Official Title: Community study of Outcome Monitoring for Emotional disorders in Teens (COMET)

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1) Protocol Title

Community study of Outcome Monitoring for Emotional disorders in Teens (COMET)

2) IRB Review History*

This project will be concurrently reviewed by the University of Connecticut Institutional Review Board (IRB), 860-486-8802.

3) Objectives*

Emotional disorders, encompassing a range of anxiety and depressive disorders, are the most prevalent and comorbid psychiatric disorders in adolescence (Costello, Mustillo, Erkanli, Keeler, & Angold, 2003). Evidence-based therapies (EBTs) exist for single disorders (e.g., depression) or small clusters of disorders (e.g., anxiety disorders) but such EBTs are rarely integrated in community mental health clinic (CMHC) settings (Weiss, Catron, & Harris, 2000) and effect sizes are modest (40-50% of youth are treatment non-responders; (Walkup et al., 2008). Thus, methods for improving outcomes for these youth, particularly in CMHCs, are needed. Transdiagnostic treatment, such as the Unified Protocols for the Treatment of Emotional Disorders in adults (Barlow et al., 2010), adolescents (UP-A; (J. Ehrenreich et al., 2008) and children (Ehrenreich-May & Bilek, 2012), is a promising new approach that uses a small number of common strategies to treat these conditions.

Another novel approach to improving clinical outcomes for youth with emotional disorders in CMHCs is the incorporation of a standardized measurement and feedback system (MFS). Emerging data suggests that MFS alone improves outcomes relative to treatment as usual (TAU) (Bickman, Kelley, Breda, De Andrade, & Riemer, 2011) but this has not been adequately tested in youth. Thus, our first aim is to examine the effectiveness of UP-A and a MFS (Youth Outcomes Questionnaires [YOQ; (Burlingame et al., 2005) relative to TAU, when delivered in CMHCs.

A serious shortcoming of RCTs comparing EBTs to TAU is the confounding effects of increased measurement and feedback to clinicians as RCTs of EBTs often "build in" monitoring that is not part of standard care. This raises the possibility that increased monitoring, rather than the unique treatment components of the EBT, may be responsible for better outcomes over TAU. Thus, the second aim of this proposal is to isolate these effects from UP-A. Finally, this study will examine theoretically-linked mechanisms (both patient and provider level) of treatment outcomes of both the UP-A and the YOQ.

This project is an NIMH-funded collaborative R01 two-site trial (University of Miami (UM) grant PIs Jill Ehrenreich-May and Amanda Jensen-Doss; University of Connecticut PI Golda Ginsburg - for IRB purposes, the UM PI will be Amanda Jensen-Doss). To address the three study aims, adolescents with anxiety and/or depressive disorders will be recruited from CMHCs in Miami and in CT (under the supervision of Dr. Golda Ginsburg at the University of Connecticut). Both adolescents and clinicians will be randomized to one of three conditions: (1) TAU alone; (2) TAU plus YOQ (TAU+); and (3) UP-A plus YOQ (UP-A). Research assessments by Independent Evaluators (IEs), children, parents, and clinicians will occur at baseline, 8 weeks and 16 weeks after treatment initiation and a 3-month follow-up.

The primary aims of this study are as follows:

- **Aim 1:** To examine the effectiveness of UP-A and YOQ compared to TAU. Aim 1 will test whether adolescents treated with UP-A and YOQ (plus TAU referred to as TAU+) demonstrate better response than those receiving TAU alone.
    - **Hypothesis 1:** A higher percent of adolescents treated with UP-A and TAU+, compared to TAU, will be treatment responders at 16 weeks after treatment initiation and at follow-up.
- **Aim 2**: To isolate the effects of evidenced-based measurement and feedback. Aim 2 will examine the relative effectiveness of the UP-A condition to the TAU+ condition.
    - **Hypothesis 2:** A higher percent of UP-A participants will be treatment responders than TAU+ participants at the 16 week and follow up assessments.
- **Aim 3:** To examine mechanisms theoretically associated with UP-A and YOQ.
    - **Hypothesis 3a:** Differences in outcomes between the UP-A and the other two conditions will be mediated by changes in: Distress Tolerance (Using the Behavioral Indicator of Resiliency to Distress; BIRD and Distress Tolerance Scale; DTS) and Behavioral Avoidance (using the Avoidance Hierarchy).
    - **Hypothesis 3b:** Among participants in the TAU+ and UP-A conditions, treatment outcomes will be better for participants whose therapists: 1) rate the YOQ results as more credible, 2) view the YOQ reports more frequently, and 3) discuss the reports with them in session more frequently. Among participants who are flagged as "at risk for treatment failure" by the YOQ, outcomes will be better for those whose therapists report changing treatment strategies in response to the YOQ feedback.
    - **Hypothesis 3c:** Differences in outcomes between TAU and the two treatments using the YOQ (UP-A and TAU+) will be mediated by differences in 1) therapy alliance and 2) therapy engagement.

4) **Background***

Over the last several decades, researchers have developed dozens of disorder-specific evidence-based psychosocial treatments (EBTs) (Chorpita et al., 2011). However, even in the most highly controlled research studies, a substantial percentage of youths with emotional disorders are treatment non-responders (e.g., approximately 40% for anxiety disorders [Walkup et al., 2008], and 52% for depressive disorders [March, Silva, & Vitiello, 2006]). Moreover, the effectiveness of these interventions in community settings has been disappointing. A recent meta-analysis of 52 effectiveness trials of youth psychotherapy concluded that, although EBTs typically outperform TAU, the average effect was small (d =.29) (John R. Weisz et al., 2013). In addition, the adoption of EBTs into community practice settings has been slow (McHugh & Barlow, 2012), 2012), suggesting that these treatments still may not be appealing and/or feasible for clinicians and highlighting the need for improved interventions.

A recent innovation in EBTs that may prove more feasible for use in community settings is transdiagnostic treatment. Transdiagnostic approaches draw from theoretical models that explain distinct conditions via common mechanisms and use flexible treatment strategies to address diverse problems simultaneously. Furthermore, this treatment approach may have quicker uptake by CMHC clinicians because: (1) comorbidity is the rule, rather than the exception for patients in

CMHCs (Jensen & Weisz, 2002), (2) protocols cutting across diagnostic boundaries reduce training burden, and (3) flexible protocols may be more appealing to clinicians (Borntrager, Chorpita, Higa-McMillan, & Weisz, 2009) and more effective than single disorder EBTs (John R Weisz et al., 2012).The primary transdiagnostic intervention examined among youth populations is the Unified Protocol for the Treatment of Emotional Disorders in Adolescence (UP-A), developed by one of the PIs, Dr. Ehrenreich-May (J. Ehrenreich et al., 2008). Since UP-A has been found to be efficacious for complex and comorbid anxiety and depression in a research setting (Allen, Tsao, Seidman, Ehrenreich-May, & Zeltzer, 2012; Bilek & Ehrenreich-May, 2012; Ehrenreich-May & Bilek, 2012; Ehrenreich-May, Queen, Rodriguez, Rosenfield, & Barlow, 2012, November; J. T. Ehrenreich, Goldstein, Wright, & Barlow, 2009; Trosper, Buzzella, Bennett, & Ehrenreich, 2009), a logical next step, and the first aim of this study, is to examine its effectiveness in community settings.

While evaluating the effectiveness of the UP-A in community settings is a sensible next step for the testing and dissemination of this approach, interpretation of a two-condition (UP-A vs. TAU) RCT is confounded by changes in variables other than treatment strategies. Although the assumed independent variable is the novel treatment, EBTs often differ from TAU in other ways. Clinicians in EBT conditions receive regular feedback through standardized assessment and supervision about how they and their clients are doing in treatment. If EBTs outperform TAU, it can therefore be difficult to determine the degree to which these differences are due to the treatment techniques themselves, or to the "confounding effects" of increased outcome monitoring and feedback to clinicians. One strategy to control for these effects is the use of a standardized measurement and feedback systems (MFSs).

MFSs consist of assessment tools, often part of an online system, to regularly track the processes (e.g., therapy alliance) and outcomes (e.g., symptom improvement) of therapy and provide reports summarizing the results of these assessments, often with "alarm indicators" that alert clinicians to treatment nonresponse or ruptures in alliance. These systems were designed to be used in community practice settings, and extensive research with adults suggests that using an MFS, without any additional efforts to change clinician treatment practices, can double the success rates of therapy and result in longer-lasting treatment effects (Hawkins, Lambert, Vermeersch, Slade, & Tuttle, 2004; Lambert et al., 2003; Shimokawa, Lambert, & Smart, 2010). Preliminary evidence suggests that measurement and feedback is also associated with improved youth treatment outcomes (Bickman et al., 2011; Stein, Kogan, Hutchison, Magee, & Sorbero, 2010). However, only one clinical trial has been conducted with youth, and limited examination has been made of its mechanisms of action (Carlier et al., 2012). Using the youth version of the most well-studied adult MFS, the Youth Outcomes Questionnaire (YOQ; (Burlingame et al., 2005), this study seeks to expand the research base on measurement and feedback, including tests of mechanisms of action, and to dismantle the "confounding effects" of increased measurement and feedback from the active mechanisms of a novel EBT for emotional disorders for youth.

5) **Inclusion and Exclusion Criteria***

Both youth and community clinicians will be considered participants in this trial. Two sets of inclusion and exclusion criteria have been developed for both groups, as follows:

Youth Inclusion Criteria:

(1) Male or female adolescents between the ages of 12-18 years at the time of enrollment with:
    (i) Clinically significant symptoms of anxiety or depression at baseline. Evidence of clinically significant symptoms will be defined as a Clinical Severity Rating (CSR) greater than or equal to 4 on any DSM-5 defined anxiety disorder (e.g., generalized anxiety disorder, social phobia, selective mutism, separation anxiety disorder) or depressive disorder (e.g., major depressive disorder, persistent depressive disorder), or an adjustment disorder with depressed mood, anxiety, or mixed anxiety and depressed mood.
    This will be determined via baseline administration of the anticipated research version of the Anxiety Disorders Interview Schedule for the DSM-5, Child Version, Child and Parent Report Forms (ADIS-5-C/P), administered by an independent evaluator on study staff.

(2) The adolescent is determined by the CMHC to be eligible for once weekly outpatient psychosocial services at the clinic and determined by the study IE to be appropriate for outpatient psychosocial intervention (e.g., no major cognitive impairment or active suicidality) based on clinical interview.

(3) The adolescent lives (for at least 50% time) with legal guardian and this guardian is willing to attend treatment sessions and participate in study assessments (every effort will be made to encourage the same caregiver to participate in all assessments).

(4) Adolescent and parent/guardian are able to complete all study procedures in English or Spanish.

Youth Exclusion Criteria:

(1) Adolescents will be excluded if they are receiving concurrent psychotherapy, family therapy or similar psychosocial interventions.

(2) Adolescents who are currently suicidal or who have engaged in suicidal behaviors within the past 6 months will be excluded (or discussed on a case by case basis). Specifically, the evaluator will meet with the IE supervisor and discuss the youth and parent responses obtained during the clinical evaluation and determine whether the youth is currently at risk of imminent suicidality and in need of an alternative treatment. The short version of the Columbia-Suicide Severity Rating Scale (C-SSRS) will be used to screen for suicidality at baseline. The C-SSRS allows the IE to gather information on suicidal behavior, suicide attempts, and presence and intensity of suicidal ideation. The information will be used to identify adolescents possessive or active suicidal ideation, intent or plan.

(3) Adolescents with a substance abuse problem within the last 6 months, as assessed by the CRAFFT and ADIS-5-C/P, will be excluded.

(4) Consistent with prior trials of the UP-A, youth with primary conditions not specified for exclusion (e.g., eating disorders, schizophrenia) will be screened. As long as study staff concur that an emotional disorder treatment focus is appropriate, these youth will be included.

(5) Adolescents with a reported history of intellectual disability or for whom there is substantial evidence (e.g., multiple learning disorders, extensive school-based accommodations for learning) that the cognitive level of the UP-A would make it inappropriate as an individual therapy modality, as determined via Family Background Questionnaire and/or based on PI judgement, will be excluded.

(6) Given additional complexities obtaining informed consent, adolescents who are currently placed in the foster care system will be excluded.
(7) If an agency is not able to provide at least three Spanish speaking therapists for the study, Spanish speaking adolescents and caregivers will be excluded at that agency because they could not be randomized to condition.

Clinician Inclusion Criteria:
(1) Clinicians will be at least part-time employees or completing an approved internship of at least one year in duration at the study clinics.
(2) Clinicians may conduct sessions in English or Spanish, but must be able to speak, read and understand English well enough to participate in English-language training and consultation meetings.

6) Number of Subjects*

The study aims to enroll approximately 222 adolescents aged 12-18 years (111 per site, at Miami and UConn) who meet study criteria. We anticipate that up to 300 participants (150 per site) will need to be recruited and screened to reach this goal.

At least eighteen clinician employees of the participating clinics (at least 9 at the Miami site and at least 9 at the UConn site) will be enrolled initially. Although every effort will be made to retain clinicians recruited to the investigation, it is anticipated that new clinicians will be trained annually to replace any clinician who leaves the organization or terminates study participation. Up to 80 (40 at each site) clinicians will participate in the project.

7) Study-Wide Recruitment Methods*

Though the study will be conducted at multiple sites, recruitment will take place locally at each of the participating clinics. Miami will be recruiting participants and clinicians from CMHCs in FL: PsychSolutions Inc., Chrysalis Health, Inc., Jewish Community Services, Goodman Psychological Services Center, Stop Parenting Alone, Live Well Therapy Group, and Behavioral Aid Solutions. We may also recruit through social media (e.g., Twitter, Facebook, Instagram), by posting advertisements through existing accounts for the CMHCs, CHMC staff, the University of Miami Psychology Department, and/or PI accounts. Specific social media accounts will not be established for the project, but rather we will use others' accounts to distribute materials about the study. At UConn, participants will be recruited through several CMHCs in CT and MA.

Adolescent/Caregiver Recruitment: Adolescents and their caregivers will be recruited from study clinics at the time of treatment initiation through intake staff. At both sites, agencies are given the option to insert four questions regarding the presence of anxiety or depressive symptoms that were adapted from the Patient Health Questionnaire (PHQ-4) into their own screening system in order to identify potential study candidates. If the person completing the phone screen answers "Yes" to any of the questions, the phone screener will next ask whether the family is willing to be contacted by study staff to learn more about the opportunity. Agencies may also opt to use their own method of identifying potential study candidates.

In addition, we will post study flyers in waiting rooms in participating CMHCs and distribute flyers about the study to local referral sources to let them know that the study is taking place in these clinics. These flyers can be used by individuals who refer adolescents for treatment if they want to send families to clinics taking part in COMET. We will also post the recruitment materials on social media. Families who contact COMET prior to contacting these clinics will be screened for the study and referred to one of the study clinics.

Families who appear to meet inclusion/exclusion criteria and express interest in participating will be contacted by study staff and provided additional information about the study. If they are interested in the study, they will be asked additional questions by phone to determine study eligibility. The information script and screening questions are in the document titled COMET Project Phone Screen. If their responses to the phone screen suggest they may be eligible for the study, they will be scheduled for an in-person research assessment, ideally coincident with their CMHC intake. To reduce the burden and risk of participation, all efforts will be made to ensure that treatment initiation is not delayed as a result of study screening procedures. We aim to have participants complete their study screening assessment as close as possible to their initial clinical intake at the CMHC. Families will be informed that they have the option to re-enter the clinic's "as usual" services should they change their mind about participating, feel that the research project is interfering with their access to services, or do not meet study inclusion criteria.

Clinician Recruitment: Eligible clinicians will be volunteers from the participating CMHCs. Clinic directors, in consultation with their staff members, and/or study staff will contact clinicians to recruit them for the study. A flyer has been developed to assist with recruitment. They will be informed that their participation is voluntary and will not affect their relationship with the clinics, and about the possibility that they may not be assigned to receive training in the experimental procedures. They will also be informed that if they are not assigned to one of the experimental conditions, they will have the opportunity to receive the training once the study is over. Therapists who agree to participate in the study will participate in a written consent process, conducted by designated study staff, explaining their role in the study and risks associated with their participation. Therapists who consented to the study and received UP-A training will also be contacted via email and/or phone to participate in a qualitative interview and complete questionnaires (the UP-C/A Therapist Beliefs Questionnaire, the Adaptations to Evidence-Based Practices Scale, and the Abbreviated Multidimensional Acculturation Scale) about their experience delivering the study's treatment programs.

8) **Study Timelines***

Subject participation: Given the flexibility of the UP-A and TAU interventions, the exact duration of subject participation is estimated to be approximately 25 weeks, plus an additional 3 month follow-up. The UP-A is delivered in 8 to 21 weekly sessions, and no treatment duration is specified for the TAU conditions. 25 weeks is estimated to account for any additional time required for screening and intake (though, as noted above, all efforts will be made to ensure that treatment initiation is not delayed as a result of study participation). However, this interval may vary slightly due to holidays, typical clinic closures or other naturally occurring delays.

Assessments will take place at the CMHC, university setting, Center for Autism and Related Disorders office, and/or in another private setting within the community at baseline, approximately 8 weeks after treatment initiation (estimated to be mid-treatment), and approximately 16 weeks after treatment initiation ([post treatment] estimated to correspond with the length of UP-A treatment, based on average number of sessions from a recent RCT of the UP-A). Finally, a 3 month follow-up assessment will take place 7 months after treatment initiation (16 weeks + 3 months). All efforts will be made to have these assessments take place within a window of +/- 2 weeks when they are scheduled to occur.

Clinician participation: Though efforts will be made to retain the same clinicians throughout the study, we anticipate that there will be personnel turnover at the clinic sites. However, the maximum duration of clinician participation will be approximately four years, as this is the estimated timeline for study completion. UP-A clinicians who stopped participating in the larger study will still be invited to take part in the qualitative interview portion of the study.

Recruitment Timeline: We anticipate that recruitment of all subjects across both sites will take approximately 3.5 years.

Investigator Timeline: We estimate that the primary analyses will be completed at the end of the fourth year of the study once all study assessments have been completed.

Table 1: Study Timeline	**Year 1 Months:**				**Year 2 Months:**				**Year 3 Months:**				**Year 4 Months:**			
	1-3	**4-6**	**7-9**	**10-12**	**1-3**	**4-6**	**7-9**	**10-12**	**1-3**	**4-6**	**7-9**	**10-12**	**1-3**	**4-6**	**7-9**	**10-12**
Participant Recruitment and Assessment																
Enrolling clinicians	**X**	**Ongoing as needed**														
Enrolling new adolescent/caregiver participants		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**		
Study assessments		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Data Management Activities																
Final Database Ready																**M-11**
Final Session Recording Collected															**M-7**	
IE Coding of Tapes for Fidelity & Differentiation	**Ongoing for consultation purposes**														**X**	**X**
Data Analysis																**X**
Preparation of manuscripts																**X**

9) Study Endpoints*

The primary study outcome will be treatment response. Response will be defined as a Clinical Global Impression-Improvement (CGI-I) of 1 or 2 at 16 weeks after treatment initiation and at the 3 month follow-up. Secondary outcomes will include scores on the Children's Global Assessment Scale (CGAS), Screen for Child Anxiety Related Emotional Disorders-Youth and

Parent Reports (SCARED/-P), and the Mood and Feelings Questionnaire-Self & Parent Reports (MFQ), as well as diagnostic status on Anxiety Disorders Interview Schedule for the DSM-5, Child Version, Child and Parent Report Forms (ADIS-5-C/P).

The following measures will be taken to monitor data relating to safety:

Throughout the study, trained study staff will monitor participants' risk of harm. It is possible that participants' clinical data might indicate, for example, that a parent or adolescent is at risk (e.g., adolescent or parent reports suicidal ideation, or an adolescent's physical safety or well-being is in question). In order to address such situations, all study therapists and staff will be thoroughly trained in the ethics of conducting research with human participants, and will be thoroughly educated about the project's data safety and monitoring procedures. All such incidents will be reported immediately to the principal investigators, and, if necessary, to the local IRB according to their policies.

In addition, we will use the short version of the Columbia-Suicide Severity Rating Scale (C-SSRS) at baseline, 16 weeks, and 3 month follow-up and following any evidence of suicidal ideation or significant adolescent deterioration. The C-SSRS allows the IE to gather information on suicidal behavior, suicide attempts, and presence and intensity of suicidal ideation. The information will be used to identify adolescents possessive of active suicidal ideation, intent or plan that may need to be excluded due to needs for more acute care.

If clinical or questionnaire data indicate that a child is showing a notable decline in functioning during the course of the study, this will be discussed with the child's caregiver and the child will be referred for additional and/or alternative treatment if appropriate.

10) **Procedures Involved***

Study Conditions:

This study will involve 3 arms, with participating adolescents and clinicians randomized within sites to each arm. Each of the treatment arms is described below:

The Unified Protocol for the Treatment of Emotional Disorders in Adolescence (UP-A): The UP-A is an emotion-focused, transdiagnostic approach for adolescents (ages 12-18) with a primary emotional disorder. It is a developmental adaptation of the Unified Protocol, a transdiagnostic treatment for adults with emotional disorders. Clinicians present all skills in the context of the emotions most salient to presenting concerns and adolescent/caregiver conceptualizations of treatment needs, thereby personalizing treatment. The UP-A is delivered in 8-21 weekly sessions, with clinician flexibility regarding the sequencing and depth with which various sections are presented to clients and caregivers, as well as the emotions targeted during the course of the intervention.

A parent or primary guardian is asked to attend all sessions of the UP-A, although the degree of involvement varies based on clinical need. At a maximum, clinicians may elect to use optional parenting materials throughout treatment and for up to three parent-alone sessions. These sessions use the guiding acronym ICE (Independence, Consistency and Empathy) to reinforce youth session materials and problem-solve concerns common in the parenting of youth with

emotional disorders (e.g., overprotection, conflict, etc.). Clinicians assigned to the UP-A Condition will also use the YOQ, as described below.

Treatment as Usual + Youth Outcomes Questionnaire (TAU+): Clinicians in the TAU+ condition will use their "as usual" therapy practices, but will be asked to use the YOQ during every session. The YOQ consists of parent- and youth-report measures of symptoms and alliance administered weekly on a tablet computer. The YOQ online system then generates reports to provide clinicians with systematic feedback about client progress, flagging "critical items" that have been endorsed (e.g., suicidality, hallucinations), presenting graphs of ratings over time, and providing empirically-derived "alerts" when clients are failing to progress or showing deterioration. Clinicians will be trained to use this feedback to modify treatment as needed, share it with families as appropriate, and use it to enhance use of supervision. The TAU+ and UP-A clinicians will use identical versions of the YOQ.

Treatment as Usual (TAU): Clinicians assigned to the TAU condition will be instructed to use whatever treatment methods and outcome monitoring strategies they typically use with adolescents with internalizing disorders. Neither the Miami nor UConn clinics currently use any measurement and feedback strategies.

Clinician Training and Consultation:

UP-A: Training for the UP-A will consist of approximately 12 hours (e.g., one to two day workshop, role-plays, and knowledge checks to ensure comprehension of materials) followed by ongoing weekly one hour consultation. Dr. Ehrenreich-May will lead trainings at both sites, hold weekly cross-site calls and oversee assessment of adherence to ensure fidelity to the treatment model over time. The UP-A consultation for each clinician's first case will be provided directly by Dr. Ehrenreich-May, who will be shadowed by the study site-specific UP-A consultant; if a clinician does not demonstrate competence in this case, or the study site-specific UP-A consultant would like additional training, Dr. Ehrenreich-May will continue to provide consultation for subsequent cases until the clinician is deemed competent and the site-specific UP-A consultant is prepared to provide consultation independently. Thereafter, site-specific study consultant will be responsible for providing consultation in the UP-A; clinicians' regular clinic supervisors will supervise crises whenever appropriate. Dr. Ehrenreich-May will hold voluntary weekly consultation calls for clinicians and study UP-A consultant, and a listserv will be created to allow clinicians to post de-identified general questions about the UP-A and to read responses to their and others' questions. Finally, all therapy sessions will be video or audiotaped and 20% of UP-A tapes will be reviewed as they become available by Dr. Ehrenreich-May and the Miami project coordinator to assure high quality UP-A treatment delivery. Clinicians evidencing challenges with UP-A delivery will be provided with corrective feedback and assistance in re-establishing acceptable levels of competence before proceeding with additional UP-A cases. UP-A clinicians will also complete adherence and competency forms for each completed session and these forms will be reviewed in consultation meetings.

Any clinicians who have received UP-A training will be contacted to participate in a voluntary qualitative interview and complete questionnaires (the UP-C/A Therapist Beliefs Questionnaire, the Adaptations to Evidence-Based Practices Scale, and the Abbreviated Multidimensional Acculturation Scale) about their UP-A experiences and perspectives. They will be verbally re-

consented, and receive separate compensation for their participation in the qualitative interview and questionnaires (outlined in detail below).

YOQ (UP-A and TAU+): Approximately 4 hours of training in the YOQ will be provided to clinicians by trainers from OQ Measures, the company that created the YOQ. Ongoing implementation support for YOQ will involve weekly 30 minute YOQ consultation calls. This consultation will be provided by Dr. Susan Douglas Kelley, an expert in the implementation of MFSs in CMHCs, and Dr. Jensen-Doss. The YOQ data system allows the TAU+ consultants to monitor whether clinicians are completing forms with clients and reviewing reports. If clinicians are not engaging in these activities, TAU+ consultants will use the consultation calls to discuss strategies for increasing adherence.

TAU (TAU+ and TAU): In order to replicate usual practice in the CMHC, the TAU+ clinicians and TAU clinicians will receive the standard dose of clinic supervision at their site.

Randomization:

Eligible adolescents will be randomly assigned within each CMHC to the TAU, TAU+ or UP-A conditions. Eligible and participating clinicians will be randomly assigned to one of the three treatment arms and replaced as needed. Replacement clinicians will not always be fully randomized, as there may sometimes be only one or two conditions needing to be filled.

We estimate that each clinician will maintain a caseload of approximately four participants per condition annually. With a total of ranging from 3-9 clinicians per condition per site, we anticipate routine availability of new youth participant slots within two weeks of initial baseline assessment across conditions. If wait times become substantially uneven across conditions (e.g., adolescent participants waiting longer for a study clinician to become available in the TAU or TAU+ condition versus UP-A), additional clinicians (or clinics) may be added as needed to such conditions to ensure rapid randomization of participants. Clinician and adolescent participants who are randomized will either receive TAU, TAU+ or UP-A in a 1:1:1 ratio. We will use block randomization of adolescents within CMHC, blocked by presence of an adolescent depressive disorder (as assessed by the ADIS-5-C/P) and use of psychiatric medications (specifically, a SSRI, SNRI or benzodiazepine) at the time of study enrollment. If adolescents are randomized to a condition for which a clinician is not currently available (e.g., the clinician in that condition has a full caseload, the clinician in that condition does not have an appointment available at a time that works for the family, the clinician in that condition has left the study and has not yet been replaced), we will move down the randomization list until the adolescent can be assigned to a clinician. In the case of siblings, both youth will be randomized to the same condition and we will cross two rounds of that condition off the randomization list. A maximum of two adolescents from the same family may be admitted to the study.

Study Procedures:

Table 2 details the study Assessment Schedule and descriptions of measures are provided below. Once informed consent and assent has been obtained from caregivers and participants respectively, an initial study assessment to determine eligibility will take place as close as possible to the standard intake at the participating CMHC, prior to treatment initiation. Consent process will occur face to face at the CMHC, University, or at a private place within the

community. This assessment will include completion of some or all of the questionnaires/procedures listed in the "Pre Treatment" column in Table 2 and described in additional detail below. Randomization will take place following this first assessment once subjects have been deemed eligible for participation. If a participant is unable to begin treatment within 4 weeks of their initial baseline assessment, an abbreviated baseline re-assessment may be conducted prior to the start of treatment. This re-assessment will include review of the symptoms previously endorsed on the ADIS-5-C/P, SCARED, MFQ, YOQ, SDQ, DTS, and Avoidance Hierarchy (see Measures, below).

If any study assessment is to occur at the University of Miami, parents/guardians will be emailed a "paybyphone" link to register their car for parking through the University's Parking and Transportation department. They may be asked to supply their license plate number so that study staff may register their car for them in the case of user or system error. License plate numbers will be discarded following termination of study participation, and will not be used for research purposes.

At every therapy session, some or all of the assessments/questionnaires listed in the "Every Session" column in Table 2 will be completed. Additional assessments will take place approximately 8 (mid-treatment) and 16 weeks (post-treatment) after treatment initiation, as well as 3 months after the post-treatment assessment. All efforts will be made to have these assessments take place within a specified time window in relation to the 8, 16, or 28 week time-point date. The windows allow for data collection up to two weeks before the time-point date and up to 2 weeks, 4 weeks, or 8 weeks after the time-point date for the mid-treatment, post-treatment, and follow-up evaluations respectively, although data may still be collected should participants miss this window. During these visits, some or all of the measures detailed in the respective assessment point columns in Table 2 will be administered. With the exception of the computer-based tasks (e.g., the BIRD task), all adolescent- and parent-report measures will be available in English and in Spanish. The Spanish translations of these measures will be submitted in an amendment prior to initiating data collection.

UP-A qualitative interview and questionnaires. Clinicians who have received UP-A training will be contacted to participate in a voluntary qualitative interview and complete questionnaires (the UP-C/A Therapist Beliefs Questionnaire, the Adaptations to Evidence-Based Practices Scale, and the Abbreviated Multidimensional Acculturation Scale) about their UP-A experiences and perspectives. These semi-structured qualitative interview will be conducted over the phone (or in person if preferred) and will last approximately 30-60 minutes. A trained research assistant will lead the interview, and once the participant has consented, will take notes and audio record the interview. The questionnaires will be completed online through a link sent to the clinician's email (or will be completed via paper if preferred) and will take approximately 10-15 minutes to complete. Given the low-risk nature of this qualitative study, participants will be re-consented over the phone prior to completing the interview and questionnaires (see consent attachment). UP-A qualitative interview and questionnaires participants will be compensated with a $30.00 gift card for their participation.

Cultural adaptations survey and qualitative interview. Participating clinicians across conditions will be contacted to participate in a brief, voluntary survey and qualitative interview about their experiences working with racial minority youth within the study and any adaptations made to the interventions they provided to these youth. Prior to the qualitative interview, clinicians will be

contacted by phone or email by research staff to assess interest and obtain consent. Those clinicians who consent to the interview will receive a link to the Cultural Adaptations Background Survey to provide information about their caseload, therapeutic approach, and work with diverse clients. This survey will take approximately 10 minutes to complete. After survey completion, clinicians will complete a semi-structured interview with trained research staff. These follow-up interviews will be conducted over the phone or via Zoom and will take approximately 30 minutes. Participating clinicians will be compensated $30.00 after completion of the interview.

Table 2: Assessment Schedule

Measure	Reporter	Every Session	Pre Treatment	8 Weeks	16 Weeks	3 month follow-up
C-SSRS	IE		X		X	X
Family Background	P		X			
Youth Demographics	C		X			
Family Contact	P		X			
Service Utilization	P		X		X	X
IE Blindness Check	IE				X	X
ADIS-5 C/P	C, P, IE		X		X	X
CGI-S	IE		X		X	X
CGI-I	IE				X	X
CGAS	IE		X		X	X
SCARED	C, P		X	X	X	X
MFQ	C, P		X	X	X	X
YOQ	C, P	X (UP-A, TAU+ Only)	X	X	X	X
SDQ	C,P		X	X	X	X
Avoidance Hierarchy	C, P, IE		X	X (C, P only)	X	X
PHQ9	P		X	X	X	X
GAD7	P		X	X	X	X
CCNES	P		X	X	X	X
DTS	C, P		X	X	X	X
S-EMBU	C, P		X	X	X	X
BIRD	C		X	X	X	X
CEMS	P		X	X	X	X
CEASE-A	C		X	X	X	X
EASI-A	C		X	X	X	X
PANAS-C	C		X	X	X	X
WAI	C, T			X	X	
BTPS	P		X			
CSQ	C, P			X	X	X
HURTE-II	C,P		X^3	X^3	X^3	X^3

Session Report Form	T	X				
EBPAS	T		X[1]		X[2]	
ASA-MF	T		X[1]		X[2]	
MFA	T		X[1]		X[2]	
TCU-ORC	T		X[1]			
UP-A Knowledge Check	T*				X[2]	
Therapist Background	T		X[1]			

C = Child, P = Parent/Caregiver, IE = Independent Evaluator, T = Therapist
1. Administered to the clinician before they start treating their first study case.
2. Administered to the clinician after they complete their first study case.
3. May be administered to participants to screen for Hurricane Irma related stressful life events at the first contact the study has with the participants after the storm.
*Administered to clinicians randomized to the UP-A condition only

Description of Measures and Data Collected:

Screening/Baseline Measures:

- **Columbia-Suicide Severity Rating Scale (C-SSRS).** The C-SSRS is a semi-structured interview designed to screen for presence and severity of suicidal ideation and suicidal behavior. There are parent and child report versions, as well as versions designed to assess suicidality at baseline (which assesses the last 6 months for study inclusion) and for later assessment points (which assesses ideation and behaviors since the last assessment).
- **CRAFFT Screening Test:** The CRAFFT is a 9 item screening questionnaire, with yes and no questions related to substance use. The questionnaire is used as an interview administered by the independent evaluator.
- **Family Background and Medical History Form**: The project created a form to gather background information, such as demographic and educational information, as well as medical history data.
- **Youth Demographics Form:** The project created a form to gather race/ethnicity, gender, and sexual orientation information directly from adolescents, as parents may report these items differently than adolescents.
- **Family Contact & Locator Form**: This form will be used to gather contact information and other identifying information, as well as additional people who could locate the family if the project loses track of them.
- **Service Utilization Assessment:** This form will be used to gather information about outside use of psychiatric services. Two versions of the form will be administered- one for the baseline assessment and one to gather updated information at subsequent assessments.
- **IE Blindness Check:** At the post and follow-up assessments, the independent evaluator will complete a form to assess whether he or she has remained blind to the participant's treatment condition.
- **Barriers to Treatment Participation Scale – Expectancies (BTPS).** The BTPS is a questionnaire rated by parents. Parents will indicate how much they agree with statements about their expectancies of barriers to treatment participation, using a 5-point scale from 1 (totally disagree) to 5 (totally agree). Only 38 items will be used in this study (questions

about relationship with therapist will not be used in this study). It yields a total score and 3 subscales. The subscales and total score have excellent internal consistency (.85 to .95).

- **Hurricane Related Traumatic Experiences- Version 2 (HURTE-II_.** The HURTE-II is a questionnaire rated by parents and/or youth. In order to more fully assess participant experiences after Hurricane Irma, caregivers or youth may complete some or all of this questionnaire during their first contact with the study after the storm.

Independent Evaluator-Rated Measures of Primary Outcomes:

- **Anxiety Disorders Interview Schedule for the DSM-5, Child Version, Child and Parent Report Forms (ADIS-5- C/P), English and Spanish Versions:** The ADIS-5-C/P is comprised of semi-structured interviews conducted with both parent and child that permit the diagnosis of all DSM-5 anxiety disorders, mood disorders, and externalizing disorders of childhood and adolescence, and also provide screening questions for selected other disorders (e.g., psychotic disorders, eating disorders, somatization disorders, and parent-report of mental retardation and learning disorders). Inquiries about current suicidal ideation or related plans are made to both adolescent and parent as part of this interview. Parents and adolescents are asked to provide ratings, ranging from 0 to 8, of the severity and degree of interference for each disorder. Clinician ratings are also recorded for disorders that border on or are clearly clinical in significance.
- **Clinical Global Impression-Severity (CGI-S):** The CGI-S is a 7-point clinician rating of severity of psychopathology. Severity ratings range from 0 (no illness) to 6 (extremely severe).
- **Clinical Global Impression-Improvement (CGI-I):** The CGI-I is a 7-point rating of treatment response anchored by 1 (“very much improved) and 7 (“very much worse”).
- **Children's Global Assessment Scale (CGAS):** The CGAS is a widely used 100-point rating scale used to measure global functional impairment.

Adolescent- and Parent-Rated Measures of Anxiety, Depression, and General Psychopathology:

- **Screen for Child Anxiety Related Emotional Disorders-Youth and Parent Reports (SCARED/-P):** The SCARED and SCARED-P are 41-item self- and parent-reports of anxiety severity across five domains: panic disorder, generalized anxiety disorder, separation anxiety disorder, social phobia, and school anxiety.
- **Mood and Feelings Questionnaire-Self and Parent Reports (MFQ):** The MFQ Self Report is a 33 item and the Parent Report is a 34 item youth mood and feelings scale that yields a total score.
- **Strengths and Difficulties Questionnaire- Self and Parent Reports SDQ):** The SDQ is a 25 item measure of youth psychopathology that yields a total score and five subscale scores: emotion problems, conduct problems, hyperactivity, peer problems, and prosocial. Separate versions are administered to youth and caregivers.

Measures of Parent Psychopathology and Emotion Regulation:

- **Patient Health Questionnaire-9 (PHQ-9):** The PHQ-9 is a 9-item parent report measure of parent depression symptoms rated on a 4-poin Likert-type scale (0=Not at all, 1=Several days, 2=More than half the days, 4=Nearly every day). It yields a total score and rating of impairment.
- **Generalized Anxiety Disorder-7 (GAD-7):** The GAD-7 is a 7-item parent report measure of parent anxiety symptoms rated on a 4-point Likert-type scale (0=Not at all, 1=Several days, 2=More than half the days, 4=Nearly every day). It yields a total score and rating of impairment.
- **Coping with Children's Negative Emotions Scales (CCNES):** This measure was adapted for adolescents from the Coping with Children's Negative Emotions Scale and consists of nine scenarios in which youth experience negative emotion. Parents are asked to identify how they respond to each scenario (e.g. "When my teenager gets down because he/she has had a bad day, I usually:"). Each scenario then has six responses which parents rate on a 7 point Likert-scale regarding their likelihood of responding that way (1 = very likely, 7 = very likely). This measure has six subscales which include emotion focused, problem-focused, minimization, punitive, expressive encouragement, and distress responses.
- **Distress Tolerance Scale (DTS):** The DTS is a 16-item self-report measure of difficulties managing distress and related emotions on a 5-point Likert-type scale. Four types of items assess the reporter's perceived ability to tolerate distress, subjective appraisal of distress, the attention consumed by the process, and the efforts made to alleviate the distress. High scores on the scale indicate high distress tolerance. Scores for a single factor demonstrate excellent internal consistency (.89).
- **Egna Minnen Betraffande Uppfostran – Short Form (S-EMBU):** The S-EMBU (Swedish for "My memories of upbringing") consists of 23 items designed to assess perceptions of parental rearing behaviors. The Short Form questionnaires (parent and child report) consist of three subscales: rejection (7 items), emotional warmth (6 items), overprotection/control (9 items), and 1 unscaled item. Items are answered on a 4-point Likert scale (1=No, 2=Yes, but seldom, 3= Yes, often, 4= Yes, most of the time).

Measures of Potential Mediators of UP-A:

- **Children's Emotion Management Scales (CEMS):** The CEMS-parent is a version of the Children's Emotion Management Scales: Anger and Sadness that has been adapted for use with parents. It also includes a worry management scale that was developed to accompany the anger and sadness scales. Items are rated on a 3-point Likert-type scale (*hardly ever, sometimes, and often*). Only the 9 items from the Dysregulated expression subscale will be used in this study.
- **Checklist of Avoidance Strategy Engagement for Adolescents (CEASE-A)**: The CEASE-A is a 29-item checklist assessing frequency of engagement in avoidance and safety behaviors in adolescents. Respondents are asked to indicate the frequency with which they use certain behaviors to manage or avoid feelings of anxiety, anger, fear, or sadness on a 5-point Likert-type scale (0 = Never do to deal with feelings; 1 = Rarely do to deal with feelings; 2 = Sometimes do to deal with feelings; 3 = Usually do to deal with feelings; 4 = Always do to deal with feelings). The CEASE-A has five subscales: Use of Distraction, Use of Individuals as Safety Signals, Use of Safety Behaviors, Avoidance of Situations that Promote Strong Sensations, and Avoidance of Emotional Situations.

- **Emotional Avoidance Strategy Inventory for Adolescents (EASI-A)**: The EASI-A is a 17-item measure assessing the use of emotionally avoidant strategies in adolescents. Respondents are instructed to use a 5-point Likert-type scale to indicate the degree to which each statement is true of them (0 = Not at all true of me; 1 = A little true of me; 2 = Somewhat true of me; 3 = Very true of me; 4 = Extremely true of me). The EASI-A has 3 subscales: Avoidance of Thoughts and Feelings, Avoidance of Emotion Expression, and Active Avoidance Coping.
- **Positive and Negative Affect Scale for Children (PANAS-C)**: The PANAS-C is a 27 item self-report scale that measures positive and negative affect in children and adolescents. Items are scored on a 5 point Likert scale ranging from 1 (very slightly or not at all) to 5 (extremely). Participants are told to respond to items regarding how often they have felt a certain way over the past two weeks.
- **Behavioral Indicator of Resiliency to Distress (BIRD)**: The BIRD measures distress tolerance by having subjects engage in a computer task that increases in difficulty as the task progresses. The BIRD, which is based on the well-validated version for adults, the PASAT, measures distress tolerance by determining how long a participant persists on a task that becomes increasingly more difficult over the duration of the task. Specifically, participants are asked to use the computer's mouse to click on the green dot that appears above a number (with numbers ranging from 1-10) before the green dot disappears. If the number is clicked on before the dot disappears, then a bird on the screen sitting in a cage is let out of the cage and the computer makes a chirping sound. If, alternatively, the green dot disappears before the adolescent clicks on the number, then an "Uh oh" noise is made. A participant receives one point for every number that is clicked prior to the green dot disappearing. There are three levels of difficulty. The first level of the BIRD lasts 3 minutes. This level begins with a 5-second latency in between dot presentations and titrates this latency based upon performance. The second level is more difficult, beginning with the average latency from the previous level for four minutes and then reducing the latency in half for the final minute making the task extremely difficult (i.e., challenge latency). The final level lasts up to 5 minutes and utilizes the extremely difficult challenge latency while the adolescent has an escape option throughout this final stage. Specifically, the adolescent is informed prior to beginning the task that once the final level has begun, the task can be quit clicking the quit game button on the computer screen. Throughout the task, a point meter remains visible on the upper right hand screen that demonstrates how many points the youth has earned. In order to motivate the adolescents to persist in the task, prior to completing the task they will be informed that they may receive up to $4 for their performance on the task. Adolescent participants will receive $1 after completing the first level and $1 after completing the second level. They will receive up to $2 after the third level depending on how long they persist in the task (i.e. $1 if they persist for less than half the time allotted for the third level and $2 if they persist for half of the time or greater). This method of using incentives to motivate participants to continue in the BIRD task has been used in other studies. Studies using the PASAT (the adult version from which this task was adapted) indicate that most subjects do terminate the task before the time limit when the task becomes most difficult, and that considerable variability exists on this measure of task persistence. As this is a computer-based task, we are not uploading a document related to this measure, but it can be viewed at http://www.millisecond.com/download/library/BirdTask/.

- **Avoidance Hierarchy**: IE, along with the adolescent participants and their parents will construct a 5-item Avoidance Hierarchy of situations and stimuli most frequently avoided, escaped or withdrawn from by the adolescent using a 0-10 scale for each item. IEs, adolescents, and parents will also rate this hierarchy at all subsequent time points. A total avoidance score will be derived by summing avoidance ratings for each of the five items across all three informants.
- **Distress Tolerance Scale (DTS):** Difficulties managing stress and related emotions will be measured using the DTS. Adolescents will also fill out the same measure their parents are completing about their distress tolerance (see above).
- **Client Satisfaction Questionnaire (CSQ):** The CSQ is a 8 item questionnaire completed by the adolescent and the parent. Adolescents and parents will indicate how satisfied they are with the services received. A total score for the scale will be used, and has demonstrated excellent internal consistency (.89).

The YOQ and Measures of Potential YOQ Mechanisms:

- **Youth Outcome Questionnaire-30 Therapeutic Alliance, parent and self-report versions (YOQ 30 TA and YOQ 30 SR TA):** These scales consist of 30 symptom items and 4 (parent version) or 5 (youth version) alliance items. The symptom items yield a total score and an alliance score. At research assessments, the YOQ will be administered in REDCap; for the UP-A and TAU+ participants, these measures will be administered every session through the YOQ website or app. The alliance items will not be administered at the baseline assessment because participants will not have met their therapists yet.
- **Therapist Behaviors measured via the Session Report Form (UP-A and TAU + only):**
  - **Viewing YOQ Reports:** Therapist viewing of the YOQ reports will be tracked through the YOQ website.
  - **Use of YOQ Feedback:** Therapists discussing feedback with clients will be coded from session recordings (see Assessment of Treatment Differentiation and Fidelity).
  - **Self-report YOQ Use:** The Session Report Forms (see Session Report Forms under *Assessment of Treatment Differentiation and Fidelity* below) for the UP-A and TAU+ will include items assessing therapists 1) indicating whether they viewed the YOQ report, 2) rating their perception of the credibility of the report on a 7-point Likert-type scale from "Not an Accurate Reflection of My Client's Progress" (1) to "Extremely Accurate Reflection of My Client's Progress" (7), 3) indicating whether they discussed the YOQ feedback with their client, and 4) indicating what, if any, changes to the treatment plan they made in response to the feedback .
- **Working Alliance Inventory (WAI):** The short version of the Working Alliance Inventory, completed by the client and therapist, includes 12 items rated on a 7-point Likert-type scale from never (1) to always (7), with items reflecting three core components of alliance: agreement on tasks, agreement on goals, and bond.
- **Engagement in treatment**: Two indicators of treatment engagement will be tracked— 1) Missed sessions will be counted and 2) premature treatment terminations will be documented. Engagement will be tracked throughout the study, although data of interest will be engagement data collected during tracked for the first 16 weeks of treatment only, given potential variability in treatment length across conditions.

Measures to be Completed by Clinicians Only:

- **Therapist Background Questionnaire and Locator Form:** These forms will be used to gather demographic and professional information about clinicians, as well as contact information to help locate the participant for future assessments.
- **Evidence-Based Practice Attitude Scale (EBPAS):** This 15-item rating scale measures provider attitudes toward evidence-based practice and includes four subscales: Requirements, Appeal, Openness, and Divergence.
- **Attitudes Toward Standardized Assessment Scales-Monitoring and Feedback (ASA-MF):** This 18-item rating scale measures provider attitudes toward using standardized progress measures for treatment planning and includes three subscales: Clinical Utility, Benefit for Treatment Planning, and Practicality.
- **Monitoring and Feedback Attitudes Scale (MFA):** This 17-item rating scale assesses provider attitudes toward routine progress monitoring and providing feedback to clients about treatment progress. It has three subscales: Benefit, Harm, and Trust.
- **TCU Organizational Climate Form (TCU-ORC):** The TCU-ORC is a measure of organizational climate that consists of multiple subscales that can be used based on project needs.
- **UP-A Knowledge Check:** This measure consists of 25 multiple-choice questions covering concepts from Core Modules 1-8 as well as Module-P of the Unified Protocol for the Treatment of Emotional Disorders in Adolescents.
- **UP-C/A Therapist Beliefs Questionnaire**: This is a 22-item measure created for the current study that assesses clinicians' beliefs about the UP-A.
- **Adaptations to Evidence-Based Practices Scale:** Six-item measure about treatment adaptations.
- **Abbreviated Multidimensional Acculturation Scale:** A measure with 42 very brief items that assesses acculturation and cultural identity.
- **Cultural Adaptations Background Survey:** A 6-item measure about clinician's caseload, diversity of clients, and intervention selection and use with clients.

Measures derived from Clinic's Medical Records:

- The following data will be derived from the clinic's medical record for each study participant:
  - **Use of medication**
  - **Treatment attendance**
  - **Session notes**
  - **Supplemental mental health service use**
  - **Funding Source for Services**
  - **Intake and Discharge Diagnoses**
  - **Reasons for Treatment Termination**

Assessment of Treatment Differentiation and Fidelity:

- All clinicians will be asked to complete a Session Report Form after each session. The items included in these forms will vary by condition, but will include reports of who attended the session, how long the session lasted, and items about session content. Clinicians may be asked to include a copy of their session progress note with the form if the project is not able to access session progress notes during the review of clinic medical records.
- All treatment sessions in all conditions will be video or audiotaped; these recordings will be used to monitor ongoing fidelity for UP-A, to quantify treatment adherence in the UP-A and TAU+ conditions, to assure differentiation of treatments, and to document characteristics of TAU.
- **The UP-A Adherence and Competence Checklist:** This measure of UP-A adherence and competency was developed for the prior RCT of this intervention. Dr. Ehrenreich-May and the Miami project coordinator will apply this system to 20% of UP-A session recordings on an ongoing basis to monitor fidelity. In addition, at the end of the project, an IE will code 20% of UP-A tapes to generate data regarding overall levels of fidelity in the trial.
- **The Treatment Adherence, Content, and Competence Checklist:** This will be completed by an IE while reviewing 20% of audiotapes of treatment sessions from all three treatment conditions to assure treatment differentiation and to characterize TAU. The subscales include: (1) treatment content; (2) session components; and (3) nonspecific factors. In addition, for the UP-A and TAU+ groups, an item will be added to the measure to document whether clinicians are discussing feedback reports from the YOQ with their clients; data regarding other aspects of YOQ fidelity (i.e., administering measures, reviewing reports) will be gathered directly through the YOQ system. To ensure that data are available for all participants, recordings will be randomly sampled within participants.

Training for Independent Evaluators:

IEs will be blind raters who have at least a bachelor's degree in psychology or a related field (i.e. postdoctoral fellows, master's level clinicians). IE training will be coordinated by Dr. Golda Ginsburg and will include a review of measures and co-rating videotaped gold standard cases. New IEs will independently rate 4 ADIS-IV-C/P and CGI criterion tapes (experienced IEs will rate 3). On the ADIS-IV or 5-C/P and CGIs, the criterion will be presence/absence of diagnosis and within one point on the clinical severity rating (CSR; rated as part of the ADIS) and CGI against the gold standard. These rating tapes may be drawn from other protocols (e.g. Protocol #20130139). These recordings and related assessment data will be transferred via secure online sharing platforms (e.g., OneDrive, Box.com, UM's SecureSend system) and visible only to authorized personnel. It is anticipated that Dr. Ginsburg will hold twice-monthly cross site conference calls. Furthermore, IEs will be provided with ongoing supervision at each site by the study PIs. To address cross-site consistency, all assessments will be video recorded and 20% of interviews per year will be blindly reviewed by the project coordinator or senior project staff under Dr. Ginsburg's supervision to assess inter-rater reliability and rater drift on the ADIS-5-C/P and CGI-S/I. In the event that an IE rating falls below the criterion, efforts will be made to re-establish the reliability criterion (e.g., having the IE redo training)

11) **Data and Specimen Banking***

N/A, no specimens will be collected as a part of this research study

12) **Data Management***

Data management at all sites will be supervised by the data management team, consisting of the three grant PIs and Dr. David Rosenfield, the biostatistician. Data management issues will be discussed in regular conference calls. Whenever possible, measures will be administered by computer or tablet computer, obviating the need for double entry and minimizing the likelihood of missing data. Research assessment data will be collected via the University of Miami's REDCap or Qualtrics systems. Site-specific data access groups will be created so that only personnel at each site can access that site's data. PI Jensen-Doss, the research coordinator, and the post-doctoral fellow at the University of Miami will have access to both data access groups to facilitate data monitoring and cleaning. The only identifying information entered into REDCap or Qualtrics will be the e-mail addresses for clinician participants to allow surveys to be e-mailed to them. When datasets are extracted from REDCap or Qualtrics, this information will be removed and fully de-identified files will be stored on the University of Miami Psychology department server. These de-identified files will also be securely transferred to the UConn site and to Dr. Rosenfield (the project statistician). Dr. Rosenfeld will not have access to any identifying information or links which could potentially identify participants. Consent forms for both sites specify that data will be shared across both sites.

When clinics send screening data to the project, they will e-mail this information, consistent with their agency standards for transfer of clinical information, or utilize an online screening form via REDCap or Qualtrics. In cases where project staff need to e-mail information back to the clinics, all files will be password protected and sent via the Psychology Department's e-mail server.

When clinicians initially transfer session recordings to the project, they will be uploaded onto Box.com or sent via SecureSend by the clinician and then downloaded by project staff and removed from these online platforms. Interviews and session recordings will also be stored on each site's secure servers or on OneDrive. Cross-site review of recordings will be necessary to facilitate cross-site supervision of clinicians and IEs, and to allow for fidelity coding of tapes. The informed consent forms will inform participants that research staff from both sites will have access to their data. When cross-site review of tapes is necessary, recordings will be transferred between sites via SecureSend.

YOQ data will be collected each session through the YOQ web-based application, whose server is managed by Rackspace®, a managed hosting firm whose security standards meet the industry' s highest standards, including HIPAA compliance, and have earned it SAS 70 Type II Certificaton, indicating third party verification of its security procedures. All data are stored on a remote firewalled web server. Users must have a password to access the application, and access within the application is controlled by a permission structure (e.g., clients do not have access to data or to view any other users, clinicians only have access to their own clients' data, etc.). The research project staff will be able to directly download data from these servers.

All paper records and clinical data will be stored securely in locked offices and/or filing cabinets accessible only to members of the study team. Electronic data files and digital recordings will be stored on secure servers at UM and UConn, accessible only by project staff. Data and recordings will be labeled with ID numbers and initials in the place of names, and information linking participant identifying information with IDs and initials will be stored securely in a password-

protected log, accessible only to study personnel. Study consent forms will indicate that data will be shared across the two sites and that project staff at both sites will have access to the data. When these data are transferred, all data files will be password protected and saved on secured servers in dedicated files accessible to project staff only.

All project staff will be educated about the importance of confidentiality, and trained on procedures used to protect this within the study. Information about participants will be kept strictly confidential (to the extent permitted by law) and information about participants will not be released without a signed release form by the child's caretaker.

Data Analysis Plan:

We plan to use GLMM (multilevel modeling, MLM, with a logistic linking function) to examine treatment effects on the dichotomous primary outcome ("response", defined as CGI-I of 1 or 2). Additional clinician-rated (e.g., CGI-S, CSR) and questionnaire-based (e.g., SCARED, MFQ) outcomes are all continuous measures and will be analyzed using traditional MLM.

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

The Principal Investigators, in accordance with the policies outlined by the University of Miami and UConn Institutional Review Boards (IRBs), are responsible for ensuring the safety of participants and the integrity of research procedures. Throughout the study, the PIs will work with all staff, Co-I's, and grant consultants, to ensure compliance with the study's procedures and data and safety monitoring plan. Finally, a Data Safety Monitoring and Board has been appointed to monitor progress of the study and at least annually (more frequently if needed). The Board members are Cindy Rowe and Annette La Greca from the University of Miami and Margaret Briggs-Gowan from UConn.

Procedures to monitor participant Safety: Throughout the study, the PIs and all study staff will monitor participants' risk of harm, as described above under 9) Study End points. Any evidence of risk of self-harm will be reported immediately to the principal investigators. When possible, at times when patients are seen for the study, a trained mental health professional will be present and available at the clinics to take appropriate measures; at all other times the principal investigators or post-doctoral fellow will help the assessors generate a safety plan. In the case that abuse or neglect is discovered, appropriate measures will be taken, in accordance with the laws of Florida or Connecticut. Prior to making this report, every effort will be made to inform the family first and discuss the situation with them. However, if the family cannot be reached, the report will still be made promptly, as required by Florida or Connecticut statutes. All families will be informed of the limits of confidentiality during the consent process.

If clinical or questionnaire data indicate that a child is showing a notable decline in functioning during the course of the study, this will be discussed with the child's clinician and caregiver and the child will be referred for additional and/or alternative treatment if appropriate.

Procedures to report any Adverse Event or Unanticipated Problem during the study: Throughout the study, the PIs will be responsible for reviewing and reporting adverse events occurring during the study to their local IRB. If any type of adverse event

occurs, the PIs will report that event to the Miami and/or UConn IRB according to the local IRB policies. If an unanticipated problem occurs to compromise the data or confidentiality of the data storage plan (e.g., a break-in to the laboratory space), the PI will notify the IRBs as well as any participant potentially affected by the event.

14) **Withdrawal of Subjects***

Participants and their parents/guardians may be withdrawn from the study without their consent if they are withdrawn from clinical care in the CMHC. Should the client be terminated or transferred in accordance with the local clinic policy, he/she will be withdrawn from the study. In addition, participants may be withdrawn for the following reasons:

- Parent/guardian no longer available to participate with the adolescent.
- Failure to adhere to clinic guidelines and/or clinician guidelines.
- The participant is no longer able to attend clinic visits or complete research assessments.
- There may be other reasons that are unforeseen at this time.
- The clinician and/or evaluator determine, during interim treatment assessments, that an emotional disorder treatment focus is no longer appropriate/sufficient. If this determination is made by the evaluator, the clinician must also agree that emotional disorder focused treatment is no longer appropriate/sufficient and alternative or additional care is necessary.
- During the course of treatment, the adolescent begins an outside psychosocial intervention similar to that given in the study, or one that the investigators feel may be confounding.

Those participants who voluntarily withdraw from treatment may be asked to complete 8 week, 16 week, and 3 month follow-up assessments for data collection purposes, if appropriate.

Clinicians may be excluded from the study for any of the following reasons:

- They leave the clinic and are no longer seeing clients at the CMHC.
- They are unable to attend and/or participate in training and consultation meetings.
- They are determined inappropriate for the research study (i.e. failure to adhere to treatment, failure to adhere to study procedures).

In the event that a clinician is withdrawn or voluntarily withdraws from the study, clients who are still in treatment will be offered to transfer to another study clinician if appropriate. All clinicians will be asked to consider the best interests of the adolescents when withdrawing from the study, and encouraged to complete treatment with study clients before withdrawing.

15) **Risks to Subjects***

There are no physical risks associated with participation in the study. There are minor psychological risks to child and caregiver participants. During assessment procedures, there may be some risk of discomfort, irritability, or anxiety resulting from discussion of personal or emotion-provoking subjects. However, this risk is not greater than that which occurs in the usual clinical evaluation process. Participants and their parents/guardians may experience mild inconvenience from having to complete additional research assessments which may take additional time.

Some UP-A treatment procedures involving exposure or activation activities may provoke minor distress or discomfort. However, these risks are known and therapists will be well trained to present such tasks in a developmentally sensitive manner that is appropriate for each participant. Appropriate provision of UP-A exposure activities will also be a routine subject during study therapist consultation with Dr. Ehrenreich-May. As is the case with any form of treatment, there is no guarantee that the treatment strategies offered in this study will be effective with all participants. Any participant who shows a notable decline in functioning during the course of the study will be referred for additional and/or alternative treatment immediately as per usual clinic procedures.

Risks to parent and adolescent participants are minimized by the use of standard clinical care procedures and assessments. The BIRD task might cause adolescents mild to moderate levels of frustration, but care will be taken to ascertain an objective rating of such (Subjective United of Distress; SUDS) before and after the task. If the adolescent shows or expresses any distress, clinically appropriate interventions will be used to help reduce distress. All IEs will be trained to assist youth throughout the evaluation process in this manner.

The risks to therapist participants are minimal, and do not exceed those routinely encountered in their work life. They may experience slight discomfort participating in project consultation or from seeing client progress reports through the YOQ, although these therapists could experience this same discomfort in the routine supervision they receive.

16) **Potential Benefits to Subjects***

Child participants will potentially experience alleviation of distress associated with an emotional disorder. In all conditions (TAU, TAU+, and UP-A), adolescents have the prospect of direct benefit, given that all study arms contain active treatments (i.e. no sham treatment or waitlist condition is being used). In both the UP-A and TAU+ conditions, subjects may benefit from the monitoring and feedback system, as well as the additional consultation provided to therapists in these conditions. The additional monitoring and assessment in the UP-A and TAU+ conditions may lead to enhanced treatment, alerts regarding issues of immediate concern (i.e. suicidality), and alerts regarding poor progress or deterioration during treatment. For adolescents in the TAU condition, the addition of 8 week, 16 week, and 3 month assessments may also provide additional monitoring during and after treatment beyond the standard monitoring in clinical care. Therapist participants will potentially have access to training and/or consultation in a new intervention and measurement/feedback systems.

17) **Vulnerable Populations***

This research involves adolescents 18 and under. A number of safeguards have been put in place and careful consideration has gone in to the decision to conduct this research with this particular population.

The PIs have extensive experience conducting research and clinical work with this population. All study staff involved will be trained in conducting research with vulnerable populations, including minors. All study therapists will have experience treating mental health concerns in

youth. In addition, all caregivers will be asked to give written informed consent, and all youth will be asked to give written assent.

As discussed above under benefits, all adolescent participants have the potential for benefit in this study. As such, the investigators believe that the research presents the possibility of direct benefit to the adolescents beyond standard clinical care or no treatment, and possible risks and discomforts resulting from the research are minimized and/or outweighed by the benefit.

18) **Multi-Site Research***

The following factors will ensure successful collaboration and completion of this multi-site study:

Each site is very experienced in the conduct of clinical trials across multiple psychiatric disorders: including efficacy tests of EBTs for emotional disorders in youth (Ginsburg, Ehrenreich-May), effectiveness tests of youth EBTs (Ginsburg, Jensen-Doss) and multi-site investigations of such (Ginsburg, Ehrenreich-May). As well, the investigators have a wealth of experience in emotional disorder assessment (Ginsburg, Jensen-Doss, Ehrenreich-May), measurement/feedback systems (Douglas, Jensen-Doss), and examination of hypothesized mediators of intervention effects in the UP-A (Ehrenreich-May) and MFS (Douglas, Jensen-Doss).

To ensure scientific integration of research procedures, the study Steering Committee (comprised of Drs. Ehrenreich-May, Jensen-Doss and Ginsburg) will oversee all managerial and administrative matters. The Steering Committee will be responsible for all decisions concerning the overall research study, including plans for data analysis and publications, and Steering Committee weekly conference calls will monitor the overall course of the study including recruitment, retention, participant eligibility decisions, randomization protocols, budget, data collection, training, assessment issues, treatment issues, data analysis, and quality assurance issues including missing data and data integrity. In addition, human subjects issues will be discussed, especially as they apply to adverse events and minority group participation.

Extensive quality assurance procedures will be ongoing to ensure cross-site comparability in administering the UP-A and MFS, and in conducting assessments. Conference calls on various study components will occur regularly. While data at each site will be collected and entered into the encrypted electronic data system, the Miami site will provide data management, under the oversight of Drs. Jensen-Doss and Rosenfield. In consultation with the study statistician, Dr. Rosenfield, the PIs will be responsible for all aspects of statistical design and analysis for the study.

Though this project will be a multi-site collaboration (between University of Miami and UConn), each participating institution will submit to their local IRB. For this reason, protocol formatting and consent documents may vary slightly based on institutional templates and materials.

Regulatory changes and procedural changes will be managed by the PIs at the University of Miami and communicated with Dr. Ginsburg at the University of Connecticut. Compliance with local regulatory policy will be the responsibility of the PIs at each site. To ensure that sites are

using the most up-to-date protocol documents and study materials, the PI's will have at least weekly meetings to discuss progress and any issues that may arise during the research. In addition, joint meetings will take place regularly with the project coordinator(s) as well as the IEs. The project coordinator(s) will be responsible for implementing procedural changes at the CMHCs. The PIs and the project coordinator(s) will communicate regularly with the IEs as well, to ensure fidelity to the project procedures and provide updates, should these procedures change.

Upon completion of the study, a final meeting will take place that the University of Miami. During this meeting, data analyses and manuscript preparation. All UM Study staff, Dr. Ginsburg from UConn, and Dr. David Rosenfield, the study's statistical consultant, will attend this meeting (their travel has been accounted for in the grant budget).

19) **Community-Based Participatory Research***

N/A

20) **Sharing of Results with Subjects***

The data collected from this study is primarily for research purposes. All assessments (including the ADIS-5 C/P) are research assessments used for the purposes of assessing study eligibility and outcomes. No information will be shared with legal guardians or participants over the age of 18 without a direct request. No information will be shared with others without a written release signed by the legal guardian or a participant over the age of 18. The consent form will inform participants that the study may share some of their assessment results with their clinician to help with treatment planning or to manage crises.

Information shared with parents/guardians and/or participants will be consistent with standard clinical practice at each of the sites (for example, therapists may wish to meet with guardians during the session to discuss the adolescent's progress and functioning). Any assessments or results derived for research purposes will be shared on an as-needed basis. For example, if ADIS-5 assessment results suggest possible suicidality that is not otherwise captured by the treating clinician, this information will be shared with the appropriate individuals consistent with local laws and IRB regulatory policy.

21) **Setting**

For the Miami site, the study will draw from the pool of clinicians and adolescent clients at three community mental health centers, PsychSolutions, Inc., Jewish Community Services, Chrysalis Health, Inc., Goodman Psychological Services Center, Stop Parenting Alone, Live Well Therapy Group, and Behavioral Aid Solutions. All centers provide mental health services in their office locations, as well as in hundreds of schools and homes in the community. All agencies have agreed to allow participant recruitment and research assessments take place at their clinics, and all clinical services will be delivered wherever the agencies typically deliver services. Participants who prefer to do so may complete their research assessments in research space at the University of Miami instead. In circumstances were participants are unable or unwilling to come

in for a research assessment, they may complete measures via RedCap or Qualtrics online, by phone, or via Zoom, as long as they have already signed a study consent form. A phone script to explain these options to families has been uploaded as a study document.

Resources Available

Project staff will include:

PIs (Jensen-Doss, Ehrenreich-May): Both PIs have extensive experience conducting research with children, with clinical populations, and in clinical settings.

Postdoctoral Fellow/Project Coordinator: This individual will hold a doctoral degree in clinical psychology, or a related field, and have a background in conducting psychosocial interventions and research with children or adolescents. This individual will be supervised closely by the PIs.

Independent Evaluators: These individuals will be graduate students in clinical psychology, or a related field, or hold at least a master's degree in a mental health field. These individuals will be supervised closely by the PIs, the postdoctoral fellow, and Dr. Ginsburg at UConn.

Research Assistant: This individual will hold a bachelor's degree. This individual will be supervised closely by the PIs and the postdoctoral fellow.

Throughout the study, Drs. Ehrenreich-May and Jensen Doss will devote approximately 20% of their time and effort. Together, they will be responsible for selection, hiring, management, and training of study staff. All study staff will be required to complete CITI training on the responsible conduct of research. Furthermore, any UM staff participating in the study will complete a training to adequately prepare them for their role in the study (e.g. IEs will undergo training in assessments; all staff will undergo training in study administrative procedures and policy). In addition, any staff member obtaining informed consent and assent from participants and their parents/guardians and participating therapists will be required to complete informed consent training to ensure adequate preparation for this responsibility

Drs. Ehrenreich-May and Jensen Doss both have dedicated faculty offices, laboratory space, offices for postdoctoral associates and additional graduate student office space, all on the same floor at UM. This space is large enough to house all UM site staff working on this grant. All of this space is wired for internet and phone access. The UM Department of Psychology has an in-house team of three, full-time consultants for hardware and software needs and an additional IT support technician. The project also has access to private rooms in the department where research assessments can be conducted, should participants prefer to come to UM for those assessments. Details regarding resources facilities at participating clinics are describe in Section 21 (Setting).

22) **Prior Approvals**

Neither CMHC has its own IRB, so no prior approvals will be submitted.

23) **Recruitment Methods**

Recruitment methods are described in detail in Section 7 (Study Wide Recruitment Methods).

Adolescent participants/their caregivers will be paid up to $220 for participation in this study ($40 for the baseline evaluation, $20 for the 8 week evaluation, $80 for the 16 week assessment and $80 for the 3-month follow up). This payment will be delivered in the form of gift cards, split evenly between the adolescent and the caregiver, and will be given to participants after successfully completing each assessment point. If participants only complete part of an assessment, payment will be prorated according to the amount of the assessment that was completed and they will receive the remainder of the payment for that assessment if they complete the assessment at another time. As detailed above in the description of the BIRD task, adolescents may also earn up to $4 in cash for their participation in the BIRD task.

If their clinics do not pay them for these activities, participating clinicians will be compensated for the time spent on extra training and consultation associated with the study at a rate of $30 per hour. The exception to this is trainee therapists, such as interns or practicum students, who are typically not allowed to be paid for taking part in training activities; these trainees will complete a trainee-specific consent form that explains this. While the respective clinics will continue to pay their regular salary for treatment sessions, study funds will provide a research incentive of $60 per case for time spent completing session-by-session study paperwork and collecting and submitting session recordings. Trainee clinicians will receive this research incentive.

In the cases where participants are asked to complete an abbreviated baseline re-assessment prior to the start of treatment, they will be paid $20 for their time to complete this re-assessment.

24) **Local Number of Subjects**

An estimated 150 youth participants will be enrolled locally at each site, with the aim of having 222 (111 at each site) adolescents complete the treatment. Up to 40 clinician participants will be enrolled locally at each site.

25) **Confidentiality**

Confidentiality of study participants will be protected by keeping all records and clinical data in secure, locked file cabinets and/or offices accessible only to study staff. At UConn, these offices will be located in the Department of Psychiatry. Study materials (including assessments, questionnaires, and recordings) will be labeled with initials and code numbers in place of patient names. Further, no information will be given to anyone (to the extent permitted by law) about participants without a signed release by the child's guardians. Electronic data at UConn will be stored on the Psychiatry Department's secure server, only accessible to study staff. Any files containing identifiable information will be password protected. Participants' identities will not be revealed in the presentation or publication of any result from this project. When de-identified data are transferred between UM and UConn, all data files will be password protected and saved on secured servers in dedicated files accessible to project staff only. All project staff will be

educated about the importance of strictly protecting participants' rights to confidentiality. All appropriate measures will be taken to further protect the confidentiality and safety of the patient and family.

26) Provisions to Protect the Privacy Interests of Subjects

Participants and their guardians will be informed about the confidential nature of study participation and treatment. All efforts will be made to ensure that the adolescent consistently meets with the same therapist throughout participation. Families will be informed that a signed release will be required to disclose information to others. Furthermore, the limits of confidentiality will be discussed—specifically as it relates to mandated reporting of abuse or neglect in vulnerable populations and in regard to suicidal/homicidal ideation. Parents and adolescents will be reminded during assessments that information is confidential, and that they may choose to skip items or discontinue should they feel uncomfortable.

Participants will be informed that information will be obtained from their clinic/medical record. The consent and assent forms will explain what information is to be gathered from medical records, and who will access this information.

Data from clinic/medical records will be collected through the study's 3 month follow-up period. Should a participant turn 18 prior to completing the follow up assessment, they will sign a study consent form before information in the clinic/medical record created after the participant was 18 may be extracted.

Any other outside communication for clinical purposes will be done according to the clinic's policy.

27) Compensation for Research-Related Injury

N/A

28) Economic Burden to Subjects

Participants will not be responsible for any additional costs for participating in the research.

29) Consent Process

Clinician Participants:

Informed consent for clinician participants will take place in a private room at the clinic or facility where study trainings are conducted. Written informed consent will be obtained from all clinicians from a project staff member. Clinicians will be informed that they may take as much time as they wish to make a decision regarding participation, and their refusal to participate will not result in any penalties whatsoever. They will be offered ample opportunity to ask questions and seek clarification. Upon signing consent, a second copy of the consent form will be given to the clinician.

As indicated in previous sections, the UP-A qualitative interview and questionnaires will involve a separate consent process. Given the low-risk nature of these qualitative procedures, participating clinicians will be re-consented via phone. The verbal consent script is included with this amendment application.

The cultural adaptations qualitative interview and background survey will involve a separate consent process. Given the low-risk nature of these qualitative procedures, participating clinicians will be recruited first by email and phone and re-consented verbally before participating in interview procedures. The recruitment script and consent are included in the amendment documentation.

Adolescent Participants:

Informed consent for adolescent participants will take place in a private room in the clinics or at the University of Miami. Any adolescent participants in this study that are under the age of 18 at the time of enrollment must have a legally authorized representative able to provide consent for their participation in research. This guardian must be above 18 years of age at the time of consent. Only legal guardians will be allowed to provide consent for adolescent participants. In cases where parents are divorced, efforts will be made to obtain both parents' consent if possible. Adolescents who are wards of the state or are unable to be accompanied by a legal guardian will not be enrolled in the study.

Written informed consent will be obtained from the parents/guardians of participating children. A member of the study team (i.e. project coordinator or independent evaluator) will obtain consent prior to the performance of any procedures. Guardians will be informed that they may ask any questions they wish to, and take as much time as necessary to consider participation. Written assent will be obtained from all participating adolescents as well, prior to any study procedures. Adolescent participants who are 18 years old will provide their own consent, which includes a release for their parents to take part in the study activities. Assent will take place similarly to the consent, with ample time to consider participation as well as the opportunity to ask questions of the study team member obtaining consent. Guardians and/or adolescents may be given a blank copy of the consent/assent form to review prior to making a decision. A second copy of the consent/assent form will be given to the guardian/adolescent once they have signed. Adolescents who turn 18 during study participation will be re-consented using an adult consent form.

If a second caregiver serves as the informant at any of the research assessments, informed consent will also be obtained from them prior to their participation. This consent form (COMET Consent Over 18 Second Adult Informant) only covers that individual's participation, as another legal guardian will have already provided consent for the adolescent.

Consent Language:

Adolescent participants and their caregivers may speak Spanish or English. Their consent and assent forms are available in both Spanish and English, and participants may choose which version they feel most comfortable with. The Spanish translation of all consent and assent forms was written by a fluent Spanish speaker, and reviewed carefully. They were back-translated to ensure that all wording is consistent in both languages.

If a participant chooses to use a Spanish consent form, the study staff member obtaining consent will obtain consent in their native language. Currently, there are a number of study team members that have been identified as fluent Spanish speakers, and we anticipate the addition of others in the future. In addition, Dr. Jensen-Doss speaks Spanish, and will be able to supervise the consent process and any other study procedures that are done in Spanish.

30) **Process to Document Consent in Writing**

The study will obtain written documentation of consent for all parts of the study except the qualitative interview and questionnaires with therapists. Given the low-risk nature of the qualitative portion of the study, participants will be consented verbally over the phone. See Section 29 ("Consent Process") details.

31) **Drugs or Devices**

N/A, this study does not involved drugs or devices.

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