Improving Quality of Care in Child Mental Health Service Settings

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Once protocol is complete, save it as a Word document. Go back to the IRB application and upload the protocol.

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A. SPECIFIC AIMS

List the broad, long-term objectives and the goal of the specific research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Efficacious mental health treatments are available to address a wide range of youth psychiatric disorders but are implemented with variable effectiveness in community practice settings. Dissemination initiatives aim to enhance quality of care in these settings, but innovative solutions are needed to improve provider fidelity and children's engagement in **sustainable ways**. There is tremendous opportunity to achieve this via technology. Treatment fidelity and children's engagement are key correlates of clinical outcome and **practical targets for intervention. Fidelity** refers to the degree to which providers adhere to a treatment protocol and deliver it competently. **Engagement** reflects children's general level of behavioral involvement in the treatment process. The strategic integration of technology-facilitated activities into the development, packaging, and dissemination of child mental health treatments may be a promising path to achieving sustained national impact.

We have completed an NIH R34 in which we piloted a tablet-based toolkit that was designed to improve engagement and fidelity in delivery of Trauma-Focused Cognitive Behavioral Therapy (TF-CBT). TF-CBT was selected as a model intervention because it addresses a wide range of symptoms using techniques that are shared by many treatments for emotional and behavioral disorders. The design of the tablet toolkit was guided by experts, providers, and families via a series of phases: (1) interviews with 21 national trainers; (2) focus groups with 21 local providers; (3) usability testing and interviews with 24 families in treatment; and (4) a randomized controlled feasibility trial with 4 community practice settings, 13 providers, and 27 families. **We met or exceeded all benchmarks for feasibility outlined in our NIMH R34 application.** Feedback from providers, children, and caregivers was positive and encouraging, supporting potential for high impact. We propose a hybrid effectiveness-implementation trial with 400 providers and 360 families to examine the extent to which a tablet-based toolkit approach may improve **fidelity**, **engagement,** and **mental health outcomes** in child mental health facilities. **We will leverage partnerships with over 70 community-based service agencies in the United States through two major, long-standing dissemination initiatives.** We will also examine costs and conduct interviews with families, providers, supervisors, and agency leaders to inform future dissemination and implementation initiatives. This study will provide valuable data toward understanding additive benefits of technology-based resources to quality of care in child mental health treatment.

Aim 1: Finalize the toolkit based on recommendations of providers and children via our R34 pilot study

- **Objective 1.1.** Enhance tailoring features; expand library of demonstration videos for children and parents
- **Objective 1.2.** Develop and integrate tutorial content (e.g., demonstration videos) for providers
- **Objective 1.3.** Launch a native version to complement the web-based version to enhance its reach

Aim 2: Conduct an RCT with 400 providers assigned to deliver tablet-facilitated vs. standard TF-CBT
We will conduct a randomized controlled trial (RCT) to examine the extent to which the tablet toolkit improves fidelity, engagement, and child mental health outcomes. We will recruit 360 youth (8-16 years) with clinically elevated symptoms of PTSD from community practice settings nationwide. **Providers (n=400) will be randomized** to tablet-facilitated vs. standard TF-CBT; each will treat 3 cases during the course of the study. Evaluators blind to condition will conduct baseline and 3-, 6-, 9-, and 12-month post-baseline interviews.

- **Hyp 1:** Higher levels of **provider fidelity (target)** will be observed in tablet-facilitated vs. standard TF-CBT
- **Hyp 2:** Greater **child engagement (target)** will be observed in tablet-facilitated vs. standard TF-CBT
- **Hyp 3:** Greater improvement in symptoms of **PTSD, depression, and externalizing behavior (clinical outcomes)** will be observed among children receiving tablet-facilitated vs. standard TF-CBT
- **Hyp 4, 5 (mediation):** Provider fidelity (**hypothesis 4 target**) and child engagement (**hypothesis 5 target**) will mediate the relation between study condition and child mental health outcomes.
- **Exploratory:** Identify provider- and agency-level variables associated with use of the tablet toolkit

Aim 3: Examine costs associated with maintaining and nationally disseminating a tablet-based toolkit

- **Objective 3.1.** Estimate costs associated with deploying and maintaining the toolkit (e.g., costs associated with training, purchasing tablets, providers' setup/tailoring activities, app maintenance)
- **Objective 3.2.** Examine cost-effectiveness of the tablet toolkit approach by comparing costs associated with deploying the toolkit per unit of clinical outcomes, across study conditions.
- **Objective 3.3.** Estimate cost savings associated with treatment efficiency in tablet-facilitated TF-CBT

B. BACKGROUND AND SIGNIFICANCE

Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State the importance and health relevance of the research described in this protocol by relating the specific aims to the broad, long-term objectives.

B1. Innovative Solutions are Needed to Improve Quality of Care in Child and Adolescent Mental Health

Mental health disorders affect 1 in 4 children in the US and are associated with costly physical and behavioral health problems.[1-3] Assuring children access to the highest quality mental health care is a top national priority. Hundreds of interventions are available to address this need; [4] over 350 mental health and substance abuse interventions are listed in SAMHSA's National Registry of Evidence-based Programs and Practices. However, mental health service delivery is highly variable in community practice settings. An IOM report characterized this as a quality chasm representing "large gaps between the care people should receive and the care they do receive" (p. 236).[5] Many factors contribute to this challenge, including provider experience, caseload diversity, children's lack of engagement, organizational culture, and funding streams. Dissemination initiatives address some of these factors directly,[6-8] but new solutions are needed to improve quality of care in sustainable ways.

B2. Provider Fidelity and Children's Engagement are Important, Practical Targets for Intervention

Provider fidelity (i.e., degree to which providers adhere to a treatment protocol and deliver it competently) and **children's engagement** (i.e., general level of behavioral involvement in the treatment process) are key quality of care indicators.[5,9-16] Higher levels of provider fidelity and child engagement are associated with improved clinical outcomes.[16-23] Both are **practical targets for intervention** that can be addressed with scalable, technology-based solutions . Studies in child education have shown that touch-screen learning, interactive games, and video demonstrations enhance children's engagement, learning, knowledge, and motivation.[24-27] These benefits also may extend to the therapeutic context, where the strategic integration of technology-based activities may enhance children's learning and skill acquisition, keep providers on protocol, and reduce risk for drop-out.[20,22] Whereas the field increasingly has invested in technology to address access barriers and clinical decision making via self-help resources, decision support aids, and telehealth solutions,[28-44] use of technology-enhanced activities in mental health care to improve fidelity and engagement is virtually unexplored.

B3. Mental Health Providers are Eager to Integrate Technology-Based Innovations into Practice

Providers often are expected to manage large, diverse caseloads that require training and expertise in a wide range of treatments as well as skills necessary to tailor their delivery based on children's developmental level, comorbidities, and cultural background. [45] **To meet these demands, many providers routinely search the app stores and internet to identify and integrate into practice videos and interactive tools that teach or reinforce concepts and skills.**[46] Research is needed to carefully inform and evaluate this practice; its impact on treatment fidelity, engagement, and efficacy is unknown. The ultimate value of technology-based tools in the

therapeutic context likely will hinge on several factors that we carefully considered in our pilot work.[45-47] **First, they should be consistent with best-practice treatments. Second, they should help providers navigate challenging treatment activities. Third, experts, providers, and patients should carefully inform their design.**

B4. Tablet-Facilitated Child Mental Health Treatment is Feasible, Acceptable, and Scalable
Technology-based resources that support treatment fidelity and facilitate patient-provider interactions may help to address the quality-of-care chasm that is pervasive in child mental health facilities. The goal is not to take the place of therapeutic interactions (as may occur with self-help models), but to support children's benefit from and participation in treatment. We found in our pilot work that a tablet-based toolkit was feasible to implement with minimal training and was acceptable to providers and patients. The scalability of this approach also is promising due to the growing number of dissemination initiatives supporting the spread of efficacious child mental health treatments nationally and the ease with which technology-based resources can be integrated. For example, Trauma-Focused Cognitive Behavioral Therapy (TF-CBT), the treatment model selected for the current study, is supported by at least 17 statewide dissemination initiatives.[48] It is already widely used by our partnering clinics and the providers who will be eligible to participate in this study, all of whom will have been trained in TF-CBT and will only refer to the study patients whom providers have determined will receive this treatment.

B5. Partnerships and Active Dissemination Initiatives Position us for Rapid, Sustained Impact
Several factors strengthen our readiness for rapid, sustained impact if data support this approach. First, part of the mission of the Technology Applications Center for Healthful Lifestyles (TACHL) and other technology centers at MUSC is to maintain widely and freely accessible health technology solutions. Examples include our portfolio of provider training courses (tfcbt.musc.edu, cpt.musc.edu, pe.musc.edu, helping-heroes.org) and self-help materials (pocketpeer.org, automated text-messaging resources for patients after traumatic injury, two apps currently under development for disaster survivors). Some of these resources are maintained on an ongoing basis without cost, whereas others are supported by small (<$5,000/year) maintenance contracts. TACHL, which Dr. Ruggiero (PI) co-directs, will therefore absorb maintenance costs for this toolkit up to 5 years after completion of the study or until a sustainable maintenance plan is in place. Second, Project BEST (Bringing Evidence-Supported Treatment to South Carolina) and the Program on Adolescent Traumatic Stress (PATS) are two highly successful and long-standing dissemination initiatives in TF-CBT led by Drs. Saunders and Hanson (Co-Is). We will leverage Projects BEST and PATS to recruit study-eligible providers into the study, and these initiatives also will position us well to disseminate the TF-CBT toolkit rapidly upon completion of the study. **Third, our team has engaged developers of other highly successful, widely disseminated interventions in the child mental health field, and the novelty of our tablet-based toolkit approach has been met with considerable enthusiasm (see letters of support from Drs. Sheila Eyberg, developer of Parent-Child Interaction Therapy; David Kolko, developer of Alternatives for Families: A Cognitive Behavioral Therapy; and Amy Herschell).** If data support the tablet toolkit approach, these partnerships likely would strengthen rapidly in an effort to adapt our approach to other well-established treatment models.

B6. Summary
Technology-based resources that are easy to use and designed for efficient integration into everyday practice can have sustained national impact.[49] The growth of mobile technology presents tremendous opportunity.[50-52] Mobile devices are promising because they are portable, low cost, and increasingly ubiquitous.[38,53,54] Mobile apps may improve children's engagement in treatment [55,56] by making treatment more interactive and pleasant, enhancing learning and skill acquisition, and preparing them for challenging activities. This may, in turn, reduce drop-out,[20,22] a pervasive problem in children's mental health care.[57] This study advances the field by rigorously evaluating the use of a tablet toolkit **designed specifically to address two key modifiable targets that are known to be associated with child mental health outcomes: provider fidelity and child engagement.** It also falls in line with a call for **practice-based research** as the next logical step following basic science research and human clinical research and as a fundamental "extending" arm of the NIH Roadmap.[58-59] This study also addresses several priorities described in the **2015 NIMH Strategic Plan for Research,**[60] particularly strategies 3.3 and 4.1 where there is emphasis on the need for **"target-based approaches to improve delivery of high-quality and efficient care"** (p. 46). The proposed work emphasizes clinical practice as the final endpoint, with a focus on improving delivery of care to the right patient at the right time, with fidelity. This research will test an innovative solution to the problem of poor fidelity and limited resources in real world settings; answers fundamental questions about feasibility; and tests the benefit, cost-effectiveness, and barriers and facilitators associated with sustainability of this solution in community practice settings.

TF-CBT[61] is an ideal model with which to conduct this study. First, it is a well-established treatment.[62-66] Second, it

addresses several interrelated clinical domains.[67] Third, it has been designated by the National Registry of Evidence-Based Programs and Practices (NREPP) as "effective" in treatment of trauma- and stress-related disorders, disruptive disorders and behaviors, and depression and depressive symptoms; and as "promising" in treatment of anxiety disorders. This underscores the applicability of our data and toolkit content to a range of child treatments. Fourth, TF-CBT emphasizes caregiver involvement, which allows preliminary exploration of tablet-based approaches with caregivers. Fifth, our preliminary work supports our capacity to lead a project of this scope, including leadership in regional and national dissemination of TF-CBT, and impact and leadership in evaluation of scalable health technology solutions.[33,68-70] Finally, our partnering sites are already delivering TF-CBT as standard care in their clinics for children who have experienced traumatic events, which allows us to conduct this study without manipulating providers' treatment decisions or delivery of usual care.

C. PRELIMINARY STUDIES

Provide an account of the principal investigator's preliminary studies pertinent to this protocol and/or any other information that will help to establish the experience and competence of the investigator to pursue the proposed project.

C1. Active TF-CBT Dissemination Initiatives (Projects BEST, PATS) that will Facilitate Recruitment

We will leverage two ongoing dissemination initiatives to support our recruitment goals: Project BEST (Bringing Evidence-Supported Treatment to South Carolina), a statewide dissemination initiative funded since 2007 by The Duke Endowment; and the Program on Adolescent Traumatic Stress (PATS), a regional initiative funded by SAMHSA since 2011. Together, as of June 2016, 30 learning collaboratives have been completed via Projects BEST and PATS with 799 clinicians (over 600 of whom are study eligible), 166 senior leaders, and > 3,500 child training cases. Drs. Hanson and Saunders (Co-Is) co-lead these projects and fostered the agency partnerships that will support the proposed effectiveness-implementation trial (see letters of support), including 4 sites that served as partners in our R34. Projects BEST and PATS are not explicitly linked to the study except that they will establish the population of eligible providers from which we will recruit. Each dissemination initiative maintains a roster of providers who completed TF-CBT training within the past 10 (BEST) or 5 (PATS) years. We will use this combined roster of over 600 study-eligible providers to identify candidates for recruitment (see Milestones).

Notably, Projects BEST and PATS offer training agency-wide, not through a selective or competitive process. More than two-thirds of providers in these agencies (~70%) complete the training, resulting in an externally valid sample of providers that is diverse with respect to years of experience, race/ethnicity, and other key variables. The learning collaborative process is comparable to that of other regional or national dissemination initiatives community-based providers may encounter.[79-81] **Recency of training is also highly variable. Only 109 of 602 rostered study-eligible providers (18.1%) completed their training within the past year.** This ensures that our sample will be diverse with respect to training recency. Finally, even among recently trained providers, we have found that knowledge and skill is highly variable. For example, we found mean post-training TF-CBT Knowledge scores of 61% in a survey of 39 providers who recently completed training via PATS.[82]

C2. NIMH R34 Phase 1: Semi-Structured Interviews with TF-CBT Certified National Trainers.

Phase 1 of our R34 was to complete individual semi-structured interviews with 21 nationally certified mental health treatment trainers, who guided development of the initial tablet-toolkit concept.[45] Data from this pilot were used to determine the components of treatment that are vulnerable to drift and activities that might assist in overcoming challenges to child engagement and provider fidelity in each component of the model.[45,47,83]

C3. NIMH R34 Phase 2: Development of Tablet-Facilitated TF-CBT

The development process for tablet TF-CBT is described in detail in our recently published protocol paper. [61] Tablet TF-CBT consists of 11 "Chapters." Introductory videos, which are available on the launch screen of each chapter, depicts a child who explains the rationale for the activity and briefly (i.e., 1 min) demonstrates the key elements of the chapter. Additional videos are brief clips designed to help providers reinforce concepts or skills taught in treatment. Some chapters feature interactive touch-screen games, such as drag-and-drop activities, drawing tools, trivia-style card games, and animated relaxation activities. **Each activity was developed to address an element of the TF-CBT protocol that was identified by experts and providers as challenging to implement with high fidelity and engagement.**

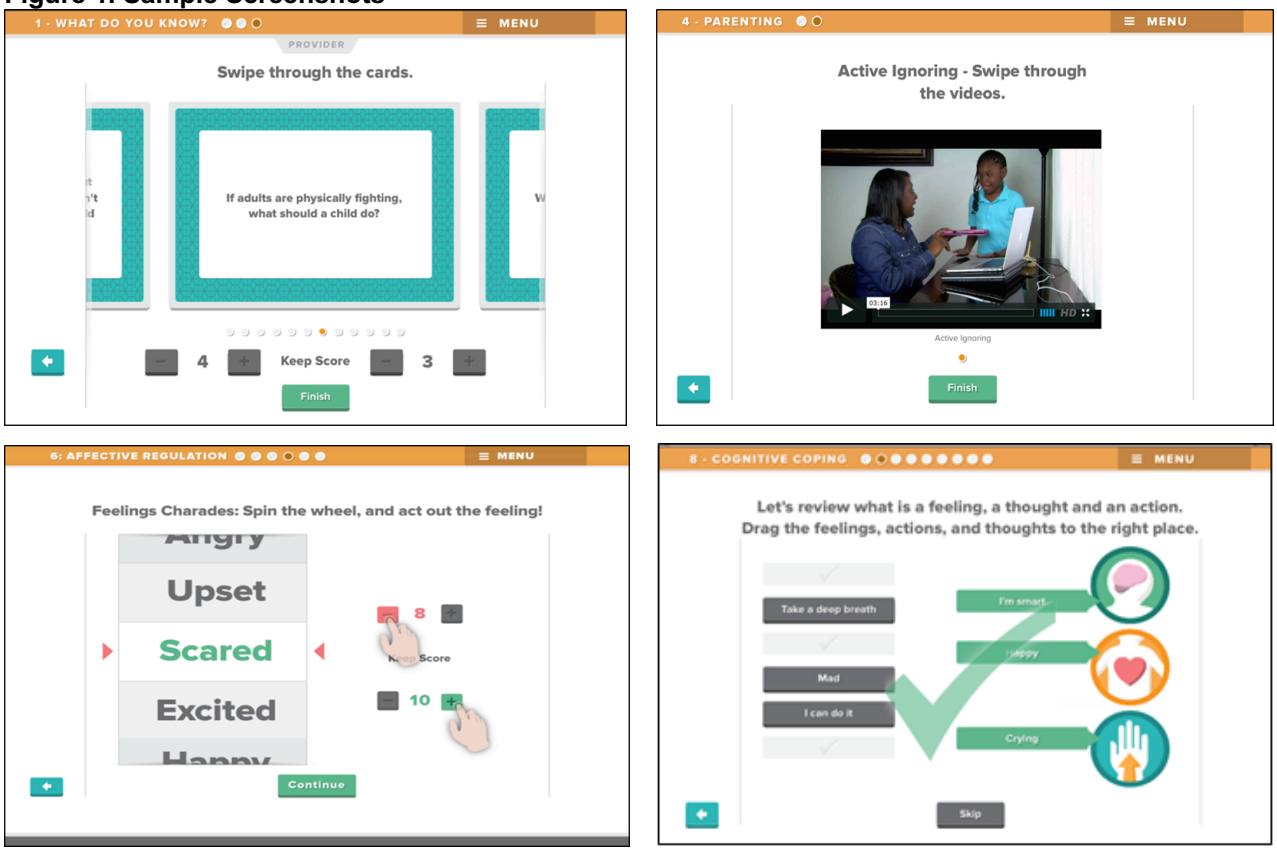
C4. NIMH R34 Phase 3: Qualitative Testing of Tablet TF-CBT. Qualitative testing was completed via focus groups with mental health providers (n=22) and focus groups and individual interviews with youth aged 8-16 years (n=24). Both samples had strong racial diversity; child focus groups were stratified by age (8-11 vs. 12-16 years).

Interviews were transcribed, independent coders produced a content analysis, and thematic categories emerged. These data guided revision of the tablet toolkit in preparation for the feasibility pilot.[47]

C5. NIMH R34 Phase 4: Randomized Controlled Feasibility Trial. We recently completed our R34 in which we conducted a randomized controlled feasibility trial to demonstrate our proposed methodology. This approach is consistent with expert recommendations to pilot test the feasibility of methods to be used in large RCTs, use data yielded by such studies to de-bug the methodology, and assess optimal strategies to execute the RCT.[84] We proposed an 8-month feasibility trial with recruitment of 10 providers from 4 local community-based clinics in SC. We aimed to recruit 20 families (referred by participating providers) during months 1-4 of the 8-month trial. Consistent with our current proposal, our research team managed all of the research elements of the trial. We conducted all consents, study assessments, random assignments, and coding and analysis of audiorecorded sessions uploaded by the providers. Providers referred patients to the study only after completing a standard intake process and determining that TF-CBT was the treatment of choice for that patient. Partnering sites were not engaged in research elements of the trial and delivered standard care (TF-CBT) to all study patients. Half of the providers were given access to the tablet TF-CBT toolkit, but there were not any requirements for providers with access to use the toolkit or any elements within the toolkit. They were given a 45-min training session to ensure that they knew how to navigate the toolkit, but were told that they were welcome to use it (or not) in whatever way they wished based on their own perceptions around how it may be helpful (or not) in their delivery of standard treatment. We proposed these benchmarks for establishing feasibility:

- **Recruitment of 20 families into the feasibility trial over our proposed 4-month recruitment period**
- **Completion of the treatment protocol by 14 families (70%)**
- **Retention of at least 14 families (70%) through post-treatment assessments**
- **Providers audiorecord at least 90% of all treatment sessions in both conditions**
- **Children, caregivers, and providers express high satisfaction with tablet-based TF-CBT**

Figure 1. Sample Screenshots



Each of these benchmarks was met or exceeded in our trial. First, we invited 17 providers to participate with the goal of recruiting at least 10 providers who referred eligible families to the study: 6 were based in child advocacy centers; 11 were based in state mental health facilities. All 17 providers consented, and **13** (76.5%) actively participated by referring and treating study families. Of the remaining 4 providers, 2 did not actively engage with the research team (i.e., did not respond to brief, weekly e-mail communications), and 2 indicated that they did not

have any appropriate cases to refer during the 4-month recruitment period. Second, we exceeded our goal of recruiting 20 families into the feasibility trial. A total of 31 families were referred to the study during our 4-month recruitment window; **24 of these families were referred within 2 months**, which led us to close recruitment early for several providers. Third, although participation rate was not explicitly proposed as a benchmark, it is notable that 27 of the 31 families (87.1%) referred by providers were consented and enrolled successfully into the study by our research team. Of these, only one family (3.7%) declined session audiorecording. Fourth, TF-CBT was completed (i.e., ≥ 6 sessions) by 88.9% of families. Fifth, we exceeded our goal of retaining ≥ 70% of families through post-treatment assessments. Fully 24 of 27 families were retained for mid-treatment assessments (88.9%), and we completed post-treatment assessments with 21 of 27 (77.8%). Sixth, we estimate that 247 TF-CBT sessions were completed for the 26 families that consented to audiorecordings. Of these, we received 221 audiorecordings (89.5%). Moreover, more than half of the audiorecordings we did not receive were accounted for by one provider. The remaining 12 providers adhered ~95% to audiorecording and uploading procedures. Seventh, coder agreement for **child engagement** was excellent (ICC *M*=0.81; range: 0.60-1.00) and coder agreement for **provider fidelity** was outstanding (ICC *M*=0.97). Eighth, all 11 tablet TF-CBT chapters were used with at least 5 families assigned to providers in the tablet TF-CBT condition; some chapters were used much more extensively than others (e.g., What Do You Know?).

D. RESEARCH DESIGN AND METHODS (including data analysis)

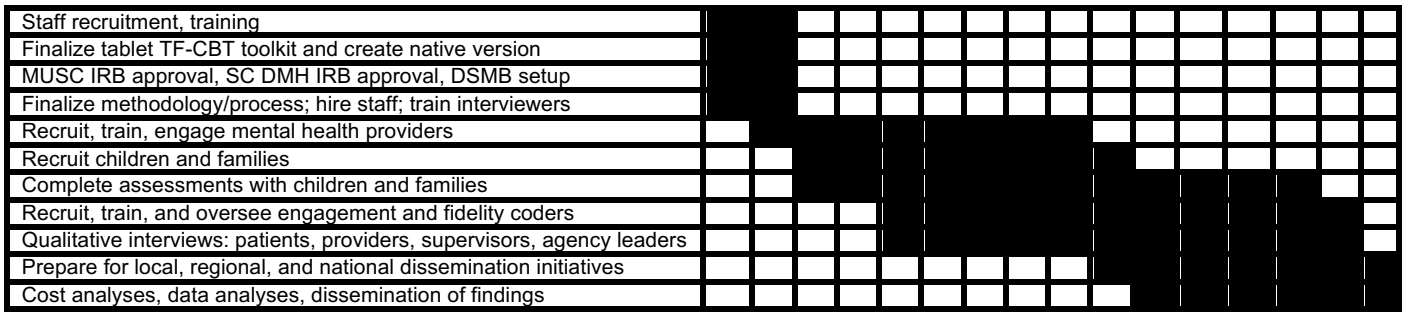
D1. Overview

We propose to use a hybrid 1 effectiveness-implementation design to evaluate and inform future dissemination and implementation of an innovative, scalable, tablet-based resource designed to improve quality of care for children and families. The resource, hereafter labeled **tablet-facilitated TF-CBT**, was developed under our R34 award and consists of 11 "Chapters" (e.g., videos, interactive games, drawing tools) optimized for use on tablets: (1) What Do You Know?, (2) You are not Alone, (3) Your Body, (4) Behavior Management (for caregivers), (5) Breathing Retraining, (6) Progressive Muscle Relaxation, (7) Affective Regulation, (8) Cognitive Coping, (9) Trauma Narrative, (10) In-Vivo Exposure, and (11) Enhancing Safety. **These chapters were carefully chosen and designed in collaboration with the TF-CBT developers, with extensive input from certified national trainers, and with extensive feedback from local mental health providers and families in treatment.**[45,47] Tablet TF-CBT is designed for use by providers in session with children and caregivers at designated points throughout the treatment process to support high-fidelity delivery of treatment and patient engagement. Pilot data indicated that providers elected to use it extensively with their patients, that it was easy for providers to use, and that it does not require significant preparation outside of regular sessions. Tablet TF-CBT was piloted with a sample that was diverse with regard to age (range=5-16 years), gender (55% girls), and race/ethnicity (30% African American). Children and caregivers from diverse backgrounds are featured in the tablet TF-CBT video demonstrations, consistent with data on learner preferences.[71-74]

This study will examine the extent to which tablet-facilitated TF-CBT, vs. standard TF-CBT, improves **child engagement (target)**, **provider fidelity (target)**, and **child mental health (clinical outcomes);** and will examine **clinic-, provider-, and patient-level facilitators and barriers to implementing and sustaining this approach in practice**. A randomized controlled trial is proposed with 400 providers in community practice settings across the United States. We have secured partnerships with clinics across the nation, which will ensure geographic (i.e., rural/urban) and racial/ethnic diversity. All of these clinics have actively partnered with us via dissemination initiatives led by Drs. Hanson and Saunders. Providers will be randomized to condition at the time that their first study patient is consented: tablet-facilitated TF-CBT (n=60) vs. standard TF-CBT (n=60). Providers will be enrolled in the study until (s)he has completed TF-CBT with 3 study cases. Most providers will need to refer 4-5 cases to the study to meet this goal. Baseline and 3-, 6-, 9-, and 12-month post-baseline assessments will be conducted by trained evaluators blind to study condition. Semi-structured interviews also will be conducted at study completion with diverse samples of ~20 families, ~25 providers (including ≥ 10 who opt out of the tablet condition or had low tablet use), ~10 supervisors, and ~10 senior leaders (i.e., agency directors, program managers) to assess barriers and facilitators associated with implementing and sustaining tablet-based resources.

D2. Timeline for the Proposed Project

Year →	2017			2018				2019				2020				21
Quarters →	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1



D3. Aim 1: Finalize the Tablet TF-CBT Toolkit (Months 1-6 [Web-Based]; Months 1-9 [Native App])
Due to the extensive iterative development process described above, finalization of tablet TF-CBT will not be an extensive process. The limited budget of the R34 necessitated that we defer some recommendations for improvement that emerged from qualitative interviews with providers and families. We will address high priority issues (e.g., enhanced tailoring features for the card-activity chapters, refining character drawings), expand our library of demonstration videos for caregivers, and create several caregiver videos to reinforce skills around relaxation, cognitive coping, and affective regulation. We will also take two key steps toward preparing the toolkit for dissemination. First, we will develop a series of demonstration videos that will serve as a tutorial to help providers navigate use of each chapter. We will develop these videos, in part, to support integration of the app into future dissemination initiatives with minimal training. Second, we will create a native version of the toolkit. This will improve reach and use of the app in service settings that do not have WIFI connectivity. Fuzzco, Inc., led development of the tablet toolkit in the R34, and will lead the technical aspects of this work.

D4. Hybrid Effectiveness-Implementation Trial
D4a. Overview. A type 1 hybrid effectiveness-implementation design is appropriate when testing the effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation. [85] The goal is to examine benefits of tablet-based resources in mental health care and inform dissemination and implementation of tablet-facilitated TF-CBT and similar technology-based approaches in community practice settings. This project will yield valuable data that address whether tablet-based resources designed to facilitate delivery of treatment can have additive benefits with regard to **child engagement** (target), **provider fidelity** (target), and **child mental health outcomes** (primary). We will also examine clinic-, provider-, and patient-level barriers and facilitators associated with implementing and sustaining this approach in mental health facilities, selecting specific Consolidated Framework for Implementation Research [86] constructs to be probed qualitatively.

D4b. Study Design. The trial will randomize to tablet-facilitated vs. standard TF-CBT 400 providers recruited from partnering agencies. We will stagger recruitment of providers to ensure an effective balance in level of coordination across clinics, providers, and patient assessments. We will recruit from clinics in the United States (~400 providers). In our pilot R34, 13 of 17 providers (76.5%) invited to participate in the study completed treatment with at least one study case. Applying this percentage to our proposed sample of 400 providers, we will need to invite roughly 520 providers to participate in the current trial. Collectively, this represents only about 25% of the total number of providers at these partnering clinics who will meet eligibility criteria for the study.

All study assessments with provider participants and family participants (i.e., baseline and 3-, 6-, 9-, and 12-month post-baseline assessments) will be conducted by independent, trained study evaluators blind to treatment condition and study hypotheses (Aim 2); whereas qualitative interviews will be conducted by the project coordinator (Aim 4). Baseline assessments will be coordinated with partnering clinics and completed via televideo. We will provide an iPad to each clinic for baseline telehealth assessments, which will be conducted using a secure, IRB-approved teleconsent platform (doxy.me). Post-baseline assessments and audiorecorded qualitative interviews will be completed by telephone by independent trained study staff. Measures were chosen based on strong psychometric support as well as their ease of telephone administration. Completion of assessments in person would have been impractical and cost prohibitive (i.e., would require numerous subawards and training, oversight, and coordination of many evaluators who are willing to travel extensively and flexibly with only partial support). Semi-structured interviews will be conducted as families complete treatment (n ~ 20) and at study completion with diverse samples of ~25 providers (including ≥ 10 who opt out of the tablet condition or had low tablet use), ~10 supervisors, and ~10 senior leaders (i.e., agency directors, program managers) to assess barriers and facilitators associated with implementing and sustaining tablet-based resources. These interviews will be completed over the telephone or using a videoconferencing program (like Facetime) called Doxy.me.

All mental health treatment sessions will be videorecorded and coded for fidelity and engagement by coders blind to study purpose and hypotheses. Videorecording of sessions is standard and typical in clinical practice for trainers or supervisors to review session recordings; in fact, most of the providers on the roster of eligible providers for this study recorded sessions while receiving training and ongoing consultation in TF-CBT.

Providers will be randomly assigned to treatment condition (tablet-facilitated vs. standard TF-CBT). Providers assigned to the tablet condition will be provided a unique study id to minimize risk of contamination. The tablet TF-CBT platform will not be accessible without a study-assigned userid. Eligible providers will have been fully trained in TF-CBT via ongoing dissemination initiatives independent of this study and will carry active child trauma cases. Each provider will treat three families during the course of the trial. We chose to recruit 400 providers and 3 families per provider, instead of fewer providers with more families per provider (e.g., 70 and 5), to minimize threats associated with provider turnover and variable patient caseloads. Providers will not be informed of their condition until their initial study-eligible family has been enrolled under their care. Although we discussed the possibility of integrating a tablet-based resource into the control condition to facilitate patient blinding, our agency partners were not receptive to this.

D4c. Recruitment of Providers. 400 providers will be recruited from partnering mental health service settings to participate in this study. Providers will be identified for recruitment from the roster of providers who have been trained in TF-CBT within the past 10 years through our BEST and PATS projects. See letters of support for a letter of commitment from South Carolina Department of Mental Health (covering 17 SC DMH centers) as well as letters from several SC-area child advocacy centers and partnering agencies nationwide. These sites collectively have significant geographic (i.e., rural/urban) and racial/ethnic diversity. This roster is maintained by Drs. Saunders and Hanson (Co-Is). **Inclusion criteria** are as follows. Providers must be full- or part-time employees of the partnering clinic and must have obtained at least a Master's degree in social work, counseling, clinical psychology, or related field. Each provider will be asked to refer 4-5 cases to the study to maximize likelihood that treatment is completed with at least 3 study cases. Although incentives cannot be given to providers due to state regulations, we propose as an alternative incentive that partnering clinics may keep study iPads for use by their providers upon completion of the study.

D4d. Randomization of Providers. Providers will be randomly assigned to the tablet-facilitated TF-CBT vs. standard TF-CBT condition. Providers will be blind to condition until their initial study-eligible family has been enrolled in the study under their care. Providers assigned to the tablet TF-CBT condition will be assigned a unique access code to enable tracking of the frequency and usage of each component of the tablet toolkit.

D4e. Orientation, Training, and Study Activities. Every effort will be made to minimize burden for agency directors, supervisors, and providers. This is important for study participation, and to demonstrate scalability and sustainability. First, there is an orientation (~60 min) in which all clinic directors, supervisors, and providers will take part to ensure consistency in procedures, channels of communication, and to address questions and concerns. This orientation will be done either in-person or via webinar if providers are unable to make the in-person orientation. Second, there is a consent and training process (30-60 min) that providers will undergo. This will include discussion of procedures around referring families to the study, audio or video recording sessions, using the "weekly metrics" secure portal (in which providers briefly report study activities for the prior week and upload sessions), and addressing questions about study procedures. Provider consent will take place immediately following the orientation. However, for providers that are unable to complete the in-person orientation and therefore have to complete the orientation via webinar, we will send them a link to teleconsent via RedCAP.

Based on "lessons learned" from our pilot evaluation, there are a small number of clinics that have restrictions on USB use of clinic computers which prevents uploading of files. For sites that are unable to upload video, we will provide them with SD cards for the video recorders that they can return it to us via certified (i.e., trackable) mail. These envelopes will also be provided to the participants. For those with audio recordings, they will be provided with multiple audio recorders that they can return to us by via certified (i.e., trackable) mail. Moreover, we will send them a form to fill out which will list each recording by file name, the session type and the subject's and clinician's initials (the minimum needed for us to identify the subject). They will notify us by email when they had mailed the SD card (if video recording) or recorder (if audio recording) and we will notify them by email when we have received it. This way, we will be able to be incompliance with HIPAA requirements that the chain of possession of the data be documented. This procedure has been used in other NIH R01 projects by key personnel in

the current study (Dr. Amy Hershell). Providers from these clinics will receive training in mailing, tracking and follow-up procedures. Third, providers in the tablet TF-CBT condition will receive additional training (~50 min) to ensure that they fully understand the structure and navigation of each Chapter. Providers will be told that they may use the toolkit flexibly based on how they feel it can best serve each patient. Moreover, it will be explicitly conveyed to providers in the experimental condition that they are free to use or not use the app – or any activity within – as they wish with study families. In our pilot study, most of the tablet TF-CBT chapters were used by the vast majority of providers and we found that providers are generally very enthusiastic about the app and are likely to use it when they feel it will be helpful to teach a concept or skill to children they are treating. Fourth, small, purposive samples of providers, supervisors, program managers, and clinic directors will complete semi-structured 30-60 min qualitative interviews to address barriers and facilitators associated with implementing and sustaining tablet-based resources in community practice settings.

D4f. Recruitment of Patients and Patient Eligibility. We will recruit 360 8-16 year old children and their caregivers. Our team already has established strong partnerships with over 70 child mental health service settings nationwide via Projects BEST and PATS. **Inclusion criteria** are as follows: participating children must be aged 8-16 years; must have been the victim of a potentially traumatic event (e.g., sexual assault, physical assault, disaster, serious accident); and must have at least one symptom on each PTSD symptom cluster (re-experiencing, avoidance, hyperarousal) based on the K-SADS-PL interview. Note: this inclusion criterion is consistent with prior RCTs of TF-CBT, but does not meet full PTSD diagnostic criteria. This threshold was set because PTSD diagnostic criteria were not standardized using child and adolescent populations until DSM-5, which could result in exclusion of children who are good candidates for treatment. Notably, using these criteria, 76% of children in our pilot study met full PTSD criteria at baseline, consistent with other TF-CBT trials. Cases will be **excluded** when the child or caregiver exhibits psychotic symptoms (e.g., active hallucinations, delusions); active suicidal or homicidal ideations; or significant cognitive disability, developmental delays, or pervasive developmental disorder. Children will be excluded if there is no consistent caregiver available to participate, consistent with criteria follow in TF-CBT efficacy studies.[30-33]

D4g. Data Collection Process and Measures. Consistent with other studies with similar RCT designs,[62,87] baseline and 3-, 6-, 9-, and 12-month post-baseline assessments will be administered by trained independent study evaluators blind to study condition and trained in the administration of all measures. Due to the number of partnering clinics and wide geographical area covered by the study, in-person interviews are cost prohibitive. It is also impractical, costly, and burdensome to patients to complete all assessments via televideo, which would necessitate significant travel to clinics after completion of treatment. Therefore, televideo will be used for the baseline assessment only, which will facilitate completion of the teleconsent process via our secure doxy.me telehealth platform. Post-baseline mental health assessments (Aim 2) will be conducted by study evaluators by telephone, scheduled directly with families, and supported by text and/or e-mail reminders. Although our NIMH R34 included children aged 6-16 years, we adjusted the age range to 8-16 years for the proposed study to address the lack of compelling data to support the inclusion of telephone-based assessments with 6-7 year old children. Several studies have been successful in conducting telephone interviews with children aged 6-7 years,[88-92] but the evidence base is considerably stronger for children in our proposed age range.[33,93-98] Our team has significant expertise in the conduct of telephone-based interviews with children affected by pediatric injury, [99] as well as large-scale epidemiologic studies we have conducted with youth, including the Bounce Back Now study (N=2,000) for youth victims of disaster,[33] the National Survey of Adolescents (N=4,023), [96] and the National Survey of Adolescents-Replication (N=3,614).[98] Well-established procedures around the protection of privacy during data collection and responding to participant distress have been developed for these studies that will be adapted for the current study. The telephone-administered measures here proposed are considerably less complex and time-intensive to administer than the measures we have administered in these prior population-based studies.

All measures were chosen because they are well-established instruments that are well validated and sensitive to treatment gains (e.g., K-SADS-PL). Assessments will be administered at baseline and 3, 6, 9, and 12 months post-baseline. Treatment fidelity and child engagement will be measured by coding videorecorded sessions with established observational coding schemes. In our NIMH R34, sessions were audiorecorded; only 1 of our 27 participating families declined audiorecording. Moreover, families reported in post-study interviews that videorecording was an acceptable alternative. Audiorecordings were optimal for coding of fidelity in our pilot study, and were satisfactory in coding child engagement. However, there were instances in which disagreement occurred in child engagement ratings due to ambiguous interactions between children and providers that will be

clearer with video feedback. For these reasons, we will seek consent to videorecord sessions, but will offer audiorecording (which was accepted by 96% of our pilot-study families) as an alternative if families express discomfort with videorecording.

Qualitative telephone interviews (Aim 4) will be scheduled directly with informants in the experimental (i.e., tablet-facilitated TF-CBT) arm of the trial to examine barriers and facilitators associated with implementing and sustaining tablet-based resources in child mental health facilities. This will occur at the completion of treatment for families; and at the completion of study requirements for providers, supervisors, and senior leaders. For each group of informants, we will use a purposive sampling approach drawing from trial participants and partners to ensure recruitment of diverse samples of families (e.g., age of child, race/ethnicity, rural/urban), providers (e.g., years of experience, level of tablet use, rural/urban setting), and senior leaders (e.g., agency directors, program managers). Given the nature of the interview, we will be requesting a Waiver of Written or Signed Consent from the IRB of Record to use for senior leader interviews (families and providers complete a consent form when enrolling in the study that includes information about this additional interview). All interviews will be de-identified and no additional identifying information (e.g., name, birthdate) will be collected through interviews with senior leaders. When approaching senior leaders to see if they are interested in participating in the interview, we will provide them with an informational sheet that explains the study's background and purpose, procedures, potential risks and discomforts, potential benefits, and contact information. The potential participants will have a chance to ask questions. Those who are interested in participating will then be scheduled for the phone-based interview at a time that is convenient for them. Each of these qualitative interviews will be guided by a semi-structured interview guide designed to identify the implementation challenges and successes, processes developed, problems overcome, and adaptations required. All interviews will be audio-recorded and transcribed verbatim for later analysis.

D4h. Measurement of Treatment Fidelity. Fidelity (i.e., degree to which a provider adheres to a treatment model) to the TF-CBT model will be measured via coding of recorded treatment sessions by independent, trained raters blind to study purpose and hypotheses. Whereas it is not possible to prevent raters from observing the use or non-use of a tablet, we will aim to minimize recognition of the tablet as the experimental manipulation by contextualizing training of the coders in a way that reinforces recognition of the wide range of tools, approaches, and styles that providers may introduce in their sessions. In our R34, we used the TF-CBT TPOCS-S coding system[100] (hereafter referred to as TPOCS). The TPOCS manual includes detailed instructions to code the specific content and technique items of TF-CBT as well as the therapeutic strategies typically used by providers implementing TF-CBT. The TPOCS is built upon the original coding system for TF-CBT.[101-102] Coders record clinicians' use of 25 different item codes that correspond to the TF-CBT PRACTICE acronym, other content items, and therapeutic techniques (e.g., establishing an agenda, Socratic questioning, teaching, reflective listening) during each session. In TF-CBT, each PRACTICE component is distinct and intended to build on each other. Providers are permitted to exercise a limited level of flexibility in implementation of the PRACTICE components based on patients' needs. The TPOCS will facilitate a components-based assessment of the thoroughness with which each component is administered. Use of iPad activities is recorded on the integrated coding form, and iPad activity use also is recorded in the tablet TF-CBT system for each study case. After the full session is coded, coders provide a rating of "extensiveness" (a 6-point rating to reflect the thoroughness or intensity of the intervention) for each item coded (by session type). Each trained coder will complete an estimated 65-70 hour training process consisting of reading the manual, in-person training, independent coding, group coding review, and certification. This training, led by Drs. Dorsey (co-developer of the TF-CBT TPOCS-S) and Davidson (certified master coder), occurs over a 6 week period; no more than 10-12 hours per week to minimize fatigue. Mean ICC across coders was .97 in our NIMH R34.

D4i. Measurement of Child Engagement. Child engagement (i.e., general level of behavioral involvement with providers during treatment sessions) will be observationally rated by independent, trained coders via review of recorded sessions. The Child Involvement Ratings Scale (CIRS)[21,103] will be used to code child engagement. Ten "child involvement" items – 6 positive, 4 negative – are rated for each session on a 6-point scale (i.e., "not at all" to "a great deal present"). The positive-involvement items emphasize the extent to which children initiate discussions, demonstrate enthusiasm, self-disclose, and demonstrate understanding. Items for negative involvement address withdrawal or avoidance in treatment. Coders will provide separate ratings for the first and second halves of each session, permitting observation of shifts in engagement within and across sessions. CIRS child engagement ratings have been associated with clinical outcomes[21] and provider flexibility in delivery of EBTs.[104] Excellent internal consistency and interrater reliability were reported for the CIRS.[21,104] Four independent raters were successfully trained to reliability in the pilot trial (ICC M=0.81; range: 0.60-1.00).

For this study, Dr. Chu will implement a training and reliability maintenance plan similar to that employed in the NIMH R34.[47] He will train four independent raters at MUSC to reliability in the CIRS and then lead bi-weekly maintenance calls to prevent rater drift as coders complete ratings. Initial reliability training will consist of a 2-day in-person didactic that reviews the CIRS manual and illustrates the individual items and scoring using "gold standard" recordings of TF-CBT that were developed in the R34. Coders will be considered reliable when they have achieved an ICC ≥ 0.60 on all 10 CIRS items compared to gold standard ratings.

D4j. Child Mental Health Measures at Baseline and 3-, 6-, 9-, and 12-month Post-Baseline Assessment
Measures that will be administered by televideo/phone to youth by independent study evaluators blind to condition:

- Kiddie Schedule for Affective Disorders and Schizophrenia for School Age Children-Present and Lifetime version (K-SADS-PL PTSD module).[105] This is a well-established semi-structured interview that is widely used and has been used in many TF-CBT RCTs.[62] We also will assess functional impairment in school, social, and family life using the K-SADS-PL. The K-SADS-PL has not yet been updated and validated for DSM-5. We anticipate that this will occur before our proposed trial start date (July 2017). If not, the study team will identify an appropriate diagnostic-interview alternative.
- Center for Epidemiological Studies Depression Scale for Children (CES-DC) assesses the severity of depressive symptomatology in children. It is a 20-item self-report measure with possible scores ranging from 0-60. Scores over 15 are indicative of significant levels of depressive symptoms.[106-107]
- Therapeutic Alliance Scale for Children (TASC).[111-112] The TASC is an 8-item measure of the child's alliance with the therapist using a 4-pt scale. It has good internal consistency and interrater reliability.[113]
- Child/Adolescent Satisfaction Questionnaire (CASQ).[114] The CASQ is a 15-item instrument that assesses child satisfaction with mental health treatment.
- The Shame Measure (Feiring et al., 1998) is a 4-item instrument that assesses feelings of shame following abuse.
- The Child and Adolescent Trauma Screen (CATS) – Youth Version is a 35-item instrument that assesses exposure to traumatic events and all 20 DSM-V symptoms of PTSD.

D4k. Caregiver Mental Health Measures at Baseline and 3-, 6-, 9-, 12-month Post-Baseline Assessment
Measures to be administered by televideo/phone to caregivers by independent evaluators (as in the R34):

- K-SADS-PL [105] to assess children's PTSD symptoms and functional impairment. (See above)
- Caregiver Satisfaction Questionnaire (CSQ).[114] The CSQ is a 15-item instrument that assesses caregiver satisfaction with mental health treatment.
- Working Alliance Inventory (WAI-short form).[116] The WAI is a 12-item measure of the parent-therapist alliance using a 7-point scale (never to always).
- Brief Problems Monitor (BPM). The BPM is a 19-item measure of emotional and behavioral functioning in children. The BPM is well-validated and comparable to the lengthier Child Behavior Checklist. [117]
- Center for Epidemiologic Studies Depression Scale (CESD-R). The CESD-R is a 20-item self-report scale of depression. It is widely used and demonstrates excellent psychometric properties. [118]
- The Child and Adolescent Trauma Screen (CATS) – Caregiver Version is the 35-item parent version of the CATS-Youth.
- The Alabama Parenting Questionnaire (APQ; Frick, 1991) is a 42-item measure to assess parenting practices.
- The Kessler 6 (K6; Kessler et al., 2002) is a widely used 6-item measure of general distress that is well-validated.

D4l. Provider Practice Measures Administered at Study Entry and Completion

- We will measure Provider Characteristics and variables relevant to adoption of EBT, including caseload characteristics, age, race/ethnicity, and years of experience; this will be measured at study entry only.
- Evidence-Based Practice Attitude Scale (EBPAS)[119,120] is 15 items, assessing providers' perceptions of appeal of EBT, openness to innovation, perceived divergence with usual care (alphas .59-.90; M=.77).
- Knowledge of Behavioral Principles as Applied to Children (25 items) to assess understanding of the application of behavioral principles to youth. Internal consistency=.42-.84; sensitivity to change.[121-124]
- Acceptability, Appropriateness and Feasibility Measure (Weiner et al., 2014) is a 12-item measure to monitor and evaluate implementation efforts. This measure has been shown to have solid psychometric properties.

- Computer Assisted Therapy Attitudes Scale (CATS, Becker & Jensen, 2013) is an 8-item measure design to assess attitudes toward computer use in treatment.
- Organizational Readiness for Implementing Change (ORIC; Shea et al., 2014) is a 12-item measure designed to assess an organization's readiness to implement new policies, programs, and practices.
- TF-CBT Organizational Support Measure is a 19-item instrument to assess a community mental health organization's activities related to the delivery of Trauma-Focused Cognitive-Behavioral Therapy (TF-CBT).
- Burnout. The Burnout measure is a two-item screener that assesses providers' feelings about their work, and their perceptions of how their co-workers feel about the work they do.

D8. Quantitative Data Analysis (Aim 2)

The RCT will include clusters of i children (n_{ij}=3) nested within j providers (n_j = 400). Analytic strategies for such a structure must address: (1) dependency in outcomes due to the nesting; (2) multiple outcome distributions; (3) linear, non-linear, and/or piece-specific change patterns; (4) variable measurement points; and (5) missing observations. Hypotheses will be tested within a multilevel modeling framework (MLM) that accounts for these issues.[127] Analysis will be carried out with HLM 7 software. Data first will be examined for violations of normality, including outliers and skewed distributions. Serious violations will be handled with best practices for MLM.[128,129] Next, site-level variation will be evaluated. Multiple providers will be recruited from the same site, which may introduce systematic variability attributed to provider location. Prior to conducting the analyses described below, an additional level will be added to the proposed models with a random effect for site. The significance of the random effect and an intracluster correlation coefficient (> 0.05) will determine if there is a marked amount of site variability. If these thresholds are met, site will be modeled as an additional level. If these thresholds are not met, it can be assumed that the majority of variability is due to differences across providers and children (i.e., effects of interest), and a random effect for site will not be included. The aims of the study do not include hypotheses for effects at the level of site. Separate models will be used for each variable described below. All subsequent models will be constructed according to the guidelines of Singer and Willet [129] with respect to including fixed and random effects. Random effects will be specified according to the likelihood ratio test and Wald test for continuous outcomes.[130] Statistical significance will be determined with by false discovery rate based on the number of tests conducted to account for multiple testing. [131]

D8a. Hypothesis 1: Higher levels of provider fidelity will be observed in tablet-facilitated vs. standard TF-CBT. To determine if the target of **provider fidelity** was affected by access to the tablet and tablet use, a 2-level MLM (level-1 child; level-2 provider) will be used. Fidelity will be measured by the TF CBT TPOCS-S. Fidelity scores will be calculated per child participant such that each provider will have 3 ratings. An aggregate score for the entire treatment of a case is consistent with prior use of these fidelity measures.[132] An aggregate fidelity score will allow the hypothesis of differences across condition to be tested while accounting for nesting of multiple cases per provider. Similarly, this measurement lends itself to use as a mechanism of treatment response (Hypothesis 5). The level-1 model will include a fixed effect corresponding to the mean participant fidelity score with a random effect corresponding to variability across participants. The level-2 model will include a dichotomous fixed effect representing the condition to which each participant will be randomized (tablet-facilitated vs. standard TF-CBT). The inclusion of additional child (level-1) and provider (level-2) covariates will be evaluated by estimating changes in model fit according to the deviance statistic for nested models and the AIC/BIC for non-nested models.[130] Case order (1st-3rd) will be included as a level-1 fixed effect to examine the potential increase in fidelity across cases due to practice effects.

D8b. Hypothesis 2: Greater child engagement will be observed in tablet-facilitated vs. standard TF-CBT. A 2-level MLM (level-1 child; level-2 provider) will evaluate the effect of access to the tablet and tablet use on the target of **child engagement**. An aggregate CIRS score for each child will be used for the reasons described in Hypothesis 1. A prototypical level-1 model will include a fixed effect representing engagement scores for children at level 1. The level-2 model will include a dichotomous fixed effect representing the condition to which each child was randomized (tablet-facilitated vs. standard TF-CBT). The inclusion of additional child (level-1) and provider (level-2) covariates will be evaluated by estimating changes in model fit according to the deviance statistic for nested models and the AIC/BIC for non-nested models.[130] Case order (1st-3rd) will be included as a level-1 fixed effect to

examine the potential increase in engagement across cases due to practice.

D8c. Hypothesis 3: Greater improvement in clinical outcomes will be observed at post-baseline assessments among children receiving tablet-facilitated TF-CBT vs. standard TF-CBT. Response to the intervention will be evaluated with a piecewise longitudinal MLM that contains 3 levels. Level-1 will correspond to measurement period, level-2 to child, and level-3 to provider. The primary outcome for Hypothesis 3 will be scores on the K-SADS-PL, UCLA PTSD Index, CDI, and CBCL. A piecewise model allows for separate change trajectories to be estimated for distinct periods of time. Patients are expected to show more rapid change during treatment than during follow-up (roughly corresponding to 9- and 12-month post-baseline period). The level-1 model will include a fixed effect for pretreatment (intercept), rate of change during treatment, and rate of change for the follow-up period. Time varying covariates (level-1) will be added to the model based on a theoretical rationale and changes in model fit. The level-2 model will account for child level covariates, including comorbid symptoms and trauma history. The level-3 model will include a dichotomous fixed effect representing the condition to which each provider was randomized (tablet-facilitated vs. standard TF-CBT). Of interest is the cross-level interaction between rate of change during treatment and the condition to which the provider was assigned. Cross-level interactions between the rate of change during follow-up also will be examined.

D8d. Hypothesis 4 and 5: Provider fidelity (hypothesis 4 target) and child engagement (hypothesis 5 target) will mediate the relation between study condition and mental health outcomes. The proposed design is consistent with an enhancement mediation design[133] to determine if provider fidelity and child engagement are the mechanisms by which tablet-facilitated TF-CBT reduces psychopathology. Enhancement designs evaluate mediation by experimentally manipulating a variable that enhances the effect of the mediator when direct experimental control of the mediator is not possible.[134] These mechanistic hypotheses will be tested with established guidelines for multilevel mediation[131]. Significance is determined by a product of coefficients test with asymmetric bootstrapped SEs and 95% CIs for the product. This requires estimation of two paths: the effect of tablet-facilitated TF-CBT on engagement and fidelity (a-paths); and the effect of engagement and fidelity on outcomes, controlling for the effect of tablet TF-CBT (b-paths). The mediation effect is estimated by the product of the fixed effect coefficients for the a- and b-paths. A Monte Carlo method is used to create a 95% confidence interval to test for the mediated effect as this effect does not assume a normal distribution. Provider fidelity and child engagement will be evaluated in separate models. Tests for mediated effects are associated with a number of challenges and assumptions such that a single study typically cannot address and overcome each of them.[133-134] As emphasized by MacKinnon and colleagues, the proposed randomized design is a relative strength that strengthens conclusions about the mediated effects. The mediation hypothesis will first be evaluated using all time points. If supported, follow-up analyses in which mechanism measures obtained from the first half of treatment will evaluate change in psychopathology in the second half of treatment. This two stage procedure will support the causal sequence of mediation - that an initial change in the mediator is associated with a reduction in psychopathology.[134] Combined, the proposed mediation model will provide important preliminary evidence to support, or reject, therapist fidelity and child engagement as potential mediators of the effect of iTF-CBT on child outcomes.

D8f. Exploratory Questions: Identify provider- and clinic-level variables associated with use of tablet-facilitated TF-CBT. We will explore candidate variables that may moderate the relation of treatment on child engagement, provider fidelity, and child mental health outcomes. These include organizational setting (e.g., general mental health clinic vs. child advocacy center), providers' professional experience, and providers' use of and attitudes toward evidence based treatment. These variables will be included as fixed effects in the models discussed.

D8g. Premature Termination. Patients will be considered dropouts if: (1) they complete fewer than three sessions or (2) serious adverse reactions or clinical complications occur that result in premature termination. A three-step approach will be used to handling missing data. First, in the event of a small proportion of missing data and evidence supporting a Missing at Random (MAR) mechanism, the MLM-based estimation procedures detailed above will be applied to the available data. Second, in the event of a non-trivial amount of missing data and evidence supporting a MAR mechanism, multiple imputations for repeated measurements will be used to estimate complete data. Third, in the event of evidence supporting a non-random missing data mechanism (i.e., MNAR), pattern mixture models will

be used to evaluate and subsequently control the effect of the missing data patterns in the statistical models.[136-138] Analyses will be conducted using all cases that were eligible for treatment at baseline and enrolled in the study (e.g., an intent-to-treat or ITT framework).

D8h. Power analysis and Sample Size. The analysis involves 3 nested levels, (1) repeated measurements nested within (2) children nested within (3) providers. Power estimates for the current MLMs accounted for the number of subjects at each level of analysis, number of measurements per subject for repeated measures outcomes, proportion of outcome variance at each level, and level of measurement of covariates.[139] Initial sample size estimates were determined by the feasibility of recruitment of providers and children from our collaborating partners. It is necessary to calculate power for providers and children due to hypotheses for provider and child specific outcomes. We will recruit 400 providers to complete TF-CBT with 3 children (total of 360 children). Power analyses using the Optimal Design software[140] suggest that 400 providers (clusters), 5 measurement points, $\alpha = 0.05$, a conservative ICC of 0.15, at 0.80 power, would detect an effect of 0.34 standard units. With 360 children, $\alpha = 0.05$, a conservative ICC of 0.15, and a cluster size of 3, at 0.80 power, would detect an effect of 0.29 standard units. Thus, we could detect small to medium effects with our proposed sample. For example, the standard effect of the UCLA-PTSD is roughly 15,[141] a standardized effect of 0.29 corresponds to a raw effect of 4.4. Alternatively, the number of providers needed to detect an effect of 0.5 standard units with the same values at 0.80 power is 60. The number of children needed to detect an effect of 0.5 standard units (raw effect=7.5) with the same values at 0.80 power is 128. Therefore, we will have sufficient power to determine differences in treatment response across study conditions as well as engagement of our targets (fidelity, child engagement). Finally, based on simulations by Fritz and MacKinnon,[133] the sample is sufficient for .80 power for the mediation test with a small-to-medium (ES=0.26) for both the a- and b-paths. We anticipate an approximate dropout rate for clinicians of 20% and for children of 30% based on our pilot data. Even with these dropout rates, we will have sufficient power to detect the previously mentioned effects.

D9. Cost-Effectiveness and Cost-Benefit Analysis (Aim 3)

We will evaluate the cost-effectiveness of tablet-facilitated TF-CBT vs. standard TF-CBT using methods outlined by Hargreaves.[134] We will collect data on the incremental cost that access to the tablet toolkit adds to standard TF-CBT. Costs include the cost of training providers in the use of tablet TF-CBT, cost of any study personnel time needed to address providers' needs while using the tablet (these were minimal in the pilot), or additional time of existing personnel for using the tablet TF-CBT toolkit (e.g., setup, tailoring activities). It also will include additional supplies, equipment, or overhead costs associated with providing tablet-facilitated TF-CBT vs. standard TF-CBT. Further, it will include technology-related costs associated with maintaining the app over time. The value of additional mental health provider time in tablet-facilitated vs. standard TF-CBT will be valued at the mean 1-hr cost of a provider based on estimates provided by the US Department of Labor Statistics. We will note the cost of development of tablet TF-CBT as well as other exclusive research costs, but because these are one-time development and research costs that will not be replicated in other facilities, we will exclude them from cost-effectiveness and cost-benefit analyses. We will define benefits as the difference in cost of health services utilization in the event tablet-facilitated TF-CBT reduces the number of sessions a provider needs to achieve the desired clinical outcomes. We will estimate an incremental cost-effectiveness ratio as: [(cost of tablet TFCBT - cost of TFCBT) divided by (effectiveness of tablet TF-CBT - effectiveness of standard TF-CBT)]. Effectiveness will be measured based on children's mental health outcomes. This ratio will estimate the increased average cost needed to gain an average of 1 point of improvement per time period in the target clinical outcome. We will examine differences in means, medians, and quartiles of cost by tablet-facilitated relative to standard TF-CBT using the appropriate tests based on the distribution of the cost variable. We will use generalized linear models with the appropriate distribution to examine the association of receiving the tablet TF-CBT with mental health session treatment costs, adjusting for patient demographics. We also will conduct a sensitivity analysis by estimating different cost models while adjusting for the clinical outcomes as we have done elsewhere. [135] We will do the same for mental health services utilization using a count model (Poisson or Neg Bin if overdispersion is encountered or zero-inflated if many zeros are present). As in the case of the clinical outcome analyses, random and fixed effects models will be estimated to account for clustering at the provider level.

E. PROTECTION OF HUMAN SUBJECTS

1. RISKS TO THE SUBJECTS

a. Human Subjects Involvement and Characteristics

- Describe the proposed involvement of human subjects.

- Describe the characteristics of the subject population, including their anticipated number, age range and health status.

All key personnel and project staff have completed and passed the CITI Human Subjects Research Protection Education Program.

Provider Recruitment. Two hundred fifty providers will be recruited statewide in South Carolina and from partnering community-based clinics nationwide. Providers will be identified for recruitment from our growing roster of over 600 study-eligible mental health providers in community mental health service settings who have been trained in TF-CBT through our *Project BEST* (Duke Endowment; led by Dr. Saunders [Co-I]) and *Program on Adolescent Traumatic Stress* (SAMHSA; led by Dr. Hanson [Co-I]) projects. *There is no requirement for inclusion relating to recency of training; in fact, only a small percentage (likely < 25%) will have completed training less than a year prior to recruitment*. These sites collectively have significant geographic (i.e., rural/urban) and racial/ethnic diversity. This roster is maintained by Drs. Saunders and Hanson (Co-Is). We will have adequate representation of African American and Hispanic providers based on demographic data available under Project BEST and PATS. We will oversample minority providers if our trajectory of recruitment falls meaningfully beneath estimates outlined in the planned enrollment report.

Drs. Saunders, Hanson, Ruggiero, or Davidson will travel to each partnering site to meet with providers to explain study procedures and obtain written informed consent from interested providers prior to initiating data collection. ***Participating providers will be assigned randomly to the standard TF-CBT condition or the tablet-facilitated TF-CBT condition.*** *Randomization will occur immediately after enrollment of providers' first study-eligible family.* All participating providers will already have been trained in the TF-CBT model as evidenced by their prior participation as a trainee via *Projects BEST* and *PATS*. Providers assigned to the tablet-facilitated TF-CBT condition will receive additional training (approximately 50 minutes in length) in the navigation of the app and use of its tailoring features. The TF-CBT model is designed to be completed over approximately 12 weekly sessions. Provider consent for the clinical trial will include agreement to (1) refer up to 5 cases to the study to maximize the likelihood that treatment is completed with at least 3 study cases per provider, (2) video-record (or audio-record, if preferred by the patient) treatment sessions for families who consent (consent is completed by the study team, not the provider), and (3) complete a brief self-report assessment battery at the beginning and end of study participation. We did not explicitly require use of the tablet TF-CBT resource for providers in our NIMH R34 pilot study. Rather, we encouraged use and invited a flexible approach to using it. For this study we will follow the same procedure by explicitly conveying to providers that they are free to use or not use the app – or any activity within – as they wish with study families. As mentioned above, in our pilot study, most of the tablet TF-CBT chapters were used by the vast majority of providers, and they reported finding it useful in teaching skills to the patients and keeping them on protocol. Videorecording of sessions is one additional role of participating providers, but this action is standard and typical in clinical practice for trainers or supervisors to review session recordings. In fact, session recordings were used for many of these same providers when initially receiving training and ongoing consultation in TF-CBT via MUSC's dissemination initiatives, led by two of our study collaborators (Drs. Saunders and Hanson). Families who express discomfort around video-recording of treatment sessions will be offered an alternative for sessions to be audio-recorded. Video-recording is preferable because we found in our pilot study that it will assist our coders in interpreting ambiguous interactions when rating children's engagement via behavioral coding (in contrast, it would likely have a negligible impact on coding of fidelity). However, we also found that adequate coder agreement was achieved and maintained with the use of audio-recordings in our pilot, and therefore we

feel that it is important to retain in our study families who decline video-recording but accept audio-recording. In our tablet TF-CBT pilot study, sessions were audio-recorded; only 1 of our 27 participating families declined the audio-recording of sessions. Moreover, toward the end of our pilot study, we submitted an addendum to our IRB application permitting us to ask questions addressing families' perceptions about video-recording sessions; all families asked these questions reported that they felt that video-recording sessions was acceptable. Therefore, we anticipate that most families will agree to video-recording of sessions. Providers will be informed that the project is not a condition of employment and will not affect their employment in any way, that they will not be penalized if they decline to participate, that measures are confidential, that they may withdraw at any time, and that study data are not part of their employment records. Additionally, providers will be explained the process of randomization as well as assignment to study condition.

Inclusion Criteria

Mental health providers from across the state and from partnering community-based clinics nationwide, will be recruited for this study. Most providers from all of these clinics meet the full inclusion criteria listed below.

1. full- or part-time employment at one of the participating clinics
2. must have obtained at least a Master's degree in social work, counseling, clinical psychology, or a related field
3. consistent caseload of potentially eligible children and families (i.e., appropriate candidates for TF-CBT)
4. trained in the implementation of TF-CBT

Exclusion Criteria

We attempted to limit exclusion criteria so that we have as ecologically valid a sample as possible. There are no primary exclusion criteria for the providers.

Child/Family Recruitment. We propose to recruit a total of 360 children and their caregivers. Participants will include children, ages 8-16 years, who are referred from clinics with participating providers for symptoms related to potentially traumatic event exposure (e.g., physical or sexual abuse, witnessed violence, disaster or serious accident), and a guardian with physical custody of the child (e.g., biological or adoptive parent, foster parent, grandparent, aunt/uncle). Participants of all races, genders, and ethnic backgrounds will be eligible. We anticipate adequate representation of racial/ethnic minority children in this sample based on demographic data available via training cases under Project BEST and PATS. However, we will carefully track recruitment of racial/ethnic minorities and will oversample African American and Hispanic children if our recruitment trajectories fall meaningfully beneath our projections.

Inclusion/exclusion criteria (below) are consistent with previous studies that have documented the efficacy of the TF-CBT protocol. Child age range was chosen based on recommendations of national trainers (Hanson et al., 2014), feasibility of administering standardized child assessments by telephone, suitability of the treatment protocol and tablet toolkit model, and prior research samples. Families will be recruited from clinics with mental health providers who have consented to participate in the study. Partnering clinics will introduce the study to potentially eligible families. Families that are interested in participating in the study will complete a small contact form that acknowledges their interest in being contacted by our study team to learn more about the project. This will be shared with our team. We will then contact the family, determine eligibility, consent families that are interested in participating, and schedule/complete the baseline interview. The administration of consent/assent and all study assessments will be conducted by an independent, trained study evaluator who is blind to condition. Interested families will be consented and assented (children ages 8 to 16) by the project clinical interviewer via teleconsent (either through Doxy.me or RedCAP). The Charleston-Dorchester and Berkeley Department of Mental Health clinics were participants in our R34 pilot study. After several

conversations with the DMH IRB, the requested that we gather signed informed consent from caregivers and assent from children separately. Moreover, they required a Flesch-Kincaid Reading Grade Level of 8.0 as to meet the literacy needs of their population. Therefore, families referred from the Charleston-Dorchester and Berkeley Department of Mental Health clinics will complete consent and assent forms that were approved by their IRB (please see DMH IRB Approval Letter). Consent/assent for all families in this study will include agreement to have treatment sessions video-recorded (audiorecording sessions will be offered as an alternative to families who decline videorecording), acknowledgement of understanding of randomization procedures and study conditions, and agreement to complete a small number of assessment measures before, during, and following therapy course (baseline and 3-, 6-, 9-, and 12-month post-baseline assessments; as well as understanding that they may be invited to complete an additional qualitative interview at post-treatment). Children and caregivers also will be informed that participation will not affect their receipt of services in any way, that they will not be penalized if they decline to participate, that measures are confidential, and that they may withdraw at any time.

Inclusion Criteria

The primary selection criteria for children participating in this study, consistent with procedures used in previous TF-CBT trials, will be that the child:

1. is between the ages of 8-16 years.
2. has experienced at least one potentially traumatic event (e.g., sexual assault, physical assault, witnessed violence, disaster, serious accident)
3. has reported a minimum of 5 current PTSD symptoms related to their traumatic event history, including at least one avoidance, one re-experiencing, and one hyperarousal symptom. *Note: this inclusion criterion is consistent with prior RCTs of TF-CBT, but does not meet the full threshold for PTSD diagnosis. This threshold was set because PTSD diagnostic criteria were not standardized using child and adolescent populations until DSM-5, which could contribute to the exclusion of large numbers of children who are experiencing clinically significant levels of PTSD and are likely to benefit significantly from trauma-focused treatment. Notably, using these criteria, 76% of children in our pilot study met full PTSD criteria at baseline. Nevertheless, measures are undergoing revision and validation since the publication of DSM-5, which includes more developmentally sensitive PTSD criteria and will create changes in the way these symptoms are assessed.* We will work with the full study team to determine how this inclusion criterion should change, if at all, once the K-SADS-PL DSM-5 instrument has been validated
4. has a caregiver who is willing to participate in the study (participating caregiver must have physical custody of the child—biological parent, grandparent, foster parent, other guardian)

Exclusion Criteria

Exclusion criteria for children and children's caregivers, consistent with procedures used in previous TF-CBT trials, include:

1. history or evidence of psychotic symptoms (e.g., active hallucinations, delusions, impaired thought processes) or personality disorder;
2. evidence of significant cognitive disability, developmental delays, or pervasive developmental disorder
3. dangerous behavior (suicidal or homicidal ideation) reported during the baseline assessment;
4. ongoing, unsupervised contact with the perpetrator in intrafamilial child abuse cases;
5. unstable home placement for cases involving foster care or other placement of the child; that is, the child must have lived in their current home setting for at least two months prior to recruitment.

medication: if a child has been referred for medication because of mental health symptoms, he or she must be stabilized (i.e., steady dosage for six weeks prior to enrollment in the study). Alternatively, children must have been discontinued from medications for a minimum of six weeks.

b. Sources of Materials
- Describe the research material obtained from living human subjects in the form of specimens, records, or data.
- Describe any data that will be recorded on the human subjects involved in the project.
- Describe the linkages to subjects, and indicate who will have access to subject identities.
- Provide information about how the specimens, records, or data are collected and whether material or data will be collected specifically for your proposed research project.

The research material obtained from human participants in this protocol will be as follows:

1. clinical information on participating children obtained by medical history and psychological interview
2. self-report questionnaires and information from structured and qualitative interviews
3. provider responses on the tablet-facilitated TF-CBT components (measured via weekly online metrics)
4. provider treatment fidelity as measured by coding recorded sessions using a established coding scheme
5. child treatment engagement as measured by coding recorded sessions using a established coding scheme

Clinical information, self-report questionnaires, recordings, and fidelity and engagement coding ratings will become part of each patient's research file. Separate files will contain the provider-related data (e.g., coding rating sheets, video recordings, audio recordings). All data will be collected specifically for this research program.

c. Potential Risks
- Describe the potential risks to subjects (physical, psychological, social, legal, or other), and assess their likelihood and seriousness to the subjects.
- Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

Risks associated with telephone-based interviews*.* One potential psychological risk of the proposed study is the possibility that some participants might experience distress when asked questions pertaining to their mental health histories via the telephone. Many people assume that asking such questions produces substantial distress, particularly in research settings and with traumatic stress populations. However, although this may be somewhat counterintuitive, the research literature, as well as our own research experience interviewing over 25,000 individuals affected by disasters and other major life stressors, demonstrates that many victims of traumatic events actually report positive benefits from their participation in assessment studies similar to the one proposed. For example, Newman et al (1999) reported findings from a sample of 1,174 adult women in an HMO setting who completed paper and pencil questionnaires asking about physical and sexual assault experiences. A subset of 252 of these women was selected to participate in follow-up trauma-focused interviews. When asked if they gained something positive from their participation, most of the women were either neutral (61%) or positive (23%) in their rating of the questionnaire portion of the research. However, 86.1% were positive about the interview portion of the research, and the remaining 13.9% were neutral. None was negative. In a follow-up assessment, 85.8% of those interviewed said they had gotten something positive out of their participation in the study. Another study examining participant reactions to various trauma assessment procedures included victims of domestic violence, rape, and physical assault (Griffin et al., 2003). Almost 8 out of 10 participants (79%) rated their participation in the clinical interviews as very or highly interesting, and only 5% said they would be unwilling to participate in a similar assessment study. These findings clearly suggest that the majority of participants in well-designed traumatic event assessment and service studies actually gain some benefits from their participation. These findings are consistent with conclusions of a recent meta-analysis (Jaffe et al., 2015), which examined results from over 70,000 participants across 70 samples and concluded that participants in trauma-focused research “generally find research participation to be a positive experience and do not regret

participation, regardless of trauma history or PTSD." Consistent with this conclusion, our previous research, including research with youth (Zajac, Ruggiero, et al., 2011), has found that many victims of traumatic events appreciate the personal validation that comes from being told their experiences are important and that the information gathered from the survey will be used to learn how to help other people who had similar experiences. In our sample of 3,614 youth who were interviewed via telephone about a series of violent and traumatic events (e.g., sexual abuse/assault, physical abuse/assault, domestic violence, community violence, school violence) as well as mental health history, we found that only 204 (5.7%) found any of the questions distressing, and that only 8 youth (0.2%) continued to be upset at the end of the interview. Thus, whereas most participants in trauma-focused research report positive benefits, only a very small percentage experience distress in the context of research interviews, and when this does arise among participants it tends to be transitory in nature for almost all participants. There is no reason to assume that participants in the proposed project would not experience similar positive effects from participation and, in fact, due to the nature of the interviews where the trauma-focused questions are considerably less detailed and explicit in this study than they were in other studies we have conducted (e.g., Zajac, Ruggiero, et al., 2011), we anticipate that distress in the context of the interviews will be even less prevalent in our study. Moreover, one of the primary aims of this study is to test the efficacy of a promising mental health intervention that is highly portable and sustainable and has potential for tremendous reach into child mental health service settings. As such, youth and families may report improved symptoms as a result of completing the proposed intervention.

Nevertheless, we do have a specific protocol, should a participant become distressed as a result of participation in this study. Our team includes several licensed clinical psychologists who can address situations in which we may learn that a high level of imminent risk is present. This procedure has been used in all of our epidemiologic studies to date, including the 1995 National Survey of Adolescents (N=4,023; PI: Kilpatrick), the 2005 National Survey of Adolescents-Replication (N=3,614; Co-PIs Kilpatrick and Saunders), and the 2011 Bounce Back Now study (PI: Ruggiero) of 2,000 adolescent disaster victims. Our protocol involves several steps. First, participants who appear to be experiencing a high level of distress during the interview will be identified by the trained master's-level interviewer. Second, they will be asked if they would like to talk to one of the investigators on the project, most of whom are licensed mental health professionals with considerable experience addressing the needs of victims of violent crime and other types of traumatic events (i.e., Drs. Ruggiero, Davidson, Danielson, Saunders, Hanson, Adams). Third, individuals who are very distressed and/or that the interviewer is concerned about will be told that a member of the project team will contact them to make sure they are okay within the same day (typically, immediately – the expectation of an immediate response is plausible in light of the fact that study interviews will be conducted exclusively during the workweek by an MUSC employee and that 6 MUSC investigators involved in this project are licensed clinical psychologists who are familiar with this protocol and willing to make themselves available to implement it when needed). Fourth, when a licensed clinical psychologist on our team re-contacts study cases where high levels of distress are indicated, that investigator will assess the nature and urgency of the distress, determine the need for clinical intervention beyond treatment already being received from the clinic through which they were recruited into the study, and arrange appropriate mental health referral, if necessary. In rare cases where a mental health referral is needed, the investigator will re-contact the participant one week after the referral to determine whether additional resources are needed or if assistance is needed in navigating the referral. In exceptionally rare cases of suicidality or extreme distress, we will follow the standard protocol that we implement in our Trauma Resilience and Recovery Program (TRRP), a mental health coordination of care service that we provide to patients after they have experienced traumatic injury; and that also is in place at the National Crime Victims Research and Treatment Center (NCVC). Dr. Ruggiero (PI) is Director of this TRRP program, which has served over 250 patients since its launch in September 2015. Dr. Davidson (Co-I) is Co-Director. Dr. Hanson (Co-I) is the Director of the Child and Family Clinic at the NCVC, and Dr. Saunders is former Director. The team therefore has considerable expertise and experience in addressing patient distress. The general process for addressing extreme distress is as follows. If a patient reports thoughts of hurting or killing him/herself, the clinician asks a series of questions to ascertain frequency of thoughts, access to lethal

means, and plan. Depending on patients' level of intent (gathered from the clinical interview and self-rating), the clinician and patient will activate a safety plan. The safety plan can include contracting for safety, having patient or others in home remove lethal means (e.g., firearms, medication), and generating steps to take if patient feels s/he cannot honor the contract. Hospitalization options may be explored when appropriate. Local, regional, and/or national hotlines are shared. Follow-up occurs as needed.

Prior to initiating subject recruitment, we will review with each of our partnering clinics local referral procedures that they would like us to follow for participants who experience distress. As previously mentioned, we have utilized these procedures in several large-scale epidemiologic studies we have conducted with adults and children. We have had to make fewer than 15 total mental health treatment referrals for participants in our studies (in which we have recruited over 25,000 participants collectively), and these studies have involved regular communication between our team and study participants. Because all of our families will be recruited from partnering clinics in which they are already engaged, these families already will have established connections with local mental health providers.

Risks associated with using technology-assisted rating forms and applications*.* Breaches of confidentiality are a concern with technology-based components of any study. However, participants will not use their names or other protected health information to log onto the application. Further, data will be collected and stored via a secure server. More information about data monitoring and safety planning is available in the *Protection against Risks* section.

Risks associated with data collection*.* We have outlined several steps to maintain confidentiality and de-identify data to protect against loss of confidentiality of disclosed materials. Nevertheless, if our protocol for maintaining confidentiality were broken, there is a risk of potential loss of confidentiality to the child and caregiver. Another common concern is the potential for assessment of potentially traumatic events to produce small to moderate amounts of anxiety; however, research has consistently demonstrated that distress in the context of such assessments is rare and transient (Griffin, Resick, Waldrop, & Mechanic, 2003; Zajac et al., 2011). For the providers, the only potential risk is that they may feel some discomfort stemming from close supervision and the perception that their work is being scrutinized. This concern was not raised in our pilot study.

Risks of harm and associated breaches in confidentiality*.* A fourth risk concerns the legal limits of confidentiality. For example, the possibility exists that we might learn that a participant is currently having suicidal or homicidal thoughts or is actively abusing or being abused and confidentiality may need to be broken to protect the participant's safety. These confidentiality limits will be documented in the written consent form and verbally explained to all participants.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent

- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.

- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.

A family can be referred under the condition that the child has experienced a potentially traumatic event and is a possible candidate for TF-CBT delivered by one of the study clinicians. In these cases, the referring party will obtain verbal consent for the family to be contacted by project staff for the purpose of conducting an initial phone screen. The initial phone contact will be conducted by the clinical study interviewer and structured to determine potential eligibility and schedule an appointment to obtain informed consent and conduct the initial assessment. Study staff will contact the family within 48 hours of referral into the project. For cases involving alleged child abuse, the intake coordinator at each clinic will determine if an alleged incident has been reported to authorities and investigated prior to referring

to the study. If the case has not been investigated, it will be referred to an investigative agency (DSS, law enforcement). This is unlikely to occur, because it is a standard procedure followed by all (or virtually all) of our partnering clinics, who have consistently maintained active caseloads of children affected by traumatic events and therefore have clear policies in place to guide assessment and treatment of such cases. Nevertheless, if it does occur and such a referral must be made, we may facilitate assignment of such cases to providers outside of the scope of the study to minimize risk that study involvement will delay receipt of treatment, which could occur if the investigation (i.e., substantiation or determination of a credible report) is open for longer than one month. Caregivers recruited into the study will be informed that any new (i.e., unreported) disclosures of abuse must be reported to the appropriate authorities, as mandated by state law.

To reduce the burden of participating in research, we will use of the RedCAP or Doxy.me tele-consenting technology. Teleconsent through RedCAP will allow the study interviewer to conduct the consent/assent process over the telephone. The interviewer will send the teleconsent link to the family and call them on the telephone. The family will be able to read consent/assent/HIPAA forms along with the provider and will have the ability to sign, date, and download their own copy all via the secure, and HIPAA compliant RedCAP system. Doxy.me was developed and is maintained by MUSC Biomedical Informatics Center (BMIC). The BMIC tele-consent application is built upon an established telemedicine platform (Doxy.me), and allows researchers to discuss a study with potential participants via video chat, where they may also share with participants the IRB-approved Consent and HIPAA forms. This enables both parties to collaboratively complete and sign documents in real-time in a location that is convenient for them. For example, Doxy.me allows a researcher to remotely guide the participant through a consent document step-by-step and help them fill out the necessary fields. This includes synchronous viewing, scrolling, zooming, and editing of the consent document. As the researcher moves their mouse, clicks, scrolls, zooms the page, or edits fields (e.g., text, checkboxes, radio buttons) on the consent document, the actions simultaneously appear on the participant's screen (and vice versa). Once the informed consent document has been completed, a PDF of the document can be generated and available to both the researcher and participant, which can be printed or saved on the local computer and printed. This process has been piloted successfully with a number of clinical populations. Through tele-consent, an independent and trained project staff member will remotely guide the legal guardian through a consent document step-by-step and help them fill out the necessary fields. Once the informed consent document has been completed, a PDF of the document can be generated and is available to both the researcher and the participant.

A separate written consent will be completed by participating providers, who will be visited in person by a member of our research team (Dr. Ruggiero, Saunders, Hanson, or Davidson, or other designated study staff). Provider consent will be obtained in-person following completion of the study orientation at partnering clinics. For providers who are unable to complete the in-person orientation, they will the option to complete the orientation via webinar at which time will be send a link to teleconsent via RedCAP. Agency supervisors and senior leaders will not be consented as study participants. If participating in Aim 4 interviews, supervisors and senior leaders will complete a waiver of signed consent.

Any participant (i.e., child, caregiver, provider, supervisor, or senior leader) may withdraw his or her consent at any time and may withdraw from the study at any time without prejudice or loss of benefits to which they are otherwise entitled. All adult participants will be asked for written consent after reading the consent form, discussing the study, and being given a chance to ask questions. They will be informed that they are being asked to participate in a research study. They will be told the nature of the procedures and randomization, informed of risks associated with their participation, asked to read the consent form, and encouraged to ask questions or discuss any pertinent issues. They will be told that declining to serve as a participant in this study will not influence or compromise the quality of their care or state of employment at the various institutions.

b. Protection against Risk

- Describe planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.
- Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a description of the plan for data and safety monitoring of the research and adverse event reporting to ensure the safety of subjects in Section 4 below.

Each child will receive psychological treatment by an experienced clinician trained in TF-CBT, who is being supervised by their agency supervisor. In addition, several investigators on the study team (e.g., Drs. Ruggiero, Hanson, Saunders, Davidson) are licensed mental health care providers with extensive experience and training certification in TF-CBT. The expertise of the team assures that we are well equipped to manage any adverse events that occur in the context of treatment. The following procedures will be instituted to minimize the risk to participants.

Confidentiality. Emphasis on confidentiality will be stressed in all aspects of the study. No information about participation in the study will be divulged without specific and written consent to release information. The only exception would be mandated reporting of new allegations of child abuse or disclosures of intent to harm self or others. These confidentiality limits will be documented in the written consent form and verbally explained to all participants. Research records of individual participants will only be identified by code rather than by name. For all phases of the project, providers also will be informed that the project is not a condition of employment, that they will not be penalized if they decline to participate, that measures are confidential, that they may withdraw at any time, and that study data are not part of their employment records. Child (ages 8 to 16), parent, and provider assent, consent, and HIPAA documents and signed information releases (as requested by patients) are the only documents containing patient identifiers and will be kept separate from study records in a locked cabinet on a secure floor.

Data Safety. With regard to data safety issues, Josh Nissenboim of Fuzzco, Inc., will work with Sachin Patel, MSc, of MUSC's TACHL Center to support electronic data security. Mr. Nissenboim and the Fuzzco team, and Mr. Patel and the TACHL team, have extensive experience safeguarding the security and integrity of sensitive materials, including protected health information and sensitive financial information. The secure servers that will house the data files collected from the tablet TF-CBT resource, provider metrics, and study interview assessments are located at MUSC in SSL (Secure Sockets Layer) 128-bit encrypted servers behind firewalls. During each stage of the study, Fuzzco and TACHL will facilitate access to study data sets as needed. Respondent confidentiality will be masked in all data files by the use of project identification numbers rather than personal information. All other electronic records, including video-recordings of sessions, are de-identified in collection and will be maintained in password protected locations on the secure server. All paper records will be de-identified and maintained in a locked file cabinet on a secure floor. The only document linking participants with identification numbers will be retained in an encrypted file on the secure server with access limited to the key study personnel. Data presented at professional meetings or published in journals or books will not allow identification of individual participants. These procedures are expected to minimize any potential adverse effects from participating in this study.

Assessment Procedures. As described in the research plan, families will complete assessments conducted by study staff at baseline, and at 3-, 6-, 9-, and 12-months post-baseline. The assessments will be conducted via telephone for several reasons. First, in-person interviews are cost prohibitive because we are recruiting families from a large geographic area across three states. Second, it would also be cost prohibitive to arrange televideo post-baseline assessments with all families. We believe that scheduling a small number of baseline interviews for new patients in collaboration with partnering clinics will be a challenging but manageable process, and we already have taken several steps toward identifying these processes with these clinics. However, it is impractical and cost prohibitive to coordinate 1,800 assessments (5 assessments x 360 participants) with our partnering clinics throughout the course of the study. Third, efforts to coordinate televideo assessments through the

clinics for all 1,800 assessments would have clear adverse effects on study retention because this would increase burden associated with transportation and time for families. Fourth, research has shown that telephone assessments are acceptable and methodologically appropriate for children as young as 8 years old, which corresponds to our lower age range for children recruited into the study. Taken together, the use of telephone methodology for post-baseline assessments will ensure that study costs, data quality, retention of participants, and burden to families associated with scheduling and transportation are all manageable and reasonable within the scope of the proposed study.

Although unlikely, should an individual become uncomfortable during the assessment, the interviewer will provide assistance or direct families to other sources of support. Many victims of crime and other traumatic events rarely report that being asked about their traumatic events is distressing. Zajac et al (2011) reported findings from a nationally representative sample of 3,614 adolescents who completed telephone-based surveys asking about exposure to physical and sexual assault, community and domestic violence, or other serious accidents. Only 5.7% of the youth interviewed found any of the interview upsetting, of which only 0.2% remained upset at the time the phone interview concluded. Only 2 (<0.1%) participants were upset enough to want to speak with a counselor at the conclusion of the interview.

Study Consent and Participant Incentives. Consent and HIPAA forms containing identifying information will be maintained securely and separately from other research materials. Measures will be taken to maximize confidentiality and include the following: (1) names of participants will appear only on consent and HIPAA forms and a digitally secure, password protected master roster; (2) only key study personnel will have access to the complete list of names and respondent ID numbers; (3) all other data will be referred to by ID numbers only. Treatment sessions will be video-recorded for fidelity and engagement coding purposes. Audiorecording will be offered as an alternative to families who decline video-recording. These recordings will be kept secure and separate from identifying information, and coding ratings of the sessions will not include identifying information. Following coding and analyses, the recordings will be destroyed. The likelihood that these methods will effectively protect the confidentiality of participants is considered to be extremely high.

The consent for the RCT Trial for caregivers, children, and providers will include agreement to video-record treatment sessions and to complete assessment measures throughout the project. At consent, child participants and their caregivers will also be informed about and given a rationale for randomization. They will not be notified of their condition (to which the clinical interviewer will be blind), and will not be able to predict their condition until they begin treatment. An initial evaluation will be conducted with all potentially eligible families by study staff. This will include a structured diagnostic interview as well as completion of self-report measures. Participants with symptoms of psychosis or personality disorder, suicidal or homicidal risk, severe cognitive impairment, or developmental disability that, in the judgment of the investigator, will make it unlikely that the patient can adhere to the study regimen will be excluded from the study. These participants may be offered other, more appropriate treatment options in the clinic or referrals that may be available based on the judgment of treating providers within the partnering clinic. All interviews and associated transcriptions will not contain any identifying information and will be maintained in a secure and password protected research drive only accessible to study personnel.

The consent will also explain that participating families will be mailed a gift card upon completion of the study assessments. The reimbursement schedule is as follows: baseline ($30), 3-month ($30), 6-month ($40), 9-month ($40) and 12-month ($50) post-baseline assessments. A small number of families (*n* = 20) also will be purposively sampled to complete qualitative post-treatment interviews for which they will receive additional compensation ($50). Provider, supervisor, and senior leader consent forms will explain that we will not be able to offer monetary incentives for participation in this study due to agency rules and regulations regarding the use of incentives during working hours. However, they will be informed the study iPads will be donated to the clinic following completion of study procedures: one iPad for each participating provider who completes the study. Additionally, provider consent forms will

state that providers who complete the qualitative interview on the use of the toolkit outside of work hours will receive additional compensation ($50).

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

This project builds upon our nearly completed NIMH funded project (R34 MH096907) in which we developed and pilot tested a patient- and provider-informed tablet-based toolkit designed to enhance the delivery of Trauma-Focused Cognitive Behavioral Therapy (TF-CBT), a treatment that addresses a wide range of symptomatology and functioning and provides an ideal and scalable framework for translation to other evidence-based interventions. This toolkit focuses on provider fidelity and child engagement during TF-CBT with the goal of improving the quality of care in mental health settings. *Our recent work has set the stage for a large-scale effectiveness-implementation trial to examine the benefit of tablet-based toolkits in child mental health treatment while also examining costs as well as barriers and facilitators to implementation and dissemination.* This study will provide valuable data toward understanding additive benefits of tablet-based resources to quality of care in child mental health treatment. *It will also address key questions around the implementation, dissemination, and sustainability of technology-facilitated treatment approaches in community practice settings.* The proposed approach is highly sustainable due to low costs of disseminating these resources, and therefore has the ability to have wide reach and impact in the general population.

The risks of this study phase are minimal from an experimental standpoint as study procedures closely follow those used in routine clinical care. Children and families receiving services using the tablet-based toolkit will be receiving these services from providers who have at their disposal resources designed to support the effective delivery of evidence-based treatment for their symptoms. It is anticipated that children and caregivers in this group will find the technology-based enhancements to treatment fun and engaging, consistent with reactions we observed in our pilot study, which may improve their treatment experience and their relationship with their providers. Providers in the proposed study will also benefit from their participation. Additionally, half, randomly selected, will receive training and access to a novel tablet-based application that is designed to assist them in increasing child engagement, structuring treatment sessions, implementing a treatment model with fidelity, reducing required time to prepare for sessions, and otherwise supporting their attempts to provide the best possible care to children and their families.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.
- NOTE: Test articles (investigational new drugs, devices, or biologicals) including test articles that will be used for purposes or administered by routes that have not been approved for general use by the Food and Drug Administration (FDA) must be named. State whether the 30-day interval between submission of applicant certification to the FDA and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration, and/or the status of requests for an IND or IDE covering the proposed use of the test article in the research plan.

Although technological advances, particularly in healthcare settings, have been occurring at an exponential rate, relatively little is known about the use of various technologies in psychosocial treatment. Progress in the mental health field has traditionally lagged behind the medical profession (Boschen, 2009). At the present time, understanding is limited regarding the incremental benefits of using technology-facilitated delivery of evidence-based treatment on treatment outcomes, particularly with regard to patient engagement, provider fidelity, and relatedly, short- and long-term child mental

health outcomes. As these technologies are becoming increasingly commonplace, it is necessary to empirically investigate their effect on treatment outcomes, particularly in the mental health setting. Doing so will ultimately increase our understanding of these resources' ability to (a) bridge the gap between empirical research and clinical practice, (b) reduce the burden of mental illness, and (c) ensure that established mental health protocols capitalize on advances in technology to improve quality of care. Data for the efficacy of treatment of the proposed treatment model for this study has been well-established, but our knowledge base regarding technology-based enhancements to addressing challenges around children's engagement and treatment fidelity in real-world clinical settings is limited. Nationally Certified Trainers interviewed in our pilot work suggested that provider fidelity to components of the treatment protocol, provider skill in delivering treatment activities, and both caregiver and child engagement are all significant barriers in the effective delivery of TF-CBT by community-based providers. They also indicated that these barriers occur in a wide range of evidence-based treatment protocols. Data from this project are critical to enabling us to determine the effectiveness of technology-assisted intervention enhancements as well as to identify the best, most cost-effective method for enhancing fidelity of therapists in real-world settings to evidence-based treatment protocols. TF-CBT addresses both externalizing and internalizing behaviors across childhood and includes both caregiver and child components, suggesting that lessons learned from further examination of this tablet-based toolkit have the potential to inform a wide variety of child and family interventions.

5. SUBJECT SAFETY AND MINIMIZING RISKS (Data and Safety Monitoring Plan)

*Studies that involve *clinical trials (see description below) must include a description of the plan for subject safety and minimizing risks of the research, including data monitoring and adverse event reporting to ensure the safety of subjects. The complexity of the plan should be determined by the level of risk to subjects. The plan should specify: 1) what will be monitored, 2) how frequently the monitoring will occur, 3) who will be responsible for the monitoring, and 4) study endpoints.*

Adverse events (AE) will be monitored throughout the study and any event will be followed to resolution or stabilization. An AE is defined as any untoward or unfavorable medical occurrence in a human study participant, whether or not it is considered to be related to participants in the research. In addition to reporting of AEs to MUSC's Human Investigators Committee within 10 days as described below, routine reporting of AEs using NIH's standard AE forms will occur quarterly as determined with NIMH staff and the Data and Safety Monitoring Board. All serious adverse events (SAE) will be reported immediately to the IRB and the federal funding agency. A serious adverse event is one that meets any of the following criteria: (a) is fatal or life threatening, (b) requires or prolongs hospitalization, (c) results in persistent or significant disability/incapacity, (d) important medical event that may jeopardize the patient or require intervention to prevent a serious outcome, (e) overdose, or (f) the development of drug dependency or abuse. An unanticipated problem (UP) is any incident, experience, or outcome that meets all of the following criteria: (a) unexpected given the research procedures and characteristics of the study population, (b) related or possibly related to participation in the research, and (c) suggests that the research places participants or others at greater risk of harm than was previously known or recognized. We will report any such events to IRB and NIMH unless they are also SAEs, in which case we will report these events immediately. The Principal Investigator will provide continuous, close monitoring with prompt reporting of adverse events to the IRB and NIMH, and will follow MUSC's adverse event reporting policy (see below). Additionally, Drs. Ruggiero, Saunders, Hanson, Danielson, Adams and Davidson are licensed clinical psychologists with extensive experience treating victims of traumatic events.

MUSC's policy for reporting serious adverse events is as follows: It is the investigators' responsibility to report all SAEs to the Human Investigators Committee (HIC) and the sponsor within 10 working days after learning of the event. An "AE Report Form" must be submitted to the HIC office. A description of the SAE and treatment, if any, must accompany the form. The report is reviewed by the HIC chairperson, designated representatives, or the full HIC, as determined by the chairperson. If the reaction is severe, the investigator may be requested to discontinue the research pending further

review by the HIC. Investigators must ensure that NIH is informed of actions, if any, taken by IRB as a result of its continuing review. Any AE will be reported to NIH in an individual AE report. In addition, we will evaluate the progress of the study, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, and other factors that can affect study outcomes. We will also consider factors external to the study, such as scientific or therapeutic developments that may have an impact of the safety of participants or the ethics of the study.

In addition, a Data and Safety Monitoring Board (DSMB) will be formed to ensure the ongoing safety of the participants. Based on prior research implementing technology-based interventions with trauma-affected populations, we do not anticipate any SAEs or UPs, but it is possible that we may see AEs. This could include suicidality or escalation of symptoms and distress. The PI will appoint members from multiple disciplinary backgrounds that are not involved in the project, including a chairperson that has previous experience leading federally funded research and services grants as well as experience in monitoring clinical trials research (Ron Acierno, Ph.D.), an associate Professor in Nursing who has led innovative research with technology in COPD and pediatric asthma (Sarah Miller, Ph.D.), a research scientist who is certified as an acute care nurse and received her PhD in Nursing from MUSC (Shannon Phillips, Ph.D.), and an established statistician and methodologist (Bonnie Dumas, Ph.D.). The Board will monitor subject participation and safety issues with a focus on study enrollment in process, study safety, and data integrity. They will be sent tables with de-identified data prior to each quarterly meeting for their review. For the duration of the RCT, including the follow-up and qualitative interviews, the board will meet quarterly to review data and monitor any potential concerns that have developed. Safety monitoring will involve review of cases involving AEs or UPs where continuing the intervention could create safety concerns, ongoing review of potential risks and our measures in place to protect participants against foreseeable risks, review of consent procedures, and review of participant privacy protections and security of data collected by our system. The institution leading this research, the Medical University of South Carolina, will have full and instant access to all reports and data reviewed by the DSMB. This will ensure adherence to the monitoring plan and requirements for reporting AEs, SAEs, and UPs. The PI also will have the ability to call an unscheduled in-person meeting in the event of any AEs, UPs, or SAEs that arise with the project. The Board also will be responsible for following up on requested actions based on recommendations from the Board in response to an AE. Outcome of SAEs will be written in the form of a report reported to the MUSC IRB and NIH.

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G. CONSULTANTS

Where applicable, attach electronic versions of appropriate letters from all individuals confirming their roles in the project. Go to the application under "additional uploads" to attach this information.
See Drs. Deblinger's letters of support.

H. FACILITES AVAILABLE

Describe the facilities available for this project including laboratories, clinical resources, etc.

MUSC expanded from a private college with a faculty of 7 physicians and 30 students in 1824 to a state university with a medical center and 6 additional colleges for the education of a broad range of health professionals. In addition to the College of Medicine, there is a College of Nursing, a College of Pharmacy, a College of Dental Medicine, a College of Health Professions, and a College of Graduate Studies. The campus is located in the heart of Charleston, South Carolina, in a 76-acre complex encompassing 89 buildings for patient care, research, and teaching. MUSC is headed by the Board of Trustees that is appointed by the South Carolina General Assembly, with two members appointed by the Governor. The Board elects the President of MUSC. MUSC has a strong research program. Federal funding constitutes approximately 64% of extramural support, with NIH as the primary funding agency. The MUSC College of Nursing ranks 12th nationally in NIH research funding among all medical

schools and the Department of Psychiatry has ranked in the top 10 in NIH funding during each of the past 7 years.

The faculty, researchers, and staff of the proposed project have numerous computing resources available to them. These will aid in data collection, entry, and analysis; facilitate manuscript and presentation development; and enable project staff to communicate efficiently. Each faculty, research staff, and administrative staff member has a personal computer workstation. Depending on their role and software needs, the computers include both Mac and Windows-based machines. Many users have printers connected to their primary computers; whereas others are connected to “public” printers located in common areas. Additionally, most printers are networked, making it possible for any user to print to any printer, whether in a public area or private office.

The standard suite of software used by Center personnel includes Microsoft Office Professional (consisting of Word, Excel, and PowerPoint); Acrobat Professional; Endnote; SPSS; FileMaker Pro; Mozilla Firefox, Safari, and Internet Explorer web browsers; Entourage or Outlook email; and, for security and virus protection, McAfee VirusScan (Mac) and McAfee Enterprise (Windows). Other productivity software used for specific needs include SAS, DeltaGraph, Prism, Photoshop, Illustrator, and InDesign. Wireless connections are also available through three Service Set IDs: (1) muscsecure - a WPA/WPA2 encrypted network; (2) musc80211 - a non-encrypted, authentication only network; and (3) muscguest - a non-encrypted, non-authenticated, external network. MUSC’s Network Service Team has recently upgraded wireless access points with multi-band radios (supporting 802.11a/b/g standards), increased wireless coverage and reliability by deploying additional access points on campus, and upgraded wireless controllers to provide centralized monitoring and management of the MUSC wireless network. Finally, MUSC’s VPN service is available through online registration. The MUSC Virtual Private Network is a system that enables secure access to the MUSC local network from a remote location, such as a home or hotel room, using broadband access (Cable Internet or DSL) to the Internet. This allows personnel to work, as if connected to the MUSC campus network, while at home or traveling.

South Carolina Clinical and Translational Research Institute (SCTR). The South Carolina Clinical and Translational Research Institute (SCTR) is funded by a Clinical Translational Science Award from NIH (PI: Brady) initially awarded in 2009 and renewed in 2015. **Dr. Ruggiero co-leads the SCTR Health Technology Solutions core of SCTR** and also serves as Co-Director of the Technology Applications Center for Healthful Lifestyles. The overarching goals of SCTR are to reduce the time it takes to turn research discoveries into new treatments, engage communities in research, and train new researchers.

Clinical and Translational Research Center (CTRC). The Clinical and Translational Research Center (CTRC), formerly referred to as the General Clinical Research Center (GCRC), is a specialized, JCAHO accredited, patient-care unit that facilitates patient-oriented research in a cost effective manner for NIH. The CTRC is a 2,500 square foot area with 8 examining rooms, a blood-drawing station, a full-body calorimeter, and a biostatistics/computer analysis study area. In addition to its outpatient facilities, the CTRC includes core laboratories, a molecular laboratory, metabolic kitchen, database management and analysis facility, and a variety of clinical research services as well as training and educational opportunities. Federally-funded studies have top priority for CTRC resources, and the use of the CTRC affords an additional level of rigorous scientific and medical oversight to assure the highest quality performance and the best possible patient care in a proven framework of protocol management and completion.

Recruitment Services and Clinical Trial Registry. The SCTR team assists principal investigators in strategic planning for short and long-term recruitment. SCTR also manages a clinical trial registry that assists potential study participants in identifying research studies that address their particular needs, and provides advertising in the community, through the MUSC Hero campaign, to promote greater awareness and understanding about the importance and value of participating in clinical research and the role it plays in improving human health.

SUCCESS Center. The SCTR team provides centralized research support services for the university. They accomplish this by communicating with all investigators about seminars and workshops being conducted on an ongoing basis. They also host a monthly workshop on topics related to career development and have ongoing grant writing forums for feedback by established investigators at the university. The intent of the SUCCESS Center is to facilitate career development via acquisition of research-related skills and grant writing, especially for junior investigators, through providing campus-wide mentorship, guidance, and resources.

Research Development and Administration. Academic research support services are organized as pre- and post-award functions reporting to the Vice President for Academic Affairs and Provost for Research, whereas accounting and reporting functions are within the Finance and Administration Division.

Office of Research Development. This office provides pre-award support, focusing on proposal development. It monitors print and electronic data sources, identifies funding opportunities, assists in developing proposal concepts, networks faculty members with complementary interests, offers grant writing consultation and workshops, assembles institutional data, and prepares competitive proposals for training and infrastructure improvement.

Office of Research and Sponsored Programs (ORSP). The ORSP handles certifications and assurances, ensures that policies and procedures are followed, helps to prepare budgets, negotiates terms and conditions, maintains a proposal and awards database, administers the program of intramural research grants, and oversees re-budgeting and close-out activities. Within this unit, the Office of Research Integrity oversees compliance with regulations for research involving human subjects, and coordinates management of conflict of interest, financial disclosure, and scientific integrity requirements.

Institutional Review Board (IRB). The use of human subjects in research at MUSC falls under the jurisdiction of federal regulation (45 CFR 46 and 21 CFR 50 and 56). MUSC investigators are granted the privilege of using human subjects under normal assurance to the government that research conducted complies with these regulations. The University has a Federal Wide Assurance for research with human subjects and is in compliance with federal policy governing use of human subjects. The Office of Research Integrity coordinates the activities of three IRB committees, which meet monthly to review protocols for the purpose of safeguarding the rights and welfare of human subjects. IRB members include a lawyer, a minister, and other lay persons as well as MUSC faculty.

Grants and Contracts Accounting (GCA). As a unit of the Division of Finance and Administration, GCA is responsible for the post-award administration of sponsored grants and contracts awarded to the University including financial reporting and administration; application of cost accounting principles and standards to sponsored program expenditures; and the development of policies, procedures, and related training to ensure compliance.

Technology Applications Center for Healthful Lifestyles (TACHL). The Technology Applications Center for Healthful Lifestyles (TACHL) is a Health Sciences South Carolina Center of Economic Excellence. MUSC launched TACHL in August 2010 with the recruitment of Frank Treiber, PhD, as the institution's Director of TACHL. One of the biggest challenges public health researchers face is the development of efficacious, cost-effective lifestyle intervention and healthcare management programs, which can be personalized to meet the specific needs and characteristics of individuals. TACHL provides a unique opportunity to address this challenge. The Center provides an outstanding environment to engage in multi-disciplinary research with scientists from diverse disciplines at MUSC, Clemson University, and the University of South Carolina. It develops, evaluates and commercializes technology for individuals, worksites, community groups and health care provider networks through multi-institutional collaborations to foster efficacious health promotion, disease prevention and health care management and work force capacity-building. Products include software and information systems for mobile smart phones, personal digital assistants, iPad®/tablet technologies, web-based computer-

assisted programs, interactive call centers and others that implement and monitor various programs including physical activity, diet, stress reduction, smoking prevention/cessation, biomarker monitoring, and medication adherence. Product development occurs via an iterative process, guided by the preferences of various users and stakeholders. For example, youth may prefer interactive game-based computer technology applications for health behavior change, young adults may prefer smartphone delivered interventions and self-monitoring/adherence programs, while seniors and others may prefer direct contact with healthcare call centers via phone and/or video conferencing via computer interface.

TACHL has the infrastructure to conduct the hardware creation, software development, deployment and maintenance of applications in a secure encrypted environment. Our programming paradigm is to develop software systems based on an n-tier architecture, where we create the presentation layer, business logic and data layer into separate software systems. These systems are developed to minimize maintenance, but provide a robust, scalable model for future growth and interaction using a unified modeling language. TACHL fosters more efficacious health promotion, disease prevention, and healthcare delivery/adherence related programs. TACHL has proven track record of designing, developing, integrating, deploying, and maintaining software application systems for various healthcare arenas. TACHL has taken the technology lead in dozens of health care grants in which it has partnered with investigators across MUSC and other institutions in South Carolina. This includes 5 active NIH K and 10 R-series awards in which we are assisting in development and rigorous testing of innovative health technology solutions. Dr. Ruggiero (PI) is Co-Director of TACHL, Dr. Patel (Co-I) is Director of TACHL Systems Architecture, and Dr. Davidson (Co-I) is a core TACHL faculty member.

Department of Psychiatry and Behavioral Sciences. The Department of Psychiatry and Behavioral Sciences emphasizes excellence in clinical care, teaching, and research. It is headquartered in its own building, the Institute of Psychiatry (IOP). The IOP is a six-story structure of three adjoining buildings that house the administrative offices of the Department, Admissions Office, numerous faculty and resident offices, and several of the Department's major research and treatment divisions. The main research divisions in the Department are the National Crime Victims Research and Treatment Center (NCVC), the Family Services Research Center, the Center for Drug and Alcohol Programs (CDAP), the Clinical Neuroscience Division, the Brain Stimulation Laboratory, the Geropsychiatry Division, the Public Psychiatry Division, and the Weight Management Center.

National Crime Victims Research and Treatment Center (NCVC). The NCVC, which occupies an entire floor of the IOP, is a division of the Department of Psychiatry and Behavioral Sciences at MUSC. Since 1974 the NCVC faculty and staff have been devoted to achieving a better understanding of the mental health effects and treatment for youth and adults who experience stressful life events. Projects of high relevance to the current proposal that have had wide impact include: (1) large-scale national epidemiologic studies and disaster mental health epidemiologic studies funded by NIH and other sources, which have provided unique data on the scope and mental health impact of violent crime among adult women (e.g., National Women's Study, National Survey of Adolescents [NSA], NSA-replication, National College Women's Study); and (2) innovative approaches to treatment and dissemination of evidence-based treatments (e.g., TF-CBT*Web*, which is a web-based training protocol in the TF-CBT model that has over 295,000 registered learners across over 100 countries since its launch in October of 2005; as well as other internet-based therapist training courses and resources including: CTG*Web*, TF-CBTWeb Consult, PE-*Web*, and CPT*Web*). The NCVC includes its own outpatient clinic, which offers evidence-based assessment, treatment, and case management to youth and adults in the lowcountry of South Carolina. To date, NCVC faculty have received more than $45 million in extramural and contract support through research grants, training grants, and service delivery grants. Researchers at the NCVC have received federal funding from NIA, NIAAA, NICHD, NIDA, NIMH, and other agencies that include NARSAD, the Centers for Disease Control and Prevention, the National Institute of Justice, the Substance Abuse and Mental Health Services Administration, and the Duke Endowment. Drs. Hanson, Saunders, Danielson, and Adams are all Co-Is on this application who are faculty members at the NCVC.

Mental Health Disparities and Diversity Program (MHDD). The MHDD program is a new program within the Department of Psychiatry and Behavioral Sciences that is dedicated to understanding and addressing mental health disparities. Faculty and staff in the MHDD program, led by Dr. Michael de Arellano (NCVC faculty member), aim to raise community awareness of mental health problems and available services via a variety of programs, including clinical research programs, community education programs, mental health prevention and treatment programs, telehealth and other school-/home-based services, and culturally competent and linguistically appropriate services. This is a top priority of NCVC and Psychiatry faculty and staff. Consistent with this mission, several state and federally funded grants involving NCVC faculty are dedicated to addressing mental health disparities and developing culturally competent technology-based resources for youth and families. Dr. Davidson is a faculty member who has an appointment in MHDD as well as TACHL