian can only consent if the IRB has approved the research under HHS or FDA regulations. For court-appointed guardians, court assent is required.**

If your study involves any of these groups, please specify below whether consent will be obtained from such surrogate/representative/guardian and describe the process for obtaining such consent:

Mothers will be asked to provide permission for their childrens' participation. In cases where a person other than the mother has legal custody of the child, that person will be asked for signed permission. If there are wards of the state, the court-appointed designee would have to provide legally effective consent. Children age 7 or above will have the study explained and asked to give assent when they attend the baseline appointment.

- 7.11. *** What protections will be offered to persons with cognitive impairment or to persons determined to be incapacitated? Describe how capacity for consent will be determined, whether cognitive capacity is expected to change significantly during the study, whether a legally authorized representative or health surrogate has been designated for purposes of obtaining informed consent, and whether court approval has been obtained (for court-appointed guardians). Describe plans to re-consent subjects after a change in the subject's cognitive capacity.**

Not applicable

- 7.12. *** How will informed assent for children and parental consent/permission be obtained?**

Not applicable

Mothers will be asked to provide permission for their childrens' participation. In cases where a person other than the mother has legal custody of the child, that person will be asked for signed permission. Children age 7 or above will have the study explained and asked to give assent when they attend the baseline appointment.

- 7.13. *** Describe plans to re-assent or obtain consent for child subjects during the study if the subject reaches the age of majority (18 years) or if there is a significant change in cognitive capacity (i.e. gets older or regains consciousness).**

Not applicable

Children who reach age 18 during the study will be consented at the next study visit.

- 7.14. *** How will non-English speaking participants be consented? (Federal regulations require the equitable selection of minorities as research subjects to assure that they receive an equal share of the benefits of research and to ensure that they do not bear a disproportionate burden.)**

Check one	Notes
<input type="radio"/> Not Applicable	
<input checked="" type="radio"/> A translated written informed consent document in a language understandable to the participant	<p><i>This should be an accurate translation of the IRB-approved English version of the full informed consent document. Translations of IRB-approved informed consent documents must be made by a certified translator. Click here for list of certified translators.</i></p>

-
- Orally, using a qualified translator to translate the English informed consent document to the participant, and a translated short form in a language understandable to the participant. See [IRB Policy IV.B. "Documentation of Informed Consent"](#)

7.15. * Informed Consent Document Templates

- Not applicable**

Please attach all consent and assent templates associated with this study. (This includes genetic consent, HIV consent, tissue banking consent, etc.)

Name	Description	Version
20111132_ICF_IRBApp_Assent_Main_ENG		0.01
20111132_ICF_IRBApp_Assent_Main_SPA.doc		0.06
20111132_ICF_IRBApp_Assent_Pilot_ENG.doc		0.01
20111132_ICF_IRBApp_Assent_Pilot_SPA.doc		0.01
20111132_ICF_IRBApp_ConsentMotherNotLegalGuardian_SPA.doc		0.02
20111132_ICF_IRBApp_ConsentParentalPermission_Main_SPA.doc		0.02
20111132_ICF_IRBApp_ConsentParentalPermission_Pilot_ENG.doc		0.02
20111132_ICF_IRBApp_ConsentParentalPermission_Pilot_SPA.doc		0.02
20111132_ICF_IRBApp_FamilyVisits_SPA.doc		0.02
20111132_ICF_IRBPAp_ConsentMotherNotLegalGuardian_Main_ENG.doc		0.01
20111132_ICF_IRBPAp_ConsentParentalPermission_Main_ENG.doc		0.01
20111132_ICF_IRBPAp_FamilyVisits_ENG.doc		0.01

8. Protected Health Information

Protected health information (PHI) is individually identifiable health information that is or has been collected or maintained by the University of Miami or JHS or created for purposes of providing medical care/treatment and can be linked back to the individual participant.

8.1.(a) * Will Protected Health Information (PHI) be accessed (used or created for treatment) prior to contact with subjects in this research?

- Yes No

8.1.(b) * Will PHI be accessed (used or created for treatment) during the course of the proposed research?

- Yes No

11. Use of Human Biological Samples

11.1. * List all samples to be used in this research:

Type of sample
View Urine samples will be used to test for drug toxicology analysis.

11.2. * Will it be possible, if so requested, to provide the participant with the sample/data for this study?

no

11.2.A. If no, please explain:

We are not retaining any biological samples, therefore we will not be able to provide them to the participants.

11.3. * Will you allow participants to request the samples/data in this study be destroyed?

no

11.3.A. If no, please explain:

We are not retaining any biological samples, therefore this is NA.

15. Conflict of Interest

As the Principal Investigator, you must be aware of any conflict of interest of the protocol team or institution. Please note that the thresholds of ownership described below apply to the aggregate ownership of each individual investigator (or other key personnel, to the best of their knowledge) and their immediate family. The immediate family includes each investigator's spouse, domestic partner and dependent children (e.g., if an investigator together with his/her spouse, domestic partner and dependent children own a total of \$10,000 or 5% worth of equities in the sponsor, it should be reported below).

"Conflicts of interest" apply to each investigator or other individuals listed as key personnel. Do not consider the combined ownership of all investigators/key personnel. Do not consider compensation for the % effort on a study.

15.1. * Does any person obtaining consent have any existing relationship (family, social, or professional, including physician-patient or student-teacher) with the subject(s)?

Yes No

15.1.A. If yes, describe the relationship(s) and how subjects will be protected against undue influence or coercion:

15.2. * Will there be any programs, bonuses, rewards or other incentives that may be offered to this site and/or its faculty or staff by the sponsor or others for rapid enrollment?

Yes No

15.2.A. **If yes, please describe:**

Note: Before accepting any awards, the IRB must be informed of the nature and value of these incentives.

- 15.3. *** Do any of the investigators or members of their immediate families receive from the sponsoring entity salaries, consulting fees, or other compensation for services that exceed \$10,000 in any twelve month period? (Note: if the sponsoring entity is the full time employer of the investigator, co-investigator or key personnel (i.e. UM or JHS) then answer "No." Do not consider compensation for the % effort on a study.)**

Yes No

- 15.4. *** Do any of the investigators or members of their immediate families serve as an officer, director, or as a member of any advisory board with the sponsoring entity?**

Yes No

- 15.5. *** Do any of the investigators or members of their immediate families have an equity interest that exceeds \$10,000 in value or represents more than 5% ownership in the sponsoring entity?**

Yes No

- 15.6. *** Do any of the investigators or members of their immediate families have any intellectual property rights (patents, copyrights, royalties) in any article(s), product(s), drug(s), device(s) or other material(s) that will be involved in this research?**

Yes No

- 15.7. *** Do any of the investigators or members of their immediate families have any other financial interest or relationship that would reasonably be affected by this research?**

Yes No

- 15.8. *** Do any of the investigators or others know of any institutional conflict of interest pertaining to this study?**

Yes No

15.8.A. **If yes, please describe:**

- 15.9. *** Has any of the technology used in the study been developed in whole or in part at the University of Miami?**

Yes No

16. Monitoring Plans

16.1. * Select the item below that most accurately reflects the plan for data and safety monitoring for this study:

Select one

- The study will be monitored only by the study investigators and/or sponsor.
- The study will be monitored by at least one individual who is not associated with the study, but not by a formally constituted Data and Safety Monitoring Board (DSMB).
- A formally constituted Data and Safety Monitoring Board (DSMB) will monitor the study.
- Not applicable

16.2. Has an internal (UM or JHS) data safety monitor or board/committee been established to provide additional oversight or monitoring of this study for safety and adherence to the study protocol?

- Yes
- No

16.2.A. If yes, describe the composition of the committee and how they will communicate findings to the IRB:

16.3. Has an external (non-UM or JHS) data safety monitor or board/committee been established to provide additional oversight or monitoring of this study for safety and adherence to the study protocol?

- Yes
- No

16.3.A. If yes, describe the composition of the committee and how they will communicate findings to the IRB: