Study Protocol – Cover Page

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i. Significance
There is a critical need to enhance teacher knowledge and skills to support the learning of students with, or at risk of developing, anxiety-related disabilities. Excessive anxiety is part of the definition of "emotion disturbance" under the Individuals with Disabilities Education Improvement Act of 2004 (IDEA). Excessive anxiety is the most common form of pediatric psychopathology and severely impairs academic functioning (Costello et al., 2003). Students with excessive anxiety present challenges to teachers because they require specialized skills to manage social, emotional, behavioral, and educational issues. Unfortunately, teacher training to address this need is lacking (Sindelar, Brownell, & Billingsley, 2010). Indeed, teachers themselves report a need for more training and support in this area (Cassady, 2011; Oliver & Reschly, 2007; Oliver, Wehby, & Reschly, 2011). The consequences of this gap in teacher knowledge and skills are grave for both teachers and students. Teachers with minimal training in identifying and managing students' anxiety are less likely to be effective in 1) providing instruction and supporting the student's ability to learn; 2) minimizing disruptions to teaching and other students' learning and 3) maintaining a positive teacher – student relationship as teachers may struggle with how to engage and motivate these students (Pianta, Steinberg, & Rollins, 1995). Conversely, when teachers are equipped with appropriate knowledge and skills, they have a significant and positive effect on students' social-emotional, behavioral, and educational functioning both concurrently and prospectively (Hamre & Pianta, 2010, 2001; Mashburn et al., 2008; Murray & Greenberg, 2001; Rowan, Correnti, & Miller, 2002). Moreover, when teachers experience mastery over students' social and emotional challenges such as excessive anxiety, teaching becomes more enjoyable, teachers feel more efficacious, and there are improvements in teacher-student relationship quality (Goddard, Hoy, & Hoy, 2004; Zee & Koomen, 2016). This proposal addresses the deficits in teachers' specialized skills by developing a teacher training and intervention (hereafter referred to as training) for identifying and managing excessive student anxiety. The proposal builds on the PIs' experience over the past two decades (supported by the National Institute of Mental Health and the Institute of Education Science) in developing feasible and effective trainings and interventions for school personnel (i.e., school clinicians and nurses). The content of the training draws from evidenced-based strategies and uses professional development models found to optimize and sustain teacher competencies in the use of new skills (Guskey, 2002; Han & Weiss, 2005). A team of national experts and local teachers will assist in the development process to ensure its feasibility and usability.

Excessive anxiety/fear is common in children and is associated with impairments in academic functioning. Pediatric anxiety disorders are common, with prevalence rates ranging from 10-20% (Costello, Egger, & Angold, 2005). Excessive *symptoms* of anxiety that are impairing but do not meet diagnostic thresholds are also common and occur in approximately 42% of children (Costello & Shugart, 1992; Rapee et al., 2012). Many of these youth qualify for services and/or accommodations under the emotional disturbance category of the IDEA or Section 504 of the Rehabilitation Act. Indeed, estimates indicate that 11-15% of youth receiving special education services under the category of emotional disturbance meet criteria for an anxiety disorder (Déry et al., 2004; Schoenfeld & Janney, 2008).

In addition to the high prevalence rates, it is well established that excessive anxiety has a broad range of negative effects on academic functioning including poor academic performance (Hughes, Lourea-Waddell, & Kendall, 2008; Mazzone et al., 2007), increased grade retention

(Stein & Kean, 2000), excessive absenteeism and school refusal (Hansen et al., 1998), and school dropout (Breslau et al., 2008; Duchesne et al., 2008; Van Ameringen, Mancini, & Farvolden, 2003). Anxious, compared to non-anxious youth, have a more negative attitude toward their teachers and school (Witteborg, Lowe, & Lee, 2009) and are viewed as academically impaired (i.e., not working as hard, not learning as well, less competent, and not performing as well in the classroom) by their teachers (Mychailyszyn, Mendez, & Kendall, 2010). Importantly, excessive anxiety is associated with academic deficits concurrently (Davis, Ollendick, & Nebel-Schwalm, 2008) and *prospectively* (Ialongo et al., 1995; Kessler et al., 1995; Woodward & Fergusson, 2001). For instance, Ialongo et al. (1995) found that high levels of anxiety symptoms in the first grade predicted poorer scores on standardized achievement tests in the fifth grade. Similarly, Duchesne and colleagues reported that high anxiety symptoms in kindergarten predicted parent-reported difficulty with overall academic performance in 9th grade (Duchesne et al., 2005). Social phobia in particular is associated with a two-fold increase in the rates of grade retention and school dropout, regardless of age, gender, socioeconomic status, or presence of comorbid depression (Stein & Kean, 2000). In light of the academic deficits associated with excessive anxiety, many of these children need and are referred for specialized educational accommodations (Schoenfeld & Janney, 2008). However, more youth are in need of support services than receive them (Kataoka, Zhang, & Wells, 2002) and access to evidenced-based services is poor. Enhancing teachers' capacity to support these students can reduce this service gap.

The benefits of training teachers to reduce student anxiety is also informed by emerging evidence that suggests reducing anxiety improves school performance (Weems et al., 2009; Wood, 2006) and may thus reduce the need for referral to special education. While no studies have examined the impact of teacher-led trainings or interventions for anxiety on educational outcomes, data from randomized controlled studies of community-based child anxiety treatments (where treatments are delivered by community or school clinicians) have shown that decreases in anxiety are associated with increases in Grade Point Average (GPA) and normalizing of GPAs of test-anxious youth to be equal to their non-test-anxious peers (Weems et al., 2009). Impressively, improvements in academic performance following community-based anxiety treatment were maintained at a one-year follow-up (Suveg et al., 2009). In one of the largest outpatient anxiety treatment studies ($N = 488$), Nail and colleagues (2015) examined changes from pre to post anxiety treatment on seven specific academic impairments including completing assignments, concentrating on work, doing homework, getting good grades, giving oral reports/reading in class, taking tests/exams and writing in class. Findings revealed that youth showing clinically meaningful improvements in anxiety (i.e., treatment responders) compared to non-responders, had significant reductions in all seven academic areas (based on parent report). Taken together, findings from these studies suggest that reducing anxiety symptoms is associated with improvements in educational outcomes which in turn lower the risk of referrals for special education services. Consequently, training teachers in anxiety reduction skills could have significant benefits for their students, classrooms, and schools. For these reasons, educational stakeholders, including parents, students, teachers, and policy-makers, would benefit from investing resources in training teachers to reduce childhood anxiety – a well-documented but often neglected contributor to academic failure, personal suffering, and economic burden. **The school context is a trigger of student anxiety and teachers are ideally poised to help if trained properly.** Teachers are often faced with anxious students who require additional

attention or assistance. Data show that at younger ages, teachers spend greater time managing the daily interactions of shy, inhibited or anxious youth compared to their non-anxious peers (Coplan & Prakash, 2003; Rudasill & Rimm-Kaufman, 2009) and anxious children are overly dependent on their teachers (Ladd & Burgess, 1999). As children age, anxious children become invisible and tend to withdraw from classroom activities (e.g., due to fears of negative social evaluation) and are more likely to miss classroom activities and instruction due to anxiety-related symptoms (Ollendick & March, 2004). The school context –and especially the classroom--is a primary setting in which anxiety-related problems occur (Langley et al., 2004). For instance, children with separation anxiety, which is characterized by excessive distress upon separating from parent(s), can experience intense symptoms of anxiety during morning drop-off time. Elementary school teachers often assist these children, peeling them away from their parents, helping them calm down, and ensuring that they stay in their classroom and engage in classroom activities. These children might request to call and check-in with their parent several times during the day, interrupting the teacher and interfering with others' learning. These children also complain of feeling ill and frequently leave the classroom to see the school nurse. For children with generalized anxiety, which is characterized by excessive and persistent worry, academic demands often trigger worries about performance and perfectionism and they are often preoccupied with fears of making mistakes, failing, and disappointing their teachers- all of which negatively impairs their academic performance and classroom behavior. These children often continuously seek reassurance from their teacher, disrupting the classroom-learning environment. Finally, social anxiety, which is characterized by excessive fears of embarrassing oneself, being criticized, or not being liked or accepted by peers, can be debilitating in the classroom. These children often avoid answering or asking questions in class, approaching teachers for help, initiating play during recess, talking to peers during lunch, or trying out for extracurricular activities. These behaviors, while noticed by teachers, are often neglected or misidentified. These and other symptoms of anxiety manifest in the classroom daily. One consequence of teachers' limited training and knowledge in how to manage these symptoms is that many of these children fall behind socially and academically.

Current teacher training for identifying and reducing excessive anxiety among students is rare and extant models are linked to one universal curriculum that is not feasible to deliver, has minimal efficacy data, and does not integrate skills across classroom and home contexts. Although teachers' primary role is to educate, the role (and need) of teachers has broadened to include understanding and even intervening to reduce mental health symptoms, including anxiety. Unfortunately, the vast majority of teachers never receive any evidenced-based training for identifying or assisting students with excessive anxiety (Reinke et al., 2011). Meta-analyses indicate that with adequate training and coaching teachers can effectively deliver "universal" classroom-based social-emotional curricula with numerous positive effects on student outcomes (Durlak et al., 2011). Only *one* teacher-led anxiety intervention has been evaluated (research groups in Australia, Canada, and United Kingdom) and evidence for its effectiveness is mixed. FRIENDS, developed by Barrett and colleagues is a universal classroom-wide intervention delivered as part of the school curricula and consists of 9-12 one hour weekly sessions (Anticich et al., 2013; Barrett, Lock, & Farrell, 2005; Barrett & Turner, 2001). The content of FRIENDS covers core cognitive behavioral therapy (CBT) components of anxiety reduction, (i.e., behavioral exposure, relaxation, and cognitive restructuring). Training consists of a 1-2 day workshops and a step-by-step guide for implementing FRIENDS. In one of several

studies by the developers, relevant findings revealed that after the teacher-led intervention children had fewer symptoms of anxiety compared to those who received no intervention. In contrast, large RCTs by Miller et al., (2011a; b) and Stallard et al., (2014) found that FRIENDS was not superior to either an attention control condition (story telling such as reading Harry Potter) or to wait-list control groups. A recent qualitative study (Skryabina et al., 2016) reported that teachers were concerned about the feasibility and sustained use of FRIENDS given its high dosage and burden. Reasons for the variations in student outcomes among these studies are unclear but may include the dose and quality of teacher training and fidelity, the complexity of the intervention, and the absence of generalizing skills across home and school settings. In addition, universal interventions for anxiety may not be an efficient use of classroom or teachers' time, as not all youth need these types of interventions. Additional study limitations include the absence of independent (blind) evaluators to assess outcomes, an absence of examining educational outcomes, lack of measurement of changes in teacher behavior, and limited teacher performance feedback and coaching to increase fidelity and quality of implementation. In sum, teacher training in anxiety management is rare. Although data indicate that teachers are capable of implementing classroom-based interventions with fidelity (Durlak et al., 2011), studies on universal models for anxiety are flawed and indicate that a novel teacher training is needed for students with elevated anxiety. The current proposal addresses these shortcomings (see Logic Model Figure 2 in Appendix).

Summary, Benefit to Stakeholders, and Aims: Teachers lack the knowledge and skills to support the learning of students with excessive anxiety who have, or at risk of developing, an IDEA disability. Excessive student anxiety is a common problem that severely impairs short and long term academic functioning and increases teacher burden. Conversely, reducing student anxiety has been associated with improvement in educational functioning. Because anxiety manifests daily in the classroom, teachers are in an ideal position to identify and help students manage their anxiety. One universal intervention for anxiety reduction exists, but its feasibility and efficacy are not established. The aims of this application are to address this gap in teacher training. Specifically, the aims of this proposal include: Aim 1) to develop the *Teacher Anxiety Program for Elementary Students* (TAPES) and assess its usability, acceptability and feasibility; Aim 2) to determine whether teachers can implement TAPES with high fidelity and quality; Aim 3) to examine the impact of TAPES, compared to a standard professional development condition, on teacher a) knowledge and b) use of anxiety reduction strategies with students with excessive anxiety (Primary Outcomes); and Aim 4) to examine the impact of TAPES on student outcomes. Exploratory aims will examine the mediators (proposed in the theory of change, see Figure 1 in Appendix) and predictors and moderators of TAPES impact on teachers knowledge and skill. If effective, TAPES has the potential to directly benefit: 1) teachers--by providing training in an important and relevant, but neglected area that will enhance their professional development and effectiveness in the classroom; and 2) children--by reducing their anxiety and improving their educational, social, and behavioral functioning. This development process will be led by a research team with over two decades of experience developing and evaluating feasible and effective trainings and interventions for school personnel (Ginsburg et al., 2012, 2016). It will also be supported by a Development Team (DT) comprised of national teacher training experts, teachers, and CT State Board of Education representatives.

Preliminary study: Survey of current teacher practices for anxious youth. In preparation for the current application, we undertook a survey with 13 CT elementary teachers and school

personnel to assess the significance and feasibility of the proposed training. Specifically, participants were asked to complete a 26 item survey that assessed: 1) the prevalence and negative impact of anxiety in the classroom, 2) teacher preparedness for managing anxiety, and 3) the feasibility of a school-home intervention (including associated trainings, coaching, fidelity monitoring, etc.). Results of the survey were as follows: With respect to perceived prevalence and impact of anxiety within the classroom, teachers reported that an average of 38.5% of children in their class had excessive anxiety (range 10 - 50%). Sixty-two percent of the respondents indicated that anxiety "often" negatively impacts the classroom and 77% indicated that reducing anxiety was a *very important* priority. Regarding teacher preparedness for managing anxiety, 54% felt confident in identifying the signs of anxiety in their classroom (46% did not!). *None (0%) of the teachers/staff received reported receiving specific training in anxiety reduction techniques. All respondents (100%) endorsed an interest in learning anxiety reduction skills.* With respect to the feasibility of the proposed TAPES training and meeting format, 90.9% of teachers reported they could hold conjoint meetings monthly or more often. In terms of length of conjoint meetings, 39% said they could meet with parents for approximately 45 minutes and 31% said 30 minutes. Teachers reported that they would be willing to dedicate a full day (53.8%), a half day (30.8%) or three hours (15.4%) to learning anxiety reduction techniques. All teachers (100%) thought that parents would be motivated to work with teachers to reduce their children's anxious behavior and improve their classroom behavior.

Description of TAPES: The proposed teacher training is appropriate for elementary teachers to enhance their capacity to support students with excessive anxiety. The training includes one full day of instruction, materials to use with individual students and their parents (in 5 conjoint meetings), and guidelines for classroom-wide strategies to reduce anxiety. The section below describes 1) the content of the teacher training and supportive empirical evidence, 2) how this training differs from current teacher practices for anxious students, 3) a proposed theory of teacher and child behavior change and 4) evidence supporting the feasibility of implementing TAPES in an authentic school environment. Because this is a *Development and Innovation* proposal, the descriptions below represent our "vision" of the components which may change during the course of the development process. Our initial proposal is based on extant teacher training literature, empirically supported anxiety reduction strategies, the expertise of the DT, and our own experience in developing and testing trainings in anxiety reduction for school personnel. This teacher training is not intended to replace or change the role of existing mental health providers or other members of schools' interdisciplinary teams. Given that teachers are members of an interdisciplinary team, we will obtain input from school personnel to ensure that the teacher-training fits within the goals/mission of the interdisciplinary team. The end product will be a fully developed training and materials to be used in a larger efficacy trial.

<u>Description of TAPES content</u>: *Overview*: The primary goal of TAPES *is to enhance teachers' capacity to identify and reduce anxiety in their students.* Toward this end, the proposed content of TAPES consists of three core components: 1) training in evidenced-based anxiety reduction strategies that teachers will implement to identify and assist specific anxious students and classroom-wide strategies helpful to all students, 2) evidenced-based material for teachers to review with parents regarding how to reduce student anxiety at home, thus improving school-home communication and shared goals and 3) training in how to conduct conjoint teacher-parent-student meetings to improve the quality of the teacher-parent-student relationship. Each component is described below.

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Training and Evidence Related to Child Anxiety Reduction Skills: Teachers will learn skills based on cognitive behavioral strategies (CBT) including relaxation training (to reduce physiological arousal), behavioral strategies (e.g., "exposure" or facing anxiety provoking situations which lowers anxiety via new learning), addressing maladaptive thoughts that maintain anxiety, and problem solving skills. To implement these new skills with specific children teachers will be trained to use a school-home journal that includes a type of daily report card that tracks behavioral exposures (Show That I Can or STIC tasks) and use a reward system for increasing brave behavior /adaptive coping skills.). These "common elements" of CBT are powerful agents of change and have been implemented by CBT experts and non-experts (Cartwright-Hatton et al., 2004; Ginsburg et al., 2011; James et al., 2013). As such, these skills are established and empirically-supported; however, they have not been evaluated when delivered by teachers. Teachers will also receive training in effective classroom-based accommodations that may be needed (e.g. untimed testing) or may need to be gradually faded if they are maintaining anxiety through negative reinforcement (e.g. allowing child to avoid participating in class due to anxiety). Another component of the teacher training includes skills that teachers deliver to their classroom (i.e., such as leading the entire class in a relaxation exercise prior to an exam; teacher using a coping model or teacher reducing their accommodation of avoidant/anxious behavior for all students). Finally, teachers will be trained in how to modify their own behaviors that have been shown to increase student anxiety (e.g., hostility, over-control). These modifications are also designed to improve the quality of the teacher-student relationship. Research on the role of teacher behavior in the development and/or maintenance of child anxiety suggests that teachers who exhibit highly controlling behaviors, such as issuing frequent directives, tend to increase child anxiety and negatively affect children's ability to learn (Assor et al., 2005). Teacher-student conflict has also been associated with anxiety symptoms, such as withdrawal (Zhang, Chen & Zhang, 2008). Conversely, positive teacher-child relationships have been found to protect youth from developing internalizing behavior problems over time (O'Connor, Dearing, & Collins, 2011). Consequently, TAPES aims to modify these teacher behaviors.

Training and Evidence Related to Parent Component. Teachers will be trained in how to communicate the core CBT anxiety reduction skills to parents in order to enlist parents' support and establish shared goals for reducing child anxiety. Specifically, teachers will be trained to use a parent guide (developed by the study team) that addresses: 1) the detection of symptoms of anxiety; 2) the use of relaxation skills; 3) training in coping self-talk and cognitive restructuring; 4) using gradual exposure, 5) problem solving; and 6) training the parent in positive reinforcement of "brave" (i.e., non-anxious or avoidant) behavior and reduction in anxiety-enhancing parenting behaviors. Educating parents about anxiety reduction will enhance teacher-parent communication by using shared concepts and collaboration. Data from family-based treatment studies for child anxiety have shown that interventions that involve parents are associated with lower anxiety and improved parenting practices (Ginsburg & Schlossberg, 2002; Manassis et al., 2014; Suveg et al., 2006). For these reasons, parent education and involvement is included as part of TAPES.

Training and Evidence Related to Conjoint Parent-Teacher-Student Meetings. Training teachers in conducting conjoint meetings will enhance teachers' ability to formalize mechanisms for sharing information about anxiety reduction and will enhance communication and relationship quality between parent, teacher, and student. Training in these conjoint meeting will also allow

the teacher to clarify roles and responsibilities with respect to helping the child, and devise a collaborative plan with similar language and tools to facilitate generalization of skills between school and home. Implementation of this component will involve approximately 5 conjoint-30 minute meetings over an 8 week period. During these meetings, parents, students, and teachers will create and modify anxiety hierarchies, mutually decide on STIC tasks, and develop a contingency management plan. Target behaviors are individualized based on the needs of the child (e.g., raising a hand to answer a question in class for a child with social anxiety; separating from parents for a child with separation anxiety). The 30-minute meeting length is based on previous school-home intervention models (Sheridan et al., 2001) and our pilot survey with teachers; its feasibility will be evaluated in the current proposal. These meetings can be supplemented by phone and email contacts between teacher and parents/students as needed.

The importance of close interaction between school and home settings has been emphasized for decades and psychosocial interventions that incorporate both parent and school components have been successful in improving academic and behavioral outcomes, though the targets have primarily been externalizing behaviors (Sheridan, Clarke, & Burt, 2008). Moreover, data from school-home intervention studies reveal that improvements in teacher-reported relationships with parents mediate intervention effects on positive changes in child outcomes, highlighting the critical role of training teachers in how to develop this collaborative relationship.

TAPES Training Format and Implementation: Students' primary teacher will participate in a one-day training (approximately 8 hours). One of the most important strategies for ensuring that TAPES is implemented with high fidelity is appropriate training and ongoing consultation. Training strategies will be based on published guidelines (Beidas & Kendall, 2010) and will include active/experiential learning strategies, opportunities for observation (via video clips), live modeling and role plays, and coached practice. Ongoing performance feedback and consultation has been found to enhance learning (Fixsen et al., 2005; Sholomskas et al., 2005) and is related to higher fidelity (Sholomskas et al., 2005). Thus, teachers will be offered 30-minutes of weekly consultation by Drs. Pella and Ginsburg for each active TAPES students. Consultation will include case review, skill rehearsal, problem-solving obstacles, and feedback regarding performance based on audiotaped sessions. Meetings will be held in person, over the phone, or via Skype at times convenient for teachers. After each teacher identifies their first child, the PIs will attend one conjoint meeting in order to provide performance feedback (all conjoint meetings are audiotaped for fidelity). The PIs will also provide in classroom coaching for 30-minutes for each student enrolled. Training materials will be available on the internet or thumb drive for reference.

TAPES differs from extant teacher trainings and other school-based interventions for child anxiety in several ways. As noted above, aside from the FRIENDS teacher training, there is an absence of teacher training for assisting students with excessive anxiety. Relative to standard professional development options for teachers, this training utilizes evidenced-based strategies to enhance learning (see Han & Weiss, 2005). With respect to extant CBT interventions for anxious youth, most are implemented in outpatient settings and have minimal to no contact with teachers. Even when CBT does occur in the context of school-based mental health services (which is rare), these services operate similarly to outpatient models in that they do not integrate teachers or parents in treatment but rather treat the child individually. Thus, TAPES differs from current teacher trainings in: 1) content, 2) format, and 3) key change processes. With respect to content, TAPES trains teachers in CBT for anxiety and incorporates conjoint parent-teacher-student

meetings to enhance relationship quality that is not part of existing professional development options. In terms of format, TAPES utilizes active learning methods and ongoing performance feedback which is not part of teacher trainings but found to improve fidelity and sustained use of new skills. With respect to key change processes, in contrast to existing teacher trainings or interventions for child anxiety, TAPES modifies teacher, child, and parent behavior simultaneously, programs the generalization and practice of anxiety reduction skills across key environments (school and home) and is expected to foster positive parent-teacher-student relationships. For all these reasons, TAPES holds the promise of positively changing teachers' behaviors, children's social-emotional educational outcomes, and the classroom environment.

Theory of teacher behavior change. The proposed theory of change for TAPES and logic model (see Figures 1 & 2) were guided by extant research and models proposed by Han & Weiss (2005) and Guskey (2002) who detail the mechanisms of teacher behavior change in adopting mental health interventions. Because this is a development grant, the components focus on pre-implementation and implementation factors that have been associated with teacher behavior change. Among the pre-implementation components (i.e., prior to training), *systemic factors* including state, county, district, and school priorities and policies must be compatible with and supportive of the new skills in order for teachers to initially adopt them (Coburn, 2003). In CT, as a reaction to the Newtown-Sandy Hook tragedy, the state has prioritized increasing the footprint of evidenced-based school mental health services (CT Law Public Act No. 13-178, 2013). The school districts that we have collaborated with have also indicated that anxiety is a high priority to address among students (see letters of support). Representatives from state and school levels are members of the DT to ensure our training is compatible with extant missions and objectives. District and principal support will be required prior to recruiting teachers. In addition to these systemic issues, several pre-training *teacher factors* influence teacher adoption, implementation, and sustained use of new skills (Tschannen-Moran & Hoy, 2001). These include higher teaching self-efficacy (i.e., teachers' beliefs that they are capable of implementing the new skills; Stein & Wang, 1988) and teacher burnout, a factor which negatively affects teachers' attitudes toward and interactions with students, and increases indifference and hostility (Maslach, Jackson, & Leiter, 1996). Both will be measured and addressed in TAPES. Finally, teachers' perceptions of the feasibility and acceptability of the new skills (Reimers, Wacker, & Koeppl, 1987) impacts behavior change. Specifically, teachers' understanding of and beliefs that the new skills will solve an important student problem, are efficacious, and are compatible with their teaching style and beliefs about children's behavior (Kealey et al., 2000) all increase behavior change. Each of these will be addressed in the TAPES development process via close collaboration between the developers and teachers (Griffin & Barnes, 1984; Ward & Tikunoff, 1982).

Several implementation factors, including training, ongoing performance feedback and initial implementation with students are hypothesized to lead to teacher behavior change (McCormick, Steckler, & McLeroy, 1995). Specifically, early in the learning process trainers must inform teachers about why they are learning the new skills and how these skills will positively impact students, (Bredeson, Fruth, & Kasten, 1983; Englert & Tarrant, 1995; Guskey, 1989; Huberman, 1992). In addition, the new skills must be flexible, low in complexity, and familiar to teachers (e.g., positive reinforcement). Learning the new skills must not be time intensive. *Training factors* are also influential to teacher behavior change. Training must include active learning approaches such as modeling, rehearsal/role plays, and be applied in an authentic

classroom setting with students. Training must include access to materials to support implementation (e.g., manuals, handouts). Finally, it is essential that training includes ongoing performance feedback both in the classroom and outside of classroom. At the core of this change model is the s*tudent improvement feedback loop.* Specifically, TAPES incorporates feedback to teachers regarding the impact of their new skill on student behavior. Data show that the most powerful change agent is direct successful experience implementing new skills. Thus, necessary to this process is that each teacher experience success in improving student behavior *and* correctly attribute improvements in student's behaviors to their use of new skills. This feedback loop from students enhances teachers' beliefs about the program skills, their own efficacy, and their motivation to continue using the new skills (Datnow & Castellano, 2000; Guskey, 2002).

The theory of change related to student outcomes. Etiological models of anxiety propose that these disorders involve excessive physiological arousal, cognitive distortions, and behavioral components such as avoidance of feared stimuli and problem-focused coping (Barlow, 1988) which are modifiable. Thus, the underlying theory of TAPES' CBT strategies for children is that teacher-facilitated change in hyperarousal, maladaptive cognitions, and avoidant behavior in the classroom will result in the reduction of anxiety and improvement in academic outcomes. The mechanisms by which anxiety exerts a negative impact on academic performance are poorly understood and have rarely been studied. Some propose that higher levels of anxiety increase physiological arousal and shift the focus of attention away from classroom instruction and toward threat cues in the environment, thus impairing concentration and working memory, and ultimately undermining children's ability to recall previously learned material (Ma, 1999; Owens et al., 2008). Indeed, findings from one study suggest that anxiety negatively impacts learning by interfering with working memory (Owens et al., 2008). Thus, interventions designed to reduce anxiety may improve academic achievement by reducing arousal and improving attention, concentration, and recall (Wood, 2006). To explore this hypothesis, we will administer measures of working memory at all evaluations. Data supporting the theoretical model of the CBT components used in TAPES comes from a large treatment literature of childhood anxiety disorders (see Silverman et al., 2008 for a review). It is hypothesized that through modifying teacher behavior, enhancing the generalization skills across school and home (through the conjoint meetings), and fostering improved communication between teachers and parents as they work on shared goals will result in positive child outcomes (Evans, Langberg, & Williams, 2003).

<u>**Feasibility of TAPES Implementation in Schools**</u>. In light of the similarities between TAPES and school-home collaborative models (i.e., conjoint meetings) we used data from these studies as a measure of feasibility of TAPES. Sheridan and colleagues (2012) demonstrated the efficacy of conjoint behavioral consultation (CBC), a structured intervention in which parents, teachers, and other support staff meet conjointly and use a structured collaborative problem-solving method to address academic, social or behavioral difficulties evidenced in the classroom (Sheridan & Kratochwill, 2007). In their large RCT, students ($N = 272$, in 82 general education classrooms) were randomized to CBC in which 4-5 conjoint meetings (each lasting between 45-60 minutes) occurred over an 8 week period or usual care (UC; existing school services). Relative to UC, children in CBC showed greater increases in adaptive behaviors and social skills based on both parent and teacher reports. Teachers in CBC, compared to UC, reported greater positive changes in their relationships with parents. Results from this RCT supported earlier uncontrolled trials (Sheridan et al., 2006; 2001) which included children in grades K-9 who had academic and

behavioral difficulties. Effect sizes were robust across all studies and ranged from .4-1.00. Moreover, parent and teacher ratings of satisfaction and acceptability were high (Sheridan et al., 2001). Surveys of school psychologists, parents, and teachers also indicated a preference for a collaborative model over a teacher-only or parent-only intervention model (Freer & Watson, 1999; Sheridan & Steck, 1995). Pfiffner and colleagues (2007) developed the Child Life and Attention Skills program (CLAS) for youth with ADHD. Relevant here, CLAS included 4-5 parent-teacher-student conjoint meetings (each 30 minutes long) in addition to other components. In their RCT, measures of treatment acceptability by parents, students, and teachers were positive. Attendance in CLAS was high-- teachers completed an average of 4.7 conjoint meetings. In sum, these studies support the feasibility and acceptability (i.e., high attendance, high ratings of intervention satisfaction) of implementing a teacher–parent-student collaborative approach.

Sustainability of TAPES Training in Schools. Although the primary aim of this proposal is to *develop* an effective teacher training, should the training have a positive impact on teachers and students, a mechanism for sustained use will be needed. Toward this end, we propose to explore state, district, and school level options for staff to assume the role of trainers and consultants for TAPES. For instance, at the state level, the State Education Resource Center (SERC) is a quasi-public agency funded by the CT State Department of Education that provides a broad range of services including professional development and job-embedded technical assistance to CT educators. This agency, whose mission is to provide resources and training to CT schools, has the experience and expertise (e.g., they provide support for Positive Behavior Interventions and Supports; PBIS) to support the sustained use and dissemination of TAPES. At the District level, we will hold meetings with the Director of Pupil Services (or equivalent depending on district) to obtain feedback regarding District level options for TAPES trainers. At the school level we will meet with school clinicians, special education teachers, their respective supervisors and principals, to explore the feasibility of training school personnel to assume the role of TAPES trainers. In year 1, we will meet at least once with representatives from each of these stakeholder groups to explore options and identify perceived barriers and solutions for TAPES sustained use. In year 3, as data are available on the impact of TAPES, we will again meet with these stakeholders to further identify options for institutionalizing the use TAPES. Finally, we will also devote one full meeting with the DT to address this issue during Stage 1.

(ii) Research Plan

Overview: Design and Methods. This three-year development project consists of 3 stages. **Stage one** (months 1-6) involves establishing a Development Team (DT) that will review the initial draft of TAPES and provide feedback to ensure that TAPES is acceptable to teachers and feasible for the school setting. **Stage two** (months 7-20) involves two <u>successive</u> open trials of the TAPES protocol with 15 teachers and 20 children. This stage will allow for "trial runs" of the training to assess feasibility, acceptability and utility of the training. Data and qualitative feedback gleaned during the first open trial will inform modifications for the second open trial. We will present and discuss data with the DT after each open trial. We will also ask 5 teachers from open trial 1 to test out the revisions for open trial 2. Based on knowledge gained in this stage, appropriate modifications will be made for stage three. **Stage three** (months 21-34) involves a pilot RCT using a randomized controlled design comparing TAPES to the Teacher Anxiety Training (TAT). TAT (developed by the PIs for use in other studies and described below) will be used to represent "typical" teacher professional development training. The RCT will be conducted in three phases. <u>Phase 1</u> consists of recruiting, randomizing, and training

teachers in either TAPES or TAT. Also during this phase (but after the training), teachers will recruit anxious children and study staff will screen and evaluate them to determine eligibility. In Phase 2 teachers will implement TAPES or TAT. Phase 3 involves a post-intervention (after 8 weeks) and a three-month follow-up assessment of the primary (teacher behavior) and secondary (child) outcomes. Trained independent evaluators (IEs) will assess primary outcomes (teacher behavior). The culmination of these iterative stages will be a final version of the training that will be ready for evaluation in a larger efficacy trial.

DETAILED DESCRIPTION OF EACH STAGE

Stage 1: Establish DT and refine initial version of the TAPES Protocol. The DT will strive to ensure that the teacher training will be acceptable, feasible, and usable in the school setting. DT Composition: The DT will consist of the PIs (Drs. Golda Ginsburg & Jeffrey Pella), two national experts in teacher training (Drs. George Sugai & Keith Herman), two experts in school-home collaborative interventions (Drs. Linda Pfiffner & Susan Sheridan), and two experts in training school-based personnel in CBT techniques for anxious youth (Drs. Drake and Pina). A representative from the CT Department of Education (Jocelyn Mackey), a CT school psychologist (Katie Gritter), and two CT elementary teachers (TBN) will complete the DT. See Appendix for letters of support. DT Procedures and Analysis: DT members will be provided with all materials at least one month prior to the first meeting so they can review the initial protocol. Next, DT members will participate in a half day meeting during which the PIs will present an overview of all study components (e.g., rationale, training strategies, methods for teacher observations). The meeting will take place using an interactive web conferencing site that enables real-time Q&A. DT members will provide detailed feedback about the TAPES strategies, study methods/measures, perceived barriers to successful implementation and adoption by teachers, and solutions to potential barriers. Information from this meeting will be used to revise the protocol in preparation for the first open trial. Within four weeks, a revised version of the protocol will be distributed to the DT for another round of revisions during a second meeting. A similar procedure will be used for each successive revision of the protocol. **Stage 2: Open Trials.** During Stage 2, teachers and IEs will be trained and will conduct two sequential open trials. Study staff will engage in screening activities of students and IEs will complete baseline evaluations on referred students. The purpose of the open trials is to evaluate the feasibility of the training, modify methods as needed, allow teachers to implement the skills learned in the training and receive real time coaching and consultation with anxious children. Data on TAPES usability, acceptability, fidelity, satisfaction, and teacher and child outcomes will also be collected (see Measures below). After each open trial, feedback (via exit interviews and standardized measures) from teachers, students, and parents will be integrated by the research team and presented to the DT for another revision of the protocol. Teachers will be asked to participate in an exit interview after they implement TAPES with an anxious child.

Stage 3: Pilot RCT. In stage 3, we will conduct a pilot RCT with 40 teachers and a maximum of 60 anxious youth. The RCT will be conducted in 3 phases.

Phase 1 - Recruitment, Randomization, Training, Student Screening, and Baseline Evaluations: In Phase 1, teachers will be randomly selected from the pool of interested participants and randomized to TAPES or TAT. Once randomized, teachers will complete their assigned training. Teachers will then identify potentially eligible students from their classes and provide information about the study to their parents. Interested parents will contact study staff and complete a brief phone screen. Students who appear eligible based on the phone screen (e.g.,

have elevated anxiety; are in elementary school) will be invited to complete informed consent and a full baseline evaluation with an IE (see Table 1 for measures). Families who "pass" the baseline evaluation (i.e., student obtains a *t* score of 60 on Spence Children's Anxiety Scale (SCAS) and/or a CSR of at least 3 on the ADIS-V) will be considered eligible (see Inclusion/Exclusion criteria below).

Phase 2 – TAPES/TAT Implementation: Teachers will implement TAPES or TAT depending on their random assignment over 8 weeks from child enrollment.

Phase 3 - Post- and Follow-up Evaluations: At the end of the 8 weeks, teachers and children in both groups will complete a post evaluation (see Table of Measures). Teachers, students, and parents will complete a TAPES satisfaction measure and provide feedback to enhance the protocol. Teachers will complete an exit interview. Students who need mental health services will be referred to the school counselor or community provider for treatment. A 3 month follow-up evaluation to assess sustained use of TAPES/TAT skills will be conducted.

Sub study: From an economic perspective, anxiety confers a high economic burden on the individual, state and national level. Based on data from 2002, the annual cost of anxiety disorders in the United States is likely to be more than $100 billion. These cost estimates are 16 years old and an updated examination of the cost of pediatric anxiety disorders is needed. Research has not investigated the potential financial benefit (e.g. school attendance, standardized test scores) or fiscal feasibility of adopting these interventions relative to current practices. Within the United States, it is also uncertain whether the cost burden of pediatric anxiety varies by demographic factors (e.g. minority status, socio-economic status, gender). Each of these cost factors represent sizable gaps in scientific knowledge. In this context, a Pre-K award was submitted to the Connecticut Institute for Clinical and Translational Science in order to fill this important gap in the scientific literature. This sub study will examine the cost of pediatric anxiety and the relative benefit of TAPES compared to usual care (UC). The purpose of this costs and benefits analysis is to provide information to school system administrators and teachers regarding the budgetary consequences of pediatric anxiety and to summarize the cost of achieving potential improvements in school functioning.

Procedures for Summer Months. We will only randomize teachers and enroll students if at least 10 weeks of school remain in the academic year to allow sufficient time to complete baseline evaluation, TAPES implementation and post evaluations.

Randomization. During the RCT, randomization will occur at the teacher level at a 1:1 (20 TAPES: 20 TAT). The randomization plan will be generated prior to the identification of teachers to minimize potential biases. Randomizing teachers to two active training conditions was selected for several reasons. The current design allows for all teachers to receive some training in anxiety identification and reduction—a major recruitment barrier in our previous school-based trials where clinicians or nurses were assigned to a no training control condition and subsequently dropped from the study. In addition, this design allows for an examination of a brief teacher training which represents typical teacher professional development offerings in CT.

Participants and Recruitment

Teacher Participants. A total of 55 volunteer *general and special education teachers* will be selected to participate (15 in the open trials and 40 in the RCT). We expect the racial/ethnic make up for the sample to reflect teachers in the state of CT: 3.04% African American, 3.56% Hispanic/Latino, 92.15% Caucasian, 1.12% Asian, and 0.13% two or more races. Teachers of all races/ethnicities may be eligible to participate and will depend on who volunteers.

Teacher Recruitment and Retention. Using our previously successful approach to recruitment of school personnel, a variety of methods to recruit teachers will be used such as district director and principal invitations to teachers, study flyers, study emails, direct calls, and outreach presentations in the school. For this proposal, we have partnered with three school districts in CT with a pool of over 460 elementary teachers (see letters of support in Appendix). Fifty-five (12%) of these 460 will be needed. We anticipate that more teachers will volunteer to participate in this study than we can include and will randomly select the 55 from the pool of volunteers. We will replace teachers who withdraw if needed. Our research team is currently working in 12 CT districts and we can expand the number of districts/pool of teachers if needed. In our previous studies we exceeded or met recruitment goals. For instance, in our ongoing IES Goal 3 study, we proposed to recruit 46 school clinicians and we have recruited over 100. Similarly, in our IES Goal 2 study, we have met (or will in the Fall 2016) our recruitment goals for school nurses.

Teacher Inclusion Criteria. All teacher participants must be a primary regular or special education teacher and employee of the CT public school system. There are no other inclusion/exclusion criteria to enhance the generalizability of the study findings. Teacher characteristics will be examined in relation to teacher knowledge, teacher behavior change, and student outcomes.

Compensation: Teachers will be compensated for attending the teacher training ($50) and conducting each of the five school-home meetings ($20 per meeting). Additionally, teachers will be reimbursed $25 for completing the baseline, post and follow-up measures on each student (total $75 per child). Teachers who complete all study components will be compensated a total of $200 in gift cards during the open trials and $225 in the RCT.

Child Participants. A total of 80 students will participate (20 in the open trials and 60 in the RCT). Within the participating CT districts there are 26 elementary schools and 6,000 students. The student body within CT is diverse in terms of gender, socioeconomic status, and racial/ethnic background (12.3% African American, 22.1% Hispanic/Latino, 57.3% Caucasian, 4.8% Asian, 2.5% two or more Races; 32.9% receive free/reduced priced meals). Children of all races/ethnicities may be eligible to participate and will depend on who volunteers.

Child Inclusion/Exclusion Criteria. Inclusion/exclusion criteria for open trials and the pilot RCT were crafted to maximize the generalizability of findings. Because the *primary* aim of this study is to evaluate changes in teacher behavior, and because children whose teacher is randomly assigned to TAT may not receive any evidenced-based assistance, children identified as needing treatment based on the diagnostic interview (regardless of group) will be referred for services. Students receiving services will also be enrolled; all service use will be documented over the course of the study. This approach mimics what naturally occurs in the classroom—that is teachers frequently work with students who may be in outpatient or school-based treatment. Inclusion Criteria: All children must: 1) attend a CT elementary school (i.e., ages 5-12 inclusively); and 2) have elevated anxiety symptoms (i.e., a total SCAS t score $\geq$ 60 based on parent and/or child report and/or a clinician severity rating [CSR] of 3 or greater on the ADIS) Students will be excluded if they: 1) have a medical or psychiatric condition contraindicating the study participation (based on clinical interview such as recent suicidality). Ambiguous cases will be decided by the PIs and the school teacher.

Child Recruitment. Teachers will identify potentially eligible youth from their classroom, describe the study to their parents and provide them with study contact information. Parents will

also be notified that their teacher is participating in a study that involves training teachers to help reduce anxiety in children and may contact study staff directly. This approach to recruitment was selected over a school-wide screening approach because it is more naturalistic and generalizable to the functioning of schools and is less intrusive and disruptive. However, if recruitments do not meet the expected levels after the first 2 months of recruitment, we will consult with the DT and teachers and adjust our strategy. In our other studies, successful recruitment strategies have included: sending study flyers home to families, providing educational seminars on anxiety to school personnel, informing school personnel (i.e., teachers, counselors, administrators) about the study and attending teacher-parent meetings to describe the study. Based on our pilot survey, teachers reported seeing excessive anxiety in 38.5% of their students; epidemiological studies indicate a minimum of 10% of youth in a given classroom will meet diagnostic criteria for an anxiety disorder, 40% are expected to have elevated anxiety symptoms that do not meet full diagnostic criteria (Costello et al., 2005; Costello & Shugart, 1992). Thus, in each classroom of 20 children, we anticipate at least 2 children will be eligible. Thus, if each teacher (55 total teachers) recruits 1-2 students, we will meet our recruitment goal of 80 children.

Compensation: Families will receive $20 gift cards after completing the baseline evaluation, $20 for the post evaluation and $60 for the follow up evaluation (total of $100 per child in the RCT).

Intervention Conditions

TAPES. TAPES includes a one day in-person teacher training and ongoing performance feedback (described above) that equips teachers with knowledge and skills to assist anxious students. Implementation of TAPES skills includes a school–home journal, daily classroom anxiety reduction tasks, and conjoint parent-teacher-child meetings. All conjoint meetings will be digitally audio-recorded and sent electronically (using a secured network) for review of fidelity and quality of implementation.

TAT: TAT is a 3-hour didactic training on student anxiety that the PIs use in their ongoing school-based studies for school clinicians and nurses (modified for teachers). The TAT content will include information on the signs, causes, consequences, and effective interventions for student anxiety. As noted earlier, this control condition was selected to enhance teacher recruitment and mimic the format of teacher professional development trainings in CT. Thus, TAT will provide a credible and acceptable control. An added value of this proposal will be to examine the impact of TAT on teacher behavior and child outcomes relative to TAPES.

Independent Evaluator (IE) Training. IEs will have a masters or doctoral degree in a relevant child mental health field and experience with conducting diagnostic assessments with anxious youth. Training and certification of IEs will include completion of: 1) didactic training that includes review and practice of all assessment measures and study procedures by the PIs, 2) review of ADIS videotaped administrations by a senior interviewer, 3) achieving inter-rater reliability (kappa) of .85 for the severity ratings on 3 cases (live or with videotapes) and 4) administration of the ADIS in the presence of a senior interviewer. All assessments will be videotaped and a random 15% of tapes will be evaluated for interrater reliability (i.e., for the severity ratings).

Measures. The selection of proposed measures to be used in Stages 2 and 3 was guided by the best available measures for the study aims and proposed theory of change, and participant burden. Measures, informants, and time points are listed in Table 1. Data will be collected from multiple informants (e.g., teacher, IEs, parent, child) using multiple formats (e.g., classroom observations, rating scales, interviews, school records). *Many of the measures were used in the*

PI's previous school-based intervention development studies and will be modified for TAPES. The assessment battery will also be modified based on DT and open trial feedback. Measures to be developed and used in the sub-study are also included in this section.

Primary Outcomes: Teacher Knowledge and Skills

-*Teacher Knowledge Assessment* is a 26-item short answer and multiple choice test of anxiety reduction strategies to gauge teachers' prior knowledge and the effectiveness of training. This measure was adapted from an existing knowledge assessment test for school clinicians, which showed an increase in knowledge pre to post-training (Ginsburg et al., 2008).

-*Classroom Observation of Teachers Skills* is a form completed during direct observations of the teacher during normal class activities (e.g., math or reading). The observations are coded by tallying the frequency of specific behaviors that have a positive or negative impact on student anxiety. Using a 5 point Likert scale, observers provide an overall rating of teacher's behavior in both domains.

Usability Measures- The following measures assess whether teachers can understand and learn how to use the skills and whether they can implement the skills effectively and efficiently.

- *Teacher Knowledge Assessment* (above) will assess ability to learn skills.

- *Classroom Observation of Teachers Skills* (above) will assess use of skills in the classroom.

-*Teacher and Child Recruitment Tracker* will be used to record recruitment of teachers/children as well as obstacles to recruitment. Obstacles will be addressed in team meetings and with DT.

-*Teacher Time Log* is a form completed by teachers to log the amount of time spent using TAPES/TAT skills with each study student.

Feasibility Measures – The following measures assess whether the training skills can be implemented within an authentic school setting.

-*Training Satisfaction and Feedback Questionnaire* (Ginsburg et al., 2008, 2011) is a 16-item measure completed anonymously by teachers who rate the helpfulness of training content and format (e.g., role play, videos), overall satisfaction and perceived helpfulness of TAPES/TAT skills for students with anxiety, and their preparedness to conduct conjoint meetings using a 4-point Likert-type scale (1 = not at all helpful to 4 = very helpful). Open-ended questions ask about the most/least helpful aspects of training and suggestions for improvement.

- *TAPES & TAT Satisfaction and Feedback Questionnaires* (Ginsburg et al., 2012) will be adapted for this study from an existing questionnaire and will assess satisfaction and helpfulness of skills used with anxious and in the classroom.

-*Exit Interviews* will be conducted with teachers after completing the TAPES program with a student. The PIs will arrange a time to talk with teachers (20 minutes) to obtain qualitative information about perceived barriers to using TAPES, experience implementing TAPES, perceived impact on students, etc. and or suggestions for future implementation. These interviews will take place during the open trials and inform revisions for the RCT.

- *Teacher and Child Retention Tracker* will be used to record the rates/reasons for attrition for both teachers and students and will be discussed weekly in team meetings and with the DT.

-*Satisfaction Forms, Meetings 1-5* will be administered to teachers, parents, and students to assess satisfaction with each school-home meeting.

Fidelity of Implementation Measures – The following measures, described above, will assess adherence and quality of implementation of TAPES:

- *S-H Fidelity and Quality Measure (Meetings 1-5)* is a form assessing the fidelity and quality of TAPES skills based on audio-recorded school-home meetings. The goals of each meeting are

rated for adherence (Was goal accomplished? Yes/No) as well as quality of implementation (1 = Poor to 4 = Very Good), which reflects the accuracy of the presentation, use of elaboration and student-specific examples, and assessment of parent/student understanding.

- *Teacher S-H Meeting Summary Form* is a 16-item measure completed following conjoint meetings. This checklist contains items that measures parent and student involvement, assesses barriers to use, and whether goals were accomplished.

- *Classroom Observations of Teachers Skills* (see above) will be used to assess fidelity.

Teacher and Child Measures Linked with TAPES Theory of Change. Several measures will be collected to assess factors that may influence fidelity of TAPES skills and/or are directly linked to the proposed theory of change:

- *Student-Teacher Relationship Scale* (STRS; Pianta, 1992) is a 15-item scale with good psychometric properties that will assess the quality of the teacher-child relationship.

- *Parent-Teacher Relationship Scale* (Vickers & Minke, 1995) is a 24-item measure of teacher-parent relationship quality. The measure has good psychometric properties (Dawson & Wymbs, 2016).

-The *Teacher Efficacy Beliefs Scale* (Tschannen-Moran & Hoy, 2001) is a 12-item psychometrically sound scale of teacher efficacy such as efficacy for classroom management and student engagement (Girio & Owens, 2009).

- The *Teacher as Social Context* (TASC; Belmont, Skinner, Wellborn & Connell, 1991) teacher involvement scale and help/support subscale will be used to assess the student's perception of his or her teacher's affection, attunement, dedication, and dependability.

-*Teacher Background Form* is a 16-item measure that assesses demographic characteristics (e.g., age, gender, race) and professional experience factors (e.g., degree, training, years teaching, class size, and confidence in reducing anxiety).

-*Maslach Burnout Inventory – Educators Scale* (MBI-ES; Maslach et al., 1996) is a 22-item measure with strong psychometric properties of teacher burnout (Iwanicki & Schwab, 1981).

-*Organizational Readiness Questionnaire* – will be used to assess teacher perceptions of the overall climate of his or her school. This 25-item measure was adapted from the organizational climate scale of the Texas Christian University Organizational Readiness for Change measure (Lehman, Simpson, Knight, & Flynn, 2011)

-The *Woodcock-Johnson IV Numbers Reversed Subtest* (Schrank, McGrew, & Mather, 2014) will be used to assess verbal working memory. This measure is included to explore the relationship between anxiety and working memory (Ma, 1999; Owens et al., 2008; Wood, 2006) which has been hypothesized to account for academic impairment among anxious youth.

- *Classroom Strategies Questionnaire* is a brief questionnaire administered to assess the frequency of teachers' use of the classroom anxiety-reduction strategies featured in the TAPES/TAT trainings.

- *Family Accommodation Scale, Anxiety* (FASA; Lebowitz et al., 2012) is a 13-item measure that provides ratings of parent's participation in anxiety-related accommodation behaviors, modification of family functioning, and related family distress. The FASA has good internal consistency and demonstrates convergent and divergent validity (Lebowitz et al., 2012).

- *Teacher Accommodation Scale, Anxiety (TASA)* is a modified version of the FASA developed for this study. The TASA will be administered to obtain frequency ratings of teacher accommodation behaviors in the classroom. Teachers will provide ratings of anxiety-related behaviors in the classroom, modification of classroom routines and/or individual responsibilities,

and related distress.

Student Outcomes:

Educational Achievement

-*School Records Form* will be used to assess information on grades, grade retentions, and referrals for disciplinary actions (e.g., suspensions, detentions).

-*Woodcock-Johnson IV Tests of Achievement* (WJ IV; Schrank, Mather, & McGrew, 2014) is a widely used, norm-referenced measure of academic achievement. Several subscales (reading, writing, and math fluency) are believed to be affected by anxiety. The measure has strong psychometric properties (McGrew, LaForte, & Schrank, 2014).

School and Classroom Behavior

-*Student Attendance and Services Form* will be used to assess weekly student attendance as well as referrals and utilization of additional academic (e.g., IEPs, Section 504 plans) and school-based mental health services.

-*School Anxiety Scale* (SAS; Lyneham et al., 2008) is a 16-item questionnaire that assesses anxiety related behaviors in the classroom (e.g., child is afraid of asking questions). The SAS-TR has acceptable psychometric properties (e.g., alpha for total score was 0.93).

-*School Connectedness* (Resnick et al., 1997) is a widely used five-item questionnaire completed by the child asking about their feeling towards school (Loukas, Suzuki, & Horton, 2006).

-*School Refusal Questionnaire* is a 12-item measure adapted from the Anxiety Disorders Interview Schedule for DSM-IV, Child Version (ADIS-IV-C; Silverman & Albano, 1996) that provides information about school absences, early dismissals, and school nurse or counselor visits attributed to anxiety.

Student Mental Health Outcomes:

- *Anxiety Disorders Interview Schedule for DSM-V, Parent and Child Versions* (ADIS-V-C; Silverman & Albano, in press) is considered the gold standard for assessing anxiety diagnoses and severity. Impairment ratings are generated for each disorder using the Clinician Severity Rating (CSR, range = 0-8; ≥ 4 required to assign a diagnosis). The ADIS-C has good test-retest reliability for the parent interview (r = 0.98) and for the child interview (r = 0.93; Silverman et al., 1999a, 1999b, 2001) and is sensitive to intervention effects (Ginsburg et al., 2012).

- *Clinical Global Impression – Severity (CGI-S) and Improvement (CGI-I) Scales* (Guy, 1976) is a measure of global anxiety severity ranging from 1 (normal, not at all ill) to 7 (extremely ill) at all time points. The CGI-I is assigned at post and follow-up assessments to provide a global rating of clinical improvement in anxiety symptoms since the baseline assessment. Scores on the CGI-I range from 1 (very much improved) to 7 (very much worse). Both measures are widely used in child treatment trials to assess symptom severity and improvement (Walkup et al., 2008).

- *The Children's Global Assessment Scale (CGAS;* Shaffer et al., 1983) is used to describe a child's global impairment and functioning at home, school, and with peers on a scale of 1 (gross impairment) to 100 (superior functioning). The CGAS has been used in child anxiety treatment studies to monitor changes in global functioning (e.g., RUPP Study Group, 2002).

- *Columbia Suicide Severity Rating Scale, Child and Parent Versions* (C-SSRS; Posner et al., 2008) is a 6-item measure used to screen for recent suicidal ideation. The C-SSRS demonstrates strong internal consistency and sensitivity to change over time (Posner et al., 2011).

- *Spence Children's Anxiety Scale, Child and Parent Versions* (SCAS; Spence, 1997, 1998) is a 38-item measure rated for frequency of occurrence (0 never to 3 always) of a broad range of anxiety symptoms. The SCAS–C and SCAS–P have sound psychometric properties, with

internal consistency reported at .89 for the total parent anxiety score and .92 for the total child score (Muris, Schmidt, & Merckelbach, 2000; Nauta et al., 2004; Spence, Barrett, & Turner, 2003; Spence, 1998). This measure was selected to facilitate comparisons with published school-based studies using the FRIENDS program (Barrett et al., 2005, 2006; Barrett &Turner, 2001).

- *Strength and Difficulties Questionnaire- Teacher version* (SDQ; Goodman, 1997) is a 25-item, widely used questionnaire about children's classroom behavior. The teacher-report version has sound psychometric properties (Stone et al., 2010).

-*Teacher Observation of Classroom Adaption-Checklist, Concentration Problems scale* (TOCA-C; Koth, Bradshaw, & Leaf, 2009; Leaf, Schultz, Keys, & Ialongo, 2002) is a measure of student behavioral adjustment that demonstrates high internal consistency and construct validity. The 7-item Concentration Problems scale will be used to assess inattentive behaviors in the classroom.

-*Avoidance Hierarchy* – is a measure of the student's top three most frequently avoided behaviors at home and at school, which are assigned by the independent evaluator at baseline. Each behavior is rated on a 7 point Likert scale to assess how often the student avoids engaging in the behavior (1 = never avoid to 7 = avoid every time).

Additional Study Measures:

- *Demographics Form*- This questionnaire assesses child/family information such as child age, family income, parental education, race/ethnicity, etc.

- *Service Utilization Form* is administered at each assessment to document involvement or changes in psychological/psychiatric services. The service utilization form will be modified to include more details related to the sub study including an emphasis on school-based services (including teachers time).

- *Parent Health Questionnaire (PHQ)* will be used to assess parent and teacher anxiety and mood symptoms. This form was adapted from two screening measures (GAD-7 and PHQ-9), which have shown good reliability and validity in primary care settings (Kroenke, Spitzer, & Williams, 2001; Spitzer, Kroenke, Williams, & Löwe, 2006).

Sub Study Measures:

- *School Attendance, Discipline, and Parent's Missed Work* – This questionnaire will obtain information from parents about their children's school attendance, disciplinary actions taken against their child and the amount of work that they have missed due to anxiety related reasons. This will be completed at baseline and all follow up assessments.

- *Child Health Utility Index (CHUD)* – This 9-item questionnaires assess the student's overall health and functioning in various domains. It is commonly used in the context of intervention cost-effectiveness research and demonstrates adequate psychometric properties (Furber & Segal, 2015).

Table 1 Assessment of Study Measures

Instrument	Purpose	Rater	Time Point	Completion time
Primary Outcomes: Teacher Knowledge and Skills				
Teacher Knowledge Assessment	Assess teacher knowledge of anxiety reduction strategies	Teacher	BL, PO	10 min

Classroom Observations of Teachers Skills	Assess accurate use of skills by teacher in classroom	IE, Teacher	BL, PO, FU	30 min
Usability Measures				
Teacher Knowledge Assessment	Assess teacher ability to learn new information	Teacher	BL, PO	10 min
Classroom Observation of Teachers Skills	Assess whether teachers can use skills	IE	Pre-Training, BL, PO, FU	30 min
Teacher and Child Recruitment Tracker	Assess teacher ability to identity anxious youth	IE	WKLY	5 min
Teacher Time Log	Assess number and length of school-home meetings and other interactions with the study child and/or parent	Teacher	WKLY	5 min
Feasibility Measures				
Training Satisfaction and Feedback Questionnaires	Assess teacher training satisfaction as marker of willingness to use the TAPES or TAT intervention or skills	Teacher	Post training	5 min
TAPES Satisfaction and Feedback Questionnaires	Assess perceptions of feasibility, satisfaction, and helpfulness of intervention	Teacher/ Parent/ Child	PO	5 min
Satisfaction Forms, Meeting 1-5	Assess parent and teacher satisfaction and perceptions of helpfulness of each meeting	Teacher/ Parent	WKLY	5 min
Satisfaction Forms, Meeting 2-5	Assess child satisfaction and perceptions of helpfulness of each meeting	Child	WKLY	5 min
Exit Interview	Document teachers experience in program; perceived barriers, etc.	PI	PO	20 min
Teacher and Child Retention Tracker	Assess interest and ability to implement intervention within constraints of the school settings	IE	WKLY	5 min
Fidelity of Implementation Measures				
S-H Meeting Fidelity and Quality	Assess adherence and quality of implementation in conjoint meetings	PI	WKLY	30 min

Measure (Meetings 1-5)				
Teacher S-H Meeting Summary Form	Assess adherence and barriers to implementing TAPES skills	Teacher	WKLY	1 min
Classroom Observations of Teachers Skills	Assess adherence and quality of implementation in classroom	IE	BL, PO, FU	30 min
Teacher and Child Measures Linked with TAPES Theory of Change				
Organizational Readiness Questionnaire	Assess teacher perceptions of the organizational climate of his or her school	Teacher	BL	1 min
Student Teacher Relationship Scale	Assess teacher perceptions of the quality of the teacher-child relationship	Teacher/ Child	BL, PO, FU	1 min
Parent Teacher Relationship Scale	Assess teacher and parent perceptions of the quality of the teacher-parent relationship	Teacher/ Parent	BL, PO, FU	1 min
Teacher Efficacy Beliefs Scale	Assess teacher efficacy for classroom management, instructional strategies, and student engagement	Teacher	BL, PO, FU	1 min
Teacher as Social Context (TASC)	Assess the student's perception of his or her teacher's affection, attunement, dedication, and dependability.	Child	BL, PO, FU	5 min
Teacher Background Form	Assess demographic characteristics and professional experience factors	Teacher	BL	5 min
MBI-Educators Scale (MBI-ES)	Assess teacher burn out	Teacher	BL	1 min
Woodcock-Johnson IV Numbers Reversed Subtest	Assess child working memory	IE	BL, PO, FU	5 min
Classroom Strategies Questionnaire	Assess teachers' use of anxiety-reduction strategies	Teacher	BL, PO, FU	1 min
Student Outcome Measures				
Educational Achievement				
School Records Form	Assess grades, attendance, and disciplinary records	RA	BL, PO, FU	5 min

Woodcock-Johnson IV Tests of Achievement	Assess child academic achievement	IE	BL, PO, FU	20 min
School and Classroom Behavior				
Student Attendance and Services Form	Assess child use of additional school services (e.g. referral to special education)	Teacher	WKLY	5 min
Child Anxiety Impact Scale	Assess the impact of child's anxiety on social and academic functioning	Parent/ Child/ Teacher	BL, PO, FU	5 min
School Anxiety Scale	Assess child anxiety symptoms in the classroom	Teacher	BL, PO, FU	1 min
School Connectedness	Asses the child feeling towards school/teacher	Child	BL, PO, FU	1 min
School Refusal Questionnaire	Assess school absences, early dismissals, and school nurse or counselor visits attributed to anxiety	IE	BL, PO, FU	1 min
Mental Health				
Anxiety Disorders Interview Schedule, Child Version (ADIS-C)	Assess child anxiety symptoms and severity	IE	BL, PO, FU	60 mins
Clinical Global Impression – Severity (CGI-S) and Improvement (CGI-I) Scales	Assess overall severity and improvement of anxiety symptoms	IE	BL, PO, FU	1 min
The Children's Global Assessment Scale (CGAS)	Assess child's overall functioning across disorders	IE	BL, PO, FU	1 min
Columbia Suicide Severity Rating Scale (CSSRS)	Screen for child suicidality	IE	BL	1 min
Spence Children's Anxiety Scale	Assess child anxiety symptoms	Parent/ Child	BL, PO, FU	5 min
Family Accommodation	Assess parent and teacher accommodation behaviors in response to child's anxiety	Parent/ Teacher	BL, PO, FU	5 min

Scale – Anxiety (FASA)				
Strength and Difficulties Questionnaire	Assess child internalizing/externalizing symptoms	Teacher	BL, PO, FU	10 min
Teacher Observation of Classroom Adaptation Checklist (TOCA-C)	Assess child inattentive behaviors in the classroom	Teacher	BL, PO, FU	1 min
Avoidance Hierarchy	Assess the top three most significant anxious/avoidant behaviors exhibited in school and at home	Teacher, Parent, IE	BL, PO, FU	1 min
Additional Study Measures				
Demographics Form	Assesses child/family information	Parent	BL	10 min
Service Utilization Form	Assess changes in psychological/psychiatric services in school and community	IE	BL, PO, FU	5 min
PHQ	Assess parent and teacher anxiety and mood symptoms	Parent, Teacher	BL, PO, FU	1 min
Sub study Measures				
School Attendance, Discipline, and Parent's Missed Work	Assess the study child's attendance, disciplinary actions, and number of parents missed work days	Parent	BL, PO, FU	5 min
Child Health Utility 9D (CHU9D)	Assess student's overall health and functioning	Parent, Child	BL, PO, FU	2 min
Total time for each assessment; Teacher 30 min; Parent 50 min; Child; 50 min				

Data Analytic Plan. Each aim is stated below along with the corresponding data analytic plan. Preliminary analyses and plans for handling missing data are described first.

Preliminary analyses will include: 1) evaluating the psychometric properties of measures, 2) verifying assumptions in analysis of covariance (ANCOVA), general linear model (GLM) and generalized linear mixed model (GLMM), and 3) examining the nature of missing data (e.g., missing at random, MAR). Specifically, we will run descriptive analyses to check for outliers to ensure that distributional assumptions of the planned analyses are appropriate. If not, analogous non-parametric methods will be used. Although all of our primary measures have a favorable psychometric history, we will ensure a satisfactory level of internal consistency for each measure through calculation of Cronbach's alpha.

<u>Missing Data:</u> With respect to missing data, we will follow Bell et al. (2014)'s recommendations which include: 1) make every possible effort to prevent missing data, 2) use the intention-to-treat (ITT) principle and all available data in analyses, and 3) conduct sensitivity analyses that assess the robustness of the results. Thus, our IEs and RAs will review all assessment materials in the presence of teachers, children, and parents to limit the amount of missing data and to help verify the correctness of the data. Because missing data may lead to biased estimation and loss of statistical power if handled inappropriately we will draw upon several approaches if missing data is present (Diggle, Liang, & Zeger, 1994). We will conduct a partial check to determine if the data are missing at random (MAR) by evaluating whether 'missingness' can be explained on the basis of measured variables. Multiple imputation (MI) has been shown to improve upon traditional simple methods for handling missing data (e.g., list-wise deletion, mean substitution; Schafer, 1997). Thus MI ITT results will be compared with other methods such as complete case or maximum likelihood methods in a sensitivity analysis (Soley-Bori, 2013).

Aim #1: *To develop and assess the usability, acceptability and feasibility of TAPES, a teacher training to reduce student anxiety.* To address this aim, quantitative and qualitative data collected from the DT's initial review of materials and participants' (teachers, children and parents) data in the open trials will be recorded and synthesized in a descriptive manner. The PIs and DT will use this information to refine TAPES' training materials. Additional information regarding feasibility and acceptability will be collected throughout the study (e.g., obtaining reasons for declining initial participation and reasons for drop outs, and evaluating satisfaction). We will review mean scores on measures of satisfaction (e.g., *Training Satisfaction and Feedback Questionnaire, TAPES Satisfaction and Feedback Questionnaire*) as well as participants' responses to open ended questions on these measures. Moreover comments from the teacher *Exit Interviews* will enable us to modify individual components in TAPES to enhance its usability, acceptability and feasibility for Stage three. During the pilot RCT in Stage three, ANCOVA will be used to compare TAPES with TAT in terms of usability, acceptability, and feasibility based on the same satisfaction measures. If needed, we will use teacher-specific (e.g., years of teaching experience, teaching efficacy) and child-specific (e.g., age, baseline anxiety severity) as covariates. For example teachers' rating on intervention acceptability will be modeled as $y_{ij} = \mu + \tau_i + B(x_{ij} - \bar{x}_i) + \varepsilon_{ij}$ where *i* indicates teacher-level randomized intervention-training group assignment, say 1 for TAPES, and 0 for TAT, y_{ij} denotes the rating from the *j*th teacher in group *i* at post training, x_{ij} denotes teacher-specific covariates, and ε_{ij} denotes the unobserved error term. If the null hypothesis $\tau_0 = \tau_1$ is rejected, it implies that teacher's view on acceptability depends on their assigned group. In addition, weekly data from *Teacher and Child Recruitment Tracker*, *Teacher Time Log*, and *Teacher and Child Retention Tracker* will be used to assess feasibility.

Aim #2: *To determine whether teachers can implement the TAPES skills with fidelity/quality.* Descriptive statistics will be used to test this aim. We will examine mean scores over time on our fidelity measures (e.g., *S-H Meeting Fidelity and Quality Measure)* to determine the ability of teachers to implement TAPES skills accurately and with high quality. We will also examine which teacher-specific and child-specific variables affect fidelity ratings.

Aim #3 (Primary Outcome): *To assess the impact of TAPES, compared to TAT, on teachers' a)* ***knowledge*** *regarding student anxiety symptoms and anxiety reduction strategies and b)* ***use of anxiety reduction skills*** *in classroom.* To achieve this aim, we will first assess the equivalence of teachers randomized into either TAPES or TAT on baseline teacher (years of experience,

burnout, teacher efficacy; teacher behavior) and child characteristics (e.g., gender, age, baseline anxiety symptoms, classroom functioning). To test the main hypothesis, that teachers in TAPES, compared to TAT, will have higher knowledge about anxiety reduction, we will examine scores on the *Teacher Knowledge Assessment* at post-training, and at the end of school year as outcomes in GLM controlling for teacher pre-training score. Let y_i denote the post-training or end of school year test score of teacher *i*, x_{i1} and x_{i2} denote teacher *i*'s group assignment and pre-training test score, respectively, and ε_i denote resident term. Rejecting $\beta_1 \leq 0$ and $\beta_3 \leq 0$ in the model: $y_i = \beta_0 + \beta_1 \times x_{i1} + \beta_2 \times x_{i2} + \beta_3 \times x_{i1} \times x_{i2} + \varepsilon_i$ suggests that TAPES teachers' post-training test scores are higher and they have a greater gain in knowledge than TAT teachers. Teacher-specific covariates can be added to the above model as needed. To test the hypothesis that TAPES, compared to TAT, will result in greater use of anxiety reduction skills in the classroom, IE's *Classroom Observation of Teachers Skills* rating for each pair of teacher and anxious student at baseline, post-intervention, and 3-month follow-up will be modeled in GLMM. Now rating, y_{ijk} are nested within teacher *k* and student *j*, who is nested within teacher *k*, in the multilevel equations: Level 1: $y_{ijk} = \pi_{0jk} + \pi_{1jk} \times \text{timepoint}_{ijk} + e_{ijk}$; Level 2: $\pi_{0jk} = \beta_{00k} + r_{0jk}$ and $\pi_{1jk} = \beta_{10k} + r_{1jk}$; Level 3: $\beta_{00k} = \gamma_{000} + \gamma_{001} \times w_k + u_{00k}$ and $\beta_{10k} = \gamma_{100} + \gamma_{101} \times w_k + u_{10k}$; where w_k denotes teacher *k*'s intervention-training group assignment with *e, r,* and *u* representing error terms in the respective levels. Teacher-specific (e.g., years of teaching experience, teaching efficacy) and child-specific (e.g., age, baseline anxiety severity) covariates can be added to Levels 2 and 3 equations as needed.

Aim #4 (Secondary Outcomes): *To examine the impact of TAPES relative to TAT on student outcomes.* Change scores on student mental health (e.g., *Spence Children's Anxiety Scale, SCAS*) and academic achievement (e.g., *Woodcock-Johnson Tests of Achievement*) from pre-to post-intervention and 3-month follow-up will be modeled as GLMM similar to above in Aim 3.

Exploratory aims: *To examine mediators (proposed in the theory of change, see Figure 1 in Appendix) and predictors and moderators (e.g. Teacher Background Form, MBI-Educators Scale) of TAPES impact on teacher knowledge and behavior.* Structural equation modeling (SEM) will be used to explore potential predictors (e.g., baseline teacher burnout as measured by *MBI-ES*), mediators (e.g., subscale scores from the *OSTES*) and moderators (e.g., years of teacher experience) on teacher behavior change (e.g., change score on the *Classroom Observation of Teachers Skills* at pre-, post-intervention and 3-month follow-up).

Sub study: Aim #1: Assess the direct and indirect cost of pediatric anxiety among youth enrolled in the TAPES intervention. This aim involves the modification of existing measures of direct and indirect cost. These measures will be administered to parents and teachers at existing TAPES assessment time points (i.e. baseline, post intervention and three-month follow up).

Aim #1a: Estimating the cost of pediatric anxiety through direct and indirect costs.

Aim #2: To examine the child and parent benefit of TAPES compared to UC. This aim involves estimating the cost of TAPES relative to the UC condition in relation to direct and indirect costs.

Exploratory Aim: To examine family demographic factors as moderators of pediatric anxiety cost.

Power Analysis. Although this is a development study proposing a small pilot RCT, attempts were made to estimate statistical power for the key outcomes based on existing literatures on similar measures (see White et al., 2011 for *Teacher Knowledge Assessment* and Barrett et al., 2005 for child anxiety using the *SCAS)*. Using Optimal Design version 3.0 calculations for both variables were based on an anticipated enrollment of 20 teachers in each group (and 1-2 students per teacher). We assumed a conservative within-teacher ICC of 0.10 (Eldridge et al., 2004) and

an alpha level was set at .05. Below is a list of minimum effect sizes (calculated as within-group difference in change score, divided by the pooled standard deviation) needed to be detectable with 80% power. With 20 teachers in each group, we will have 80% power to detect the effect size found by White et al. (2011) of $d = 1.19$ on teacher knowledge. With 30 students in each group, we will have 80% power to detect the effect size found by Barret et al. (2005) of $d = .92$ on child anxiety (effect sizes based on moderately anxious students at pre-post timepoints).

Time Table : We are requesting funds for three years. The first six months will be for administrative study start-up tasks (hiring, IRB approval), IE training, and TAPES refinement and review of materials with DT (Stage 1). Months 7 – 20 (Stage 2) will be devoted to recruitment of teachers and students for open trials and further adaptation and refinement of TAPES. Months 21 to 34 will be devoted to implementing the RCT. The final two months (35-36) will be devoted to completing data analyses and manuscript preparation.

Personnel: Relevant Expertise of Research Team. The core UCHC research team (Drs. Ginsburg & Pella) along with our consultants have over 20 years of experience in conducting research on the development, evaluation, and dissemination of school-based programs for teachers and school personnel. In addition, the team has extensive experience providing education and training in anxiety reduction skills to school-based and community personnel. Both Dr. Pella & Ginsburg moved to UCHC in 2014. In that time they have successfully partnered with 7 CT school districts which now serve as authentic environments for their funded research. They have trained over 40 school clinicians and 17 school nurses as part of their research—exceeding initial recruitment goals. Together they also established the Child/Adolescent Anxiety and Mood Program (CAMP). CAMP conducts community-based research focusing on child and adolescent anxiety and mood disorders, with an emphasis on intervention and dissemination. CAMP now has research coordinators, postdoctoral fellows, and research assistants who work together to recruit research participants and implement studies funded by NIMH and IES. CAMP holds weekly and monthly research meetings that are attended by residents, fellows, and faculty. Currently, CAMP members include 2 faculty, 3 postdocs, 2 Masters level staff, and 8 student research assistants. Finally, Drs. Pella and Ginsburg share responsibility for teaching seminars on child anxiety for psychiatry residents at UCHC. Together, they have given numerous seminars and presentations on childhood anxiety and CBT to a variety of audiences (e.g., parents, teachers, counselors, physicians, and psychiatrists) and have trained school-based clinicians and nurses in the principles and strategies of delivering CBT to anxious youth within schools. These prior experiences have prepared the investigative team to successfully conduct this proposed study. This project reflects a significant and logical next step in this program of research by training teachers in the identification and support of anxious youth. Below is a list of key personnel that will also support this grant, their qualifications, roles, responsibilities, and percent of time and calendar months per year to be devoted to the project are listed below. Evidence of publishing in peer-reviewed scientific journals is documented in the biosketches. Each team member has experience that will ensure the successful implementation of this study.

Dr. Golda Ginsburg (PI) is a Professor of Psychiatry at UCONN Health and has been developing and evaluating trainings and interventions for anxious youth for over 20 years. Most relevant to the current proposal, she has completed several school-based studies for anxious students (R34 MH90027497) and is the PI of an IES Goal 3 RCT efficacy trial evaluating a school-clinician delivered treatment for anxious students. She also is the PI of an IES intervention development

grant to train school nurses to help anxious youth. She has been the PI or Co-PI on over 10 federally and/or privately funded clinical trials, including the large NIMH-funded landmark multi-site clinical trials for depression (Treatment of Adolescent Depression Study; TADS), anxiety (Child/Adolescent Anxiety Multi-modal Study; CAMS; Child/Adolescent Anxiety Multi-modal Extended Long-term Study; CAMELS) and Tourette's (Comprehensive Behavioral Intervention for Tics; CBIT). She is also the PI of an NIMH-funded grant to evaluate different treatments for adolescents with anxiety and depression in community clinics and has NIMH grant support to conduct a follow-up study of an anxiety prevention trial based on her previous NIMH efficacy trial. She will devote 20% time and effort in years 1-3 be responsible for all scientific, clinical, and administrative tasks.

Dr. Jeffrey Pella (Co-PI) is an Assistant Professor of Psychiatry in the Department of Psychiatry UCONN Health and has been working in the field of developmental psychopathology and child anxiety for 8 years. He was the recipient of the Graduate School of Social Sciences Studentship Grant during his doctoral studies and has worked on several federal and state funded grants. Most notably, he coordinated a multi-site sequential multiple assignment randomized control trial at the University of Maryland, comparing the effectiveness of family trauma treatments. At the UCONN, he has over two years' experience working in the public school system. He has worked extensively with school clinicians, teachers, principals and administrative staff. Dr. Pella will devote 60% time and effort with salary support for years 1-3 of the study. He will be the primary liaison to schools and will oversee classroom observations. He will also assist in training new teachers. Dr. Pella will also assist in training IEs and will conduct baseline -assessments. Dr. Pella will assist with oversight of the data management, conduct data analyses, and prepare manuscripts and presentations resulting from this study. Dr. Pella will lead recruitment efforts through outreach to schools.

Grace Chan, Ph.D. (_Statisitican; Co-I_) Assistant Professor Department of Psychiatry UCONN Health will devote 2%, 2% and 10% effort and salary support for years 1, 2 and 3, respectively. Dr. Chan will provide statistical support for this project and will conduct the primary data analyses on the RCT, provide consultation to and oversee the quality of work conducted by the PIs for secondary data analyses.

George Sugai, Ph.D. (Consultant, DT Member) is a Professor at the University of Connecticut, Storrs Campus. He is also the co-director of the national Center on Positive behavioral Interventions and Supports which give schools assistance for identifying, adapting, and sustaining effective school-wide disciplinary practices. He is an internationally renowned expert of school-based interventions and teacher training. He will participate as a member of the DT, be available for consultation on an as-needed basis, and share relevant materials from his school-based interventions.

Keith Herman, Ph.D. (Consultant, DT member). Dr. Herman is an Associate Professor at University of Missouri. His expertise includes developing, testing, and training teachers in mental health interventions. He is co-developer of the Classroom Check-Up. His primary commitments will be to provide consultation regarding teacher training, coaching, and classroom assessments. He will participate as a member of the DT and will also be available for consultation on an as-needed basis via email and telephone during the grant.

Linda Pfiffner, Ph.D. (Consultant, DT member). Dr. Pfiffner is a Professor at UCSF. Her expertise includes developing, testing, and training clinicians in school-home interventions. Her primary commitments will be to provide consultation regarding the development and

implementation of training components and navigating administrative/systems issues in the schools. She will participate as a member of the DT and has also agreed to be available for consultation on an as-needed basis via email and telephone during the grant.

Susan Sheridan, Ph.D. (Consultant, DT member). Dr. Sheridan is a Professor at University of Nebraska. Her expertise includes developing, testing, and training school personnel in school-home interventions. She is the developer of the CBC model and has agreed to share relevant materials from this intervention. Her primary commitments will be to provide consultation regarding the teacher training and feasibility of implementation in the schools. She will participate as a member of the DT and has also agreed to be available for consultation on an as-needed basis via email and telephone during the grant.

Armando Pina, Ph.D. (Consultant, DT member). Dr. Pina is an Associate Professor in the Psychology Department of Arizona State University. Dr. Pina is an expert in the developmental course of internalizing problems in children and adolescents. He has developed brief psychosocial interventions for school personnel and tested mechanisms implicated in the prevention and reversal of disorder development. His primary commitments will be to serve as a DT member and provide consultation regarding the feasibility of the training and related skills. He has agreed to consult as-needed and provide material from his own school-based work.

Kelly Drake, Ph.D. (Consultant, DT Member), Assistant Professor of Psychiatry in The Johns Hopkins University School of Medicine has extensive training and experience in clinical research with anxious youth and training school personnel in delivering manualized CBT. She has worked with Dr. Ginsburg for over 20 years. She will participate in the DT and will assess fidelity of teacher implementation as needed.

Katie Gritter, M.A. (Consultant, DT member). Katie Gritter is a licensed School Psychologist in the Braeburn Elementary school of the West Hartford public school system. She has over five years of experience working with children in the school system. She has worked as a clinician in an IES-funded study and been trained in CBT skills. She works extensively with anxious students and their teachers. Her primary commitments will be to serve as a DT member and provide consultation regarding sustainability and feasibility of the teacher training in CT schools.

Jocelyn Mackey, Ph.D.(Consultant, DT member). Dr. Mackey is a representative from the Connecticut State Department of Education. She assists Connecticut school districts to better serve at-risk primary grade children through the availability of early intervention mental health programs for the detection and prevention of emotional behavioral and learning problems. Her primary commitments will be to serve as a DT member and provide consultation regarding sustainability and teacher training.

Resources to Conduct the Project. If awarded, the project administration will be housed at UCONN Health (UCHC) which is the state university medical center of Connecticut (CT) located in Farmington (a suburb of Hartford, the capital of CT). UCHC is home to the School of Medicine, School of Dental Medicine, John Dempsey Hospital, UConn Medical Group, and UConn Health Partners (among others). It has a thriving research enterprise which includes several externally funded research centers. UCHC is part of the University of CT system and shares many resources with the Storrs campus (where there is a well-respected School Psychology program and Department of Education). Thus, the current project will be supported by an abundance of resources. The major components of UCHC relevant for this project include: the Department of Psychiatry, Division of Child and Adolescent Psychiatry, Connecticut

Institute for Clinical and Translational Science (CICATS) as well as participating elementary schools which will serve as the implementation sites for this project.

<u>UCHC Department of Psychiatry:</u> This project will be awarded to the Department of Psychiatry (Department), a department with a distinguished history beginning in 1969. The Department provides community psychiatric services as well as consultation clinics, inpatient units, emergency/crisis services, and day hospitals. The Department ranks the highest in external federal funding within the SOM and is home to several federally funded research centers (e.g., Alcohol Research Center). <u>The Division of Child and Adolescent Psychiatry:</u> One of the major components of the Department is the Division of Child and Adolescent Psychiatry (Division) where PIs are faculty members. The Division has administrative, faculty, clinical and research space for all staff. There is also a separate office building (Kane Street Clinic) devoted to clinical and research activities, where the PIs have their office space and research space (see below).

<u>The Connecticut Institute for Clinical and Translational Science:</u> CICATS was created in 2009 to transform and improve the way clinical and translational science is conceived, conducted, and disseminated. CICATS is both an academic unit of UCHC, and a partnership of institutions in the region dedicated to advancing clinical and translational research. The overall vision of CICATS is to serve as an engine to expedite and enhance the research, development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. CICATS aims to reduce barriers to the development, completion, and dissemination of clinical research—including school based research. The center provides services, support, and consultation in the following areas: education and training, regulatory support, IRB protocols, ethical concerns, legal and policy issues, subject recruitment, data management, data analysis, and study design and conduction. Toward this end, this center will provide support to the PIs as needed in the implementation of this project.

<u>Computing and Office Resources:</u> Computing resources and office space is available to all faculty and support staff for this project. Our research lab includes individual offices for evaluations, a large office suite, a conference room, storage space, and a waiting room (when evaluations are done on site rather than at the school). All offices are equipped with lockable file cabinet storage, telephones with voicemail, and a network printer. Computers are equipped with word processing, database management, bibliographic reference manager, and the statistical software necessary to conduct analyses and prepare manuscripts. Access to a shared drive for sharing files is also available. The space is large enough to house all site staff working on this grant. The Division has an IT administrator that provides support as a key element of the service. Servers provide functions including printing, e-mail and software applications. Network directories are backed up to protected file servers daily. There is also phone support, on-site support and remote control support for desktop PC and network problems. Anti-virus software is run daily on the networks as well. UCHC will provide access to tools (e.g., copying machine, fax, computers, phones) needed for project implementation.

<u>Access, Availability, and Cooperation of Schools and Teachers for this Project:</u> Three CT school districts have agreed to participate in this study (see letters of support). Within these districts there are approximately 26 elementary schools, 460 teachers and 6,000 students. Thus, we will draw from a large pool of teachers. We will randomly select teachers from the volunteer list if more volunteer than needed. For the past two years we have been working with school personnel in seven school districts. We have a strong and positive relationship with these school districts and can recruit more districts if needed.

Resources to Disseminate Results of the Project: Dissemination of research findings has been a core activity of the research team. In the past year alone, the PIs have presented at over 15 national and local venues (including to school personnel and parent organizations), presented 7 posters/talks at national or local conferences, and published 5 peer-reviewed manuscripts (2016 only-see biosketches). Thus, the individual team members have the proven capacity to disseminate research findings. In addition, UCHC has a communications office that regularly requests research from faculty and submits press releases to appropriate public interest sources. Findings from the current pilot study will be disseminated in several ways. We will present findings at national conferences (e.g., NASP; SPR), to CT State Department of Education, and to participating school districts. Audiences that will benefit from this research include state and local school personnel (e.g., administrators, teachers, principals, counselors). Finally, we plan to publish findings in a peer-reviewed journal (e.g., *School Mental Health*) and will have the final iteration of the training and related materials for testing in a large efficacy study.