Study Title

Culturally Modified Family Based Therapy for Haitian Youth in South Florida (CIFFTA).

NCT number: 03876171

Date: July 19, 2018

INSTRUCTIONS:

1) Protocol Title

Culturally Modified Family Based Therapy for Haitian Youth in South Florida (CIFFTA).

2) IRB Review History*

None

3) Objectives*

The study will pursue the following Specific Aims:

Aim 1. To adapt CIFFTA and the assessment instruments necessary to test its efficacy to the unique Haitian sociocultural contexts. This process of adaptation has the purpose of optimizing CIFFTA's acceptability and cultural appropriateness. It will rely on ethnographic methods (participant observations, focus groups, and interviews) to guide the adaptation process.

Aim 2. Determine, via a pilot efficacy trial, the impact of CIFFTA compared with standard-of-care for reduction of drug use, risky sexual behaviors, and delinquency risk among Haitian adolescents ages 13 to 17 in Miami-Dade County. The ethnographic component of the study will monitor the delivery of the intervention, collecting process data, and affording the investigators needed perspective on the intervention's impact.

Aim 3. To generate preliminary data on the usefulness of assessment tools and CIFFTA's efficacy among the population. These data will help evaluate the effect of the intervention and its best form of implementation. They will also provide preliminary evidence to justify a full clinical trial of CIFFTA in a population of at-risk Haitian youth.

Primary study outcomes include: intervention attendance and completion; sustained abstinence in substance use through biochemical verification and self-report; family functioning; sexual risk behavior; and conduct disorder. Secondary outcomes include: recidivism in delinquency, improvement in family communication, and peer/gang involvement. Outcomes will be assessed through follow-up instruments at three points: 3, 6 and 12 months.

4) Background*

Despite preventive efforts made over the last three decades, it is clear that some populations have not benefited from attempts to deter them from risky behaviors. Haitian youth constitute an important but understudied population who may be particularly

difficult to "reach" via the usual preventive and intervention strategies due to circumstances of immigration, poverty, and marginalization.

This study will develop and implement a culturally specific, family-based individual, drug use, sexual risk and delinquency risk reduction program for Haitian adolescents aged 13-17 in Miami-Dade County. First, instruments for the intervention will be pretested with 10 Haitian youth and their families and then refined based on cultural acceptability interviews and focus group data. Second, we will conduct a pilot randomized trial with 88 at-risk Haitian youth and their families. We will test the CIFFTA model against the Standard of Care currently being offered by the Miami-Dade's Juvenile Service Department (JSD) to Haitian adolescents in their diversionary program. The goal of the pilot study is to obtain preliminary data on CIFFTA's feasibility, cultural acceptability and efficacy.

Research activities will include recruitment of Haitian families whose youths are in the JSD program in Miami-Dade Juvenile Justice System; participant observation in households of recruited families in Miami, Homestead, and Florida City; modification of CIFFTA for use in Haitian families; implementation of a pilot intervention in a limited number of youth and their families; process and outcome evaluation of those interventions; analysis of data resulting from these activities; and design of an intervention to be applied on a larger scale after completion of the present project.

5) Inclusion and Exclusion Criteria*

Eighty-eight (88) adolescents aged 13 to17 and their families will be recruited into the study to obtain 80 after attrition. Age, place of residence (Miami-Dade), and Haitian ancestry will constitute the main criteria for selection. Other criteria of inclusion are: adolescents that are NOT incarcerated and with no prior mental health care or history of psychoactive medication, to increase the homogeneity of the sample in terms of a naive population; adolescents in families who have lived in the US for 3 years, to avoid confounding initial culture shock with other conventional aspects of maladjustment; families with a range of organizational structures (nuclear and non-nuclear), to achieve variability and observe differences in family dynamics with regard to response to the intervention. Youths with a documented history of mental retardation and/or organic dysfunction will be excluded; the youths in question will be referred to appropriate agencies.

6) Number of Subjects*

Eighty-eight (88) participants will be recruited into the study. Instruments for the intervention will be pretested with 10 Haitian youth.

7) Study-Wide Recruitment Methods*

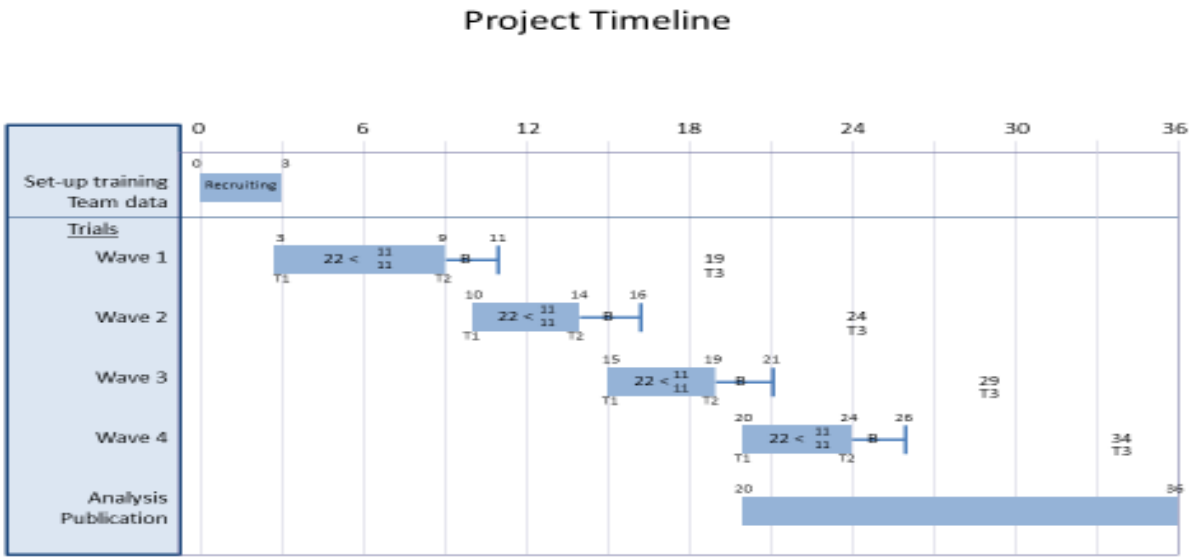
This project's recruitment approach will consist of the following steps: (a) after initial referral by the JSD, potential participants will be approached by the ethnographer who will describe the scope of the study and ask the participant if

she or he wants to be enrolled. If the participant agrees, his/her family will be contacted. Once a family is contacted, the ethnographer will schedule the first home visit with the parent(s)/caretaker(s) of the potential participant. S/he will explain (a) the objectives of the study, (b) the possible recruitment of the youth under his/her care as well as their own participation, (c) the possible risks that this participation could involve, and (d) the content of the parental consent form. If the parent(s) of the potential participant express(es) interest in the study, the ethnographer will explain the study to the potential participant. The procedure for introducing the study to potential participants and their caretakers will be written in English, French and Haitian Creole. After obtaining the verbal agreement of the parent/caretaker and the verbal assent of the participant, ethnographer will recruit the participant and his/her parent(s) or caretaker(s). S/he will explain in detail the adolescent assent form and obtain the participant's signature (as well as the parent consent form) prior to any further activity related to the study. The ethnographer and each participant will then schedule a time and a place for the baseline interview. The baseline questionnaire that addresses questions of demographics, family structure, immigration, neighborhood context and risky behaviors will be administered to participants at baseline at the participant's home. The ethnographer, who will have received specialized training in the conduct of structured interviews, will conduct the baseline interviews. Each interview is expected to take 1-2 hours; participants will be offered $25 for their time. At this point, the interventionist will contact the participant and her/his parent/caretaker to schedule the first intervention session. Subsequent contact between the interventionist and the participant will be once a week on a pre-scheduled appointment basis.

8) **Study Timelines***

This is a multi-wave study, with approximately all the participants recruited by the end of Year 02 and the remainder in the beginning of Year 03. At baseline, we will conduct comprehensive assessments of all study constructs and repeat all other assessments annually. Activities during the first three months will consist of the following: Staffing, Instrument Calibration, Ethnographic Update. Each wave will be composed of 22 participants to be randomized into two groups (11 each). Each undergo assessment at intake (T1) and outtake (T2), a booster session 3 months after outtake and a final assessment at 12 months. Data analysis process will be initiated at the third month and continue throughout the study implementation.

Publications are expected to start from month 20. The table below details the activity processes.



9) Study Endpoints*

Primary outcomes are: intervention attendance and completion; sustained abstinence in substance use through biochemical verification and self-report; family functioning; sexual risk behavior; and conduct disorder.

Secondary outcomes include recidivism in delinquency, improvement in family communication, and peer/gang involvement.

10) Procedures Involved*

RCT procedures

CIFFTA has three major components – Family-Based Therapy, Individual Therapy, and Psycho-educational Modules – delivered over 16 weeks in a six sessions (60 minutes each) per month format. In this study, the therapy will be delivered in the home to reduce missed sessions and premature termination. Special training will focus on how to structure the home environment to reduce distractions. Three sessions per month will typically be a session which may include Family-based Therapy or Psycho-educational modules with the family or parents alone (e.g., parent training). The other three sessions are typically with the adolescent alone and include Motivational Interviewing or Psycho-educational modules designed for the adolescent.

In the early stages of treatment with the family (weeks 1-3) the therapist uses motivational interviewing to enhance the family's motivation to change their behaviors and specialized engagement strategies to make sure all family members are active in treatment of the adolescent. The therapist helps families understand the urgency of changing key behaviors but also instills hope that change is possible. The therapists helps identify the many stressors impinging on the adolescent and family.

In the early stages of treatment with the adolescent (weeks 1-3) the therapist uses motivational interviewing to develop discrepancies between current behaviors and desired outcomes and to acknowledge the stressors she/he confronts each day.

In the middle stages of treatment (weeks 4-13) family sessions focus on teaching parenting practices, increasing family cohesion and support, and reducing parenting disengagement or conflict. Psycho-educational modules are used to teach concepts (e.g., parenting, immigration and acculturation related stressors) that increase readiness for successful family therapy to improve the family's supportive interactions. Parents are helped to understand the adolescents' co-occurring disorders and vulnerabilities that underlie the behavior problems and they learn to validate the adolescent's struggles.

In the middle stages of treatment (weeks 4-13) adolescent sessions focus on setting goals for their lives, becoming more active in changing behaviors that are risky, and learning life skills that can be helpful in their day-to-day lives. Psycho-educational modules are used to teach concepts (e.g., risky drug use and sexual behavior, interpersonal effectiveness, emotion regulation) that can be generalized to everyday life.

In the later stages of treatment (weeks 14-16), both individual and family sessions focus on relapse prevention and successful termination from treatment.

CIFFTA uses a flexible manual that allows for tailoring of the intervention through the selection of psycho-educational modules that address specific family and adolescent clinical and cultural issues that are central to that lives of that family. Individual and family level targets of change must be specifically able to address the ecological factors as well. For example, parenting practices may be improved to better monitor the adolescent's peers; parental leadership and guidance may focus on taking a more active role in advocacy in schools and in teaching adolescents how to handle racism and discrimination; and adolescent skills may become important in better addressing peer pressure in the peer context.

Overall intervention process.

Pretest. CIFFTA instruments only will be pretested with a subsample of 5 Haitian youths and their families. Youths and families will be selected purposefully and will NOT be included in the study sample. Because the whole trial is consist of testing the applicability of CIFFTA within this population, the study will not be tested prior implementation. The instruments will be tested for fidelity of translation.

Study Process. Randomization will be done after baseline data are logged and will be carried out via computer-generated sequential assignment; in that sense, interventionists do not control randomization and interviewees will be blind to condition. At baseline, we will conduct comprehensive assessments of all study constructs and repeat all other assessments (see timeline). Outcomes anticipated will include lowered risk for re-offending (i.e. YLS scores), rates of recidivism (i.e. re-arrest), drug/alcohol use, and improved psychological adjustment and family functioning of those youths in the intervention group relative to those in the comparison group. Similarly, we expect parents/caregivers of these youths to see improvement in their child's behavior (i.e. less conduct disorder reported) and improved family functioning overall.

Ethnography.

Ethnographic methods will be employed including: in-depth interviews; focus group discussions; and observation of participating families in daily life. The ethnographers will conduct observations as the study begins and during follow-up data collection. With regard to Aims 1 & 3, the ethnographic observations and interviews help the research team to monitor the fidelity of the intervention. Ethnographic data will also help to define the processes by which change takes place. To summarize: the ethnographic data will: a) guide the development and implementation of the intervention (see also timeline); b) enable us better to understand barriers and facilitators to change that will inform further modification of family-based interventions of this kind; and c) facilitate interpretation of the outcome analysis results.

In order to give the study a chance of determining the intervention's impact in preventing drug use, we intend to collect urine samples at baseline and all follow-up time points. The urine tests will not be the only measures of drug use employed during the follow-up period, but in an institutional setting like the JAC, they are likely to be the most accurate.

Field observations. Ethnographers will be trained to capture processes and describe events, communications, behaviors, activities and cultural materials that make up the particular contexts in which Haitian live. They

will make regular visits to pre-selected, highly frequented locales, gendered or not, where Haitian youths "hang out."

In-depth Interviews. In-depth interviews will begin after field observations have been initiated, and therefore should benefit from findings of observations in progress. The Interview Guide serves as a preliminary template to be used by interviewers. It will generate information on topics such as (a) life experiences, (b) drug use, (c) identity, (d) lifestyle, (e) personal experiences, such as forms of sociability and beliefs associated with youth behaviors and the juvenile justice.

Focus Group. Focus groups will be guided by the following criteria: (a) they will be homogeneous with regard to age (parents or adolescents only); (b) they will follow a relatively structured interview guide with high involvement of the ethnographer as moderator; and (c) they will have six to ten participants each. Topical areas for the focus group will include the following: impact of the interventions; behavior changes of adolescents of parents; changes in the family.

Instrumentation.

The primary constructs for the youth participants will include: risk for re-offending, criminal history, patterns of drug/alcohol use, psychological adjustment, evidence of conduct disorder, family functioning, and acculturation. Constructs for the caregiver(s) will include their assessment of their child's conduct, family functioning, and their own level of acculturation. At baseline, information will also be gathered on participants demographic status. The instrument will be administered at participants' homes. Along with the demographic data, the baseline questionnaire will incorporate measures from the instruments described below, culminating in a unified tool taking no more than one hour to administer.

Behavioral, emotional, and academic functioning. We will administer standardized measures of youths' emotional and behavior disorders. Parent and youth reports on the Achenbach System of Empirically Based Assessment will assess youth's behavioral, emotional, and academic functioning. Parents will complete the Child Behavior Checklist (Achenbach 1983); and youth also will complete the parallel Youth Report Form (YRF). These measures yield scores for internalizing and externalizing problems and academic competence, and have DSM-5 scales for multiple problem areas: depression, anxiety, somatic, attention deficit/ hyperactivity, oppositional, and conduct problems.

Risk for re-offending. Level of risk will be assessed with the Youth Level of Service/Case Management Inventory (YLS/CMI) developed by Hoge and Andrews (51) that screens for risk in eight domains (conduct disorder,

school, criminal friends, alcohol/drug use, leisure/recreation, personality/behavior, family circumstances, and attitudes/orientation) yielding overall risk scores ranging from (0-8). The YLS/CMI is administered to all juveniles processed in the JSD. The same instruments will be used to assess youth from the GRP.

Drug use and psychological adjustment will be assessed with the Comprehensive Adolescent Severity Inventory developed by Myers and colleagues (52). The CASI covers a broad range of psychosocial and risk behaviors including information on substance abuse (e.g. age of first use, current patterns of use, friends' use), criminal activity, mental health, peer relationships, family/household relationships, education, and sexual behavior. Among other things, the instrument gathers information concerning youth use of a range of substances and will be adapted to assess ATOD use at baseline and post-intervention. In this way, we will be able to determine participants' historical and recent use (i.e. past 30 days, past 3, 6, and 12 months), if any, of drugs and alcohol. Similar assessments are made of sexual risk behavior and a global assessment of psychological adjustment is included that yields a continuous measure of global functioning. Adequate levels of internal consistency, test-retest reliability and validity coefficients are reported.

Conduct Disorder. Youth problem behaviors will be measured using the Conduct Disorder instrument from a Revised Behavior Problem Checklist (53) utilized previously by BSFT staff (54). The RBPC is an empirically derived measure consisting of 89 problem behaviors. We will adapt the instrument to include behaviors that are particularly salient among Haitian youths and exclude others that are deemed less salient. For each youth, the primary caregivers will rate the severity of each behavior on a 3 point scale (0 = no problem, 1 = mild problem, 2 = severe problem). The Conduct Disorder Subscale as used for this study consists of 22 items (α = .92) measuring the youth's disruptive behavior at home (e.g., "disobedient; difficult to control"). The Conduct Disorder Subscale will be administered at intake and again at termination.

Family Functioning. Family functioning will be assessed by the Cohesion and Conflict Subscales from the Family Environment Scale [FES] (55). Family cohesion and conflict are specifically targeted because they have been found to be among the strongest predictors of youth problem behavior and these two scales have been found to capture much of the variability attributed to the FES (56). In prior work, the FES has demonstrated good internal consistency reliability (α = .93 for adults and .94 for children) (55). We will also modify this instrument for adaptability to the Haitian immigrant context. As with the other instruments, reliabilities of the modified Family Functioning instrument will be ascertained for additional internal consistency and test-retest reliability as

necessary. Parents' involvement in the day-to-day lives of their youth children will be further assessed with a 5-item paternal-child centeredness scale developed by Schaefer (57) that typically yields reliability coefficients in excess of .80.

The Bicultural Involvement Questionnaire, designed by Szapocznick (24) and adapted for use in Haitian populations by Jean-Gilles (58) measures the degree of comfort and enjoyment respondents receive from engaging in behaviors representative of the culture of origin (e.g. speaking the native language, consuming native food, listening to ethnic music) as well as behaviors representative of the host (U.S.) culture. Scores deriving from this measure include one for monoculturalism with respect to the native (Haitian) culture, and another for adaptation to the host (U.S.) culture. Szapocznick & Kurtines (24) report internal consistency coefficients of .93 and .89 for these scales on samples of 12 to 16 year old Hispanic youths. The internal consistency coefficients for the Creole version of the BIQ subscales were .72 for monoculturalism and .87 for Americanism, respectively.

Youth Urine Toxicology. As part of our research component, we plan to collect voluntary urine specimens for analysis at the times of the youths' initial and follow- up interviews in order to validate self-report. We will follow procedures informed by NIDA's CJDATS workgroup guidelines. Urine specimens will not be collected on youths incarcerated for more than two days. The use of four substances will be probed using the Onsite CupKit® urine screen procedure (positive threshold levels are noted in parentheses): (1) methamphetamines (500 nanograms per milliliter [ng/ml] of urine), (2) opiates (300 ng/ml of urine), (3) cocaine (300ng/ml of urine), and (4) marijuana (THC) (50 ng/ml of urine). The surveillance window for the four drugs is as follows: methamphetamines and opiates = 48 hours; cocaine = 72 hours; marijuana: moderate users = 5 days; heavy users = 10 days; chronic users = 20 days. Although we considered hair analysis, urine screens were selected because of they are the most widely used and accepted method for supervision monitoring (Lipsey & Wilson, 1998), they are minimally invasive, can be collected in the community during follow-up assessments and carry fewer taboos on collection (Meyers et al., 2002). Urine screen results will be kept confidential, and will be collected in containers marked with pre-printed labels without personal identifying information. To assure integrity of the sample, the Onsite CupKit® automatically checks for temperature, and the interviewer will ensure that there is no one else in the restroom.

Overview of Assessment Procedures and Attrition

The 3-month follow-up assessment will be measured from the end of the intervention, as will be the 6-month and the 12-month follow-up

interviews. All participants entered into the study will be tracked for the follow-up assessments, even if the individual drops out of treatment early. Whereas this is not expected to be a significant problem given the few number of treatment sessions, our design calls for an intent-to-treat assessment and data analytic plan. If the youth or parent cannot be located, records of official agencies (e.g., law enforcement, department of juvenile justice, local jails, department of corrections, state attorney, department of motor vehicles) will be searched. Our tracking efforts will be informed by the successful strategies used by Stouthamer-Loeber et al. (1992), Farrington et al. (1990), and in the Family Empowerment Intervention project (Dembo & Schmeidler, 2002) to minimize attrition. One of the greatest advantages in using family–based approach is that it creates conditions to build relationship over time within the communities studied and with the families. Based on our experiences conducting family-based studies, we will use procedures proven instrumental in obtaining high retention rates.

11) Data and Specimen Banking*

As part of our research component, we plan to collect voluntary urine specimens for analysis at the times of the youths' initial and follow- up interviews in order to validate self-report. We will follow procedures informed by NIDA's CJDATS workgroup guidelines. Urine specimens will not be collected on recruited youths for more than two days.

The use of four substances will be probed using the Onsite CupKit® urine screen procedure (positive threshold levels are noted in parentheses): (1) methamphetamines (500 nanograms per milliliter [ng/ml] of urine), (2) opiates (300 ng/ml of urine), (3) cocaine (300 ng/ml of urine), and (4) marijuana (THC) (50 ng/ml of urine). The surveillance window for the four drugs is as follows: methamphetamines and opiates = 48 hours; cocaine = 72 hours; marijuana: moderate users = 5 days; heavy users = 10 days; chronic users = 20 days.

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& Wilson, 1998), they are minimally invasive, can be collected in the community during follow-up assessments and carry fewer taboos on collection (Meyers et al., 2002). Urine screen results will be kept confidential in containers marked with pre- printed labels without personal identifying information. To assure integrity of the sample, the Onsite CupKit® automatically checks for temperature, and the interviewer will ensure that there is no one else in the restroom.

12) **Data Management***

Qualitative data:

Research staff will be monitored during every step of data collection by appropriate investigators. Instruments will be reviewed periodically to insure validity and reliability. Data will be entered by our personnel into a database under the supervision of PI. Control measures will be instituted to ensure accuracy of data entry procedures prior to analysis. Also, all data will be analyzed at our data processing center, under guidelines of our data safety and monitoring plan. All written and tape-recorded materials in this study will be transcribed using Microsoft Word on a daily basis and stored in locked the PI files cabinet. They will be coded and analyzed using procedures described in Schensul et. al.

The PI, with the assistance of the project's co-Is and Post-Doctoral Associate, will analyze the data using SPSS®, STATA®, the R statistical package or relate statistical software. Outcome measures will include drug use, delinquency/crime, family functioning, educational performance, and emotional/ psychological functioning. Predictor and outcome data will be analyzed using confirmatory factor analysis, generalized linear mixed effects modeling, latent growth modeling, structural equation modeling, analysis of variance, logistic regression, and stepwise multiple regression. The significance levels will be adjusted to control for multiple outcome measures. For the primary hypotheses, power is anticipated to be .80.

To ensure the consistency and integrity of the independent variables, project research assistants will record on a regular basis all random assignments, other contacts, and assessments. These records will be audited regularly by the PI and Co-Is. To ensure high quality data, all research staff will be closely trained in proper data collection and entry. All data will be checked promptly after collection for completeness, quality, and accuracy. This will include screenings for out-of-range values and missing data. Apparent anomalies will be immediately brought to the attention of the interviewer for clarification and any indicated follow-up. We will monitor three key outcome measures on a bimonthly basis.

For urine tests:

Urine specimens will be collected using the Onsite CupKit®, which produces test results within 3 to 5 minutes. As such, no biological specimens will be kept for storage.

Urine specimens will be collected, but not stored.

Because youths tend to underreport the use of such socially disapproved drugs as cocaine (Dembo & Schmeidler, 2002), urine testing is a valuable component of our data collection plan. Based on previous experience conducting research on delinquent youth (e.g., Dembo & Schmeidler, 2002), and because the urine test data will be treated as confidential, we anticipate a low rate of refusal to provide a

specimen at each time point. If preliminary analyses at each data collection point indicates a low concordance rate (kappa < .80) between self-reported use and urine toxicology results for a given drug (e.g., marijuana) both self-report and urine test results will be used to construct drug use measures for our analyses (e.g., self- reported use or a positive urine test = use; no self-reported use and a negative urine test = no use). If a high concordance rate is found (kappa > .80), the self- reported use data for that drug will be used.

13) Provisions to Monitor the Data to Ensure the Safety of Subjects*

All data collection protocols include Informed Consent Forms. They also include Confidentiality Safeguards, Mandatory Reporting Safeguards, Staff Training Safeguards, Data Safeguards, Discomfort with Assessment Procedures or Disclosure Safeguards, and Dissatisfaction Safeguards. In addition, the PI will constitute an external Data safety and Monitoring Board (DSMB).

Confidentiality safeguards. The Data Safety and Monitoring Plan guidelines require that the degree of monitoring be commensurate with the degree of risk to study participants. The primary risk to study participants is loss of confidentiality. In order to ensure protection of study participants' confidentiality, participant locator information, including names of family, will be encrypted and stored in password protected files accessible to the PI. Participant identifier will be destroyed at the end of the study. Study participants' names will not be used in computer files; only each participant's unique code number will be linked to the data.

Mandatory reporting safeguards. The PI will report any participant safety issues to the IRB within three working days. Reportable issues include: 1) serious adverse events associated with study procedures, 2) any problems or complaints related to conduct of research personnel, and 3) any incidents or problems related to recruitment and consent. The PI will also provide, on an annual basis, a full report to the IRB detailing any problems encountered during the years in which the research project is in contact with human participants.

Discomfort with Assessment Procedures or Disclosure Safeguards. Some people may experience mild fatigue or concerns when responding to the interview schedule. Others may experience psychological distress when questioned about sexual behaviors and forms of sociability. Some of the participants that are involved in disruptive behaviors may be taking risks by enrolling in this study because of the information related to delinquency, drug use, and other risky behaviors collected from them. We may even have to report to the appropriate authorities sexual abuse and crimes resulting in injury or death. We will adhere to the following procedures for responding to adverse events associated with subjects' participation in the study.

Data Safeguards. Fieldworkers will be monitored at every step during the data collection process and questionnaires will be reviewed to insure validity and

reliability. Data will be entered by our data entry personnel into a database under the supervision of the PI. Control measures will be instituted to ensure the accuracy of data entry procedures prior to conducting the analysis. Upon collection from the field interviewers or other investigators, the Post-Doc will place in their respective locations in the file cabinets all transcripts, field notes, USB keys, and completed interview schedules. The PI will develop a readily usable filing system. Data and study related materials will be secured in a locked file cabinet at the PI's office. Only staff directly involved in the assessment of each participant will have access to documents that contain identifying information. This list includes the study's principal investigator (PI), co-Principal Investigators, the Post-Doctoral Research Associate/Field Manager and the Therapists.

A single password-protected file with identifying information will be kept for tracking purposes only. As mentioned above, only the study's principal investigator (PI), co-Principal Investigators, the Post-Doctoral Research Associate/Field Manager and the Therapists.

Staff Training. Research staff will be extensively trained regarding the importance of confidentiality and procedures for maintaining sensitive information. The PI will strictly monitor procedures relating to protection of data and confidentiality and staff's adherence to same. Research staff will complete NIH requested human subjects research training.

Data Safety and Monitoring Board (DSMB). The PI will constitute a DSMB composed of a University of Miami experienced faculty, a member from the Community Advisory Board for the Miami-Dade County Juvenile Delinquency Alternative program (J-DAP), and a member of the Institute for Child and Family Health, and a member from a Haitian community center.

The University of Miami's IRB will oversee and monitor the involvement of participants in the study to ensure their safety. We will submit a yearly report to the Office of Human Subject Protection reporting on the conduct of the research, the safety of the participants, any adverse event that may affect a participant and the study's compliance with federal, state, and University regulations. Under the University of Miami's IRB policy, the IRB may request an audit by the Office of Research Compliance of any study it has approved to ensure the validity and integrity of the data. Unexpected adverse events will be directly reported to the University's IRB for immediate decision.

Data review may indicate a need for early termination of the study, amendment to the protocol or other changes to the data collection plan or study forms (for example translation). We will obtain permission from the Program Official prior to effectuating the suggested changes and implementing them. The University of Miami IRB will be notified of any planned changes and all amendments to study procedures will be approved by the IRB prior to implementation.

The PI acknowledges the requirement to report DSMB activities to the Program Official at NIDA on an annual basis as part of the non-competing progress report.

Clinical trial information for this study is posted at ClinicalTrials.gov in accordance with NIH guidance.

14) Withdrawal of Subjects*

Potential Adverse Events (AEs) and Serious Adverse Events (SAEs)

In this study, SAEs will be defined according to NIH criteria. We will carefully and continually monitor all participant data on a monthly basis for potential SAEs induced by any of the experimental interventions or by other circumstances. Any SAE, whether or not related to the study interventions, will be reported immediately to the study's IRB at the University of Miami and to NIDA Program Official within 24 hours and follow up report within 2 hours. The initial SAE Report will be followed by submission of a completed SAE Report to both institutions. In the event that a participant withdraws from the study or the PI decides to discontinue a participant due to an SAE, the individual will be monitored by the investigator via on-going status assessments until 1) a resolution is reached; i.e., the problem requiring intervention has resolved or stabilized with no further changes expected; 2) the SAE is determined to be clearly unrelated to the study intervention; or 3) the SAE results in death. Outcomes of SAEs will be periodically reported to NIDA. A summary of the SAEs that occurred during the previous year will be included in the annual progress report to NIDA.

Procedures for Research Team Management of AEs, SAEs and other Study Risks.

Project staff will be trained to recognize symptoms of psychological distress and to make appropriate referrals with follow-up. Psychological support through licensed practitioners at the J-DAP go-to counselor staff at the Miami-Dade Juvenile Justice Services and the Juvenile Assessment Center. In addition, licensed practitioners at the Center for Haitian Studies (University of Miami) will be available for participants who experience discomfort with disclosure and/or psychological distress. When appropriate, community resources such as Haitian churches, informal networks, and Haitian CBOs can also be mobilized to help minimize potential adverse effects. In the event that a participant informs research staff about potential harm to self or others (e.g., child abuse, crimes resulting in injury or death, suicidal actions, or ideation), the PI must be informed and the incident reported to the appropriate authorities. We will comply with these guidelines. The project Post-Doc will also produce a safety report for the PI, describing any adverse events within two days of their occurrence. This will ensure that an appropriate response is made and any negative trends are identified.

15) Risks to Subjects*

This study involves minimal risks with no prospect of benefit. We do not anticipate any adverse effects. Nevertheless, if a serious adverse event occurs, it will be reported to the Institutional Review Board (IRB). Risks related to study procedures will be monitored closely, and any changes to increase safety will be addressed. Risks identified as possible outcomes for all of our study subjects participating in the assessment:

1) possible violation of confidentiality,
2) possible discomfort due to assessment procedures,
3) possible psychological stress associated with discussing issues related to stigma and disclosing sensitive personal information,
4) possible disclosure of information about health status or abuse that would need to be reported to families and/or the appropriate agencies and ensuing investigation of the allegation(s) and further action, as indicated,
5) possible dissatisfaction with the assessment procedures, and
6) possible dissatisfaction with the intervention activities.

In addition, sensitive information about the participants may constitute a serious risk, as the information in essence will consist on records of delinquency, drug possession or serious first offense.

16) Potential Benefits to Subjects*

Potential Risks and Benefits There are several risks associated with this study. Potential breach of confidentiality, feelings of discomfort about sensitive information shared during interviews, focus group discussions and during therapeutic interventions. Some participants may experience psychological distress when questioned about risky behaviors associated with drug use and sexual activity, among others.

This research will develop and implement a culturally specific, family-based individual-based, sexual risk and delinquency risk reduction program for Haitian adolescents ages 13-17 in Miami-Dade County, Florida. As there are no documented interventions that have been specifically modified or created for this distinct cultural group, this preventive/intervention program could eventually allow clinicians to offer family-based interventions that integrate individually-oriented approaches to therapy and are better suited to the Haitian American sociocultural context.

17) Vulnerable Populations*

. The youths to be recruited are minors aged 13-17.

18) Multi-Site Research*

This is not a Multi-Site Research.

19) Community-Based Participatory Research*

This study is not a Community-Based Participatory Research

20) Sharing of Results with Subjects*

Not Applicable.

21) Setting

When a youth is arrested in Miami-Dade, he or she is brought by the arresting officer to the JSD. At the JSD the child goes through an initial arrest process, including fingerprinting, mug shots and other typical intake and assessment procedures. During the intake the youths are asked to self-identify as to their ethnicity. The child is given an assessment which includes a determination of whether or not the appropriate criterion is met for entering a diversion program. Criteria for the various diversionary programs include prior criminal history and the nature of the current arrest. If the child is eligible for a diversionary program then the range and type of programs and services which might be suitable are considered. Programs are offered for substance abuse, educational needs, psychotherapy, family-based interventions, anger management, community service and so forth. If the parents and the youth both agree, then a diversion program is assigned.

Once assignment to a diversion program has been made, participation by the youth, and in many cases also by a parent, becomes a mandatory condition of the program. A case manager is assigned to monitor program compliance. If either fails to participate the program will not be completed and the youth may then be referred to the court system and may face prosecution and further sanctions. When parents/guardians picking up a project eligible youth meet or when project staff meet eligible youth at the community diversion program, only then will they be informed about their eligibility of the proposed project. Parents/guardians and youths who are interested in participating in the project will then be informed that project services are provided in-home, confidential, and that participation is voluntary. Project's procedures will be performed at the home of the participants in the Haitian neighborhood in Miami-Dade.

22) Resources Available

The PI and Co-Investigators have each at least more than 30 years of large-scale experiences in the field of public health. They have over 3 decades of community-

based research in the Haitian community in Miami-Dade. All research clinical staffs have been performing CIFFTA in diverse ethnic contexts in Miami-Dade for over two decades. They are well-trained in human subject protection and research implementation. They are well-informed of their tasks and duties and they will be trained for this study to be implemented in the Haitian community. The 88 at-risk youth (ages 13-16) of Haitian descent will be recruited in Miami-Dade County with the intention to analyze 80 participants because of attrition. Sample sizes are derived from power calculations based on data from published work.

Two therapists will deliver the CIFFTA intervention. Therapist will have experience in working with adolescents with behavior problems and with Haitian families. The first phase of therapist CIFFTA training will consist of a 3-day training workshop that includes the use of didactic material, the intervention manual, and the presentation of videotaped sessions from our previous CIFFTA work. This workshop will also include presentations by the PI and Dr. Page on what is known about Haitian families in our community. The second phase will include intervention implementation with 1 pilot case. A therapist is required to work with a pilot case over at least a one-month period and work with that pilot cases will be supervised directly by the study PI, the CIFFTA Developer, and the CIFFTA supervisor. Because the implementation of the psycho-educational modules is fairly straightforward, training and certification efforts will focus primarily on the individual and family-based therapy components. Any rating below “adequacy” will require retraining on that specific component. Interventions will be delivered over a briefer period than is typical of the actual intervention in the trial but will be sufficient to ensure comfort and competence in the key intervention components. There will be a 2 day workshop following the pilot phase to solidify any issues that remain and to incorporate any manual clarification that will assist in achieving high levels of competence and fidelity/adherence. This training format has been utilized successfully in our family training institute. SOC therapists will already be experienced in delivering the community standard and will not require additional training.

Intervention Integrity/Fidelity Checks: Weekly clinical meetings will be held to supervise the team. Each therapist will receive formal supervision in these meetings, in addition to consults as needed. Recorded therapy sessions will be reviewed, the clinical complexity of cases will be discussed, and good manual implementation will be emphasized. An independent adherence rater will randomly select 20% of the sessions at different intervention phases (early, mid, and late) for adherence ratings to document the adequacy of intervention delivery. Ratings that fall below adequacy on any dimension/component will trigger increased supervision focus for that dimension and if necessary, re-training. Adherence raters will be trained using the established CIFFTA adherence checklist. The condition supervisor will be held as the gold-standard for inter-rater reliability on adherence ratings and raters will be trained to achieve an intra-class

correlation coefficient of .70 or higher, and at least 80% agreement across items. Inter-rater reliability will be checked regularly to avoid drift.

23) Prior Approvals

There was no prior approval.

24) Recruitment Methods

This project's approach will consist of the following steps: (a) after initial referral by the JSD, potential participants will be approached by the ethnographer who will describe the scope of the study and ask the participant if she or he wants to be enrolled. If the participant agrees, his/her family will be contacted. Once a family is contacted, the ethnographer will schedule the first home visit with the parent(s)/caretaker(s) of the potential participant. S/he will explain (a) the objectives of the study, (b) the possible recruitment of the youth under his/her care as well as their own participation, (c) the possible risks that this participation could involve (see Human Subjects), and (d) the content of the parental consent form. If the parent(s) of the potential participant express(es) interest in the study, the ethnographer will explain the study to the potential participant. The procedure for introducing the study to potential participants and their caretakers will be written in English and Haitian Creole. After obtaining the verbal agreement of the parent/caretaker and the verbal assent of the participant, ethnographer will recruit the participant and his/her parent(s) or caretaker(s). S/he will explain in detail the adolescent assent form and obtain the participant's signature (as well as the parent consent form) prior to any further activity related to the study. The ethnographer and each participant will then schedule a time and a place for the baseline interview. The baseline questionnaire that addresses questions of demographics, family structure, immigration, neighborhood context and risky behaviors will be administered to participants at baseline at the participant's home. The ethnographer, who will have received specialized training in the conduct of structured interviews, will conduct the baseline interviews. Each interview is expected to take 1-2 hours; participants will be offered $50 for their time. At this point, the interventionist will contact the participant and her/his parent/caretaker to schedule the first intervention session. Subsequent contact between the interventionist and the participant will be once a week on a pre-scheduled appointment basis.

25) Local Number of Subjects

88

26) Confidentiality

Participants' contact information will be entered into the confidential password-protected tracking system. Their study information, however, will be de-identified in a separate file. If at the time of assent, consent or if it has been determined later

that a participant is no longer eligible, the participant will be discontinued from the study and told that the study inclusion criteria are no longer met. All information regarding that participant will be destroyed. Every precaution will be taken to prevent any violations of confidentiality. Confidentiality of subject records is assured by assigning the participants research numbers and storing computer files without identifying information. A single password-protected file with identifying information will be kept for tracking purposes only. Only Dr. Marcelin, Dr. Santisteban and the Postdoc will have access to the password protected files. All personal information and data contained in computer systems will be password-protected and stored in locked facilities. Paper records are kept in locked file drawers in a locked room.

This study will have an extended NIDA Certificate of Confidentiality to protect the subjects' confidentiality.

27) Provisions to Protect the Privacy Interests of Subjects

Parents/guardians and youths who are interested in participating in the project will be informed that project services are provided in-home, confidential, and that participation is voluntary. Interviews will be done at a comfortable place chosen by the study participant where there is no intrusion from a third party and where participant feel safe providing response to questions, examinations, and procedures.

Trained research staff will ensure participants of the study that all information regarding that participant will be destroyed and that every precaution will be taken to prevent any violations of confidentiality. Confidentiality of subject records is assured by assigning the participants research numbers and storing computer files without identifying information.

28) Compensation for Research-Related Injury

Not applicable.

29) Economic Burden to Subjects

There is no cost to participate in this study.

Consent Process

We will obtain signed assent from children participating in this research study as it is appropriate for the age, maturity and psychological state of the child. The consent/assent process will occur in the youths' homes by appointment, after they and their parents/guardians have left the Juvenile Services Department/Juvenile Assessment Center. Parents/guardians and youths will be informed that participation in the study is completely voluntary.

Non-English Speaking Subjects

Although Haitian youths in this study are bilingual, their parents are most likely to be Creole speakers. The consent and assent forms will be translated in Haitian Creole and the process will be done in the language parents or youth is most comfortable with.

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

We will not apply for waiver in this study.

Cognitively Impaired Adults

No cognitively impaired individuals will be enrolled in this study.

Adults Unable to Consent

Not applicable.

30) Process to Document Consent in Writing

Informed consent attached.