

**Medical University of South Carolina (MUSC) – Lead IRB  
Behavioral Health Research Collective (BHRC) – Secondary IRB  
Protocol Version 1 (initial submission to MUSC IRB), 7/3/14**

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**Study Title:** Evaluation of the VillageWhere Mobile Phone Application

**INTRODUCTION TO THIS IRB APPLICATION:** This application corresponds to NIMH grant number 1R43MH097349-01, *Using Mobile Technology to Enhance MST Outcomes* (MUSC PI, Cindy Schaeffer; co-PI Dr. Linda Dimeff is with the Evidence Based Practice Institute). The primary purpose of this grant is to develop a mobile smartphone application for use by youth who are receiving outpatient or intensive in-home treatment for an emotional or behavioral problem, such as truancy, curfew violation, criminal arrests or substance use, and for which improved parental management of youth behavior is a treatment focus. Consistent with interventions used in empirically-supported treatments for externalizing behavior disorders, the mobile app will help parents improve their parenting skills by helping them devise and implement a behavior plan, monitor youth activities, and deliver rewards for good behavior.

Note that our original intention for this study, as articulated in our NIMH grant, was to develop and test the VillageWhere app only with juvenile offenders receiving intensive in-home treatment. After talking with numerous stakeholders during the formative evaluation, we quickly learned that the demand for this app is far greater than providers treating juvenile offenders; therapists and treatment provider administrators repeatedly requested the ability to use and test the app with the broader population of youth they serve, namely, those involved in family-oriented treatment focused in part on improving parent management of youth behavior. Study PIs (Drs. Schaeffer and Dimeff) have received permission from their NIMH program officer to expand the study aims to this broader population.

This Phase 1 (R43 framework) NIMH grant involves two components. The first, a **formative evaluation** of the useability and acceptability of the technology to the target population (i.e., youth and parents receiving treatment, therapists, and administrators), was the focus of a separate IRB protocol approved earlier this year (Protocol # 00027375, *Developing Mobile Technology to Enhance MST Outcomes*). The formative evaluation pertains to Specific Aims 1 and 2 listed below and will conclude in the fall of 2014. The second component, the **summative evaluation** (Specific Aim 3), is the focus of the present application. It involves a preliminary test of whether the newly-developed app meets its intended purpose (i.e., to enhance parental management skills and improve youth functioning) and its real-world applicability to parents and youth. Note that sections A and B of this protocol (aims and background) are taken directly from the grant application and refer to both components of the project. Section C describes outcomes from the formative evaluation, and Sections D – J describe the proposed (new) procedures for the summative evaluation only.

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## A. SPECIFIC AIMS

The concept for this project emerged from an invited NIDA-sponsored workshop, *Digital Media & Communications Technologies in Adolescent Drug Abuse Treatment* (April 26-27, 2010), that sought to promote the use of innovative technologies in preventing and treating drug abuse and other mental health problems in youth to improve treatment accessibility, utilization and outcomes for adolescents. Twenty-first century youth are technologically “wired” (via the Internet), connected (via Facebook and other social networking sites), and frequently in contact (via texting from their cell phones). In the U.S., 75% of teens now own a cell phone<sup>[4]</sup>, and on an average day talk for 33 minutes, spend 1.5 hours texting, and send 118 text messages<sup>[5]</sup>. We (Drs. Henggeler, Dimeff, and Schaeffer) began to speculate how we might leverage mobile technologies and the Internet to improve outcomes for antisocial youth engaged in Henggeler’s Multisystemic Therapy (MST)<sup>[18]</sup>, a highly efficacious treatment for the most disturbed and severe youth with antisocial behaviors. This study is the product of these post-NIDA workshop discussions.

**The Problem:** Each year over 2 million adolescents are arrested in the U.S.<sup>[1]</sup>, and many more (9-18% of all youth) engage in serious delinquent behavior, such as heavy drinking, illicit drug use, and school drop-out<sup>[2]</sup>. The most effective interventions to address these problems are family-based, with a strong clinical emphasis on helping parents regain control of youth behavior through better monitoring of activities and consistent use of contingencies (rewards and punishments) for appropriate and deviant behavior<sup>[3]</sup>. Such models are expensive (costs of about \$5,000 to \$10,000 per youth) and time-intensive (4-6 months on average), owing largely to the clinical intensity necessary to increase the skills of parents who themselves often have limited resources (e.g., few social supports to assist in monitoring). A core component in all family-based interventions for antisocial youth, including MST, is to increase parents’ effectiveness in monitoring their youths’ whereabouts and reinforcing appropriate behavior. The primary aim of this proposal is to develop and evaluate a sophisticated multi-component technology suite designed to enhance parents’ ability to manage youth behavior. Specifically, we will develop a mobile phone app (**VillageWhere; VW**) for youth that uses contextual intelligence (where predefined information gathered through the GPS and Contacts is constantly analyzed) to notify parents of youth activities and prompt youth to change behavior, and gamification to reward youth and maintain youth engagement. The app will integrate with an Internet-based portal/dashboard for parents that will show youth whereabouts and consolidate information critical for parental management ([www.VillageWhere.com](http://www.VillageWhere.com)). When incorporated into empirically-supported interventions for antisocial youth, such technology could enhance clinical outcomes while reducing treatment length and cost and expanding treatment access to more youth.

**Overarching Multi-Phase Project Goal:** Our overarching goal is to improve outcomes and expedite treatment delivery for youth with antisocial behavior through the use of digital and communications technologies that will improve parental monitoring and reinforcement of appropriate behaviors. Working within the context of MST, the most extensively researched and widely-disseminated of the empirically-supported interventions for youth antisocial behavior, our Phase I aims (current proposed project) include:

- **Aim 1:** Iteratively design and develop VillageWhere, a highly innovative and scalable mobile app system to significantly enhance parental monitoring and reinforcement of antisocial youth;
- **Aim 2:** Conduct usability and acceptability tests with target-end-users (parents, youth, and therapists) and key stakeholders (i.e., probation officers, clinic administrators), as well as extensive interviews with youth to establish *and maximize the appeal of* key components of VillageWhere;
- **Aim 3:** Conduct an open trial to evaluate VillageWhere with 20 parent-youth dyads receiving MST to identify additional barriers to use and further assess acceptability

We will build a fully functional Android-based integrated mobile phone app and Internet-based parent dashboard that is easy-to-use and acceptable to users and key stakeholders, and will build a design document for the iPhone. To ensure our success, we will partner with one of the leading mobile design institutes (PugetWorks), the organization responsible for dissemination and quality assurance of MST (MST Services), and the MST treatment developer

(Scott Henggeler, PhD). Should Phase I outcomes appear promising, we will proceed to Phase II to complete the full system, develop apps for the other major mobile phone platforms (i.e., iPhone, Blackberry, Nokia), and conduct an open trial to assess clinical acceptability and feasibility over the four-month course of MST. We will then submit an R01 to evaluate the efficacy and cost-effectiveness of VillageWhere compared to MST-as-usual in a randomized controlled trial (Phase III).

The project's potential for achieving its aims and ultimate commercial success is bolstered by the team's multidisciplinary experience. Concomitantly, both MST Services and Evidence Based Practice Institute (EBPI) are powerful dissemination organizations with deep existing market penetration into community mental health and juvenile probation systems to facilitate eventual sales efforts. Moreover, because VillageWhere will target a core component of all evidence-based family interventions for antisocial youth (i.e., parental management practices) its reach will be much greater than MST alone and may benefit even those families with antisocial youth who are not currently engaged in treatment.

## **B. BACKGROUND AND SIGNIFICANCE**

**B1. Juvenile offending, delinquency, and drug abuse affect large portions of adolescents, at great cost.** Epidemiologically, substantial portions of youth engage in serious conduct problems. Approximately 9% are arrested before the age of 18<sup>[1]</sup>, 8% drop out of high school<sup>[19]</sup>, and 18% report heavy drinking and drug use<sup>[2]</sup>. If untreated, youth who engage in criminal offending or drug abuse are very likely to continue these behaviors as adults<sup>[20;21]</sup>. The lifetime personal costs of these problems include comorbid mental health conditions, low wages, incarceration, and disrupted family relationships<sup>[22;23]</sup>. From a societal perspective, justice system and victim-related expenditures related to antisocial youth cost \$194 billion annually<sup>[24]</sup>. Similarly, the total annual cost of substance abuse for youth and adults is \$143 billion for alcohol<sup>[25]</sup> and \$181 billion for illicit drugs<sup>[26]</sup>; these problems result in over 100,000 deaths each year<sup>[27]</sup>. Clearly, reducing adolescent involvement in conduct problems is likely to yield great short- (i.e., in adolescence) and long-term (i.e., in adulthood) benefits.

**B2. Low parental monitoring and inconsistent discipline are two main risk factors for serious conduct problems.** Extensive evidence supports a link between poor parent management practices (low monitoring and inconsistent discipline) and youth antisocial behavior<sup>[9;28]</sup>. Cross-sectional and longitudinal research has found sizeable direct effects of low parental monitoring on the onset and escalation of youth externalizing problems, delinquent behavior, substance use, and criminal activity, in samples of both adjudicated and non-adjudicated adolescents<sup>[29]</sup>. Low monitoring also has indirect effects on youth antisocial behavior, mediated by higher association with deviant peers, lower self-control, and greater acceptance of deviant norms<sup>[30;31]</sup>. Although monitoring involves multiple components<sup>[7;8]</sup>, direct monitoring techniques (e.g., verifying youth whereabouts with 3<sup>rd</sup> parties, live supervision) are critical for mitigating delinquent behavior among youth with serious conduct problems<sup>[9;10]</sup>. Similarly, inconsistent parental discipline has both direct<sup>[32-34]</sup> and indirect<sup>[35;36]</sup> (through deviant peer associations) effects on a range of conduct problems throughout adolescence. Low parental monitoring and inconsistent discipline are highly intercorrelated and are part of a larger pattern of conflict, negative affect, and detachment in many families of youth with serious conduct problems<sup>[37]</sup>.

**B3. Social reinforcement also maintains youth antisocial behavior.** In the absence of reinforcing family relationships, antisocial youth seek support from similar deviant peers. Thus, in addition to insufficient parental monitoring and discipline, youth antisocial behavior is maintained through both negative (i.e., avoiding conflictual interactions with parents) and positive (i.e., approval of deviant peers for delinquent behavior) reinforcement mechanisms<sup>[37;38]</sup>. Once this pattern is established, it is difficult for parents to provide enough positive reinforcement to effectively "compete" with the reinforcement youth receive from peers, given that adolescents spend twice as much time with peers as parents<sup>[39;40]</sup>. Providing frequent, immediate reinforcement of positive behavior is particularly critical for youth in early and middle adolescence, when neurobiologically the ability to delay gratification is still quite poor<sup>[41]</sup>, especially for those with externalizing behavior problems. For such youth, providing larger but

delayed rewards (e.g., a weekly allowance) is much less reinforcing than smaller but immediate rewards (e.g., frequent parental praise)<sup>[42]</sup>.

**B4. MST is an efficacious treatment for serious juvenile offending and adolescent drug abuse.** MST is a highly effective intervention for youth with serious conduct problems and emotional disturbance, as noted in several comprehensive reviews of the juvenile justice<sup>[3;43]</sup>, substance abuse<sup>[27;44;45]</sup>, and children's mental health<sup>[46]</sup> literatures. Ten randomized clinical trials with juvenile offenders and substance-abusing adolescents indicate 26-63% reductions in criminal recidivism, 50-64% decreases in incarcerations and out-of-home placements, improved school attendance, significant decreases in substance use, and significant increases in drug abstinence<sup>[47]</sup>. MST uses a home-based model of service delivery, provides 24/7 therapist availability, and engages all relevant ecological systems (e.g., parents, schools, grandparents, etc.) in clinical interventions. Only empirically-supported techniques (from family-systems, behavioral, and cognitive-behavioral models) are used, and an extensive treatment adherence and quality assurance system facilitates real-world outcomes<sup>[47]</sup>.

**B5. Improved parental monitoring is a key mechanism through which reduction in antisocial behavior is achieved in MST and other empirically supported treatments (ESTs) for conduct problems.** Research suggests that improving parental management practices is paramount to MST's success. Using two samples of juvenile offenders participating in clinical trials of MST, Huey et al.<sup>[11]</sup> demonstrated a mediational pathway between therapist adherence to the MST model, improved parental monitoring (i.e., direct supervision, rules, communication), decreased deviant peer affiliations, and reductions in delinquent behavior. Similarly, Schaeffer et al.<sup>[12]</sup> found that MST provided as part of Juvenile Drug Court was associated with significant increases in parent supervision which, in turn, predicted reductions in delinquent behavior and drug use. Studies of two other ESTs for conduct problems, Multidimensional Treatment Foster Care (MTFC)<sup>[48]</sup> and Multidimensional Family Therapy (MDFT)<sup>[49]</sup>, found that improvements in parental monitoring (i.e., direct supervision, verifying activities) mediated treatment effectiveness (i.e., reductions in antisocial behavior among offenders<sup>[15]</sup>, decreased substance use among clinically-referred adolescents<sup>[50]</sup>). Together, these studies suggest that improving parental monitoring is essential for a successful outcome with conduct problem youth.

**B6. Although parental monitoring and discipline are main treatment targets in MST, clinical success in these areas can be difficult to achieve.** While clearly effective, MST also has room for improvement. MST clinicians report that it is often difficult to get parents to provide monitoring, discipline, and reinforcement of positive behaviors at levels sufficient to deter youth antisocial behavior. Many parents of juvenile offenders are socially isolated<sup>[51]</sup> and lack connections to other adults who can assist in monitoring (e.g., calling the parent at work to verify that the youth is home). Similarly, schools attended by juvenile offenders are often overcrowded and underfunded<sup>[52]</sup>, resulting in little school communication with parents about youth attendance. Insufficient information about youth whereabouts and activities is a barrier to parents providing consequences for negative behaviors and positive reinforcement for appropriate behaviors. VillageWhere will help keep parents informed, provide another venue for positive reinforcement, and facilitate parent-child communication.

**B7. Youth use of mobile phones could enhance parent's ability to monitor/act.** A recent survey of 85 MST therapists serving 330 juvenile offenders revealed that among youth receiving MST, 70% have a computer, 71% text, 74% play videogames, and 80% use Facebook; 98% of therapists rated MST youth as being equally or more interested in technology as mainstream youth<sup>[53]</sup>. This reality offers an opportunity for parents of delinquent youth to monitor youth more easily and accurately (e.g., instead of phoning the school, attendance can be verified automatically through GPS) and to provide more frequent, contingent rewards for good behavior (e.g., immediate praise to youth via text message) than previously possible. Mobile features, including GPS and Contacts, can assist parents in intervening when corrective actions are necessary (e.g., youth is in an unauthorized location and needs to be picked up), which may directly prevent youth antisocial behavior. As adults become increasingly reliant upon the Internet for daily activities (e.g., paying bills<sup>[54]</sup>), an online parent dashboard that organizes youth information, facilitates responding, and provides therapist support is likely to have great appeal to parents struggling to regain control over youth delinquent behavior.

**B8. MST is the ideal platform for product development and initial implementation.**

A large network of MST providers allows ample opportunity for iterative testing with the target population (i.e., serious juvenile offenders) and for the development of clinical protocols for ethical use of the technology. The proposed study was presented to 16 MST experts (i.e., faculty at the center where MST was developed, staff at MST Services who disseminate MST, and a juvenile justice administrator) who were overwhelmingly positive about the initiative. Specifically, they noted that in the absence of tools for managing how juvenile offenders use technology such as cell phones, parents and probation officers tend to attempt to restrict youth access to them. Given youth interest in these devices, such restrictive and punitive approaches are often ineffective (youth get access anyway) and iatrogenic (e.g., youth steals or lies in order to get/use devices), and further marginalize antisocial youth from the experiences of mainstream youth. It is our hope that VW will provide parents with an effective alternative, one that harnesses youth inherent desire to use technology to promote positive behavior.

**B9. The proposed study fits with objective 3 of NIMH's Strategic Plan to develop new and better interventions for mental disorders.** Building on two empirical knowledge bases (i.e., link between parental management practices and youth conduct problems, mechanisms of change in treatments for conduct problems, Strategy 3.1), the proposed study would develop a set of highly personalizable (Strategy 3.1) technologies to enhance parents' ability to manage youth behavior. The newly developed technology would facilitate therapists' adherence to MST (Strategies 3.1, 3.2) by providing another means for targeting parental management during sessions and giving them objective feedback about parent behaviors. Such technology also would help parents better gauge youth progress (Strategy 3.4). The technology and its implementation will be developed and tested with input from therapists, parents, and other stakeholders (Strategy 3.3). Although it will be developed in conjunction with one EST (MST), it will be flexible and generalizable for use within other ESTs for youth with antisocial behavior and substance abuse, or by parents who wish to improve their management of youth behavior independent of seeking treatment. Thus, consistent with Objective 3, the potential for this technology to be applicable in diverse settings and with multiple youth populations is great.

**C. PRELIMINARY STUDIES**

As noted in the introduction, the formative evaluation to develop the VillageWhere app is nearing completion. Consistent with best practice standards for software design and build, we used an iterative developmental process to build the app, progressing from conceptual designs drawn on paper and low fidelity mock-ups to high fidelity models that provided a feeling for how the app would function when in use. Target end users (those individuals for whom the app is intended for eventual use, namely parents and their youth engaged in an intensive home-based treatment [MST] and/or other cognitive-behavioral therapies for externalizing behaviors, and MST or CBT therapists) as well as stakeholders (clinic administrators, facility directors) provided feedback at key moments during the developmental process to ensure usability and acceptability standards were met.

***Preliminary Effort to Identify Potential Design Elements.*** Before getting started, we thoroughly reviewed all available mobile phone apps available for iPhone and/or Android phones that involved features comparable to those we had initially wished to include in the VillageWhere app (e.g., Life360). We identified and reviewed the features for over 10 such apps available on the market in December, 2013 and carefully studied customer reviews to determine preferences and dislikes by users. We also studied *how* the apps were designed (flow patterns, visual designs, use of text vs. icons).

***Preliminary Effort to Identify MST User Profiles.*** We developed three typical case-user profiles involving MST families and youth, the "deep end" of the spectrum of families (i.e., adolescents with juvenile justice involvement) for whom VillageWhere is intended. These user profiles allow the design team to ensure the app actually works for those individuals it is designed for and in the context of their lives. Each user scenario involved the following elements: age/sex of the youth, a detailed story about his/her last offense (what he/she did, what happened), marital and educational status of parents, and where they live/work. These

user profiles were then cross-referenced throughout the remainder of the app design and development.

***Preliminary Development of Blueprint.*** The app development team (Drs. Schaeffer, Dimeff, and Koerner) met in December, 2013 in New York City with Parsons School of Design Professor, David Carroll, MS, for initial development of a conceptual blueprint. We then met again in Seattle, WA in February, 2014 to further refine the design blueprint and ensuring that it met the functional design requirements while simultaneously working for the real-demands/needs of our target end-users based on the case user profiles (described above).

***Iterative Development: From Blueprint to Build.*** Following completion of the design, we began the development of the app in detail moving from simple drawings and low-fidelity diagrams to a dynamic pre-build version that illustrates how the app will work and function when complete, including how the parent and youth apps “communicate” in real-time. Throughout all phases of development, we have individually interviewed target end-users, therapists, and more recently, stakeholders, to gain insights to improve usability and acceptability. Feedback has been overwhelmingly positive across groups. As hoped, user tests with youth and families has helped us identify those elements and paths that were confusing and required re-engineering of the design. Feedback from therapists and administrators has been helpful in identifying eventual barriers to use and implementation. Target end-users are enthusiastic to have the app available for use in real-world practice.

***The app and its features.*** The VillageWhere app assembles components of existing smartphone technology to allow parents to keep track of the youth’s behavior and send him or her reminders and rewards, and youth to see what the parent’s expectations are for him or her on a given day, get reminders to do things, and get praise or other rewards for doing the right thing. The features of VillageWhere for which beta versions currently exist and will be available for use in the present study include:

- 1) **Map.** Uses GPS function on youth’s smart phone to allow the parent to set up “geofences” denoting where the youth is and is not allowed to be at various times of day. The parent can always see where the youth is at a given moment, and can set up alerts to be notified if a youth leaves or enters a geofenced area.
- 2) **Game Plan.** The parent enters into the app the behavioral expectations for the youth at various times of day (e.g., attend school, refrain from fights, go to after school program, be home before curfew) and what the youth can earn instantly or over time if expectations are met. The feature is prepopulated with common expected behaviors and ideas for rewards, and parents can opt to set up prompts for the youth for appropriate behavior throughout the day (e.g., “its 7:45. Time to leave to catch the school bus!”) Once set up, both parents and youth have a quick-reference reminder of family rules.
- 3) **The Store / My Store** (parent / youth). An area where youth desired rewards and privileges are listed and their “prices” (i.e., what behaviors are expected and how many to earn privileges). This area has appealing graphics depicting privileges to engage youth.
- 4) **Our Progress.** Graphic displays of how the youth is doing over time on various behavioral targets (e.g., school on time, meeting curfew) and how the parent is doing on implementing the game plan consistently (e.g., parent forgot to provide privilege two times last week even though youth earned privilege).
- 5) **My Supports.** A list of short (2-3 minutes each) video clips for parents and adolescents to watch to bolster skills commonly addressed in mental health treatments for adolescents (e.g., for parents, *Staying Firm in the Face of Youth Protests*; for adolescents, *Communicating Effectively with Parents*),

## **D. RESEARCH DESIGN AND METHODS**

### **D1. Overview.**

This protocol describes procedures for conducting an initial real-world test of VillageWhere (VW) usage among parents and youth to whom the technology will ultimately be marketed, namely, those participating in family-based treatment in which improving parental management of youth behavior is a treatment goal. Generally, improved parental management is a goal when youth present to treatment for an externalizing or other behavioral problem. The study will use a single-group (i.e., all participants will use VW) repeated-measures (i.e., pre- and post-usage) design over either a 2 week (i.e., field test) or a 6-week (i.e., open trial) assessment period (see section DX for more details). The intent of the 2-week field test is to prepare for the 6-week open trial by testing study procedures and to ensure that all software “bugs” are identified and fixed before proceeding to the 6-week open trial.

Clinical outcomes that are expected to show improvements as a result of VW usage (e.g., parental monitoring, use of rewards) will be assessed at both time points, and user satisfaction/acceptability measures will be administered post-usage. Parents and youth will also participate in a qualitative post-usage exit interview as another way of assessing their experiences with the technology and suggestions for improvement.

Because we expect that initial markets for VW will be parents who learn of the technology in the context of treatment (i.e., their treatment providers recommend that they use the app to help meet treatment goals), mental health therapists working with the population will also be recruited as research participants. Therapists will be offered training in app features and will receive a guidebook about the app for reference. Dr. Schaeffer, one of the study PIs, a child clinical psychologist, and an expert in empirically-supported treatments for youth externalizing behavior problems, will create a 30-minute training video and deliver the training content in the video. Therapists also will be given the option of downloading the parent version of the app to their own personal smartphone to facilitate their understanding and support of the app, but this will not be required. In addition, Dr. Schaeffer will hold weekly “office hours” for the purpose of providing therapists with as-needed support and to field questions about the app and/or study procedures. When a parent-youth dyad on the therapist’s caseload completes their 2- or 6-week trial, the therapist will complete user acceptability/satisfaction measures and participate in a qualitative exit interview about the experience.

The NIMH R43 funding mechanism motivating this protocol imposes a rigorous timeline; we (the study PIs) must complete both the formative (product development, previous IRB application) and summative (current application) evaluations in a 12-16 month window that ends approximately January 2015. Although we have attempted to anticipate and articulate all study procedures in this protocol, unanticipated issues that require rapid resolution may arise. Thus, we have inserted some points of flexibility within this protocol (e.g., number of participants recruited for field based beta testing) so that we can be responsive to study needs in real time without seeking IRB protocol amendments. We will of course seek approval(s) for amendment(s) to this protocol if we find the need to do something outside of the boundary conditions described here.

After recruitment, screening, informed consent/enrollment, and a baseline (i.e., pre-usage) clinical assessment battery, parents and youth will download the app onto their smartphones, and therapists will help parents program the app to be consistent with the family’s extant treatment goals pertaining to parental management of youth behavior. Then, parents and youth will use the app over a 2-week testing period (in the case of the initial field test) and 6-week period (the open trial). Instructions for using the app will vary slightly for participants in the field test versus those in the open trial. During the testing period, the therapist will be available to assist the parent and youth with any questions or concerns about the app as part of their regularly scheduled treatment sessions. App usage data (e.g., what features used, time spent using features) will be collected automatically from the server, and parents and youth will be prompted by the app to provide brief daily satisfaction ratings. At the end of the 6-week trial, parents and youth will complete the assessment battery again (i.e., post-usage).



## **D2. Collaboration**

The investigators have established collaborative agreements with six mental health provider organizations who serve large numbers of adolescents with moderate to severe externalizing behavior problems (see Letters of Support in Appendix 1). These organizations provide mental health services to this population using a range of treatment modalities. Youth are generally allocated to a particular level of service based on problem severity. For example, an adolescent engaging in truancy and rule-breaking behavior may be offered participation in once-weekly multiple family group therapy (i.e., several parent-youth dyads meet together for improved parental management of behavior); a youth abusing substances may receive once-weekly individual and once-weekly dyadic (parent-youth) outpatient sessions; and youth with criminal arrest histories may receive multiple in-home family-therapy oriented treatment sessions each week (i.e., Multisystemic Therapy). These modalities are reflective of current standards of care for youth with varying severities and types of externalizing behavior problems. A common component of each of these modalities is a strong emphasis on parental involvement in treatment and a focus on improving parental management of youth behavior, consistent with the empirical literature regarding what makes treatments for youth externalizing behavior problems effective.

Our partner organizations, located across the U.S., are as follows: Advanced Behavioral Health (ABH; Connecticut); Catholic Charities (Western New York State); Children's Village (New York City and New Jersey); the Maryland Innovations Institute (Maryland); the Portland DBT Institute (PDBTI); and the University of Washington Public Health and Justice Policy Center. Collectively, these organizations employ over 200 mental health therapists who serve youth with externalizing and other behavior problems. We will recruit therapists, parents, and youth to participate in the study from this pool.

## **D3. Study Setting**

Study procedures involving participants will occur within participants' homes (parents and adolescents) and workplaces (therapists). Participant procedures will be conducted using phone calls, in-person interviews, smartphone applications, and internet websites dedicated to this study. Other study procedures (e.g., data storage and analysis) will occur at the Family Services Research Center on the MUSC campus or at the Evidence-Based Practice Institute (e.g., site at which research assistants will conduct phone interviews with participants for data collection).

## **D4. Study Recruitment**

Since participation of the adolescent's therapist is required in order for a parent-youth dyad to be eligible for the study, therapists will be recruited first. Once enrolled, participating therapists will then assist in the recruitment of eligible parent-youth dyads from their existing caseloads. We seek a final sample size of no less than 24 therapist-parent-youth triads (i.e., 72 individual participants) who complete all study procedures. To account for potential premature participant dropout (e.g., youth is incarcerated in week 2; parent loses mobile phone service due to unpaid bills), we plan to enroll  $N = 30$  therapist-parent-youth triads. These triads will be allocated between the field test ( $n = 4-6$  triads) and the open trial ( $n = 20$ ).

Within each triad, all 3 participants must agree for any individual in the triad to complete study procedures. Among enrolled triads, all parent-youth dyads must be unique, but their linked therapist participants do not. If a given enrolled therapist's caseload yields more than one parent-youth dyad also enrolled, that therapist will be linked to more than one parent-youth dyad in the study. Thus, while the final sample size will be no less than  $n = 24$  parents and  $n = 24$  youth, it is possible that the number of enrolled therapists will be lower (e.g.,  $n = 12$  therapists, if each therapist had two parent-youth dyads from her caseload enrolled).

Conversely, we expect that for some enrolled therapists, we will be unsuccessful in recruiting any linked parent-youth dyads from their caseloads (due to disinterest in the study or ineligibility). To account for this possibility, we will continue to recruit and enroll therapists until an  $N$  of 24 parent-youth dyads completed is achieved. One implication of this approach is that more therapists may be enrolled in the study than will actually have the opportunity to engage in study procedures (e.g., we may need to enroll  $N = 40$  therapists to achieve  $N = 24$  parent-youth dyads).

The recruitment procedures that follow are informed by experiences recruiting therapists and having therapists refer parents and youth to the study during the formative evaluation of VW (previous protocol). As described below, two separate lottery drawings (one for therapists, one for parents/youth) will be used as one part of a more comprehensive recruitment strategy.

**Recruitment of therapists.** All in-home and outpatient therapists who treat adolescents and who are employed by one of the collaborating agencies are eligible to participate. Our strategy for recruiting therapists will rely primarily upon direct email communications and an informational video advertising the study. These will be supplemented by phone and in-person meetings as needed. (Dr. Schaeffer met in person or by phone with most of the front-line staff at these organizations during the formative evaluation stage and informed them of an upcoming email recruitment campaign for this next stage of the study).

We will develop a 3-4 minute informational animated video that explains the study to therapists and requests their participation. We will also create a parent/youth version of this video (see details below in *Recruitment of Parents* section) requesting parent/youth participation. We will encourage therapists to watch the Family Recruitment Video as well as their own so that they will feel comfortable with how parents and youth will be recruited before agreeing to the study themselves. In our formative evaluation, we found that therapists sometimes were hesitant to refer parents and youth because they feared it would require a lot of additional work. Hopefully, seeing the family video will help therapists see that if they choose to participate themselves, the burden on them to help in recruiting parents and youth will be minimal.

All eligible therapists will receive an email from Dr. Schaeffer and Dr. Dimeff (for Portland DBT Institute) informing them that enrollment for the summative evaluation stage has begun and requesting that they watch two videos to learn more. Links to the videos, which will be posted on YouTube, will be sent in the email. The scripts that will be used in these recruitment videos are included with this protocol as Appendix 2 and 3 (Script for Therapist Recruitment Animated Video, Script for Family Recruitment Animated Video). These videos will be “unlisted” on YouTube, meaning that only individuals with direct links to the video can watch them (i.e., people cannot stumble upon the video while browsing YouTube).

To encourage therapists to consider participation, we will provide incentives for watching each of these videos. Specifically, after the therapist watches each video, a prompt will pop up that will ask them to click on a link to be entered into a lottery to win a tablet computer. The link will open to a RedCap (secure online data collection system administered by MUSC) interface, where the therapist will be asked to enter his/her name and contact information for notification if they win the lottery drawing. After entering the name, the therapist will get a screen with a message that says “You have earned one ‘virtual raffle ticket’ (one chance to win) for entry in the tablet drawing. The drawing will take place in ESTIMATED MONTH OF DRAWING. We will inform you immediately if you are the winner.” The therapist will be asked a final question after entering contact information: “Are you willing to be contacted by a member of the research staff to learn more about possible participation in the study?” All therapists who respond “yes” to this question, or who inform us of their interest in participating some other way (e.g., by replying to the recruitment email or calling Dr. Schaeffer), will be telephoned by a member of the research

staff to learn more and, if still interested, to schedule a time to engage in the informed consent process (see below).

Therapists can watch the two videos in either order they choose. Therapists will earn one raffle ticket for each different video watched, up to two tickets total. Therapists will not be given additional raffle tickets if they elect to watch either video multiple times. Each video will prompt the viewer to enter contact information for the drawing / willingness to be contacted.

**Recruitment of parents.** Within 1 week of a therapist enrolling in the study, a member of the research team who has clinical training (i.e., Dr. Schaeffer, Dr. Dimeff, or Dr. Kelly) will meet with him/her (either in person or by telephone) one or more times to provide personalized guidance in how to refer parents and youth to the study. Research staff conversations with therapists will NOT involve any information that identifies a client's identity or reveals clinical details about the case. The goals of these meetings are to:

- 1) Help the therapist identify one or more parent-youth dyads on his/her current caseload that might be eligible for participation. This step is undertaken to resolve any ambiguities about parent-youth eligibility the therapist may have (e.g., if a client's 12<sup>th</sup> birthday is 2 weeks away, can I approach that family now?) and allow them to go directly "to the source" (the researcher) about any questions. In the formative evaluation, we heard from supervisors that therapists sometimes failed to approach eligible cases because of misunderstandings about study requirements and procedures.
- 2) Reduce burden on therapist supervisors. In the formative evaluation we found that therapists frequently took eligibility and referral questions to their supervisors.
- 3) Ensure that the therapist does not use coercive tactics to persuade families to agree to a referral. The research staff person will clearly outline how therapists are to use the recruitment tools provided in an ethical manner. Only trained research staff will conduct the consenting process with parents and youth.

To be eligible for the study, a parent must 1) be English language fluent, 2) have an adolescent aged 12-17 years who is expected to remain in treatment with the enrolled therapist for at least six more weeks, 3) possess an Android-based "smartphone" with a data plan, 4) possess, or be willing to set up, an email account; 5) be willing to allow the adolescent receiving treatment to participate in the study; and 6) be willing to allow the adolescent participant to use a smartphone with a data plan during the course of the study. Therapists will provide the screening for criteria #1 and #2 and will only approach those parents on their caseloads who are fluent in English and whose adolescent's case is expected to still be in need of clinical services (i.e., case is expected to remain open) for at least another 6 weeks. Therapists also will only approach those parents who they deem to be clinically stable (e.g., not suicidal, not severely impaired by substance abuse), based on their clinical judgment. Study staff will screen for (or affirm the therapist's impression of) criteria #3-6 upon referral.

We will develop a 3-4 minute informational animated video that explains the study to those parents deemed likely eligible by therapists. At an appropriate time during or immediately following a clinical session, enrolled therapists will provide a brief introduction to the study and ask the parent to watch a video to learn more about it. The video will be available on YouTube and accessible by hyperlink. The parent can watch the video on the therapist's computer or smartphone or, if the parent prefers, the therapist can email the hyperlink to the parent so that s/he may watch the video at their convenience. Any parent who does not watch the video with the therapist will be given a flyer by the therapist that contains the URL for the video (included as Appendix 4, Family Recruitment Flyer). The purpose of the video is to ensure that all parents approached receive the same information about the study in a standardized way, to minimize the referral burden to therapists, and to minimally interfere with the clinical session. A video also has the advantage of conveying basic study information verbally (rather than in written format as

in on a flyer or through email), which may be helpful if parental literacy is poor. The video will be animated to make it enjoyable and engaging to watch. The script that will be used in this recruitment video is included with this protocol as Appendix 4 (Script for Family Recruitment Animated Video).

To encourage parents to consider participation, we will provide an incentive for watching the video. Specifically, after the parent watches the video, a prompt will pop up that will ask him/her to click on a link to be entered into a lottery to win a tablet computer. The link will open to a secure RedCap interface that will ask the parent to provide his/her name and contact information, including email address, to be notified if they win the lottery drawing. Once the parent enters the information, s/he will see a screen that says,

“You have earned one ‘virtual raffle ticket’ (one chance to win) for entry in the tablet drawing. The drawing will take place in ESTIMATED MONTH OF DRAWING. We will inform you immediately if you are the winner.”

Then, the parent will be presented with one final question:

“Are you willing to be contacted by a member of the research staff to learn more about possible participation in the study? If you agree, you will earn one additional raffle ticket. You do not have to decide about being in the study today, only whether you are willing to hear more about it.”

Any parent who responds “yes” to this question will receive one an additional chance to win and will see this message:

“Thank you for your willingness to learn more about the study. A member of the research team will call you in the next few days. A second raffle ticket has been entered for you.”

All parents who indicate on RedCap that they are willing to be contacted for participation will be telephoned by a member of the research staff. During the initial phone call the staff member will verify that it was the parent (not the youth or another family member) who agreed to be contacted; determine eligibility (see Parent Screening Questions, Appendix 5), answer questions, and either proceed to the informed consent process or schedule a time for the parent to engage in a consenting session.

In some cases a parent may express interest in participating to the therapist without visiting or indicating such on Redcap. When this occurs, the therapist will obtain a release of information from the parent granting permission for the therapist to provide the research team with the parent’s contact information.

**Recruitment of adolescents.** As part of his or her own consenting process, the parent will be asked to also provide consent for the youth’s participation. After a parent has been enrolled and has provided consent for youth participation, the research assistant will arrange with the parent a way for the youth to watch the family recruitment video (e.g., the assistant can email the link to the parent or ask the therapist to show it at a session). We expect that in many cases, the youth will have already watched the video (e.g., parent and youth watched it together). If this has occurred, the assistant will ask to speak with the youth about the study immediately following parent enrollment, either in person or on the phone, to begin the assenting process. If the youth has not yet had an opportunity to watch the video, the research assistant will delay approaching the youth until this has occurred (i.e., until the youth has provided contact information on RedCap and an agreement to be contacted).

The youth’s experience watching the recruitment video will be identical to that of the parent’s. Specifically, after entering contact information, the youth will see:

“You have earned one ‘virtual raffle ticket’ (one chance to win) for entry in the tablet drawing. The drawing will take place in ESTIMATED MONTH OF DRAWING. We will inform you immediately if you are the winner.”

Then, the youth will be presented with one final question:

“Are you willing to be contacted by a member of the research staff to learn more about possible participation in the study? If you agree, you will earn one additional raffle ticket. You do not have to decide about being in the study today, only whether you are willing to hear more about it.”

Any youth who responds “yes” to this question will receive one an additional chance to win and will see this message:

“Thank you for your willingness to learn more about the study. A member of the research team will call you in the next few days. A second raffle ticket has been entered for you.”

## **D5. Informed Consent**

Two separate consent forms will be developed, one explaining study procedures for therapists and one for parents/youth (see Appendix 6 and 7). A youth assent form (Information Form for Youth Assent, see Appendix 8) also will be used. Participants also will sign a HIPAA form during the consent procedure (see Appendix 9 and 10). For all participants, enrollment will not be considered complete, and research procedures will not be initiated, until study staff has obtained signed original copies of consent and HIPAA forms (verbal consent alone will be insufficient).

**D5.1. Consent process for therapists.** Therapists who indicate a willingness to be contacted for the study (see recruitment section D4) will be telephoned by a member of the research staff to learn more and, if still interested, to schedule a time to engage in the informed consent process either by telephone or in person. We assume that most consenting sessions will be conducted by telephone. If by telephone, prior to the consenting session, the research assistant will either mail (hard copy) or e-mail (PDF version) a copy of the consent and HIPAA forms to the therapist. Therapists will be asked to read along with the research assistant as s/he reads the consent form out loud, pausing after each paragraph to verify therapist understanding and answer questions. Part of the therapist consent process will involve explaining that due to the linked nature of this study, the therapist may not be able to participate in all study procedures, if a parent-youth dyad on their caseload is not able to be enrolled. (see Therapist Consent Form, Appendix 6).

At the end of the process, the therapist will indicate verbally whether they consent; if yes, s/he will be asked to sign the form. The research assistant will then use the same procedure (read out loud as therapist reads along) to obtain therapists signatures on the HIPAA form. Upon completion of both forms, the therapist will be asked to mail the documents to a study staff member at MUSC. The therapist will be provided with a preaddressed and stamped envelope for this purpose if requested. Once received they will be signed by research assistant who conducted the consenting session. This procedure (i.e., for obtaining informed consent from off-site individuals by telephone, with subsequent U.S. mail transmission of the signed forms), has been approved for use in prior study protocols by the MUSC IRB previously, including in the Developing Technology to Enhance MST study (Cindy Schaeffer, PI) and in the MST Transportability Study (Sonja Schoenwald, PI).

For therapists who complete the informed consent process in person with a member of the research staff, the staff person will either hand carry or mail forms back to MUSC. Once received at MUSC, all consent and HIPAA forms will be scanned, uploaded (scanned versions) to a secure password protected file on the MUSC homeroom drive, and filed (hard copies).

**D5.2. Consent process for parents and youth.** The research assistant will schedule a consenting session with the parent during the call for screening and recruitment (see section D4). We expect that most parents will engage in the consenting process by telephone. After scheduling the consenting session, the assistant will arrange with the parent a way for him/her to receive hard copies of the informed consent, HIPAA, and Information for Youth Assent (see below) forms. The assistant will provide the following options: 1) hard copies mailed to parent's home; 2) hard copies delivered to the parent through the adolescent's therapist; 3) PDF versions of the forms emailed to the parent (the parent will be informed that the forms will need to be printed). Regardless of option chosen, all potential parents will have a pre-addressed stamped envelope provided (either through the mail or delivered by the therapist) for returning the forms to MUSC.

Before the consenting session begins, the research staff person will verify that the parent has the consent and HIPAA form in hand; if not, a new set will be mailed or delivered to the parent, and the interview will be rescheduled. When the parent has the forms in hand, the research assistant will conduct the informed consent interview in the same manner as described for therapists (i.e., parent reads along as assistant reads both forms out loud and pauses after each paragraph to verify understanding/answer questions). Once complete the assistant will obtain the parent's verbal consent for his/her own participation and for the participation of the linked youth. The parent will be asked to sign on the appropriate lines of the consent form indicating his/her agreement for both to participate. The research staff person will ask the parent to hold on to the forms until the youth assent process is complete (see below). Once the youth has indicated assent by signing the parent's consent form, the parent will be asked to return both forms to MUSC using the pre-addressed envelope provided.

For parents who complete the informed consent process in person with a member of the research staff, the staff person will either hand carry or mail forms back to MUSC. Once received at MUSC, all consent and HIPAA forms will be scanned, uploaded (scanned versions) to a secure password protected file on the MUSC homeroom drive, and filed (hard copies).

Part of the parent consent process will involve the parent deciding whether the adolescent participant will use his/her own Android-based smartphone during the study, or will receive one with a prepaid (temporary) data plan from the study to use temporarily. Parents will be informed that if the parent accepts a phone for temporary use and fails to return it at the end of the study, the family's compensation for participation in the study will be reduced by the dollar value of the phone. The parent's decision whether to receive a study phone or not will be reflected on a checkbox on the parent's consent form. Research staff conducting consent will also ask the parent to sign a statement indicating that they have been told that the phone will serve as part of their compensation for participation if they keep it (see Appendix 11, VillageWhere Study Policy on Smartphone Use, Return, and Compensation). Research staff will ensure full parental understanding of both options (accepting phone or not) before the parent signs.

**D5.3. Assenting process for youth.** The research assistant will schedule with the youth through the enrolled parent, either by phone or in person. The assistant will verify that the youth is looking at the Information for Youth Assent form (see Appendix 8) provided to the parent; if not, another form will be sent to the youth in the same manner used previously (email, mailing, or hand delivered by the therapist), and the session will be rescheduled. The research assistant will read the Information Form for Youth Assent out loud while the youth reads along quietly. Then, the assistant will read the youth volunteer's statement (located at the end of the parent's consent form) and ask the youth to agree or disagree. If the youth agrees to participate, the assistant will ask the youth to sign the parent's consent form in the designated area.

If the youth is uncertain about participating or refuses, the research assistant will reiterate to the youth that s/he does not have to participate, and will inform the youth that his/her parent and/or therapist MAY talk to the youth about participating again in the next few weeks.

The research assistant will then inform the parent that the youth is uncertain about or unwilling to assent at this time, and will encourage the parent to talk with his/her therapist about whether or not to pursue the matter with the youth further.

Because oppositionality is one of the most common presenting problems in treatment for this population (i.e., youth in family-based treatment in which improved parental management practices is a treatment goal), we feel it is appropriate to consider approaching some youth who initially refuse one additional time about participating, on a case-by-case basis and at the therapist's discretion. By virtue of their clinical training (all will have Masters degrees in psychology, social work, or related field), the population they serve (parents and youth for whom effective parental management of youth behavior is an issue), and the agencies they work for (all provide quality training and supervision), the therapists in this study are expected to be highly knowledgeable about appropriate and inappropriate ways for therapists and parents to address adolescent oppositionality and defiance.

When a youth refuses or expresses uncertainty in an assenting session, a clinical member of the research staff will inform the therapist and will discuss with him/her whether s/he believes it is appropriate in the particular case to further pursue recruitment of the youth. Research staff will reiterate the voluntary nature of study participation for parents AND youth. If the therapist deems it appropriate to pursue recruitment further, the research staff member will instruct therapists in ways to prevent any potential coercion with the youth by the parent or therapist. Research staff will use the Checklist for Coaching Therapists to Avoid Coercing Youth for this purpose. The therapist will then talk with the parent about whether and how for the research team to approach the youth again. The therapist will inform the research staff member if and when the youth should be recontacted by the research assistant. Research staff will cease all recruitment activities with any youth who refuses or remains ambivalent upon a second attempt to obtain youth assent. Also, if a member of the research staff feels at any time that the youth has been coerced to participate (e.g., if the youth discloses that "my therapist is making me do this, but I don't really want to"), the therapist and parent will be informed that the parent-youth dyad is no longer eligible to participate, and the parent's enrollment will be administratively withdrawn by study staff.

## **D6. Research Methods: Parents and Adolescents**

### **D 6.1: Procedures: Parents and adolescents.**

***Pre-assessment procedures.*** After parent and youth enrollment is complete in a given family, the research assistant will schedule a time for each to complete a baseline assessment session by telephone or in person (we expect that most will be by phone). Once scheduled, those parents who have elected to have a phone provided for adolescent by the study will be shipped an Android phone with a prepaid data plan, to arrive just before the scheduled baseline assessment session.

Also immediately after enrollment of parent and youth, the research assistant will create an account for each on the VillageWhere server. The purpose of this account is for each individual to have the ability to download the app to his/her smartphone (see below). The account name will be the individual's email address, and a password will be created for them.

***Parent and youth baseline assessment.*** The session will involve each participant completing a set of questionnaires related to the app's clinical targets (see measures section) and the family's demographics. During the session, the research assistant will introduce each measure, read items to the participant if necessary, and answer questions. Participants will respond to the questions using either an internet connection to the RedCap secure interface on the MUSC server, or on paper (participant will choose modality). If the session will be paper-based, research staff person will mail, email, or hand-carry measures to the family's home along

with a self-addressed stamped envelop for return before the scheduled session time. If by RedCap, the research assistant will email (or verbally provide) the link to the questionnaires to the participant during the session phone call. Parent and youth sessions will be conducted separately, and each participant's answers will remain confidential from the other's. We expect that most assessments will occur using RedCap.

After questionnaires are complete, the final part of the parent's baseline assessment session will be to schedule a post-usage assessment session for both parent and youth, give the parent the go-ahead to download the VillageWhere app, inform the parent how to do so, and provide brief instructions for app use (see "downloading the app" and "instructions for app usage" sections below).

Once both parent and youth baseline sessions are complete, the parent will receive a thank-you card by mail, thanking the family for completing the baseline assessment and informing them that \$35 compensation has been banked for them for the sessions (\$25 for parents, \$10 for youth; see below). The note will also remind parents that payment may take the form of a check made out to the parent or retention of the study-provided phone, and will be provided at the end of study procedures.

**Downloading the app.** Once both baseline sessions are complete, the parent and youth each will receive an email with a link to the VillageWhere server and his/her study-created password. The parent's activation email will be sent only to the parent; the youth's activation email will be sent to the youth and parent. Both activation emails will be sent immediately after both have completed the baseline assessment; participants will click on the link using their smartphone, enter their email address and password, and click to download the app. After this procedure is explained to the parent, the research assistant will offer to assist the parent or youth in downloading the app if desired, either immediately or in a subsequent phone call.

Research staff will monitor whether or not each participant has downloaded the app by looking on the server. If after one week of sending the initial activation email the participant has not downloaded the app, the research assistant will remind the participant to do so on day 7 (first reminder email) and every other day thereafter (days 9, 11, and 13) by email. If by day 14 the participant has still not downloaded the app, the research person will make two phone calls and two text message attempts to reach the participant during days 14-21. Participants who have not downloaded the app within 21 days of the baseline assessment session will be administratively withdrawn from the study.

The dyad's (parent and youth) app usage testing period will be considered to begin on the next calendar day after the second dyad member's app is downloaded (i.e., after whomever's app – parent's or youth's - is downloaded last).

**App data generation.** Any app usage by parent or youth participant will result in the generation of information about type, duration, and other details of use (e.g., time of day) by the app itself (see measures section); these data will be captured on the server and will be deidentified. These data are substantive indicators critical for meeting one of the study's goals, namely, to determine whether and how (what features, etc.) real-world consumers are likely to use the app.

**Family app usage periods and daily satisfaction ratings.** The study will use 2 different app usage testing period lengths, depending on the timing of participant enrollment:

- **Field-Based Beta Testing Group** - the first 4-6 parent-youth participants will test the app for 14 days. The purpose of this phase is to ensure that the app is "bug free" and features perform as expected before it is subjected to a full initial open trial. Only four parent-youth dyads will participate in this phase if early users experience no or only



minor, easily-fixed glitches with app functioning. Five or six parent-youth dyads will participate if we determine that fixes to the app were substantial enough that the product needs to be retested with several additional participants before the open trial. The field-based testing group can be viewed as a pilot phase for the open trial. Except for the shorter testing period and different usage instructions (see next section), the procedures for this group will be identical to those in the open trial group (e.g., compensation, baseline and post-testing batteries, therapist involvement, etc.).

- **Open Trial Group** – Twenty parent-youth dyads will test the app for 45 days. Data obtained from this group will be the main basis upon which substantive conclusions about the app's success (the aims of this study) will be drawn.

Once each day during the testing period, the app will prompt each participant to answer three questions regarding his or her satisfaction with the app on that day. Participants will respond to the questions directly on their phones (within the app). Answering the questions will take less than 5 minutes. Data generated by these daily prompts will be stored on the app server. If during field-based beta testing users complain about the frequency being too high and too intrusive, we will reduce the frequency of collection (e.g., to twice each week) based on initial user feedback.

Phone-based data collection (i.e., automatic app usage data and self-report daily satisfaction ratings) will cease the day after the last day of the testing period (i.e., day 15 or day 46, depending on group).

**Instructions for using the app.** Verbal instructions for how to use the app will be provided to parents as part of their baseline assessment session (see Parent and Youth Baseline Assessment Section, above). These instructions to parents will vary, depending on whether the parent is participating in the Field Test or the Open Trial. Those parents in the **Field Test** will be encouraged to use the app as much as possible over the next 2 weeks. These parents will be told that the purpose of this phase of app usage testing is to debug any remaining problems with the app, and so the research staff would greatly appreciate it if they made an effort to use the app every day and to explore all of its features. These parents will also be instructed to encourage the youth to use the app as much as possible during this period.

Parents participating in the **Open Trial** will be told that they should use the app in whatever ways they wish and using whatever degree of clinical support from the therapist all parties (parent, youth, and therapist) deem necessary or helpful.

**Post-usage assessment battery and exit interview.** When calling to schedule or to confirm a scheduled post-usage assessment session, research staff will inform parents that each participant's timely completion of the session (i.e., within 2 weeks of the testing period ending) will earn the participant an additional raffle ticket for the tablet computer lottery.

On or about day 15 (for Field Test participants) or 46 (for Open Trial participants), the parent and youth each will complete the post-usage assessment session, by phone or in person (most are expected to occur by phone). In these sessions, the same battery of questionnaires related to clinical targets will be administered (on paper or using RedCap), plus several questionnaires related to satisfaction with and acceptability of the app. The session will conclude with a 30-45 minute open-ended "exit" interview with a member of the research staff during which the participant will have an opportunity to share thoughts and opinions about the experience of using the app and offer any suggestions for improvement.

Before closing with the parent, the research assistant will ask the parent whether or not s/he would like to keep the youth's phone or return it, for those families in which the parent elected for the youth to use a study phone. If the parent elects to return the phone, a

preaddressed stamped mailing package will be mailed to the parent for shipping. If the parent elects to retain the phone, the parent will be reminded that the cost of the phone will be deducted from the parent-youth dyad's overall earnings for participation. As of this writing, basic Android-based smartphones ranged in price from \$40 - \$80. All participants electing to be given a phone will receive the same make and model phone, and the exact cost of the phone ultimately purchased for this project will be inserted in the appropriate spot on the VillageWhere Study Policy on Smartphone Use, Return, and Compensation form (currently blank; see Appendix 11). Parents who elect to return the study phone will be mailed a check for the total study compensation as soon as the phone is received and when both parent and youth post-usage assessment sessions have occurred. In families who did not use a study phone, a check will be mailed immediately upon completion of both participants' post-usage assessment session/exit interview.

**Post-study app usage.** Parents and youth will not be allowed to continue to use the server-supported features of the app after they end their participation in the study. Within two weeks of a parent-youth dyad completing all study procedures, the participating parent will receive an email stating that their VillageWhere app will expire in one week, and to please make arrangements accordingly. On the day of expiry, research staff will cancel the parent-youth dyad as users of the app on the server. On the day before the users are removed, the parent will receive one additional email alerting them to the cancellation. Although the features of the app that require server support (e.g., the GPS locator) will no longer function on parent and youth phones, other features (e.g., the youth's daily behavioral expectations depicted in the Game Plan feature) will still appear on participant phones and may be of some value to participants.

**D 6.2. Measures: Parents and adolescents.** Enrolled parents and adolescents will generate 4 types of data: a) self-report questionnaires administered before (pretest) and after (post-test) the app usage period; b) app usage data, generated by the app whenever the parent or adolescent uses it and automatically stored on the app's server; c) daily app satisfaction ratings, prompted by the app, completed directly on the phone, and stored on the app server; and d) an open-ended qualitatively-oriented exit interview.

**Self-report questionnaires.** Tables D6.2a and D6.2b outline the measures that will be administered to enrolled parents and youth, respectively, at pre- and/or post-usage assessment points. Full questionnaires are provided as Appendices 12 and 13 to this protocol. Measures pertaining to participant functioning and parenting behavior are all commonly used in studies with populations similar to those in the present study (adolescents presenting to treatment and their families), including intervention outcome studies, and are psychometrically sound (i.e., good reliability and predictive validity). Additional psychometric information about these measures is available upon request. With the exception of the history of arrest questions (collected for descriptive purposes), these measures are expected to show improvements over time as a result of VillageWhere app usage for those participants in the open trial.

A family demographics measure, administered only to parents, was created for this study in order to describe the sample. The System Usability Scale (Dimeff et al., 2009) is commonly used in product development studies and relates to the user's satisfaction with and opinion of the acceptability of VillageWhere. A brief technology use and comfort questionnaire was created for this study.

Note that any measure listed at only the pre- or post-time point will only be administered at that time point. All measures will be entered into the RedCap system for data collection.

**Table D6.2a. Parent Self-Report Measures**

<b>CONSTRUCT</b>	<b>SCALE</b>	<b># OF ITEMS PRE-TEST</b>	<b># OF ITEMS POST-TEST</b>	<b>CITATION / OTHER INFORMATION</b>
▪ Family demographics	Created for study	25	---	n/a
<b><i>Youth Functioning</i></b>				
▪ Rule-breaking behavior	Subscale of the Child Behavior Checklist (CBCL)	17	17	Achenbach & Rescorla (2007)
▪ Aggressive behavior	Subscale of the Child Behavior Checklist (CBCL)	18	18	Achenbach & Rescorla (2007)
▪ Anxious / depressed	Subscale of the Child Behavior Checklist (CBCL)	13	13	Achenbach & Rescorla (2007)
<b><i>Parent Functioning and Behavior</i></b>				
▪ Life stress	Perceived Stress Scale (PSS)	10	10	Cohen, Kamarack, & Mermelstein (1983)
▪ Sense of control and efficacy in parenting	Parent Locus of Control scale	20	20	Campis, Lyman, & Prentice-Dunn (1986)
▪ Supervision of youth behavior	Loeber Parenting Scale, Supervision subscale	8	8	Loeber, Farrington, Stouthamer-Loeber, & Van Kammen (1998)
▪ Discipline consistency	Loeber Parenting Scale, Discipline Consistency subscale	5	5	Loeber, Farrington, Stouthamer-Loeber, & Van Kammen (1998)
▪ Discipline effectiveness	Loeber Parenting Scale, Discipline Effectiveness subscale	3	3	Loeber, Farrington, Stouthamer-Loeber, & Van Kammen (1998)
▪ Rewards for youth good behavior	Loeber Parenting Scale, Positive Parenting subscale	9	9	Loeber, Farrington, Stouthamer-Loeber, & Van Kammen (1998)
<b><i>App Acceptability and General Technology Use</i></b>				
▪ App useability / acceptability	System Useability Scale	---	10	Dimeff et al. (2009)
▪ Use of and comfort with technology	Created for study	---	5	n/a

**Table D6.2b. Youth Self-Report Measures**

<b>CONSTRUCT</b>	<b>SCALE</b>	<b># OF ITEMS PRE</b>	<b># OF ITEMS POST</b>	<b>CITATION / OTHER INFORMATION</b>
<b><i>Youth Functioning</i></b>				
▪ Rule-breaking behavior	Subscale of the Youth Self Report (YSR)	18	18	Achenbach & Rescorla (2007)
▪ Aggressive behavior	Subscale of the Youth Self Report (YSR)	18	18	Achenbach & Rescorla (2007)
▪ Anxious / depressed	Subscale of the Youth Self Report (YSR)	13	13	Achenbach & Rescorla (2007)
▪ History of arrest	Created for this study	3	---	n/a
▪ Alcohol and drug use	Center for Substance Abuse Prevention (CSAP)Scale	12	12	SAMHSA (2006)
<b><i>Parent Behavior</i></b>				
▪ Supervision of youth behavior	Loeber Parenting Scale, Supervision subscale	8	8	Loeber, Farrington, Stouthamer-Loeber, & Van Kammen (1998)
▪ Discipline consistency	Loeber Parenting Scale, Discipline Consistency subscale	5	5	Loeber, Farrington, Stouthamer-Loeber, & Van Kammen (1998)
▪ Discipline effectiveness	Loeber Parenting Scale, Discipline Effectiveness subscale	3	3	Loeber, Farrington, Stouthamer-Loeber, & Van Kammen (1998)
▪ Rewards for youth good behavior	Loeber Parenting Scale, Positive Parenting subscale	9	9	Loeber, Farrington, Stouthamer-Loeber, & Van Kammen (1998)
▪ Parental surveillance and knowledge	Parent Knowledge Scale	15	15	Steinberg, Elmen, & Mounts (1989)
<b><i>App Acceptability and General Technology Use</i></b>				
▪ App useability / acceptability	System Useability Scale	---	10	Dimeff et al. (2009)
▪ Use of and comfort with technology	Survey created for this study	---	5	n/a

**App usage data.** The App Usage Data Elements document within Appendix 14 outlines the data that will be generated by app usage itself for each participant (parent and youth). Examples of fields that will be generated are number of times each app component is opened, times of day opened, and participant responses to prompts. These data will be stored on the same server where the app operates and available for download after the dyad has completed their participation.

**Daily app satisfaction ratings.** During the evening of each day the app will prompt the participant with a pop-up notice to provide three brief Likert-scale ratings of their experience with the app that day. Daily rating questions for parents and youth appear in the App Use End of Day Ratings measure in Appendix 15. Parent ratings pertain to app helpfulness, satisfaction with the app, and sense of self-efficacy in managing youth behavior. Youth ratings pertain to feeling rewarded for good behavior, satisfaction with the app, and degree of hassle in using the app. When prompted the participant will click "OK" and be taken directly to a screen containing the three questions. When the participant has completed the questions the answers will be stored on the app server for later download at the end of the usage period. Participants can elect to not answer the questions when prompted, and prompts will not affect the participant's ability to use the phone.

**Qualitative exit interview.** Following their completion of the post-usage assessment battery, parent and youth participants will engage in a 30-45 minute open-ended interview, either in person or by phone, with a member of the research staff. (Most are expected to occur by phone). The interview provides an opportunity for participants to say in their own words their experiences using the app and suggestions for improvement. The interview consists of 2 questions for participants in the field-based beta test group or 6 questions for those in the open trial (see Appendix 16).

## **D7. Research Methods: Therapists**

**D7.1 . Procedures: All enrolled therapists.** Note that there is no therapist version of the app, and thus the therapist's own personal or workplace mobile phone use is irrelevant to the study. However, if an enrolled therapist already uses an Android-based smartphone and would like to download the parent version of the app to familiarize him/herself with it, s/he is welcome to do so at no cost, and the research team will facilitate app installation. Downloading the app to their own phone, or using a smartphone at all, is not a requirement for enrolled therapists. If a therapist elects to download the app, s/he may use it as they wish, and no data will be collected on his/her app usage.

Research staff will offer the option of downloading the app to therapists after the consenting session is complete; if a therapist wishes to do this, an account on the VillageWhere server will be set up using the therapist's email address. Research staff will email the therapist his/her password and a link for where to download the app.

As explained in the recruitment section above, all enrolled therapists will be asked to inform eligible parent-youth dyads on their caseloads about the study using the family recruitment video, and to refer parents who verbally request more information directly to the study (by obtaining a release of information from the parent to send research staff the family's contact information). A member of the research team who has clinical training (i.e., Dr. Schaeffer, Dr. Dimeff, or Dr. Kelly) will meet with the therapist (either in person or by telephone)

one or more times to provide personalized guidance in how to talk with parents and youth about the study in ways that are not coercive.

Also, as noted, we expect that some enrolled therapists will not be able to further participate in the study because no parent-youth dyad on the therapist's caseload also was enrolled, despite referrals of one or more dyads by the therapist. To acknowledge therapists' willingness to participate and his/her family referral efforts, we will allocate two additional virtual raffle tickets to any therapist who enrolls but does not participate in the study (see Lottery Ticket Allocation section below).

**D.7.2. Procedures: Enrolled therapists with linked parent-youth dyad client participants.** Due to the linked nature of this study's design, procedures outlined in this section pertain only to those enrolled therapists for whom a parent-youth dyad on his/her caseload also was enrolled. Note that there is no pre-usage assessment session for therapist participants.

***Informing therapists of linked dyad enrollment and introductory phone call.*** As soon as a parent and youth on an enrolled therapist's caseload also are enrolled, research staff will call the therapist to inform him/her of such, the approximate date of the start of the family's usage period, and to explain next steps. This phone call, expected to take 20 minutes, will introduce the following points to the therapist and encourage the therapist to read a protocol or watch videos to learn more about each:

- a. Therapists should use an upcoming clinical session to set up the app with the parent, specifically, to type in the youth's existing behavior plan into the Game Plan feature (if a behavior plan already exists in the family) or, if one does not already exist, to create a behavior plan using Game Plan;
- b. In sessions thereafter, therapists should periodically ask the parent how his/her use of VillageWhere is going, to communicate to parents that discussing the app in sessions is welcome and appropriate (see "App Inquiries" section below);
- c. At no time should discussing VillageWhere in a session take precedence over any other clinical issue deemed more important or clinically necessary (i.e., that therapists should always use their best clinical judgment as to whether and how much it is appropriate to discuss the VillageWhere app in the session).
- d. Additional support regarding how to incorporate the app into treatment sessions is available to the therapist if desired. These include a clinical protocol, training videos, and weekly office hours.

***Training on app features and therapist role.*** After the introductory phone call, research staff will email the therapist a clinical protocol document explaining best practices for using the app with parents and youth. The protocol will outline all of the app's features and provide clinical recommendations for how to support the participating family's app use in treatment during the family's testing period.

The email will also inform the therapist that a series of brief training videos showing and explaining specific app features is available to watch if desired. Some videos will focus on the details of a specific app feature, whereas others will provide general advice for using the app clinically. Each video will have a duration of five minutes or less. Participating therapists may watch all or none of these videos, and can watch them in any order they wish at any point during their participation. The clinical protocol and video segments will be redundant in the information they provide, but will offer the therapist a range of options for obtaining information with minimum burden or time investment.

**Helping the parent set up the youth's behavior plan in the app.** The clinical protocol (and a video segment) will outline to therapists how they should help the parent set up the Game Plan feature of VillageWhere in a regularly scheduled session during the first two weeks of the family's usage period. Therapists will be asked to look at the parent's version of the app on the parent's smartphone and guide the parent through how to enter the behavioral expectations the parent has for the youth (e.g., where the youth should be and what s/he is allowed to do before school, at school, after school, and on weekends) into the app. Helping the parent to set up Game Plan will be an expectation for therapists in both the Field Test (2-week test) and the Open Trial (6-week test).

**App inquiries.** The app inquiry procedure pertains only to those therapist-parent-youth triads participating in the Open Trial. During the introductory phone call with the therapist, research staff will explain what is expected of the therapist after s/he helps the parent set up the app's Game Plan feature. Specifically, the study procedure is for the therapist to make at least two additional inquiries about the app to the parent (i.e., "app inquiries") during two different regularly-scheduled treatment sessions. Two times during the family's six-week app use testing period (during weeks 3 and 4), therapists will receive an email asking them to inquire about the family's app use during a session this week, if clinically and logistically possible. Emails will be similar to the following: "This is a friendly reminder to please make your FIRST (SECOND) "app inquiry" with your linked parent during a session this week, if you have not already done so. Remember that an app inquiry involves simply asking your linked parent if s/he has any questions about the VillageWhere app or wants any help with it. As always thanks for helping with the VillageWhere project, and contact us if you need anything. Research Team."

The purpose of app inquiries is to ensure that the linked parent is explicitly invited to obtain support in using the app as part of treatment, but does not experience pressure from the therapist to use or discuss the app. Therapists will be asked, as part of their post-usage assessment battery, whether or not they discussed the app in treatment and if so, how extensive was the support provided. We expect natural variability on this dimension and will examine this variable's association to parent and youth usage data and clinical outcomes.

**Optional "Office Hours" for additional therapist support and troubleshooting.** Therapists can elect to participate in "office hour" conference calls over the course of his/her linked family's testing period for app support and to have questions answered. Office hours will be led by a clinically trained research staff member (Drs. Schaeffer, Dimeff, or Kelly) and attended by the research assistant (who will have the most information about troubleshooting the app itself). All enrolled therapists with a family in their testing period are welcome (but not required) to attend. Several such calls, each lasting one hour, will occur at various times throughout the week, and therapists may call in to whichever one best fits their schedule and remain on the call for as long as they wish. Therapists will be informed that if none fit his/her schedule they are welcome to contact Dr. Schaeffer or the study research assistant directly at any time to have questions answered. This service is offered to therapists to increase their comfort level in being able to answer any questions a family might have or to address concerns. A log of questions raised during office hours will be kept to inform future app development.

**Post-usage assessment battery and exit interview.** On or about Day 15 (for therapists linked to a field-based beta testing family) or Day 46 (for those linked to an Open Trial family), the research assistant will email the therapist requesting that s/he complete the post-usage assessment battery on their computer using RedCap. Questionnaires inquire about therapist demographics, professional credentials, and opinions about the app. Once completed,

the assistant will schedule an “exit interview” with the therapist, lasting approximately 60 minutes, during which the participant will have an opportunity to share thoughts and opinions about the experience of using the app and offer any suggestions for improvement (see Exit Interview in Appendix 16 for interview questions). Exit interviews are expected to occur mostly by phone but will be done in person if feasible and desired. Once both the assessment battery and exit interview are completed, therapists will be mailed a check for \$50 as compensation for study participation.

**D7.3: Measures: Therapists.** Enrolled and participating herapists will provide data in two ways: 1) completing three questionnaires after all of their linked parent-youth dyads have completed study procedures; and 2) participating in an exit interview with study staff.

**Self-report questionnaires.** Table D7.3 outlines the measures that will be administered to enrolled therapists who have a linked parents-youth dyad. Full questionnaires are provided as Appendix 17 to this protocol. A therapist demographics measure asks about personal and professional characteristics and is collected for the purpose of describing the sample. Therapists will complete the brief technology use and comfort questionnaire created for all participants in this study, and will complete an additional survey regarding experiences with VillageWhere from the therapist perspective.

All therapist self-report measures will be collected one-time only, at the end of their participation in the study (i.e., when their last linked parent-youth dyad finishes its usage period and post-usage data collection sessions). Questionnaires will be entered into the RedCap system for data collection.

**Table D7.3. Therapist Self-Report Measures**

CONSTRUCT	SCALE	NUMBER OF ITEMS
▪ Demographics	created for study	10
▪ Use of and comfort with technology	created for study	5
▪ Therapist experience with VillageWhere survey	created for study	6

*Note.* All therapist self-report items are administered only at the post-assessment time point.

**Exit interview.** After completing their self-report battery, therapists will participate in the same six-item open-ended exit interview used with parents and youth (see Appendix 16). The interview is expected to take 30-45 minutes to complete.

## **D8. Selecting Lottery Winners (among those enrolled and those never enrolled)**

Once all study procedures are complete for all participants, lottery winners will be selected. Recall that we seek to allocate lottery tickets to individuals in the recruitment pool (as an incentive to consider participation) as well as to those enrolled. A summary of how lottery tickets are to be allocated to each type of potential and actual participant appears in Table D8. Each parent-youth dyad can earn up to 6 chances to win, and each therapist, 4 chances.



Parents and Youth		Therapists	
Activity	# of Tickets Allocated	Activity	# of Tickets Allocated
Parent watches Family Recruitment Video	1	Watches Therapist recruitment video	1
Youth watches Family Recruitment Video	1	Watches Parent recruitment video	1
Parent agrees to be contacted by research team to learn more about study	1	Enrolls in study (whether a linked parent-youth dyad also enrolls or not)	2
Youth agrees to be contacted by research team to learn more about study	1		
Enrolled parent completes post-assessment within two weeks of end of usage period	1		
Enrolled youth completes post-assessment within two weeks of end of usage period	1		
<b>Maximum possible lottery tickets:</b>	<b>6</b>	<b>Maximum possible lottery tickets:</b>	<b>4</b>

A database of entries (excel spreadsheet) by participant /potential participant type (therapist or parent/youth) will be maintained in a password protected file on the MUSC homeroom drive. Ticket holder entries will appear on the spreadsheet in the order in which the entries were made (i.e., on the date and at the time the entry occurred, e.g., entry 37, therapist X watched video 1 on 6/16/14 at 2:05; entries 38 and 39, enrolled therapist Y could not participate because no one on caseload consented; etc.). An online random number generator will be used to select one number within the full set of entries obtained for each participant type (e.g., select a number between 1 and 39 for therapist entries, if #39 represents the last entry obtained in the therapist lottery). The individual or dyad who generated that entry will be the winner for that participant category. Winners will be notified immediately by email or phone, and arrangements will be made to ship the tablet computer directly from the retailer to the person's home or workplace. The value of each tablet computer (2 total) will not exceed \$300.

#### **D9. Participant Reimbursement.**

**Enrolled parents and youth.** All participating parents will receive \$25 for completion of the baseline assessment session and \$50 for completion of the post-usage session. Youth will receive \$10 for completion of the baseline assessment session and \$25 for completion of the post-usage session. Taken together, a parent-youth dyad that completes all study components will earn \$110. Compensation will be in the form of a check issued by other institution engaged in this research (the Evidence-Based Practice Institute), made out in the parent's name and mailed to the parent. Youth will not directly receive any compensation for participation.

When a parent elects to have a study phone provided for the youth, the youth will receive either 30 (in Field-Based Beta Testing) or 60 (in the Open Trial) days worth of phone usage (i.e., a prepaid phone card that includes voice, text, and data will be activated on the phone by study staff). The value of each month of service is approximately \$35.

Parents who either decide to keep a study phone or who fail to return it will have the actual cost of the phone deducted from the total family compensation earned. As noted above, phone costs are not yet known exactly but are not expected to exceed \$80. Thus, assuming a phone cost of \$80, a family who elects to keep the phone after the usage period is over and who completes all study procedures will receive \$30 (i.e., \$110-\$80). Parents will be given two weeks after the day they receive the self-addressed envelope to return the phone and will receive two reminders (by email or phone call) to return it. Any phone not received by the end of this two week period will be considered retained by the family. If a family receives a phone, fails to return it, and completes only a portion of study procedures that is insufficient to cover the cost of the phone, the parent will not be charged for the difference. For example, a parent and youth that complete the baseline but not the post-usage assessment will have earned only \$35, but will not be charged the balance of \$45.

Checks will be mailed to parents after all of the family's study procedures are complete and the phone's return status (if relevant) is known. A receipt outlining the components of the payment will accompany the check.

Note that in the parent-youth lottery drawing, the winner may or may not be someone who is enrolled in the study. If the winner is an enrolled participant, the tablet computer, valued approximately \$300, can be viewed as additional compensation.

***Enrolled therapists who do not participate.*** Some therapists will enroll, but not end up with a parent-youth dyad from their caseload also enrolled. Compensation for these participants will be two additional chances to win a tablet computer in the therapist lottery drawing. The lottery winner for the therapist drawing may or may not be someone who is enrolled in the study. If the winner is an enrolled participant, the tablet computer, valued approximately \$300, can be viewed as compensation. Also, all enrolled therapists can download the VillageWhere app to their personal smartphone if they so choose.

***Enrolled therapists who participate.*** Therapists will receive \$50 for participation, to be allocated in the form of a check immediately following their completion of the post-usage assessment session and exit interview.

## **D10. Data Management Procedures**

Participants will be assigned a participant identification number which will be used to label all data collected. A single list of participant names linked with ID numbers will exist in a password-protected electronic file stored on an MUSC homeroom drive accessible only to study staff. Research staff must use their personal identification numbers and passwords to access the homeroom drive itself.

Original signed copies of participant consent and HIPAA forms will be stored in a locked file cabinet in a locked office at the MUSC Family Services Research Center accessible only to the PI and the project manager. As a backup system in the event of fire or other physical damage to the building, scanned copies of these forms also will be created before filing and will

be uploaded to the MUSC secure homeroom drive created for this study. Participant ID numbers will not appear on consent and HIPAA forms.

The MUSC RedCap data collection system will be the primary means used for capturing self-report data. REDCap is a secure, web-based application for building and managing online surveys and databases. Participants will enter data directly into REDCap from their personal computers. REDCap provides automated export procedures for data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R). In the event that any participant wishes to complete the questionnaires using hard copies, completed copies will be labeled only with participant ID numbers and will either be hand transported to MUSC by research staff or mailed to the Project Manager's MUSC research office by insured carrier (i.e., UPS or USPS). In no case will consent / HIPAA forms and questionnaires be transported or mailed together. Once paper versions of questionnaires arrive at MUSC they will immediately be scanned, uploaded as PDF documents to the MUSC homeroom drive, and entered into the RedCAP system. Once scanned copies and entered data are verified and checked for accuracy, original hard copies of questionnaires will be shredded.

App usage data and participant daily satisfaction ratings will be de-identified and stored on a server maintained by the Evidence-Based Practice Institute. The server used for data storage is the same one from which the app itself operates. The server is protected by a firewall, and is password protected. Only the PIs and research staff trained in procedures for conduct of ethical human subjects research will have access to data on the server. All data conveyed through the app will be secured by Secure Sockets Layer (SSL) encryption. SSL encryption is the same system used by banking and other commercial institutions and is considered to be the highest level or "gold standard" of online data protection. This technology is what is used for online purchases by encrypting the transmission of data between the web browser and the server that stores the data. Encryption keeps the data from being able to be viewed during transmission. Therefore, the data (which is already de-identified) cannot be viewed by others during transmission.

Individual exit interviews will not be recorded. Notes from these interviews will be labeled using only PIDs and participant type (parent, therapist, or youth).

## **D11. Data Analysis**

Data from demographics questionnaires and the Technology Use and Comfort Survey will be used to describe the sample itself. App usage and SUS data will be used to describe the success of the app itself. On the SUS, scores below a 3.5 on a five-point Likert scale (1 = poor; 2 = fair; 3 = good; 4 = very good; 5=excellent) will indicate a need for further app refinement in subsequent research. An aggregated mean score of 3.5 or higher will support app feasibility. App usage data will be aggregated and subjected to descriptive analyses to determine most preferred features and feature use sequences. Correlational analyses will link app usage data to participant satisfaction ratings and to measures of parent/youth behavior and functioning, to determine if certain app features were more highly preferred or more linked to changes in functioning than others.

Average scores on the SUS will also be compared between parents and adolescents. Between-group comparisons on the USAS will involve independent samples t-tests; effect size estimates also will be computed.

Pre- to post-usage change will be assessed on all parent and youth measures of functioning and behavior. Paired-samples T tests will be used and effect sizes obtained.

Qualitative data obtained from exit interviews will include annotations from investigators noting likes, dislikes, points of confusion, suggestions for improvement, misunderstandings, and potential unintended consequences. Qualitative data will be analyzed using a grounded theory approach (a data-reduction method for qualitative data used to generate and test hypotheses from the ground up).

## **E. PROTECTION OF HUMAN SUBJECTS**

### **E1. 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.

Three categories of human subjects will participate: 1) Parents of adolescents who are receiving mental health treatment, 2) adolescents receiving mental health treatment, and 3) therapists providing mental health treatment to parents and adolescents jointly. Participants will include at least 24 parents and 24 youth (at least 4 each in the field-based beta testing phase, 20 each in the Open Trial). Depending on problems encountered during the field test phase of the study, additional parents and youth might be needed to “debug” app problems prior to the open trial. The maximum number of parent and youth enrollees will not exceed 30 of each. Estimating therapist enrollment is difficult, because it is not yet known how many therapists will need to enroll in order to recruit a minimum of  $N = 24$  parent-youth dyads. We assume that a maximum  $N = 40$  enrolled therapists will be sufficient to recruit the parent-youth sample.

Parent and therapist age ranges will vary, but all will be adults (age 18 or older). Youth participants will range in age from 12-17 years old. All participants are expected to be physically healthy. In terms of mental health functioning, adolescent participants will be heterogenous, but all will have functional impairments sufficient to warrant their participation in either in-home or outpatient mental health treatment. Functional impairments may include internalizing symptoms (e.g., depressed mood, anxiety, social withdrawal), externalizing symptoms (e.g., oppositional behavior, drug or alcohol use), and failure to meet the developmental demands of their natural environments (e.g., to attend school, interact appropriately with peers, or refrain from criminal activity). A unifying factor across this heterogenous sample of adolescents is that all will be receiving family-oriented mental health treatment in which one goal is improved parental management of adolescent behavior.

Parent participants will likely be experiencing some distress caused by factors related to the adolescents' need for mental health treatment. Some may have mental health symptoms of their own (e.g., depression, anxiety). Therapist participants are not expected to be experiencing any distress or symptoms.

Parent and youth participants will be asked to download and use a new mobile phone application designed to help them meet one of their treatment goals, namely, better parental management of youth behavior. Participants will use the app as they wish over a 2- or 6-week testing period, and app usage data will be obtained. They will participate in pre- and post-usage assessment sessions and an exit interview post-usage. After receiving training, therapist participants will be asked to help parents set up the behavioral management feature of the app

as part of a regularly-scheduled treatment session and to offer the parent help using the app if desired. Once the app use testing period is over for their linked parent-youth dyad, therapists will answer questionnaires about the technology and participate in a qualitative exit interview.

## E2. Targeted Enrollment

### Targeted/Planned Enrollment Table

Total Planned Enrollment 108

TARGETED/PLANNED ENROLLMENT: <b>Therapists (n = 40)</b>			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	5	2	7
Not Hispanic or Latino	25	8	33
<b>Ethnic Category: Total of All Subjects*</b>	40		
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	1	1	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	2	8
White	25	5	30
<b>Racial Categories: Total of All Subjects*</b>	32	8	40

*\*The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects".*

In outpatient and in-home therapy settings, higher portions of mental health therapists tend to be female than would be expected by chance.

TARGETED/PLANNED ENROLLMENT: <b>Parents (n = 24)</b>			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	4	1	5
Not Hispanic or Latino	18	1	19
<b>Ethnic Category: Total of All Subjects*</b>	24		
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	1	1	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	3	1	4
White	15	3	18
<b>Racial Categories: Total of All Subjects*</b>	19	5	24

Mothers tend to participate in the mental health treatment of adolescents more often than fathers. This phenomenon is due to several factors, including the cultural expectation that mothers (not fathers) are the primary caretakers of children; mothers less likely to face employment barriers to participation in treatment than are fathers; and single-parent households tend to be female-headed. Thus, parent participants are expected to be predominantly female.

Because an inclusionary criteria for the study is that the parent be English-language fluent (this preliminary version of the app exists only in English at this time), fewer Hispanic participants are expected than would be by chance.

TARGETED/PLANNED ENROLLMENT: <b>Adolescents (n = 24)</b>			
<b>Ethnic Category</b>	<b>Sex/Gender</b>		
	Females	Males	Total
Hispanic or Latino	1	3	4
Not Hispanic or Latino	8	12	20
<b>Ethnic Category: Total of All Subjects*</b>	24		
<b>Racial Categories</b>			
American Indian/Alaska Native	0	0	0
Asian	1	1	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	4	5
White	3	14	17
<b>Racial Categories: Total of All Subjects*</b>	5	19	24

More boys than girls are referred for mental health treatment, and are referred more commonly than girls for a problem involving poor parental management of youth behavior.

- Identify the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
- If you propose to exclude any sex/gender or racial/ethnic group, include a compelling rationale for the proposed exclusion. For example, 1) the research question addressed is relevant to only one gender or 2) evidence from prior research strongly demonstrates no difference between genders.
- Provide either a description of the plans to include children or, if children will be excluded from the proposed research, then you must present an acceptable justification for the exclusion. For example, 1) the condition is rare in children as compared to adults or 2) insufficient data are available in adults to judge risk in children.
- List any collaborating sites where human subjects research will be performed, and describe the role of those sites in performing the proposed research.

### **E3. Rationale for the Inclusion of Children under the age of 18**

Participation of youth is critical, as the aims of the study are to test a technology that is designed to improve parent management practices with youth receiving mental health treatment. The study also seeks to determine whether app components designed for youths themselves are appealing to youth.

### **E4. Collaborating Sites**

Six sites have agreed to allow the PI to recruit participants within their organizations. These sites are: 1) Advanced Behavioral Health (ABH, Connecticut); 2) Catholic Charities (upstate New York); 3) Children's Village (upstate New York and New York City); 4) the Maryland Innovations Institute (Maryland); 5) the Portland Dialectical Behavior Therapy Institute (PDBTI); and 6) the University of Washington Public Behavioral Health Justice Policy Institute. Therapists working within these organizations will be recruited using work email addresses provided by the organization. Parents and adolescents receiving mental health services from

these organizations will be exposed to study recruitment materials by enrolled therapist participants. Parent and youth research activities will take place almost exclusively within their homes and other natural settings, with the exception that these participants may watch a recruitment video following a treatment session while in the treatment provider organization's facility, and may discuss the app with their therapist for clinical purposes.

Although these collaborating organizations will be instrumental in helping study staff recruit participants, their involvement will not rise to the level of "engaged in research activities," as defined by the federal Office of Human Research Protections (OHRP). Per OHRP guidelines set forth at <http://www.hhs.gov/ohrp/policy/engage08.html>, an institution is considered *engaged* in a research project when its employees: (1) collect data about the subjects of the research through intervention or interaction with them; (2) collect identifiable private information about the subjects of the research; or (3) conduct the informed consent process with human subjects. In the present study, staff at participating organizations will **not** be conducting any of these activities. Further, OHRP guidelines state specifically that merely making referrals of potential participants to research projects or otherwise assisting with participant recruitment does not elevate to the level of research engagement (see *OHRP Guidance on Engagement of Institutions in Human Subjects Research*, Section III, B4).

The Evidence-Based Practice Institute (EBPI) is a collaborating site in this research; Dr. Linda Dimeff, EBPI's Chief Scientific Officer, is a Co-PI on the grant that funds this research. She and several other EBPI staff serve as research staff on this study, and EBPI maintains the app server. All EBPI staff involved in this study have completed all MUSC IRB-required CITI training modules and are included as MUSC study staff in this application. The IRB with whom EBPI is enrolled, the Behavioral Health Research Consortium (BHRC), will also review this application. No study procedures will commence until both the MUSC and BHRC IRBs approve all study procedures.

## **E5: Inclusion/Exclusion Criteria**

**Inclusion criteria, therapists.** Any English-speaking outpatient or in-home therapist who works for one of the collaborating organizations and who provides family-based treatment to adolescents in that setting will be eligible to participate. Therapists come from a variety of professional backgrounds (e.g., psychology, social work, counseling).

**Exclusionary criteria, therapists.** Therapists will not be recruited if they are not English-speaking.

**Inclusion criteria, parents.** To be eligible for the study, a parent must 1) be English language fluent, 2) have an adolescent who is expected to remain in treatment with the enrolled therapist for at least six more weeks, 3) possess an Android-based "smartphone" with a data plan, 4) possess, or be willing to set up, an email account; 5) be willing to allow the adolescent receiving treatment to participate in the study; and 6) be willing to allow the adolescent participant to use a smartphone with a data plan during the course of the study.

**Exclusionary criteria, parent.** Parents who do participate in the adolescent's mental health treatment or whose English language fluency is insufficient for using the app and engaging in interviews in English will not be eligible.

**Inclusion criteria, youth.** Any youth aged 12-17 who at the time of recruitment is a participating in in-home or outpatient treatment at a collaborating organization, and for whom

the treatment is expected to last at least 6 additional weeks, is eligible. Youth must also be English-language fluent.

**Exclusion criteria, youth.** Youth who are younger than 12 or older than 17 years of age will not be eligible. Youth who lack English language fluency sufficient to use the app or engage in interviews in English also will not be eligible.

## **E6. 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.*

All data collected will be for the purpose of this research study only. Sources of data include participant self-report questionnaires, phone app usage data, daily satisfaction ratings, and a qualitative exit interview. Responses to questionnaires will be recorded either on secure online REDCap questionnaires (for research sessions that occur by telephone) or on paper (at participant's request); ultimately all questionnaire responses will be entered electronically by research staff. Data files will be uploaded / transferred from REDCAP to a secure password-protected MUSC homeroom drive and stored. At all stages of collection, entry, storage, and analysis, data will be linked to participants using only arbitrary participant ID numbers. Access to the master electronic file that links participant names to ID numbers will be accessible only to research staff on a secure MUSC homeroom drive; both the drive and the file will be password protected.

## **E7. 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.*

Because therapists will be recruited through the organizations in which they work, there is a risk that therapists will feel pressure to participate because their employer is collaborating with the study. Similarly, because parents and youth will be told about the study by the adolescent's therapist, there is a risk that parents and youth will feel pressure to participate in order to please the therapist.

Actual risks of participation in the study are minimal. Other than survey exit-interview completion, the activities of therapists will be similar to those performed in the context of their employment (i.e., recommending interventions to clients and learning how to implement them). Therapists will not reveal any personal information about themselves other than demographic information, and will not be asked distressing questions, only their opinions about the new technology.

Risks to parent and youth participants include 1) possible distress when answering questions related to individual and family functioning; 2) conflict between the parent and adolescent regarding app usage (e.g., youth resents increased monitoring of his/her behavior by parent); 3) embarrassment if their answers to questionnaires were revealed to others; and 4) embarrassment or concerns about ramifications if app-generated data were to become known to outside sources.



Ways of mitigating these risks are outlined below in the next section, adequacy of protection against risk.

## **E8. ADEQUACY OF PROTECTION AGAINST RISKS**

**E8a. Recruitment and informed consent.** Recruitment procedures are described in section D4. Informed consent procedures are described in section D5.

### **E8b. 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.*

**Risks unique to parent and youth participants:** Because the therapist will encourage them to watch the recruitment video, parents and youth may feel pressure to participate in order to please the therapist. Similarly, an adolescent participant may feel pressured to participate by his/her parent. Several safeguards will be put in place to avoid potential coercion:

- 1) Before an enrolled therapist provides the recruitment video to a parent, a clinically-trained member of the research staff (i.e., Drs. Schaeffer, Dimeff, or Koerner) will meet with the therapist (in person or by phone) to discuss how s/he should use the recruitment tools provided in an ethical manner, and should never use coercive tactics. This meeting will also review ways for the therapist to help ensure that the parent does not attempt to coerce the adolescent into participation;
- 2) Therapists will use a standardized recruitment video and recruitment flyer (included with this application) when approaching parents. Parents can watch this video on their own time away from the therapist. Adolescents will be encouraged to watch the video as well. Having a video should reduce the potential for coercive conversations regarding participation.
- 3) The consent process will be completed by trained research staff who will emphasize the voluntary nature of participation to all participants. If at any point in study procedures a member of the research staff has reason to believe that an individual has been coerced to participate, the individual and his/her linked participants (i.e., the full therapist-parent-youth triad) will be administratively withdrawn from the study.
- 4) Therapists do not receive any incentive for referring a family or if a family on his/her caseload ultimately enrolls.

These and similar procedures have been successful in avoiding coercion in other studies conducted by Dr. Schaeffer (e.g., HR# 16773, Vocational Outcomes for Youth with Substance Abuse Problems and High HIV Risk, HR # 27375, *Developing Mobile Technology to Enhance MST Outcome*) in which therapists referred clients to the research project

Risk of embarrassment due to participation in the research procedures themselves will be minimized by conducting all data collection sessions individually; parents will not hear youth responses to questions and vice versa. The use of the REDCap online data collection system

provides an extra layer of privacy; the participant will read the questions and have them read to him/her by the research staff member, and can respond silently on the REDCap interface

If a parent or youth experiences distress while answering assessment questions, a clinically-trained member of the research staff (Drs. Schaeffer, Dimeff, and Kelly all are clinical psychologists) is available to speak to him/her. And, all parent and youth participants will be receiving mental health treatment throughout the course of the study. Participants will be informed of the limits of confidentiality during the informed consent procedure, and research staff will immediately report any distress involving potential harm to self or others to the individual's therapist.

Risk of embarrassment due to app usage will be minimized by instructing parents and youth to use the app in whatever way they choose in the course of their day-to-day lives, and only in ways that feel comfortable to them. The study does not require participants to use the app at any particular time, so participants can opt to not use the app during sensitive times (e.g., the parent may choose to not use the app while at work; the youth can choose to not use the app while with peers). Another source of risk is potential conflict between parents and adolescents over app usage and the increased monitoring of youth behavior it may provide. Such conflict is not expected to exceed the parent-adolescent conflict already occurring for this patient population, i.e., adolescents participating in mental health treatment for which improved parental management of youth behavior is a treatment goal. Therapists in this study are professionally trained to address such family conflict. Nevertheless, therapist training materials related to providing support for app usage will provide additional guidelines for addressing such conflict (e.g., under some circumstances, therapists may advise parents to not allow youth access to the phone for a period of time).

A final source of potential risk is if parent or youth app usage data were to become known to someone outside of the study (e.g., if the app server were "hacked" or a participant loses his/her phone in a public place), resulting in either embarrassment or legal difficulties for the participant. As noted in the Data Management section (D10), with regards to hacking, the server is extraordinarily secure, on par with any banking or other commercial site. Nevertheless, to minimize risks associated with a server breach, all app-generated data will be de-identified on the server.

To minimize the risk of a phone with the app installed being found or seen by someone else, several safeguards will be in place:

- 1) Parents and youth will be encouraged by research staff to password-protect their smartphones (i.e., the smartphone itself) while participating in the study, if they have not already done so.
- 2) Use of the app requires a login (email address and password), and the participant can manually log out to close the app at any time.
- 3) The therapist will never have direct access to the parent or youth's phone or to app data on the server, unless the parent or youth directly and voluntarily shows the therapist the phone during a treatment session. Although therapists will help parents set up the app, this will be done without the therapist actually physically manipulating the parent's phone. Therapists will be instructed such as part of their training.

4) No personal data about the youth's whereabouts or activities (e.g., GPS location data, whether or not the youth met a behavioral expectation on a given day) is stored on the phone itself; all such information is stored only on the server. If an outside individual wanted to obtain these data from the VillageWhere server, a subpoena would be required.

5) The personal data generated by the app does not exceed the data already being collected and stored by the smartphone itself on cellular provider servers (e.g., GPS location data) or locally on the phone (e.g., pictures taken with the phone). In other words, the VillageWhere app functions only to assemble some of the youth's naturally smartphone-generated information and make it user-friendly for parents to access and respond to, in the interest of providing increased monitoring and improved parental management of youth behavior. Thus, use of VillageWhere does not increase the risk of personal data becoming known to outside sources beyond the risks inherent in using any smartphone.

The sole exception to the above is data that the parent chooses to enter into the app that is not otherwise smartphone generated (e.g., in the GamePlan feature, the parent marks whether or not the youth refrained from fighting with his sister on a given day). Again, records of all data entered into the app (i.e., by the parent or youth) or generated by the app (i.e., app usage data) are stored only on the server, and not locally on the phone itself.

**Risks unique to therapist participants.** Because their employers (i.e., organizations collaborating with study PIs) have agreed to allow recruitment for the study in the workplace, therapists may feel obligated to participate. To mitigate this concern, several safeguards will be put in place:

- 1) Prior to recruitment, study PIs (Drs. Schaeffer and Dimeff) and provider organizational leadership (e.g., president or CEO) will jointly hold informational meetings with staff in which the leadership will ensure staff that participation is voluntary.
- 2) Research staff will emphasize the voluntary nature of participation during the consent process; if ever a staff person feels the therapist has been coerced to participate by his/her employer, the therapist will not be allowed to enroll and study PIs will be informed immediately. The PIs will cease recruitment activities at any organization that is suspected of or confirmed to be coercing therapists.
- 3) Recruitment will occur through phone/email contact between research staff and therapists, and research staff will not reveal to the provider organization whether or not the staff person agreed to participate. Therapist supervisors are likely to eventually learn of a therapist's involvement in the study, but only after the therapist has made his/her personal decision to be in the study.

**Risks for all participants.** Risks associated with providing personally identified information will be minimized through the use of participant ID numbers, locked file cabinets and the study FAX machine maintained in locked rooms, password-protected study computers, and password-protected storage of data on a secure MUSC homeroom drive. REDCap data transfer procedures also are secure. Materials containing participant names will be kept separate from participant ID numbers at all times. Participant names and ID numbers will be paired in a single

password-protected spreadsheet stored on a secure MUSC homeroom drive accessible only to research staff and only with staff login using NetID numbers and personal passwords.

### **E9. POTENTIAL BENEFITS OF PROPOSED RESEARCH TO 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.*

**Parent and adolescent participants.** Potential benefits of being in the study (using the app) for these participants are: 1) increased parental knowledge of youth whereabouts and activities, which may lead to feelings of decreased worry about the youth and enhanced self-efficacy as a parent, as well as less exposure for the youth to risky situations (e.g., skipping school, walking through a bad neighborhood); 2) increased youth sense that s/he is getting acknowledgment for good behavior; 3) improved parent-youth communication; 4) satisfaction in knowing that the participant has contributed to the general research knowledge base and to the development of a technology that may improve the lives of families receiving adolescent mental health treatment, and 5) participants may simply enjoy the research procedures.

The future benefits to adolescents receiving mental health treatment, their parents, and to the treatment providers working with them are potentially great. If the technology being tested in this study is shown to be effective in increasing parental monitoring of youth whereabouts and parental rewarding of positive behavior, the severity of adolescent behavior and mental health problems is likely to be reduced, and treatment times are likely to be shorter. These potential outcomes would result in a higher quality of life for adolescents receiving mental health treatment (e.g., less exposure to risky situations such as drug use or criminal activity; fewer arrests; lower likelihood of incarceration) and their parents (less concern for youth, easier to provide effective parenting).

**Therapist participants.** Potential benefits of study involvement include: 1) enjoyment of research procedures, 2) enjoyment of having a new potentially beneficial tool to offer to parents struggling to manage youth behavior; 3) knowledge that s/he is contributing to the development and refinement of a tools that may make their clinical work more efficient and effective in the future.

### **E10. 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.*

This program of research related to VillageWhere development is the first ever to develop a technological tool to support interventions with adolescents receiving family-oriented mental health treatment and their parents. The formative evaluation indicated that the product is appealing and acceptable to all stakeholders (youth, parents, treatment providers, treatment administrators, and juvenile justice officials). Adolescent mental health concerns that involve a parental behavior management deficit, ranging from youth depression to serious juvenile

offending, are a serious public health and safety threat. Increasing the effectiveness and reach of interventions for this population will greatly increase the public good.

#### **E11. 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.*

Because the study is not a clinical trial, a data safety and monitoring board will not be convened. The plans for monitoring participant safety and the confidentiality of data provided have been detailed elsewhere in this application.

##### **\*Clinical Trials**

*A clinical trial is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).*

*Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Behavioral human subjects research involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fits these criteria of a clinical trial. Human subjects research to develop or evaluate clinical laboratory tests (e.g. imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test will be used for medical decision-making for the subject or the test itself imposes more than minimal risk for subjects.*

## F. LITERATURE CITED

Literature cited in Section B (with superscripts) is omitted to reduce overall protocol length; these can be provided upon request.

### Literature cited, all other sections:

- Achenbach & Rescorla (2007). Manual for the ASEBA school-age forms and profiles (2<sup>nd</sup> edition). Burlington, VT: University of Vermont Research Center for Children, Youth, and Families.
- Campis, L.K., Lyman, R. D., & Prentice-Dunn, S. (1986). The Parental Locus of Control Scale : Development and validation. *Journal of Clinical Child Psychology, 15*, 260-267.
- Cohen, S., Karmack, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior, 24*, 386-396.
- Dimeff, L.A., Koerner, K., Woodcock, E.A., Beadnell, B., Brown, M.Z., Skutch, J.M., et al. (2009). Which training method works best? A randomized controlled trial comparing three methods of training clinicians in dialectical behavior therapy skills. *Behaviour Research and Therapy, 47*, 921-930.
- Loeber, R., Farrington, D. P., Stouthamer-Loeber, M., & Van Kammen, W. B. (1998). *Antisocial behaviour and mental health problems: Explanatory factors in childhood and adolescence*. Mahwah, NJ: Erlbaum.
- Substance Abuse Mental Health Services Administration (SAMHSA)(2006). Overview of the national outcome measures for the Center for Substance Abuse Prevention (CSAP) and Treatment Block Grant program. Available at [https://www.pmrts.samhsa.gov/csams/CSAPdocs/CSAP\\_NOMs\\_Overview\\_8\\_11\\_06.doc](https://www.pmrts.samhsa.gov/csams/CSAPdocs/CSAP_NOMs_Overview_8_11_06.doc).
- Steinberg, L., Elmen, J.D., & Mounts, N.S. (1989). Authoritative parenting, psychosocial maturity, and academic success among adolescents. *Child Development, 60*, 1424-1436.

**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.*

An accomplished public administrator and juvenile justice expert, Ms. Julie Revaz of the Judicial Branch within the State of Connecticut, is a consultant to this project to help ensure that any technology developed complies with state and federal laws pertaining to juveniles and to standards within juvenile justice administrative settings. Her letter of support is attached.

**H. FACILITIES AVAILABLE**

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

The study will be conducted within the Family Services Research Center (FSRC) in the Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina. Currently the FSRC includes 9 doctoral level faculty members. The FSRC has approximately \$6 million per year in federal research grants and training/consultation/policy contracts, all of which pertain to the development, validation, and transport of clinically effective and cost effective, family-based services for youth presenting serious clinical problems. The FSRC includes 5,000 square feet of space. The space is fully equipped with furniture.

The FSRC is linked by modem to MUSC’s DEC station 500/240 computer and by virtue of this to the internet system. All computers and network connections are maintained by the MUSC Center for Computing and Information Technology.

**I. INVESTIGATOR BROCHURE**

If applicable, attach the electronic version of the investigator brochure. Go to the application under “additional uploads” to attach this information. - n/a

**J. Appendices**

<ol style="list-style-type: none"> <li>1. Letters of Support from Collaborating Organizations             <ol style="list-style-type: none"> <li>a. Advanced Behavioral Health (ABH)</li> <li>b. Catholic Charities</li> <li>c. Children’s Village</li> <li>d. Maryland Innovations Institute</li> <li>e. Portland DBT Institute</li> <li>f. University of Washington Public Health and Justice Policy Center</li> </ol> </li> <li>2. Script for Therapist recruitment video</li> <li>3. Script for Family recruitment video</li> <li>4. Family recruitment flyer</li> <li>5. Parent screening questions</li> <li>6. Therapist consent form</li> <li>7. Parent/youth consent form</li> <li>8. Information Form for Youth Assent</li> <li>9. HIPAA, staff version</li> <li>10. HIPAA, parent-youth version</li> <li>11. VillageWhere Study Policy on Smartphone Use, Return, and Compensation</li> </ol>	<ol style="list-style-type: none"> <li>12. Parent self-report measures             <ol style="list-style-type: none"> <li>a. Family Demographics</li> <li>b. CBCL subscales Perceived Stress Scale</li> <li>c. Parent Locus of Control Scale</li> <li>d. Loeber Parenting Scale, Parent Version</li> <li>e. System Useability Scale</li> <li>f. Use of and Comfort with Technology Scale</li> </ol> </li> <li>13. Youth self-report measures             <ol style="list-style-type: none"> <li>a. YSR subscales and history of arrest</li> <li>b. CSAP alcohol and drug use questions</li> <li>c. Loeber Parenting Scale, Youth Version</li> <li>d. Parent Knowledge Scale</li> <li>e. System Usability Scale, Youth Version</li> <li>f. Use of and Comfort with Technology Scale</li> </ol> </li> <li>14. App Usage Data Elements</li> <li>15. App Use End of Day Ratings</li> <li>16. Exit interview questions</li> <li>17. Therapist self-report measures             <ol style="list-style-type: none"> <li>a. Demographics Questionnaire – Therapists</li> <li>b. Technology Use and Comfort Survey</li> <li>c. Therapist Post-Assessment Survey</li> </ol> </li> <li>18. Letter of support from JJ consultant</li> </ol>	
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