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Computer Assisted Family Intervention to Treat Self-Harm Disparities in Latinas and Sexual/Gender Minority Youth

Study Protocol date: 2/3/2022

1) Protocol Title

Computer Assisted Family Intervention to Treat Self-Harm Disparities in Latinas and Sexual/Gender Minority Youth (CA CIFFTA)

2) IRB Review History*

IRB for NIH "Just in Time" was approved on 9/1/2017.

3) Objectives*

The study described in the protocol is a randomized trial at UM. The study will enroll 100 11-18 year old youth with a self-reported act of self-harm in the past 6 months and their families. This study is designed to refine and test the efficacy of a computer assisted culturally informed and flexible/adaptive intervention for Latino adolescents for whom self-harm behaviors are a health disparity—specifically, Latinas and sexual/gender minority youth. The specific aims of this study are:

1) To build on the Computer Assisted CIFFTA intervention by creating a web-site and web-based delivery system and by adding content that is relevant for the factors that maintain self-harm in Latina adolescents (e.g., depression, family conflict, substance use, and emotion dysregulation) and for unique stressors often linked to sexual/gender minority youth and those exposed to trauma.
2) To investigate the preliminary efficacy of the Computer Assisted CIFFTA in reducing self-harm and in modifying the factors that place youth at risk for self-harm (e.g., depression, family conflict, substance use, and emotion dysregulation) when compared to controls (Treatment-As-Usual).
3) To investigate the linkages between co-existing problem areas (e.g., self-harm, risky sexual behavior, substance use) to see if there is evidence of a syndemic.
4) To investigate the relationship of culture-related variables (e.g., acculturation, familism, and Hispanic Stress) to the key factors hypothesized to contribute to self-harm behavior (i.e., depression, family conflict, substance use, and emotion dysregulation).

4) Background*

Significance and Rationale

Suicide is the second leading cause of death in youth ages 10-24, and self-harm—which includes nonfatal suicide attempts (SA) and non-suicidal self-injury (NSSI)—is prevalent and is a risk factor for future suicide attempts and suicide completion. Self-harm does not typically emerge in a vacuum; it is commonly found to occur with other mental health (e.g., depression and emotion dysregulation) and behavioral (e.g., alcohol and drug use, risky sexual behavior, and externalizing behavior) symptoms. Evidence suggests that these behaviors occur in clusters as described by Syndemic theory and, if

untreated, lead to severe adverse substance abuse, violence, and HIV/AIDS (SAVA) disparities in youth and other vulnerable populations. A cross-sectional investigation of high school youth found that engagement in risky sex, self-harm/cutting, and externalizing behaviors tended to co-occur among youth who reported using illicit substances. In a study with adolescents participating in an intensive psychiatric treatment program, risky sexual behaviors, including inconsistent condom use, were found to be associated with self-harm behaviors. In the treatment of these youth, research has suggested that (a) several stressors are likely to arise with non-suicidal self-injury and suicide-related injuries and (b) any program seeking to treat existing risk factors and prevent repeated self-injury and suicide should be prepared to address these stressors. Among these stressors are the marginalization experienced by sexual and gender minority youth, traumatic experiences, chronic family conflict, and alcohol use. In addition, culture-related variables may place Latinas at even higher risk due to breakdowns in family protective factors.

Hispanic/Latino adolescents, self-harm, mental health, and risky sexual behaviors

A set of health disparities often linked together in Hispanic/Latino youth are self-harm behaviors, rates of depressive symptoms, and HIV rates. According to the 2015 Youth Risk Behavior Surveillance System (YRBSS) survey of high school students, Hispanic youth reported feeling sad or hopeless at higher rates than non-Hispanic White youth, 35.3% versus 28.6%. Among all high school students who completed the survey, 17.7% of youth reported having seriously considered attempting suicide in the previous year and Hispanic rates were higher than non-Hispanic youth. Hispanic/Latino females appear to be at particularly high risk—reporting the highest prevalence of having felt sad or hopeless (46.7%), of having seriously considered attempting suicide (25.6%), of having made a suicide plan (20.7%), and of having attempted suicide (15%) in the past 12 months. Another health disparity area also found in Hispanic/Latino females— and possibly linked to self-harm and depression profiles—involves risky sexual behavior and HIV risk. Hispanic/Latino youth have an earlier age of onset for sexual intercourse than non-Hispanic White youth and are less likely to use condoms consistently, which may place them at increased risk for pregnancy, STIs, and HIV. According to the 2015 YRBSS, the high school prevalence of having ever had sexual intercourse was highest among Hispanic/Latino females at 39.8%. In 2014, Hispanic teen birth rates were more than two times higher than the rate for non-Hispanic White teens. In 2013, of new diagnoses in the United States among youth 24 and younger 20% were Hispanic/Latino youth compared to 17% of non-Hispanic White youth. Among male adolescents ages 13-24 living with a diagnosis of HIV infection at the end of 2012 in the US, 20% were Hispanic/Latino compared to 15% non-Hispanic White. Of the new infections in 2015, Hispanic/Latino gay and bisexual adolescent males were infected at the second highest rate. Among females in the age group who were diagnosed, 18% were Hispanic/Latina compared to 13% non-Hispanic White female adolescents.

There are individual, familial, acculturation and immigration-related factors, and trauma-related factors that have been hypothesized to contribute to this self-harm disparity in Latinas. Zayas (2011) postulates that this set of factors can have a debilitating effect on mental health, negatively impacting an individual's ability to cope and increasing the risk for self-harm behaviors. Traumatic immigration experiences and prolonged immigration-related separation between caregivers and youth can also cause

high stress and family disruptions resulting in increased risk for self-harm behaviors. A recent study of Hispanic/Latino youth found that the female adolescents with exposure to a traumatic event and who reported low family cohesion reported more symptoms of anxiety and depression. These findings are consistent with literature pointing to the negative effects of poor family cohesion on symptoms of depression and highlights the importance of identifying and addressing these experiences in treatment to avoid worsening symptom and self-harm. Hispanic/Latino youth may experience family conflict and a loss of family cohesion as they acculturate to the US culture. Studies have suggested that Hispanic/Latino girls and boys have different acculturation experiences and that Hispanic/Latino girls may acculturate faster than boys when they are attracted to less traditional gender roles in the United States. Due to gender role expectations in Hispanic/Latino families, adolescent females report greater responsibilities at home, less freedom to socialize outside of the home, and greater supervision than males. Research has also suggested that females place more importance on interpersonal connections and closeness than males and that Hispanic/Latino females are more negatively affected by family conflict than their male counterparts. Thus, girls may experience more family conflict and less family cohesion when parents and other relatives impose rules on them and when they rebel against these gendered restrictions. As a result of the family disruptions, parenting quality and other protective family factors can decline and the adolescent girl may be exposed to high levels of negative emotion from parents or other family members. These factors may negatively impact her ability to cope and regulate emotions, and impact internalizing and externalizing behaviors leading to self-harm behaviors.

LGBT and Sexual and Gender Minority Youth and Self-Harm

Lesbian, gay, bisexual and transgender youth are a minority group that are at increased risk for self-harm. In the year preceding the YRBSS 2015 survey, 60.4% of gay, lesbian, and bisexual students reported feeling so sad or helpless that they stopped doing some usual activities, 42.8% had seriously considered attempting suicide, and 29.4% had attempted suicide one or more times. LGBT youth are at increased risk of negative health outcomes such as increased rates of STIs/HIV, increased use of alcohol and drugs, and issues related to weight. LGBT youth engage in high risk sexual behaviors such as early age of first sexual intercourse, more lifetime and recent sex partners, and drinking alcohol or being high during last sexual intercourse, and are less likely to use a condom during intercourse than heterosexual peers. They are also five times more likely to use alcohol and drugs than their heterosexual peers. Meta-analyses show that adolescents and young adult MSM show high rates of several serious symptoms including substance use, risky sexual behaviors that can lead to HIV, and self-harm behaviors. Further, these researchers hypothesize that the strong linkages between the rates of these behaviors point to a possible syndemic in which contextual conditions (e.g., marginalization and victimization) may significantly contribute to the co-occurrence of these symptoms.

Minority Stress Theory suggests that sexual minorities experience unique, recurring stressors that lead to unhealthy behaviors. LGBT youth experience homelessness at a higher rate than their non-LGBT counterparts and experience stressors such as discrimination, rejection, violence, abuse, lack of support, and trauma. Previous research has linked PTSD symptoms and self-harm behaviors. A 2016 CDC report

comparing LGB youth to heterosexual youth in high school showed that LGB youth were more likely to be physically forced to have sex (18% LGB vs. 5% heterosexual), to experience sexual dating violence (23% LGB vs. 9% heterosexual), to experience physical dating violence (18% LGB vs. 8% heterosexual), and to be bullied at school or online (at school: 34% LGB vs. 19% heterosexual; online: 28% LGB vs. 14% heterosexual). LGB students were more likely to miss school in the recent past due to feeling unsafe at school. In combination or individually, these risk factors greatly increase the risk for self-harm and/or suicide in LGBT youth. Parental rejection following their child's disclosure has also been associated with various negative outcomes, including depression, substance abuse, academic and conduct problems, and troubled interpersonal relationships.

Hispanic/Latino LGBT youth possess unique cultural factors that place them at additional risk for self-harm behaviors and being both an ethnic minority and a sexual minority results in a compounding of adverse outcomes. A large national study showed that compared with White LGBT youth, Latino LGBT youth were more likely to attempt suicide. Latina LGBT youth had significantly higher rates of suicide attempts in the previous year than any other racial/ethnic group in the study. Latino LGBT boys reported twice the amount of feeling sad in the last year than boys of other racial categories. Fewer than half of LGBT Latino youth have an adult in their family they can turn to if worried or sad, compared to 80% of their non-LGBT Latino peers; and among LGBT youth ages 13-17 who disclosed to their parents, about one-third lacked family acceptance.

Additionally, LGBT Latino youth are more likely to face harassment and violence in the community than their non-LGBT Latino peers. Results of an online survey of approximately 2,000 LGBT Hispanic youth suggest that they may experience differences in the process of coming out, parental and family support, and the extent to which they feel a sense of belonging in their community when compared to non-Hispanic White LGBT youth. Hispanics are among the most religiously observant populations in the country and while faith can be a protective factor, it can conflict with an LGBT identity.

Issues in the treatment of self-harm risk and its underlying conditions

Research investigating ways to reduce the risk of future self-harm behavior and co-occurring behaviors (e.g., HIV and STIs) should consider factors that help to maintain these conditions and that can be modified through treatment. The literature suggests that depression, emotion dysregulation, family conflict, and substance use can each create the conditions that increase risk for repeated acts of self-harm. For example, studies support the link between non-suicidal self-injury and emotion dysregulation such that engagement in NSSI results in negative affect reduction and emotion regulation. When adolescents report more than one of these conditions, they may be at particular risk for self-harm. Treatment of these conditions can substantially change the course of the syndemic and development long term.

Family based interventions have been among the most efficacious treatments across a wide variety of adolescent disorders including ADHD, Depression, and Disruptive Behaviors and have been recommended for use with the LGBT population. Family interventions are also the preferred mode of treatment for ethnic minority adolescents. The utilization of a treatment that works well for Hispanics is important given the evidence that Hispanics receive less treatment, poorer quality treatment, and treatment that is not culturally competent. Statistics show that Hispanics utilize mental

health services at half the rate of non-Hispanic Whites despite reporting more mentally unhealthy days.

Despite the efficacy of family-based interventions, there have also been major implementation challenges that require continued treatment innovation. One set of implementation challenges includes: sustainability of a multicomponent treatment that requires considerable staff time to deliver, difficulties related to scheduling and reaching underserved populations, and transportations. The logistics of frequent office visits may be one of the problems contributing to the underutilization of services by minority adolescents and families. The significance of the proposed Research Project is that it has the potential to deliver services effectively and efficiently—because some of the key interventions are packaged and delivered through a web-based platform that is easy to use, requiring fewer office based visits, and allowing families to access resources at times that are more convenient to families with multiple jobs. The technology can be made more attractive to adolescents, relevant to their concerns, and consistent with their lifestyles. Interventions with prominent technology components may keep adolescents continually engaged in therapeutic activities that would otherwise be confined to scheduled sessions.[31,52] The benefits of technology are described further in the Innovation section below.

A second set of challenges is the difficulty in creating a "one-size-fits-all" treatment. Adolescents and families display great diversity in terms of cultural background, life stressors, strengths and needs, and clinical symptoms. In the proposed treatment, we aim to reduce the risk of repeated incidents of self-harm and suicide related behavior and we understand that to accomplish this goal, our treatment must have interventions that focus on those factors that we hypothesize to maintain the risk. In other words, our treatment must seek to decrease depression, emotion dysregulation, family conflict, and substance use. In order to increase the ecological validity of the treatment sessions, the manualized intervention must also be designed to address the day to day stressors that emerge in the lives of Latina and LGBT youth and that contribute to depression, emotion dysregulation, family conflict and substance use. Content that includes discussion of marginalization, traumatic events, culture-related factors at the individual and family levels must all be clearly articulated in the treatment manual if it is to have a high degree of ecological validity.[6] A major challenge for many manual-guided interventions is that they must adapt considerably to address these unique culture-related (e.g., facing stressors due to acculturation, immigration, discrimination due to race, ethnicity), unique life stressors (e.g., rejection due to being LGBTQ, exposure to trauma, discrimination and rejection), and clinical profiles (e.g., family risk factors, co-occurring psychiatric disorders). When manualized interventions do not clearly articulate the treatment adjustments needed to address these complexities, clinicians are required to make adjustments in an idiosyncratic fashion. These adjustments become challenges to fidelity and become more difficult to replicate. A second area of significance of the proposed work is that it will utilize a culturally informed intervention delivered in an adaptive framework that includes modular material that can be selected to address many of these commonly found stressors (e.g., emotion dysregulation, minority and acculturation stress) and the explicit decision rules that facilitate replication. In the Innovation section below, we describe the adaptive framework of the Culturally Informed and Flexible Family-Based Treatment for Adolescents (CIFFTA).

The proposed study: (a) enhances the content of the original Computer Assisted Culturally Informed and Flexible Family-Based Treatment for Adolescents (CA CIFFTA) to directly address the new key targets (e.g., depression, emotion dysregulation, LGBT and trauma-related stressors), (b) refines the technological aspects of CA CIFFTA for web-based delivery and use feedback and data from our first small trial, and (c) tests the preliminary efficacy of the new intervention and its delivery system in a randomized trial of 100 adolescents and their parents. We seek to reduce risk for repeated self-harm and risky sexual behavior by showing treatment effects on depression, emotion regulation, substance use, and family functioning. With the large numbers of adolescents that go without services due to service utilization obstacles and stigma, technology-related innovations that can enhance treatment effects and/or reduce barriers should be considered an urgent need.

5) **Inclusion and Exclusion Criteria***

Inclusion Criteria: To be included in the study, the adolescent must: (a) be 11 to 18 years old; (b) self-report an act of self-harm in the past 6 months, (c) meet cut-off criteria on two of the four maintaining factors (depression, emotion dysregulation, family conflict, substance use), and (d) live with at least one parent-figure who agrees to participate in assessments and treatment. Participants should be 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 recorded for fidelity/process assessment and supervision). All family members in the household are invited to participate in treatment. Our success at engaging family members is evident in that an average of three family members per household participated in family intervention studies.

Exclusion Criteria: Exclusion criteria include: (a) history of DSM V Developmental Disorders, Elective Mutism, Organic Mental Disorders, Schizophrenia, Delusional Disorder, Psychotic Disorder, and Bipolar Affective Disorder. We will exclude youth who are actively in crisis and reporting current ideation with a specific plan and with means to complete the plan. If a youth is referred in this state, it will be a priority to utilize a warm-handoff procedure to connect them to a more intensive treatment program.

Eligibility Screening: Staff at the referral sites will be trained to identify youth appropriate, namely a self-harm event, for the study. When a youth/family is identified as potentially appropriate the referral site will ask the family to sign a release of information so that study personnel can contact them to schedule a formal screening. If the form is signed, the referral site will contact the designated study personnel (assessor) and provide the contact information for the family. The study personnel will contact the family and schedule an appointment to conduct the screening. When the family attends the appointment, the screening measures (Self-harm, family conflict, emotion dysregulation, depression and substance abuse) will be administered to determine eligibility. (see sections below)

6) Number of Subjects*

A total of 100 11-18 year-olds with a self-reported act of self-harm in the past 6 months and their families will be involved in the proposed study.

7) Study-Wide Recruitment Methods*

NA. This is not a multicenter study. Subjects will be recruited by methods under the control of the local site. See recruitment procedures in section 24) Recruitment Methods.

8) Study Timelines*

Both conditions will be tested as 16-week interventions. There will be an additional 8-week period of continuing care, then 6 months of no contact, followed by a final assessment. The final assessment will occur 12 months after baseline. The duration of an individual subject's participation in the study will be 1 year (including all follow-up assessments).

The duration anticipated to enroll all study subjects is 35 months. Recruitment will begin in month 8 of the study and end in month 43.

The estimated date for the investigators to complete this study (including primary analyses) is 60 months.

9) Study Endpoints*

1. Primary
    a. Self-harm
2. Secondary:
    a. Depression
    b. Family functioning
    c. Alcohol/substance use
    d. Emotional dysregulation
    e. Risky sexual behaviors

There are no safety endpoints in this study.

10) **Procedures Involved***

Procedures for Phase I: During the first months, we will identify existing video taped segments from previous pilot work that can be utilized in this new study, videos that need to be created, and written text from the original scripts can be used as templates. Likewise, scripts that had been previously created for different themes will be modified for this new population and updated. Videos to be delivered on our website will be brief 10-15 minute videos. We will also focus on integrating Motivational Incentives and Motivational Interviewing components, and aftercare interventions into computer supported activities. The development and programming of all applications will take place in this phase. We will organize multiple events so that parents and adolescents can experiment with the use of the technology and give our team feedback on what works well and what can be improved. Feedback will focus on both content and technical aspects of the intervention. The assessment battery will be finalized and lead to the creation of the REDCap battery, which will be for entry of data directly during the interview and for measures of more sensitive issues (e.g., risky sexual behavior). The REDCap system has been utilized successfully in prior research. This phase will also include therapist and assessor selection and training.

Therapist Training. Therapists should have at least a master's degree in counseling, psychology, or a related field. The PI will train the assessor and the therapist who will be bilingual, fluent in English and Spanish, and must have experience working with adolescents and families. Should we need to recruit a therapist less experienced with family therapy, we will utilize the therapist training model we have used in large clinical trials and which consists of a 3-day training workshop that includes the use of didactic material, treatment manuals, and the presentation of videotaped sessions from our pilot work.

Procedures for Phase II: The Randomized Clinical Trial

One hundred adolescents (11-18 years of age) with a self-reported act of self-harm in the past 6 months will be recruited into the study. Following screening, consent and baseline assessment, the adolescents and their families will be randomly assigned to either the (1) Technology assisted -CIFFTA or 2) Treatment As Usual. The comparison condition was selected to test our intervention against a standard of care in the community which is usually delivered in the traditional face-to-face method with no technology. CIFFTA treatment services will be delivered at the Institute for Individual and Family Counseling (IIFC), which is a training clinic for graduate students in the School of Education and Human Development at the University of Miami or virtually via HIPAA compliant Zoom. The IIFC provides affordable counseling services to the local community and serving as a center for counseling research. Families randomized to TAU will be referred to services in the community which will be delivered in person or virtually via HIPAA compliant Zoom. Randomization will be stratified by gender, type of self-harm, trauma exposure and LGBT status. During the treatment phase, the two conditions will be tested as 16 week interventions. We will not try to match face to face intervention hours but we will try to match overall contact hours (in the experimental condition some of these hours will be with technology). During the "continuing care"

phase the CIFFTA families will have the opportunity to interact with the therapist via the website for a period of 8 additional weeks and can access all website resources. To match dosage time during aftercare, TAU will receive telephone calls in which the therapist asks how things are going and reiterates some of the main messages of treatment. The participation of adolescents and families in clinical services and final assessments will end around month 54 of the study. Months 55-60 will focus on data cleaning and logic checks, data base locks, and the analysis, interpretation and reporting of findings. Assessments will be conducted at baseline, 16 weeks post baseline/treatment termination, and at T3: 6 months post completion of continuing care. Assessments will be collected in person or virtually via HIPAA compliant Zoom. Data from self-reported satisfaction with the intervention, youth outcomes, and service utilization outside of the program will be collected throughout the course of therapy.

Participant Recruitment Plan. The research team has considerable experience in running trials with this population. Nicklaus Children's Hospital Inpatient Psychiatry Department will provide referrals to the UM CIFFTA project. They have extensive experience treating the population, which is the focus of this project. This collaboration will allow the teams to work hand in hand through the referral and assessment process. Nicklaus Children's Hospital will not be releasing any information to the UM CIFFTA program. Banyan Health Systems Mobile Crisis Unit (See letter of support) has been operating a 24-hour mobile crisis response team (MCT) for the past decade. The MCT responds to an average of 80 calls per month where approximately 20% are for teens and the vast majority is Hispanic. The unit functions as an outreach service, which provides evaluation and crisis intervention. Following an in-depth evaluation in which current mental health and/or substance abuse issues are assessed, the MCT assists in determining which community services are most appropriate based on need, location and family preference. Additional referral sources are needed, long-time UM partners such as the Mailman Center Adolescent Clinic at University of Miami Medical Campus, ConnectFamilias, the YES Institute, Regis House, Larkin Hospital, the Institute for Individual and Family Counseling within our School of Education and Human Development, and the Miami-Dade County Public School System which has special programs for LGBT youth will be utilized.

Screening and Assessment Procedures. Interested participants will have the study explained to them by UM study personal and will be asked to sign an informed consent/assent and begin the screening of inclusion/exclusion criteria. Paper consent forms will be used for face-to-face interactions. Youth and families participating via HIPAA compliant Zoom will read and review the consent and assent forms virtually through the Zoom screen share option. The consent and assent forms will be sent via email to the family before the online meeting so that the family also has the consent and assent forms readily available. Consent and assent forms will be signed via DocuSign. Screening and assessments will take place either in person or virtually via HIPAA compliant Zoom. Participants that do not meet criteria for the study will receive a referral using warm handoff procedures. Participants that meet inclusion criteria will sign informed consent/assent for the RCT, complete the baseline assessment will be randomized upon completion of baseline and will be given the name of the therapist who

will be contacting them within 48 hours. These activities are conducted by study personnel (UM researchers) at the UM site, the IIFC or virtually via HIPAA compliant Zoom. If a participant is randomized to the control condition, a warm hand-off process will be used to connect the family to an agency staff member for the treatment. If a referral is identified by the Nicklaus Children's Hospital Inpatient Psychiatry Department staff, they will contact the youth's caregivers directly to explain the study. If the family is interested in participating in the study, the Nicklaus staff will obtain a release of information so that the UM staff can contact the youth and caregiver to sign consent, screen and assess the family. If the family is not randomized to the CIFFTA program, the UM staff and the Nicklaus staff will work together to place the youth in an outpatient program in the community. Nicklaus Children's Hospital will not be releasing any information to the UM CIFFTA program. All participants will be assessed again 16 weeks post baseline/treatment termination, and at T3: 6 months post completion of continuing care (12 months after baseline). Bachelor's/Master's level research assistants who are bilingual in English and Spanish will be available to administer all assessments. Each assessment interview lasts approximately 2 hours and consists of two parts, an interview (adolescents and parents separately) and responding to questions on the REDCap. The assessor interviews parents while the adolescent completes the REDCap battery and then they switch. The Measures appendix provides an overview of the measures, the time-points and the target of data collection. To increase participation families will be paid $75 for T2 and$100 for T3 completed assessments. They will receive the money either in person or cash deposits via Zelle. The fees may be slightly higher than studies that work with only one participant. The fee is meant to compensate 2-3 participants (typically adolescent and two caregivers) for 2 hours of assessment time. Interview data are entered directly into the REDCap system. In addition to the baseline assessment that all families receive at the start of the study, families will be asked to participate in an additional semi-structured interview right after the baseline (1 hour semi-structured interview for the child and 1 hour for the parent/caregiver). This interview is voluntary and asks additional qualitative questions about family functioning and self-harm to gather details on these concepts (these types of questions are asked in the baseline and follow-up assessments). To compensate for each family's time participating in these interviews, each youth will be offered a $15 gift card to either Target or Amazon and each parent/caregiver will also be offered a $15 gift card to either Target or Amazon.

Therapist Supervision and Adherence Monitoring. Weekly clinical supervision/consultation meetings will be held for the CA-CIFFTA, led by Dr. Mena. Recorded therapy sessions will be reviewed and good manual implementation will be emphasized. In the CA-CIFFTA condition, reports generated weekly showing usage (in minutes) of the web-based components will be reviewed. An independent adherence rater trained to rate therapy sessions will randomly select 20% of the CA CIFFTA sessions at different phases (early, mid, and late) of treatment. Ratings that fall below adequacy on any dimension/component will trigger increased supervision focus for that dimension and if necessary, re-training. The condition supervisor will be 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.

Prevention of Dropouts from the study. To ensure sample retention procedures include: 1) conducting assessments at convenient locations when necessary(e.g., homes), 2) paying families for their participation in assessments, 3) conducting service utilization phone interviews between the T2 and T3 assessments and updating all contact information at regular intervals, 5) obtaining the names of three contact persons who may be contacted by the Assessment Specialist when the family is unreachable (included in the consent form), and 6) sending out birthday and holiday cards to all participants. In our experience, the utilization of such procedures for tracking and contacting participants dramatically increase retention rates in the study. In our previous large NIDA randomized trial with high–risk Hispanic youth with Substance Abuse Disorder, we were successful at obtaining approximately 75% of the caregiver and 70% of the adolescent scheduled assessments 16 months after baseline.

Control/Comparison Condition: Treatment As Usual

Once a participant is engaged, assessed, and randomized to TAU, the crisis team will refer to their usual treatment agencies in the community and complete the warm handoff of the participant and share the assessment data we have collected. We will coordinate carefully with the TAU agencies so that we can minimize the overlap of data collected. Banyan will often provide the service needed by the TAU participants but will refer out to other services when those agencies and their locations are more convenient. Our long-standing collaboration with Banyan will facilitate the coordination of assessment measures and ensure a successful warm-handoff of clients. Services will be delivered in person or remotely via Telehealth. Considerations in selecting the comparison condition. A great deal of thought has gone into the selection of the Treatment as Usual condition. We wanted to compare CA CIFFTA's ability to retain and bring about change in participants compared to what is typically done in the community. Although running an in-house comparison condition gives us more control of the delivery of services and tracking of clients, it would be difficult to know how that compared to the services that are typically provided in the community. Service utilization interviews will allow us to track the precise services that are received in the TAU condition.

Treatment Condition: Computer Assisted Culturally Informed and Flexible Family-Based Treatment for Adolescents (CA CIFFTA).CA CIFFTA will consist of a hybrid intervention utilizing some Office Based CIFFTA sessions and some technology-delivered material (e.g., psycho-educational modules and the collect of information on risk patterns and situations). CIFFTA will be delivered in person or virtually via HIPAA compliant Zoom. During the treatment phase CIFFTA participants will be offered 1. 5 hours of contact per week that includes 45 minutes of face-to-face time per week plus approximately 45 minutes of intervention time delivered via the web over 16 weeks. During the 8 week continuing care phase participants will continue to access the website and its resources and will receive targeted messages focused on how to handle the conditions found in T2 that might be expected to fuel relapse (family or interpersonal conflicts and continuing depression). CA CIFFTA will: 1) deliver psycho-educational modules (e.g., depression, risky sexual behavior information, emotion regulation and distress tolerance, handling marginalization, coping strategies for traumatic experiences) via multimedia formats that include text, audio, video and graphics,2) facilitate contact

with the counselor via computer-based messaging, 3) collect diary-card type information (e.g., affective struggles, high risk environmental cues) to be used in treatment, 4) document usage of all website components, and 5) facilitate continuing care (post-treatment) checkups to prevent relapse. Many of the videos originally created for the original CA-CIFFTA (e.g., psycho-educational material on adolescent depression, substance use risk, risky sexual behavior, and others offered in both English and Spanish) will be updated/enhanced. As in the pilot, parents and adolescents will watch videos and click the symptoms of concern to them. This information will be automatically transmitted to therapists and used in the next session.

***T*he modules proposed are presented in the table below**

	Family Sessions		Adolescent Sessions	
	Treatment	Psycho-educational Modules (M= Mandatory O= Optional)	Treatment	Psycho-educational Modules
Early Stage	-Engage family members -Assess family History -Identify core family themes -Tailoring treatment -Motivational Interviewing	-Co-occurring adolescent disorders (M) -Parenting Module (M) -Health Promotion (M)	-Engage adolescent -Motivational interviewing -Goal Identification -Tailoring treatment	-Co-occurring disorders(M) -Health Promotion (M)
Later Stage	-Strengthen parenting practices -Strengthen parent-adolescent attachment and relatedness -Ensure a safe, predictable, validating home environment -Improve communication -Help parents understand and work with core adolescent issues and stressors	-Separations (O) -Safety from bullying (O) -Acculturation Stress (O) --Divorce (O) -Discrimination (O) -LGBT support -Consequences of trauma -Self-harm risk factors -Substance use risks	-Monitor behavior hidden in family sessions -Improve decision making -Prepare for family interactions -Understand co-occurring disorders and relapse	-Interpersonal effectiveness(O) -Teen Dating (O) -Emotion regulation (O) -Distress Tolerance(O) -Mindfulness(O) -Safe coping following traumatic events (O) -Risky sexual behavior (O) -Substance use risks

CA CIFFTA will facilitate the tailoring of the intervention making the intervention strategies and the timing of health messages unique to individual high risk youth. The initial assessment identifies the high risk areas reported by adolescents and parents (e.g., emotion dysregulation, low distress tolerance, depression, substance use, family conflict, acculturation-related conflicts) and these data are used to create a "tailoring profile". When an adolescent is high on any of the indicators shown above, the treatment is tailored to include the corresponding modules on emotion regulation, distress tolerance, working through acculturation-related conflicts, and substance abuse and risky sexual behavior information for both parents and youth. Participants can access content on the website specifically selected for them. Mobile assessments may be able to identify the high-risk times of the day, places, interpersonal (e.g., conflicts with family or peers) and intrapersonal (e.g., feeling bad due to boredom, frustration) processes that constitute risk for that individual. This method is similar to diary card methodology developed by the Linehan/DBT research group to identify high risk situations, emotions, people and times. During the continuing care period, messages that have been found helpful to the adolescent and related to their risk process will be delivered periodically. The Center for Research and Education on Aging and Technology Enhancement team has experience

delivering interventions through a variety of telephone technologies (e.g., screen and video phones)[26,27] and they have partnered with the PI in the pilot work that is the precursor to this more advanced effort.

The technology system will collect usage data that will be securely housed on the project servers. Data will be collected without requiring that the participant actively send them. Interaction and usage information is automatically delivered to the counselor's cellular phones via an existing secure server housed at the University Data Center. Data collected in real-time do not contain names or identifying information, only case numbers. In addition, the system will require a password to see messages sent to the participant. Physical access to servers at the Data Center are controlled by security systems, intruder alarms, and monitored by the Department of Security video surveillance/recording systems. The Data Center provides appropriate environmental control via HVAC systems, uninterruptible Power Supply and emergency generators to maintain power without interruption, and FM200 and Inergen fire suppression systems to extinguish fires without damaging equipment or backup tape systems. The Data Center also provides secure backup for all data systems. Real-time information sent to counselors was successful in guiding the counselors' work in our preliminary study. For development purposes, we will set-up a desktop development environment with Android SDK and an alternate development environment for development in iOS. We will also subscribe to Apple's iOS developer program.

Adaptations for youth who report being LGBTQ and/or exposed to trauma, and families. CIFFTA's design lends itself to adaption to diverse populations. Its logic and emphasis on tailoring facilitates the treatment's extension to new populations with unique stressors. During the development phase of this study (first 7 months) we will build on existing modules. Some of the expected adaptations will focus on modules for kids on how they can cope with stressors related to LGBT-related rejection and alienation, emotion regulation and distress tolerance for ameliorating self-harm behaviors, using evidence-based coping strategies for risk factors result from exposure to traumatic events (see Seeking Safety strategies). A module for parents who are having a hard time accepting their son's/daughters being a gender/sexual minority youth will help them to understand the normative stages some parents must go through, allow parents to express their concerns, distress, and fears, so that they are more ready to have a productive family therapy session with their sons and daughters. A parallel module may be offered to youth to increase their readiness to have a family session in which a loving and caring relationship can be created.

Measures*:* Measures have been selected for: 1) Screening; 2) Ultimate Adolescent Outcomes, e.g., Self-harm; 3) Immediate Outcomes, e.g., depression, emotion regulation, family conflict, and substance use; 4) Cultural Factors; and 5) Additional Measures, e.g., trauma, minority stress. Measures will be administered at Screening, Baseline (T1) 4 months after baseline (Termination or T2), and 12 months after baseline (T3). Spanish versions of the measures are available. Every effort has been made to reduce participant burden. The total battery is expected to take 90 minutes to administer to youth and 40 minutes to parents. These will be administered in person or via HIPAA compliant Zoom. Measures are attached.

11) Data and Specimen Banking*

NA.

12) Data Management*

Data will be collected using the REDCap web-based system. The REDCap data will be collected on secured laptops and the data will be stored on the University of Miami secure data network. REDCap is a web-based data management system that is backed-up and supported on site at the University of Miami. REDCap acts as a central database for facilitating processes related to study and patient management, including scheduling/calendaring, data collection via electronic CRF, data and safety monitoring, study reporting, and milestone tracking. Access to the system is limited to authorized users. Each user has his/her own individual username and password managed by the University single sign-on system. Only authorized members of a study team have the ability to identify a patient associated with their study. Key personnel and their roles on IRB approved protocols are used by the UM REDCap support team when establishing access rights. Changes to study or patient information require a user e-signature for validation as an extra precaution.

Patients associated with this study will have their ongoing study-related status tracked using this system. All study measures will be programmed electronically in REDCap and will be used to collect the data. The assessor will interview the parent using the REDCap system where responses to questionnaires will be entered directly into the web-based system. At the same time, the adolescent will also be completing questionnaires on the REDCap system. Upon entry into the study, participants will be assigned a study ID and will only be identified with the study's ID code for the participant on all measures. The codes that link the name of the participant and the study ID will be kept confidential in a secured cabinet. All documents collected which contain the names of participants will be kept confidential in a locked cabinet, in a locked room at the UM School of Education and Human Development. The study statistician will analyze the data.

Procedures for the proposed study will follow quality assurance (QA) procedures established by CLaRO for data management and safety, to ensure quality and consistency in the implementation of the protocol and data quality, to adhere to regulatory requirements and, most importantly, to protect the safety of study participants. All CLaRO studies will have a QA review prior to initiation which must be passed before commencing study enrollment, upon conducting baseline procedures with the first five study participants, and then every 4 months for interim reviews. For the initiation review the Study Monitoring team reviews protocol procedures and their manualization, documentation of staff training, evaluates that the study site is prepared to conduct the study, and ensures that the Regulatory

Binder is complete. Interim monitoring visits verify that study screening, consent, and data storage procedures are being conducted as stated in protocol, review 100% of informed consent and assent forms, and review a random selection of 10% of case files (all of the first five cases are reviewed in the first interim QA visit) on the following parameters: eligibility criteria and documentation, randomization documentation, lab records, data reports, study milestones, progress notes, intervention documentation, participant remuneration receipts, and verifying that time points are completed according to protocol. After each QA visit the Study Monitoring team prepares a written report that is sent to the study PI and to the corresponding CLaRO PI. These reports include deficiencies noted and plans for corrective action. The Study Monitoring team follows up with the study team to ensure that the corrective plan and any required reports to the IRB are filed in a timely manner. Protocol violations that are recurrent or serious will be brought to the attention of the CLaRO Executive Committee for determinations regarding corrective action.

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

DATA SAFETY MONITORING BOARD AND PLAN

Composition of DSMB

This proposed study will have a Data Safety Monitoring Board (DSMB) consisting of three individuals: Dr. Guillermo Prado, Dr. Brian McCabe, and Dr. Soyeon Ahn. The Chair of the Committee will be elected during the first meeting.

Guillermo Prado, Ph.D. is Dean of the Graduate School, Leonard M. Miller Professor of Public Health Sciences, Director of the Division of Prevention Science and Community Health at the University of Miami. He has a doctoral in epidemiology and a master's in statistics. His research broadly focuses on the development and evaluation of parenting interventions for Hispanic youth and their families. Dr. Prado's research has been funded by over $15 million dollars of continuous NIH funding as PI since the first year of his doctoral program and by over an additional $80 million as Co-I or mentor. As Dean of the University of Miami's Graduate School, Dr. Prado has developed programming around responsible conduct for research, professional development, and grantsmanship for all graduate students at the University of Miami. Dr. Prado has also had key roles in training components on NIH funded centers of excellence. He was the co-chair of NIDA's Center for Prevention Implementation Methodology as well as Director of Training for an NCI funded U54. Dr. Prado is currently the Director of the Investigator Development Core of the NIMHD funded Center for Latino Health Research Opportunities. Finally, Dr. Prado is President-Elect of the Society for Prevention Research and a Board Member of Research!America, the country's largest not-for-profit public education and advocacy alliance committed to making research to improve health a higher national priority.

Brian McCabe, Ph.D. is an Assistant Professor in the Department of Special Education, Rehabilitation, and Counseling at Auburn University. He earned his PhD in Counseling Psychology at the University of Miami. Dr. McCabe researches prevention and intervention strategies using an eco-developmental approach. This work examines the interactions between risk and protective processes, specifically connections between mental health, substance use, sexual behavior, and social relationships for people in varied life stages. Recent projects have been with Hispanic/Latinx immigrants and college students.

Soyeon Ahn, Ph.D. is a Professor at the University of Miami School of Education and Human Development. Currently, Dr. Ahn is the director of the Statistical Supporting Unit at the School of Education and Human Development Dunspaugh-Dalton Community and Educational Well-Being (CEW) Research Center and is the Associate Dean for Research. Dr. Ahn's research focuses on the application of the existing data analytic techniques in resolving the complicated data issues in meta-analysis (research synthesis). She has published numerous methods papers and several peer-reviewed articles on the application of meta-analytic methods in educational and behavioral science have appeared in substantive journals such as Scientific Studies of Reading, Journal of Pediatric Psychology, Journal of Counseling Psychology, and Research Quarterly for Exercise and Sport (RQES). She has served as an ad-hoc reviewer for journals including JEBS, RER, BRM, Research Synthesis Methods, Psychological Reviewer, Educational Reviewer, and RQES. Dr. Ahn is a member of: (1) Society for Research Synthesis Methodology (Elected in 2013), (2) Campbell Collaboration (C2) Methodology Group, and (3) American Educational Research Association (Division D: Measurement and Research Methodology). She has served on the grant review panels for several programs in the National Science Foundation since 2011. Dr. Ahn has been involved in doctoral research methodology training and statistical support for educational and behavioral science research occurring within and outside the University. She also teaches several higher-level statistical courses.

Charge of the Board DSMB

The purpose of the DSMB will be to provide oversight on the human subject issues described in the protocol, including review (overall and by condition) of the number and type of adverse and serious adverse events. The trial is focusing exclusively on two high risk groups, Hispanic females and Hispanic LGBT youth with a history of self-harm. Adverse events that will be monitored include, but are not limited to psychiatric hospitalizations, suicidal attempts, arrests and child abuse, including sexual abuse. The DSMB will be blinded to condition but will review the number of adverse and serious adverse events by condition in group format. If it becomes apparent that there may be an imbalance by condition, the DSMB will offer its recommendation to the PI regarding the conduct of the trial. Any action that results in the temporary or permanent suspension of the trial will be undertaken with consultation with the study's NIMHD project officer and University of Miami's IRB. The DSMB will provide a copy of the meeting's minutes to the PI.

The University of Miami IRB will provide general study oversight for all grant activities. The Principal Investigator will report DSMB activity to NIMHD as part of the Annual Progress Report.

Statement of No Conflicts of Interest
None of the DSMB members have any conflicts of interest to report, other than they are faculty at the University of Miami.

Frequency of Meetings
Drs. Prado, McCabe, and Ahn will convene as a DSMB three times a year (i.e., every four months).

PI Acknowledgment of Requirement to Report DSMB Activity
Daniel Santisteban, Ph.D, the Principal Investigator, understands that he is required to report DSMB activity in the Annual Progress Report to NIMHD.

The DSM and DSMB reports will include the participants' sociodemographic characteristics, treatment retention rates, any quality assurance or regulatory issues that occurred during the previous year, a summary of AEs and SAEs (Adverse Events and Serious Adverse Events), and any actions or changes with respect to the protocol. The DSM report to NIMHD will also include, when available, the results of any efficacy data analyses conducted. The PI will also: 1) determine if an AE or SAE was study related and to what degree, 2) determine whether an AE or SAE that are study related are listed in the Informed Consent Form or should be listed, 3) ensure that when the AE or SAE was discovered, if it was related and/or possibly related to the study procedures that there was timely and complete reporting to IRB.

AEs and SAEs are sometimes more difficult to identify in behavioral research with adolescents. Based on our experience working with high-risk youth, we have identified common AEs and SAEs that occur in this population, that will be used in training staff to identify AEs and SAEs, and that will be reported during protocol implementation.

Adverse Events	Serious Adverse Events
1. Arrest	6. Physical/Sexual Abuse
2. Runaway	7. Suicidal Behavior
3. Kicked out of Home	8. Homicidal Behavior
4. School Suspension/Expulsion related)	9. Hospitalization (psychiatric, drug
5. Violence (Victim/Exposure)	10. Death
	11. Other (indicate if serious)

Adverse events for this study may be identified during regularly scheduled intervals or may be reported at any other times during the study. For adolescents and their parent/caregivers that are participating in assessments, the ten adverse events listed above will be queried specifically at T2 and T3 time points. An "other" category has been included to capture unexpected adverse events reported by participants, which do not fall

within the scope of any of the ten defined AEs/SAEs for this study. All assessments conducted by the study assessor are opportunities for identifying adverse events if reported by the participant and/or a family member. The assessor will be trained to identify AEs and SAEs at each of the time points. Additionally, anytime during the study, a participant or his/her family member may report an AE/SAE to their therapist. These events will be identified, classified as serious or not**,** and will be handled in the same manner as AEs/SAEs during the formal assessments.

Therapists will be trained to identify adverse events, and categorize serious adverse events, based on direct reporting during sessions. Upon identification of an adverse event, the assessor or therapist should categorize the event for seriousness to guarantee that appropriate care and reporting occur within approximately 24 hours. As soon as an adverse event is identified either by querying or direct report, the event will be recorded in the AE log. In addition, the PI and Clinical Supervisor at the site will be notified of any and all AEs. In both treatment conditions, action may be taken by the therapist to respond to non-serious events (e.g., booster sessions, or increase in the frequency of sessions). If a therapist is the one to identify the event, after notifying the PI and Clinical Supervisor, they are to notify and inform the assessor, who is then responsible for conducting further evaluations and completion of the AE log. All non-serious adverse events require no further reporting. Adverse events will be reviewed by the Principal Investigator (PI) weekly to evaluate relatedness to the intervention and whether resolution occurred. Ser“serious and non-serious events that are

SAE’s include 1) Physical/Sexual Abuse 2), Suicidal Behavior, 3) Homicidal Behavior, 4) Hospitalization (psychiatric or drug related), and 5) Death. All of these problems may involve imminent danger to self or other. In cases of current suicidal, homicidal, and abusive behaviors, participants in both conditions will be immediately referred to the clinical supervisor to ensure that appropriate crisis intervention services are provided. Serious adverse events listed in this study will also be reported for any family participant. The reporting procedures for SAEs experienced by any participant in the study will be in accordance with the University of Miami IRB reporting policy and determining whether they are unexpected and probably related or expected and non-related will guide reporting. When an SAE occurs, the Clinical Supervisor and the PI must be notified when possible within 2 hours of identification. The Clinical Supervisor will be responsible for ensuring appropriate and timely care of participants. The PI will be responsible for assessing relatedness to the intervention and forwarding the report to the UM IRB and study sponsor. In the event that a participant either withdraws from the study or the PI decides to discontinue a participant due to an SAE, the participant will be monitored by the PI via ongoing status assessment until 1) a resolution is reached or 2) the SAE is determined to be clearly unrelated to the study intervention. Outcomes of the SAE will be reported to the sponsor on a quarterly basis. A summary of the SAEs that occurred during the previous year will be included in the annual progress report to the sponsor.

Study assessors will contact participants in the TAU condition one time per month via telephone to monitor AEs and SAEs that may have occurred as well as to offer referrals

to the youth/family if needed. The procedures to be followed by the assessor are detailed below.

Telephone contact:

The assessor will contact the parent figure and the adolescent and will speak to each one separately.

Questions to Ask Parent

- How has ____ been doing in the last month?
- Has there been a change in the problems that brought _____ to our program?
- Questions should be specific to intake assessment e.g. ADHD, Depression, Anxiety, Violent or Aggressive Behavior, Drug use, Suicidal thinking, gestures or attempts, etc.
- If there has been a deterioration in functioning in core area (school, peers, severe family conflict) ask for specific behaviors or incidents that occurred in the last 4 weeks. (Check for occurrence of AEs and SAEs)
- Has the youth been attending therapy?
- Has the youth been admitted to a crisis or inpatient treatment program?

Questions to ask Adolescent

- How have you been doing in the last month?
- You were having some problems with (ADHD, Depression, Anxiety, Violent or Aggressive Behavior, Drug Use, Suicidal thinking, gestures or attempts, Self harm without suicidal intent, etc.) when you first came in, how are you doing today?
- Have things become worse or better for you?
- If there has been a deterioration in functioning in a core area (school, peers, severe family conflict) ask for specific behaviors or incidents that occurred in the last month. (Check for occurrence of AEs and SAEs)
- Have you been attending therapy?
- Have you been admitted to a crisis or inpatient treatment program?

Criteria for Referral **(**if not currently attending therapy**)**

- Suicidal thinking, gestures or attempts
- Self-Harm without Suicidal Intent
- Violent or Aggressive Behavior
- Moderate to Severe Depression
- Moderate to Severe Anxiety
- Significant Deterioration in School Functioning (may be related to ADHD or other problems)
- Significant Increase in Drug Use
- Significant Deterioration in Family Functioning

Community Referral Sources

- Banyan Health Systems
- Regis House

14) Withdrawal of Subjects*

Participants will be told that this study is completely voluntary and that they have the right not to participate in any intervention procedure. They can also completely withdraw from the study at any time without any negative consequences.

Participants will be told that their participation in the study may be stopped at any time by the investigator of the sponsor without their permission. Possible reasons for removal may include: 1) adolescent is at particular risk for self-harm and more intensive services are needed or 2) adolescent is not attending treatment sessions and may be at risks for self-harm and/or other risky behaviors.

15) Risks to Subjects*

No side effects have been noted in the current literature in association with the behavioral questionnaires, interviews, or assessments 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 some risk in this type of study because of the higher than average incidence of high risk behaviors, such as self-harm that may require that we report some information to outside agencies. All of the steps that may be taken to protect the well-being of family members deemed to be in danger will be described fully to all participants and we will do everything possible to minimize harm to the youth, family or any of its members. The Principal Investigator has conducted six treatment development randomized trials with high risk adolescent populations, including one with adolescents meeting DSM IV criteria for Borderline Personality Disorder, and is highly experienced in working with youth and ensuring their protection from any undue risks.

16) Potential Benefits to Subjects*

There may be direct benefits to participating in this study. The most important benefit from participation in this study will accrue to adolescents who decrease their self-harm behaviors and risky sexual behaviors and improve their psychosocial functioning and family functioning. Families will also receive a total of $175 if they complete all assessments.

17) Vulnerable Populations*

Children ages 11-18 will participate in this research study, which meets the additional regulatory requirements described in the HHS regulations, Subpart D. The study protocol, assessments, and consent/assent forms will be submitted to the UM IRB for review and approval. All children (11-17) who agree to participate in the study will sign IRB approved study assent forms. Youth who are 18 years old will sign study participant consent forms. Parent/caregivers will be required to give permission for their child to participate in the study.

The purpose of the research is to build on the Computer Assisted CIFFTA intervention by creating a web-site and web-based delivery system and by adding content that is relevant for the factors that maintain self-harm in Latina adolescents (e.g., depression, family conflict, substance use, and emotion dysregulation) and for unique stressors often linked to sexual/gender minority youth. Selecting youth in middle school and high school (11-18) is justified given the nature of the study and specific research questions to be addressed. CIFFTA was designed and developed for youth in this age range and their families.

The Principal Investigator has conducted six NIH funded trials focused on developing and testing a treatment intervention for high-risk minority youth and their families and has expertise in working with youth. The Project Coordinator/Clinical Supervisor has been Co-principal Investigator and Investigator on these studies and possesses much experience in working with youth and their families. The entire sample will be comprised of youth and their families therefore there will be sufficient youth for meaningful analyses and results to be derived from the study.

18) Multi-Site Research*

NA. This is not a multi-site research study.

19) Community-Based Participatory Research*

NA. This study is not considered community-based participatory research.

20) Sharing of Results with Subjects*

NA. Participants' improved and symptoms will be discussed as part of the clinical process; however, we will not be sharing individual-level scores (e.g., test results, scores). Overall study results will only be shared with participants who express an interest.

21) Setting

Study personnel will identify and recruit participants from the main recruitment sites, Banyan Health Systems Mobile Crisis Unit, Mailman Center Adolescent Clinic at the University of Miami Medical Campus, ConnectFamilias, the YES Institute, Regis House, Larkin Hospital, the Institute for Individual and Family

Counseling within our School of Education and Human Development, and the Miami-Dade County Public School System which has special programs for LGBT youth will be utilized.

For the CIFFTA condition, treatment and assessment will take place at the Institute for Individual and Family Counseling or virtually via HIPAA compliant Zoom. For the TAU condition, all study assessment procedures will take place at the IIFC or virtually via HIPAA compliant Zoom and individuals in this condition will receive treatment from treatment agencies in the community either in person or virtually via Telehealth.

22) Resources Available

Research Team Qualifications

- **Dr. Daniel Santisteban**

Daniel A. Santisteban, Ph.D., the Program Director is the developer of the CIFFTA intervention that is on the NREPP list of evidence based practices and that is listed on the Children's Trust RFP. He has supervised adolescents and family-based prevention and treatment services in Miami-Dade County for over 25 years. Dr. Santisteban has extensive experience in ensuring high quality training, tailoring of interventions to adolescent/family needs, cultural competence, and creating tools to achieve high levels of fidelity to the evidence based practice.

- **Dr. Maite Mena**

Maite P. Mena, Psy.D. has been a leader in the development and testing of the CIFFTA treatment for over a dozen years and has contributed to all aspects of the CIFFTA program. Dr. Mena has extensive experience in establishing good working relationships with referral sources and other community partners. She has been a key player in the development of teams and procedures that ensure high quality implementation of CIFFTA services. Dr. Mena will co-supervise all study therapist during the CA CIFFTA delivery.

- **Dr. Karina Gattamorta**

Karina Gattamorta, Ph.D. is a Research Associate Professor at the School of Nursing and Health Studies at the University of Miami. In 2013, she was awarded a Diversity Supplement under the supervision of Dr. Daniel Santisteban that allowed her to pursue interests in health disparities research focusing on Hispanic adolescents. She has conducted preliminary research examining the role of families and the coming out experiences of Hispanic sexual minorities. Her research aims to understand and ultimately help reduce health disparities in mental health, substance abuse, and HIV risk among sexual minorities.

- **Therapist(s)**

Therapist(s) will be Masters-level counselors that have experience with adolescents and families and that have expertise in working with diverse families. The therapist will be a Spanish speaker able to provide the intervention in Spanish. The therapist will be trained in CIFFTA and will be capable of providing all interventions within a tailored framework. The therapist(s) will be supervised by Dr. Muir.

Other Resources:

- **Banyan Health Systems Mobile Crisis Unit**

Banyan has been operating a 24-hour mobile crisis response team (MCT) for the past decade. The MCT responds to an average of 80 calls per month where approximately 20% are for teens and the vast majority is Hispanic. The unit functions as an outreach service which provides evaluation and crisis intervention. Following an in-depth evaluation in which current mental health and/or substance abuse issues are assessed, the MCT assists in determining which community services are most appropriate based on need, location and family preference. If additional referrals are needed, long-time UM partners such as the Mailman Center Adolescent Clinic at University of Miami Medical Campus, ConnectFamilias, the YES Institute, Regis House, the Institute for Individual and Family Counseling within our School of Education and Human Development, and the Miami-Dade County Public School System which has special programs for LGBT youth will be utilized.

- **Nicklaus Children's Hospital Inpatient Psychiatry Department-Dr. Janet Rosen.**

23) Prior Approvals

This study was approved by the IRB on 09/01/2017 for an NIH "Just in Time" request.

24) Recruitment Methods

The research team has considerable experience in running trials with high risk-youth who are Hispanic. The main recruitment sites will be Nicklaus Children's Hospital and Banyan Health Systems Mobile Crisis Unit. If additional referrals are needed, community agencies with a long-time research partnership with the applicant such as, the Mailman Center Adolescent Clinic at University of Miami Medical Campus, ConnectFamilias, the YES Institute, Regis House, the Institute for Individual and Family Counseling within our School of Education and Human Development, and the Miami-Dade County Public School System which has special programs for LGBT youth will be utilized.

Staff at the referral sites will be trained to identify youth appropriate with this study and in line with the inclusion criteria stated above. They will explain the study to any adolescent and family interested in hearing about it. Staff will then ask families that are interested to sign a release of information to be contacted by

the research study assessor or the family and Crisis Unit staff may contract our staff together. The assessor will be Bachelor's/Master's level research assistant who is bilingual in English and Spanish and will administer all informed consents, assents, and assessments. The assessor will contact the family's that gave permission and explain the study in more detail to them. If the family is interested in participating an appointment for the adolescent and family to come in and hear more about the study will be set up. If they continue to be interested, they will sign an informed consent and assent, in their preferred language that allows the screening of inclusion/exclusion criteria to be made. After the screening has been conducted, the families that do not meet inclusion/exclusion criteria for the study will receive a referral to an appropriate treatment program via warm-handoff procedure.

Materials used for the recruitment of participants (e.g., flyer) have been uploaded for review.

25) Local Number of Subjects

A total of 100 youth will be accrued locally. The participants' families will also be included in the study.

26) Confidentiality

The issues surrounding confidentiality are of supreme importance and sensitivity because highly personal clinical information will be obtained from the adolescent and their family members. Participants will sign a statement attesting to their understanding that the information they provide will be held as personal and confidential to the extent permitted by law. Consent and assent forms (described above) will clearly state the right to refuse participation at any time. Further, the refusal to participate will not influence any of the services the adolescent or his/her family may receive. In addition to the confidentiality assurances, the participants in the study are protected by a Certificate of Confidentiality under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d), authority delegated to the National Institutes of Health (NIH).

Regarding data/records confidentiality, the UM School of Education and Human Development has an established set of procedures designed to ensure the protection of confidentiality. All project staff will be specifically trained on issues of confidentiality. Due to the use of the web-based REDCap system there will not be any hard copies of the assessment data of the participants. Passwords are used to restrict entry into the REDCap database. There will be very few documents with identifying information (consent forms) and all documents with identifying information will be stored at the UM School of Education and Human Development in locked file cabinets within a locked office. Videotapes, which represent very sensitive clinical material, will also be stored in Box, a secure,

HIPAA compliant data storage system maintained by the University of Miami. Use of the videotapes is restricted to the UM School of Education and Human Development and IRB and PI approved research study staff. It should be noted that in our years of clinical research (over 35 years), not a single incident of violation of confidentiality has occurred.

The technology system that will be used in the study will collect usage data that will be securely housed on the project servers. Data will be collected without requiring that the participant actively send them. Interaction and usage information is automatically delivered to the counselor's cellular phones via an existing secure server housed at the University Data Center. Data collected in real-time do not contain names or identifying information, only case numbers. In addition, the system will require a password to see messages sent to the participant. Physical access to servers at the Data Center are controlled by security systems, intruder alarms, and monitored by the Department of Security video surveillance/recording systems. The Data Center provides appropriate environmental control via HVAC systems, uninterruptible Power Supply and emergency generators to maintain power without interruption, and FM200 and Inergen fire suppression systems to extinguish fires without damaging equipment or backup tape systems. The Data Center also provides secure backup for all data systems.

27) Provisions to Protect the Privacy Interests of Subjects

During the recruitment and consent/assent process, and prior to any data collection, participants will be assured that their information is confidential, and will only be accessed by study staff members. As described above, participants will sign a statement attesting to their understanding that their information will be kept private and confidential to the extent permitted by law. Participants know that they will be assigned unique case numbers (and that their names will not be used) to protect their identity. Participants will be encouraged to ask questions throughout the consent/assent processes and will be provided contact information for both the Principal Investigator (Dr. Daniel Santisteban) and the University of Miami's Human Subjects Research Office.

28) Compensation for Research-Related Injury

NA.

29) Economic Burden to Subjects

NA. Participants may incur costs associated with transportation to and from intervention sessions.

30) Consent Process

For those families that meet the inclusion/exclusion criteria and are interested in participating in the research study, the study assessor will obtain a second assent

from the adolescent and informed consent from her/his primary caregiver to participate in the randomized trial. The assessor will provide the adolescent and family members with a copy of the consent and assent forms in person or via Zoom with the screen share option, and, because subjects may have a low level of literacy, will then read the consent and assent forms out loud. Consent and assent forms will also be emailed to the family. The study assessor will explain to the adolescent and her/his family the purpose and procedures of the study. All of their family members will be asked if they are willing to participate in this study. Adolescents and caregivers will be asked if they are willing to be randomly assigned into one of two treatment conditions: CA CIFFTA or TAU. The assessor will explain that they have no way of predicting which family will receive which kind of treatment because this is established by chance (as if by the flip of a coin). If the family decides to participate, they will get paid $75 at T2 and $100 at T3. The nature of the confidentiality that surrounds research studies will be discussed with the adolescent and family members, explaining that confidentiality is assured to the extent allowed by law. Specifically, that the information they provide is strictly confidential, except for the case of potential abuse of a child, or danger to their own lives or that of others. The adolescent and family members will be informed that information collected from the research instruments will be used only for research purposes and reported in aggregate form and composite case studies (a strategy for creating case studies in which several cases are integrated into a single case study and all identifiers are removed, to protect confidentiality). They will also be informed that therapy sessions will be videotaped, and they will be asked to provide permission for videotaping sessions for supervision, research, and training. Consent and assent forms clearly specify that any family member has the right to request that their videotapes, and corresponding transcripts be erased/destroyed in part, or in whole at any time during the course of the study or thereafter. In addition, informed consent and assent will be obtained allowing research study staff to call three persons who are close to the adolescent and family members for the purpose of contacting families that may be unreachable at any of the assessment time points.

Once the entire consent and assent form has been read and explained, the assessor will give the adolescent and family members a chance to ask any additional questions. If the family agrees to participate, they will be asked to sign the informed consent and assent forms and will be given copies of each signed form. Youth and families engaging in the consent process via HIPAA compliant Zoom will sign the consent and assent forms with DocuSign. If they do not want to participate, the referral procedure listed above for screen failures will be followed. After the adolescent and family sign the consent and assent forms the assessor will establish a convenient date and time for conducting the baseline assessment (T1). Although most assessments will be completed at the office, some may be done in the participant's home to facilitate data collection. The entire consent and assent process, will be documented by the assessor in the form of a study contact note.

The consent and assent forms for participation in the study and for videotaping family therapy sessions are submitted within this protocol for approval to the University of Miami Institutional Review Board (IRB) Behavioral Subcommittee for the Protection of Human Subjects.

Non-English speaking participants will be provided with consent and assent in Spanish. Consent forms have been translated and back-translated by study personnel.

Waiver or Alteration of Consent Process – NA.

Subjects who are not yet adults, which include adolescents ages 11-18 in the current study will go through a similar process for as their parents/family (explained above). After the parent or guardian has consented, study personnel will provide the assent form to the adolescent.

Cognitively Impaired Adults – NA.

Adults Unable to Consent – NA.

31) Process to Document Consent in Writing

We will be following the "SOP: Written Document of Consent (HRP-091)." Consent and assent forms have been uploaded for review.

32) Drugs or Devices

NA.