University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Complete Research Protocol (HRP-503)

PROTOCOL TITLE:

Include the full protocol title.

Response: Enhancing the Effectiveness of Individualized Education Programs Using a Daily Report Card

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response: Gregory A. Fabiano, Ph.D.

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VERSION:

Include the version date or number.

Response: Version 3 (10/16/18)

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response: This protocol is funded by a grant from the Institute of Education Sciences.

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response: Research files will be kept in Diefendorf Hall Room 304.

Location: 304 Diefendorf Hall

Address: 304 Diefendorf Hall

Department: Department of Counseling, School, and Educational Psychology

1.0 Objectives

1.1 Describe the purpose, specific aims, or objectives of this research.

Response: *The purpose of this study are to determine the effectiveness of the daily report card (DRC) approach to supporting children with ADHD in special education in schools compared to a business as usual condition. Children in the study will be randomly assigned (like flipping a coin) to business as usual, or to treatments that increases, if needed, across the school year. All children will have progress carefully monitored across the school year.*

The objective is to observe whether the addition of the DRC approach is superior to special education procedures as usual .

1.2 State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Response:

Aim 1. Investigate the efficacy of using a DRC mechanism to link the child with ADHD's IEP to daily classroom behavior.

<u>Hypothesis 1.</u> Children who have a DRC linked directly to their IEP goals and objectives will exhibit better classroom behavior and exhibit better academic productivity outcomes than children who receive school as usual (SAU) in which an IEP has been developed but has not been enhanced through use of a DRC. Children who have a DRC will also demonstrate better outcomes on measures of IEP goal attainment, school functioning, and academic progress.

Aim 2. Investigate moderators of treatment outcome.

Hypothesis 1. It is hypothesized that grade level will moderate intervention effects. It is hypothesized the DRC intervention will be more effective in the primary grades (i.e., K-3) relative to intermediate grades (i.e., 4-6) as the less complex class schedule and academic demands (e.g., fewer long-term assignments; fewer organizational demands on the student) will facilitate greater adherence and implementation and therefore better outcome.

Hypothesis 2. It is hypothesized that the presence of ADHD + comorbid aggressive/oppositional behavior (i.e., comorbid disruptive behavior disorders; DBD) will moderate intervention effects. Specifically, it is hypothesized that the DRC intervention will be more effective for children with comorbid DBD because they will have increased classroom/social impairment and therefore more opportunity to exhibit improvement.

Hypothesis 3. It is hypothesized that IEP quality will moderate intervention effects. Specifically, it is hypothesized that the DRC intervention will be more effective for children with low-quality IEPs as its use will serve to scaffold poorly constructed or incomplete IEP goals/objectives.

Aim 3. Investigate mediators of treatment outcome

Hypothesis 1. As we outline in our logic model below, the fidelity of implementation (Fabiano et al., 2014), which includes improved positive teacher-child interactions, increased frequency/consistency of feedback, and enhanced home-based contingency management are all thought to be enhanced through the intervention and will mediate improvement in functional domains. These indicators will be investigated individually as mediators as well as jointly.

2.0 Scientific Endpoints

2.1 Describe the scientific endpoint(s), the main result or occurrence under study.

*NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should **not** be a date.*

Response:

Primary scientific endpoints are blinded observations of classroom behavior collected at the end of the school year and teacher ratings on the Disruptive Behavior Disorders Rating Scale, Impairment Rating Scale, Academic Performance Rating Scale, and BASC-2 rating scale. Teachers will also complete a rating of IEP goal attainment at the end of the school year.

Secondary outcome measures include assessments of academic achievement, classroom functioning, impairment, parent and teacher satisfaction with treatment, and student-teacher relationship.

3.0 Background

3.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

Response: *This proposal is submitted under goal 3 and it aims to evaluate "research that integrates the disciplines of special education and mental health with the goal of preventing school-based behavior problems and improving the academic outcomes for students with disabilities" (pp. 34; IES RFA Special Education Research Grants, Social and Behavioral Outcomes to Support Learning topic, FY2018). Specifically, this proposal will investigate the efficacy of an intervention to enhance the special education supports used for children with ADHD (i.e., the manner in which goals/objectives on the IEP are monitored and addressed; targeting of social/behavioral goals).*

The purpose of this proposed study is to provide evidence for the efficacy of using a daily report card intervention (DRC) as a means of linking the child with ADHD's IEP goals and objectives to his/her daily functioning in the classroom environment. A Goal 2 study was recently completed to develop and provide preliminary support for the DRC intervention for this purpose (Fabiano et al., 2010). The proposed investigation will be a multi-site study conducted in elementary schools throughout the Western New York and South Florida area. Participants will be 216 children (grades K-6), who have been diagnosed with ADHD and have an IEP (e.g., Specific Learning Disability, Emotionally Disturbed, Other Health Impaired).

In the proposed study, the efficacy of the DRC as an enhancement to children with ADHD's IEPs will be investigated in an experimental study. Children will be randomly assigned on the individual level to a condition where a behavioral consultant works with the child's teacher(s) to construct a DRC, implement it, and monitor it, or to an IEP only, school as usual (SAU) condition, where teachers will attempt to meet the IEP goals and objectives as they typically would. A DRC is an operationalized list of target behaviors (e.g., "completes reading assignments with 80% accuracy or better," "has no office time outs during the day") that are evaluated each day by the teacher. The DRC is used as a means of providing the child and parent feedback on progress on a daily basis, and it doubles as a mechanism teachers can use to track and monitor the

child's behavior and progress on key functional domains. The DRC can be easily linked to IEP goals and objectives, providing a bridge between the IEP and the child's daily functioning in the classroom. Parents will also be taught in parenting meetings how to reward their child at home for successful attainment of DRC goals and how to communicate effectively with their child's teacher.

Measures of key outcomes will include observations of behavior in the classroom conducted by observers naïve to group assignment or study hypotheses, academic performance outcomes, parent and teacher ratings of functioning, and IEP goal attainment. Primary measures of outcome will be analyzed using ANCOVA procedures. Secondary measures will include teacher ratings of ADHD and disruptive behavior/impairment. Additional analyses will investigate moderators (grade level, comorbid aggressive behavior, IEP quality). It is further hypothesized that classroom environment and fidelity of implementation at school/home will mediate outcomes (i.e., classroom climate, the fidelity of teacher monitoring/feedback regarding behavior, consistency of parent-implemented consequences at home).

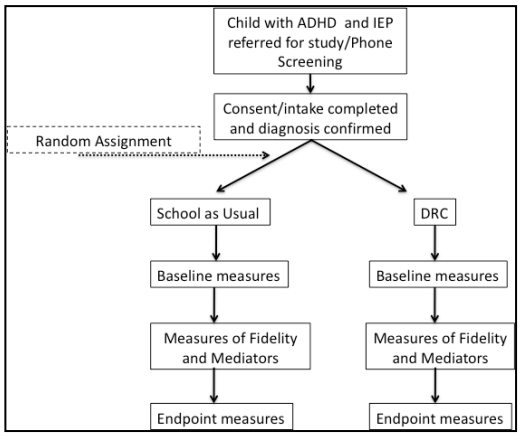
3.2 Include complete citations or references.

Response: Response: None included (see grant application for expanded background, preliminary studies, and references)

4.0 Study Design

4.1 Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).

Response: This project will use a randomized, between group design. The sequence of recruitment, randomization, and assessment is summarized in the Figure below. After informed consent and assent is obtained, and completion of the intake and review of inclusion and exclusionary criteria, the child will be randomly assigned to one of two groups. Participants will be randomly assigned to either (1) School as Usual (SAU) or (2) Daily Report Card (DRC), with 108 participants per group. The recruitment plan will aim for an equal number of subjects in the DRC and SAU groups, and participants will be



stratified within randomization across potential moderator variables including medication and grade level.

5.0 Local Number of Subjects

5.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response: The total sample will include 216 participants (108 at the Buffalo site and 108 at the Miami Site).

5.2 If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).

Response: We expect to screen three times as many subjects as are needed to meet recruitment goals. Our estimate is we will screen 700 participants in order to obtain the targeted sample size of 216.

5.3 Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response: Using the Common Core of Data (http://nces.ed.gov) information from the 2011-12 school year, the western New York district represents approximately 16,694 students in grades K-6 and the south Florida district includes approximately 186,467 students in these grades. Using the same database, it is estimated that 4174 students (Buffalo site) and 18,647 (Miami site) in these grades have IEPs. Given our pilot work (Fabiano, Naylor et al., 2009) and the work of Forness & Kavale (2002), it is further conservatively estimated that approximately 25% of these students in special education will have ADHD, yielding a total sample of 1,044 students in Buffalo and 4,662 students in Miami eligible to be screened for participation in each year. These estimates suggest for our study recruitment plan of enrolling 36 children per site, per year, we need to enroll 3% of children at the Buffalo site and 0.8% at the Miami site in the total pool of potential participants during each of the study years. These estimates indicate our recruitment plan is feasible.

6.0 Inclusion and Exclusion Criteria

*6.1 Describe the criteria that define who will be **included** in your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

Inclusion: *Include all presentations of ADHD.*

Inclusion: *Grades K-6*

Inclusion: *Current Individualized Education Program*

Inclusion: *Estimated IQ greater than or equal to 70*

6.2 Describe the criteria that define who will be ***excluded*** *from your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

Exclusion: *Presence of psychosis or severe developmental delays such as autism.*

Exclusion: *A child in foster care*

Exclusion: *Child is home-schooled or on home-instruction*

6.3 Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response:

☐ Adults unable to consent

☒ Individuals who are not yet adults (infants, children, teenagers)

☐ Pregnant women

☐ Prisoners

6.4 Indicate whether you will include non-English speaking individuals in your study. ***Provide justification if you will exclude non-English speaking individuals.***

In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may ***not*** *be routinely excluded from research as a matter of convenience.*

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

Response: The present study focuses on students in special education settings. Children who require additional school supports, including supports for English-language learning are not eligible due to the study aims. In addition, this study includes numerous norm-based questionnaires that are normed on English-speaking samples, and there are not routinely equivalent norm-referenced measures available for alternative languages.

7.0 Vulnerable Populations

If the research involves special populations that are considered vulnerable, ***describe the safeguards included to protect their rights and welfare.***

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

7.1 For research that involves ***pregnant women,*** *safeguards include:*
NOTE CHECKLIST: Pregnant Women (HRP-412)

Response:

☒ **N/A**: This research does not involve pregnant women.

7.2 For research that involves ***neonates of uncertain viability or non-viable neonates,*** *safeguards include:*
NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

Response:

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

7.3 For research that involves ***prisoners****, safeguards include:*
NOTE CHECKLIST: Prisoners (HRP-415)

Response:

☒ **N/A:** This research does not involve prisoners.

7.4 For research that involves ***persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")****, safeguards include:*
NOTE CHECKLIST: Children (HRP-416)

Response:

The project will safeguard the rights of children by requiring parenting permission for one legal guardian (similar to the approach utilized in school and pediatric settings) and will also assent children over the age of seven. Children seven and under will not be assented due to their developmental level and cognitive

capability making it unlikely they could reasonably provide informed assent to the procedures (See Attached Checklist HRP-416).

☐ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

*7.5 For research that involves **cognitively impaired adults**, safeguards include: NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)*

Response:

☒ **N/A:** This research does not involve cognitively impaired adults.

*7.6 Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. **Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response: N/A

8.0 Eligibility Screening

*8.1 Describe **screening procedures** for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).

Response:

Parents interested in participating in the study will contact the University at Buffalo investigators, and the family will be screened for study eligibility. This will be done over the phone or in person and initial eligibility criteria will be confirmed (e.g., child is in an eligible grade level). Families will then be invited to a meeting with the investigators where parents will be asked to enroll following an informed consent process.

☐ **N/A:** There is no screening as part of this protocol.

9.0 Recruitment Methods

☐ **N/A:** This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

9.1 Describe when, where, and how potential subjects will be recruited.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g.

searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).

Response: Multiple approaches will be utilized to recruit participants into this study. We will ask that our partner schools in Western New York distribute study recruitment flyers in their family resource centers, during parent/teacher conferences, to children referred to school-problem solving teams or school counselors, and in backpack mail folders sent home each week.

We will also utilize direct mailings to families in the Western New York area using every door direct mailers, marketing company lists, and targeted zip code mailings (specific flyers will be approved via amendment if different than already approved study flyers). We will also advertise on the radio and social media such as Facebook and Instagram (final form ad to be approved prior to air date).

Parents who receive mailers or view the advertisement on social media will have the option of calling a study number, or inputting their contact information in a web-based form that will be emailed directly to the study team.

Parents who provided prior verbal permission to send information via the Center for Children and Families mailing list will be mailed flyers as well.

We will also disseminate the IRB-approved flyer to local professionals, post in public places (e.g., libraries, coffee shops), and email/mail to professional lists.

For any parent who calls the study number, or who has requested to be added to a list for contact in the future about studies from the Center for Children and Families, the IRB-approved phone screen will be conducted to determine initial study eligibility.

9.2 Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

NOTE: Privacy refers to an individual's right to control access to him or herself.

Response: Recruitment materials will be general in nature, and they will require the participant to call the study line for more information rather than directly approach a subject (i.e., control of communication is in the hands of the potential participant rather than the researcher). Screenings will only collect identifiable information if the participant appears to meet eligibility criteria.

9.3 Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior

to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response: Please see attached telephone screening form, study information sheet, and recruitment flyer. Additional recruitment materials will be submitted for approval as appropriate.

10.0 Procedures Involved

*10.1 Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.

Response: *This project will use a randomized, between group design. The sequence of recruitment, randomization, and assessment is summarized in the Figure below. After informed consent and assent is obtained, and completion of the intake and review of inclusion and exclusionary criteria, the child will be randomly assigned to one of two groups. Participants will be randomly assigned to either (1) School as Usual (SAU) or (2) Daily Report Card (DRC), with 108 participants per group. Pre and post-test assessment occur in January and May of the academic year, respectively, resulting in approximately 16-20 weeks of treatment delivery.*

The recruitment plan will aim for an equal number of subjects in the DRC and SAU groups, and participants will be block randomized across potential moderator variables including medication and grade level. In the Goal 2 study, for which these variables were unselected, 52% of the final sample was prescribed medication and 66% were in grades K-3 and 34% were in grades 4-6. Thus, it appears that the plan to have an equal number of subjects in each block is feasible with careful attention to recruiting participants in the older grades in the present application. Block randomization based on child psychoactive medication status will promote equal distribution of participants across this variable. The medication variable will be defined as "no medication" if the child is not prescribed psychoactive medication immediately prior to randomization and as "taking medication" if the child is prescribed psychoactive medication and it is being actively administered at the time of randomization. In sum, an equal number of participants (N=72/year) will be enrolled in four blocks each year (i.e., No medication/Primary grade; No medication/ Intermediate grade; Taking medication/Primary grade; Taking medication/Intermediate grade). Random assignment will be conducted following the completion of all baseline measures by a blinded member of the study team (Dr. Yu). Following randomization, a form letter will be generated that informs the study staff and participating family of group

assignment. Consultants will then be randomly assigned to the case with an equal number of DRC and SAU cases assigned to each consultant.

For those students who are medicated with stimulant medication, we will ask parents to obtain permission from the child's doctor to withhold medication for the assessment days in January and May so as to collect information on the child's behavior when unmedicated.

Intervention Groups

DRC group. Students assigned to the DRC group will have a consultant assigned to the student for the duration of the school year. During the month of January, the consultant will work with the child's primary special education teacher (or regular education teacher if the child spends the majority of his or her day mainstreamed) to establish a DRC over the course of three consultation visits. The How to Establish a Daily Report Card manual contains a standard DRC instruction packet that is provided to teachers to explain the rationale of the DRC, procedures for creating, modifying, and evaluating the DRC, procedures for parents to create home-based rewards for DRC performance, and information on trouble-shooting. In addition, the packet contains consumable hand-outs that may be used to facilitate the meeting of these goals. This packet will be used as a starting point in all DRC consultations, and it was successfully modified, used, and evaluated in our Goal 2 project.

The first visit will be spent reviewing the IEP with the child's teacher(s) and conducting an interview to determine the behavioral procedures the teacher currently uses to manage child behavior as well as identify potential target behaviors not currently included on the IEP. At this meeting, target behaviors will be identified, operationally defined, and integrated into a DRC. The teacher will be asked to implement the intervention during the week between the first and second visit. At the second consultant visit, target behaviors will be refined, and using the data collected by the teacher, criteria for each target behavior will be modified (e.g., a child who averaged 10 verbally intrusive behaviors per class would have a target behavior changed to "Has 8 or fewer verbally intrusive behaviors"). The third consultant visit will be conducted to fine-tune and trouble-shoot the DRC and inform the teacher of the home rewards established by the parents. During this visit, the consultant will also establish a weekly time for the teacher to fax/call in a summary of DRC results for the week. DRCs will be implemented across settings and classes; however, a single teacher will be identified for assessment completion, observations will be conducted in that teacher's class, and this individual will be required to attend all consultant meetings.

The DRC will include direct accounting for IEP goals as well as other behavior problems common to a child with ADHD, and it is necessarily

idiosyncratic to address the heterogeneity that is typical in samples of children with ADHD. For example, a child with an IEP due to low achievement in reading, who also exhibits disruptive behaviors and noncompliance, might have targets established such as "Completes assigned reading tasks with 80% or better accuracy;" "Interrupts class discussion 4 or fewer times per class/interval;" and "Has 2 or fewer instances of noncompliance during the transition to lunch." A standard list of common DRC goals has been created and will be used to facilitate initial target behavior selection. These goals clearly overlap with the actual goals created as part of the development project (Fabiano et al., 2010). The DRC would be evaluated and completed by the teacher daily, and feedback will be provided to the child throughout the day on progress made toward DRC goals.

At the end of each day, the teacher will send the DRC home with the child so that the parent is provided feedback on a daily basis regarding the child's behavior at school. Parents will attend three individual parent training meetings to introduce them to the DRC also conducted in January in the child's school, and they will establish home-based rewards contingent on the child's DRC performance. For example, for a child with three DRC goals evaluated twice per day (i.e., before lunch and before dismissal), there are six possible "yes's." A given parent might remove computer access for this child previously provided non-contingently and only provide 10 minutes for each "yes" reported for the day (i.e., a child who earned all "yes's" on a particular day would be rewarded with 60 minutes of computer time). This binary approach of yes/no is easier to explain to the child, and permits the child to track his/her own progress across the day (i.e., number of yes's earned), relative to a continuous rating, which may be harder for the child to comprehend/quantify. In addition to the home-based contingency management based on school feedback, which makes the child accountable at home for school-based behavior, the DRC serves as a mechanism of daily communication between the parent and teacher. Given the variability in behavior expected with a child with ADHD, such daily communication is often crucial for preventing deterioration in functioning and presents the parent and teacher with multiple opportunities to problem-solve.

After the three initial meetings with the child's teacher, consultants will meet monthly with the teacher (and parent if available) to provide feedback on the child's behavior during the month using a graphical representation of the child's DRC performance. This information will be used for data-driven decision making, a procedure shown to be better than teacher impressions/ judgments when intervention planning/monitoring (Fuchs et al., 2000) and potentially critical for IEP monitoring. DRC goals will be adjusted as needed. It is expected that these monthly meetings will serve the purpose of ensuring IEP goals and objectives are consistently addressed on the DRC throughout the year.

SAU group. Consultants will conduct an initial meeting with each teacher of children in the SAU group to describe study procedures, establish regular classroom observation times, and obtain an updated copy of the child's IEP. All procedures will be implemented in the IEP as planned (e.g., counseling, school interventions). This condition is conceptualized as a school as usual control and serves as the counter-factual condition for the study.

To account for consultant contact with the teacher, consultants will meet with the teachers in the SAU group once per month. During these meetings they will collect information on how the child is functioning, and obtain information on any new, discontinued, or modified interventions (reward and/or punishment). The consultant will work with the teacher to construct a list of goals and criteria for meeting goals consistent with the approach used in the DRC group. This list of goals will not be used to develop DRCs or other classroom interventions but will be used by the observer to record teacher feedback to the child related to targeted behaviors. Our goal 2 study had teachers fill out an Individualized Target Behavior Checklist (ITBC; Pelham, Fabiano, & Massetti, 2005), which was constructed in the same manner as a DRC, but feedback on target behaviors was not provided to the child or parents and contingencies were not provided at school or home. Our Goal 2 study suggested that the ITBC had no appreciable effect on behavior (Fabiano et al., 2009, 2010) replicated by other studies (Pelham, Fabiano, et al., 2016).

In order to control for consultant effects, following random assignment to study group, each child will be randomly assigned a behavioral consultant in a counter-balanced fashion (i.e., therapists will be equally distributed across DRC and SAU groups to control for therapist effects), and will then work with the teacher for the school year. Consultants will be M.A. level school/clinical psychology specialists or special education teachers appointed to the project at each site. We have chosen to use individuals with these credentials to increase the external validity of the intervention as these individuals are likely to be called upon to consult with teachers regarding the behavior of children with ADHD as well as be involved in the assessment of children with ADHD and creation of IEPs in many school districts.

Our approach in this study will be to work directly with parents and teachers rather than through a formal IEP amendment process as we expect this to be consistent with the manner this intervention will eventually be used in practice, if found to be efficacious. We expect that similar to our Goal 2 project, districts will informally implement the DRC procedures through collaboration with the consultant. Should a district wish for a more formal approach, it is actually quite easy to amend the IEP through a parent and/or district request without convening an IEP meeting. As stated in the law [34 CFR 300.324(a)(6)], amendments to a child's IEP after the annual IEP meeting may be made by the entire IEP

team at an IEP meeting or by amending the IEP without another IEP meeting. Thus, "in making changes to a child's IEP after the annual IEP Team meeting for a school year, the parent of a child with a disability and the public agency may agree not to convene an IEP Team meeting for the purposes of making those changes, and instead may develop a written document to amend or modify the child's current IEP" [34 CFR 300.324(a)(4)(i)]. Thus, the proposed study procedures will be consistent with regulations mandated under P.L.108-446 (IDEA, 2004). Of note procedures were implemented with 100% of participants in a prior study across numerous districts without issue (Fabiano et al., 2010).

10.2 Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response:

Measures will be used that capture the domains of functioning important for children with ADHD classified as students in need of special education. Therefore, measures will span aspects of behavioral and academic functioning in the school setting and use multiple sources (child, observer, teacher, and parent). Below we describe measures of these relevant study outcomes as well as information on the reliability and validity of the selected measures. Although sometimes implemented in studies of ADHD treatment (AACAP, 2007), we elected not to require that students be taken off medication for the study duration for practical and ethical reasons; our block randomization approach for the medication variable addresses this issue.

Primary Measures of Behavioral Functioning.

Observations of Classroom behavior. Independent observations will be conducted using the Student-Behavior Teacher-Response observation system (SBTR; Pelham, Greiner, & Gnagy, 2008; Vujnovic, Fabiano et al., 2014). The SBTR is an observation code that collects information on: (1) the frequency of student rule violations; (2) whether a teacher observed the misbehavior; (3) if observed, the teacher consequence employed and whether it was an appropriate consequence. The SBTR system also records the number of praise statements and commands issued. The SBTR is a well-defined and validated observation system for use with children with ADHD in classroom settings. The SBTR system documents child functioning across a number of disruptive behavior categories (e.g., be respectful, obey adults, work quietly, stay on task), and it is consistent with an evidence-based assessment procedure for ADHD (Pelham, Fabiano, & Massetti, 2005). It represents the evolution in a well-established observational code, as it is a modified version of the behavioral observation code used in the analogue classroom studies noted above (Atkins, Pelham, & Licht, 1985, 1988, 1989; Fabiano et al., 2007; Pelham et al., 1993), as well as including the procedures used in the STP

classrooms to measure teacher fidelity to behavior management (Pelham, Fabiano, et al., 2005; Pelham & Hoza, 1996).

The SBTR has been successfully employed as a primary outcome in our Goal 2 project (Fabiano, Vujnovic et al., 2010; see preliminary study 2), along with two other IES-funded projects, one a between-group study of school-wide social and character development programs (Pelham, P.I., http://www.sacdprojects.net), and the other a study designed to investigate the best dose and sequencing of school-based treatments for children with ADHD (Pelham, P.I., R324B06045). The SBTR observation system has good inter-rater reliability – the mean difference between the observers on total rule violations recorded was 1.8 (SD=2.3; Range=0-12). For the total rule violations variable, the correlation between the two observers was .96 ($p < .001$), supporting the inter-rater reliability of the observation measure. The SBTR observation system also demonstrated moderate correlation with the DRC recorded by the teacher ($r = -.46$), suggesting the half-hour observation relates in the expected manner to the DRC completed over an entire school day (Fabiano, Vujnovic, et al., 2009).

The SBTR observations will occur on three separate days in the month of January (before intervention begins) and three separate days in the month of May for each child. Each observation will last for thirty minutes. Time of day and activity will be controlled. Observers will be blind to the child's treatment condition. To ensure the reliability of this measure, 20% of observations will be completed simultaneously with a second observer to allow the calculation of estimates of reliability. Please see the Table in the Treatment Integrity section below for how these observations are independent and distinct from the integrity observations.

Teacher ratings of behavior. Teachers will be administered the following measures during the first two weeks of the month of January and again in May. The following measures will be used as indicators of student outcomes as secondary measures to the primary observational measure.

Disruptive Behavior Disorders (DBD) Rating Scale. ADHD, ODD, and CD Diagnostic and Statistical Manual of Mental Disorders (DSM-IV; APA, 2000) symptoms will be measured using the DBD rating scale (Pelham, Gnagy et al., 1992). The DBD is a 45-item measure that asks parents to rate the DSM symptoms of ADHD, ODD, and CD on a 0-3 point Likert scale (i.e., Not at all, Just a little, Pretty Much, or Very Much). For this study, the average score for the DSM ADHD symptoms will be used as one outcome. The teacher DBD rating scale has good internal consistency (coefficient alpha = .91-.96). Across a number of studies the DBD has also shown sensitivity to behavioral treatment effects (Pelham, Fabiano, & Massetti, 2005).

Strengths and Difficulties Questionnaire (SDQ): In order to obtain information about the child's functioning across inattentive/hyperactive, emotional symptoms, peer problems, conduct problems, and prosocial

behavior, the SDQ will be administered at intake and during the pre-post assessments during the subsequent academic year. There is an SDQ for parents and teachers, and there is a version for 4-10 year olds and 11-17 year olds (all versions are attached in CLICK).

Domain-Specific Improvement Rating. At the endpoint assessment, teachers will complete impressions of improvement on each of the child's academic and socially related behaviors (Guy, 1976; Pelham et al., 2000). This measure will ask teachers to rate improvement on each goal/objective at the end of the school year on a seven-point Likert scale (Very much worse to Very much improved; the midpoint indicates No change). Thus, scores can range from 1.0-7.0. Scores will be averaged across items to provide an overall index of improvement at post-treatment. Ratings of improvement have long been used in numerous pharmacological and behavioral treatment studies. This scale has been shown to be sensitive to behavioral treatment effects in Summer Treatment Program classrooms (Pelham & Hoza, 1996; Pelham et al, 2000), parent training interventions (Fabiano, Chacko, et al., 2009), our Goal 2 Study (Fabiano, Vujnovic, Pelham, et al., 2010), and a randomized trial of a school-wide behavioral intervention (Pelham, Massetti, et al., 2007). The global improvement rating has demonstrated inter-rater reliability (e.g., Tolin et al., 2007; r = .81), and clinician-rated improvement scores correlate with parent reports of improvement for individualized target behaviors (Arnold et al., 2003).

Impairment Rating Scale (Evans, Allen, Moore, & Strauss, 2005; Fabiano et al., 2006). The IRS is a rating scale that asks teachers to rate the severity of the child's problems and need for treatment and/or special services in important functional domains (i.e., relationship with peers, relationship with the teacher(s), academic progress, classroom functioning, self-esteem, overall need). There are six items on the scale, and scores on the measure range from zero (Not a problem/Definitely does not need treatment or special services) to six (Extreme problem/Definitely needs treatment or special services). Test-retest reliability estimates range from .60-.89 over a period of six months, and .54 to .76 over one-year. Ratings on the IRS predict mental health or school services, and there is evidence of convergent and discriminant validity on the measure (Fabiano et al., 2006). The average score for each of the individual domains rated will be used in the analysis; scores range from 0.0-6.0.

Rating of IEP Goals (Fabiano, et al., 2010; Guy, 1976; Pelham & Hoza, 1996; Pelham et al., 2000). At each of the classroom observations, observers will be furnished with a copy of the child's DRC. In the case of the SAU group, an Individualized Target Behavior Checklist (ITBC) will be provided (Fabiano et al., 2010; Pelham et al., 2005). The observer will complete this DRC/ITBC each day following the whole-day observation. In addition, the observer will ask teachers in the DRC group for a copy of the day's DRC and ask teachers in the SAU group to complete the same

ITBC. Therefore, we will have the teacher ratings of IEP goal attainment over the three days at baseline and endpoint with built-in procedures to assess inter-rater reliability.

At the endpoint assessment, teachers will complete impressions of improvement on each of the child's academic and socially related IEP goals and objectives with those unrelated to social or academic outcomes, such as fine motor or speech goals, removed (Guy, 1976; Pelham et al., 2000). This measure will ask teachers to rate improvement on each goal/objective at the end of the school year on a seven-point Likert scale (Very much worse to Very much improved; the midpoint indicates No change). Thus, scores can range from 1.0-7.0. Scores will be averaged across items to provide an overall index of improvement at post-treatment. Ratings of improvement have long been used in numerous pharmacological and behavioral treatment studies. This scale has been shown to be sensitive to behavioral treatment effects in Summer Treatment Program classrooms (Pelham & Hoza, 1996; Pelham et al, 2000), parent training interventions (Fabiano, Chacko, et al., 2009), our Goal 2 Study (Fabiano, Vujnovic, et al., 2010), and a randomized trial of a school-wide behavioral intervention (Pelham, Massetti, et al., 2007). The global improvement rating has demonstrated inter-rater reliability (e.g., Tolin et al., 2007; r = .81), and clinician-rated improvement scores correlate with parent reports of improvement for individualized target behaviors (Arnold et al., 2003).

<u>Primary Measures of Academic Functioning.</u>

Academic Performance Rating Scale (APRS). The APRS is a 22-item measure that asks teachers to rate different aspects of a child's academic performance in the classroom (DuPaul, Rapport, & Perriello, 1991). The APRS (DuPaul et al., 1991) includes an Academic Productivity factor (7 items) that relates to work completion and accuracy, independent work, and following directions (coefficient alpha = .94; test-retest reliability over two weeks = .93), an Academic Success (12 items) factor related to the child's academic achievement, recall, and ability (coefficient alpha = .95; test-retest reliability over two weeks = .91).

The factors demonstrate predictive validity as children with ADHD were rated by teachers as significantly worse than students without ADHD and the measure correlated significantly with measures of academic achievement and academic efficiency, even with ADHD symptoms partialed out (DuPaul et al., 1991). Items are rated by teachers on a five-point Likert scale, and scores were summed for each of the two factors. Scores from 5-35 for the Academic Success factor ranged and from 5-60 for the Academic Productivity factor.

Secondary measure of distal academic achievement -- Wechsler Individual Achievement Test – III (Pearson, 2009). Participants will be administered the WIAT-III at the beginning and end of the study year to assess

academic achievement. This standardized, norm-referenced measure will take approximately 90 minutes to complete and has strong test-retest reliability (r > .90; Pearson, 2009) yielding composites of Total Reading, Basic Reading, Reading Comprehension and Fluency, Written Expression, Mathematics, and Math Fluency.

<u>Social Validity (i.e., whether outcomes are acceptable, relevant, and useful)</u>

Student-Teacher Relationship Scale (STRS; Birch & Ladd, 1998; Pianta, 1994, 1996, 1997; Pianta, Steinberg, & Rollins, 1995). To investigate differences in the student-teacher relationship, the STRS will be administered. The STRS a 28-item scale completed by the teacher. Teachers respond to items on a five point Likert scale ranging from 1 (Definitely does not apply) to 5 (Definitely applies). The STRS total score (coefficient alpha = .89; test-retest reliability over four weeks = .89) will be used as an index of the student-teacher relationship. The STRS also exhibits predictive validity (Pianta, 1996). Scores on the STRS range from 5-140.

Parent and Teacher Satisfaction. To obtain a measure of teacher and parent satisfaction with the intervention, and compare it to satisfaction in the SAU condition, raters will complete a measure of consumer satisfaction at the end of school. The measure used will be the satisfaction measure used with teachers and parents in the MTA study (Pelham et al., under review). The measure may be divided into three factors: treatment satisfaction, perceived improvement, and demands of treatment. The internal consistency of the items on the parent factor were acceptable for the treatment satisfaction (coefficient alpha = .87), perceived improvement (coefficient alpha = .72), and demands of treatment (coefficient alpha = .84). On the parent version, test-retest correlations ranged from .42 to .62, representative of this type of measure.

Moderators

Grade. The grade of the children in the study will be used as a proxy for age. Students will be grouped as K-3 (primary) and 4-6 (secondary) for moderator analyses. The grade level moderator is important to investigate given clear evidence that effective behavior modification procedures decrease incrementally as children move up in grade (Brophy, 1986; Fabiano et al., 2002; White, 1975) and that more teachers are typically involved in working with the student at the intermediate/middle school level relative to the primary grade level.

Comorbidity. To investigate outcomes for disruptive behavior, the scores for ratings on ODD/CD symptoms will be used to identify the presence of comorbid Oppositional Defiant Disorder or Conduct Disorder. In the

Goal 2 study sample, the coefficient alpha for disruptive behavior disorder items from the DBD scale was .96. Comorbid disruptive behaviors were significantly improved in the Goal 2 study (Fabiano et al., 2010), making this a reasonable candidate for moderational analyses.

IEP Quality. IEP quality will be assessed using a composite rating by study investigators. Prior to quality ratings, IEPs will be de-identified to remove the participant name and information as well as any information about the school or district. Ratings will evaluate the alignment between needs listed in the IEP with goals/objectives stated in the IEP. This will be one way to determine the quality of the IEP document itself – well-written IEPs should have IEPs with close alignment between academic, behavior, and social/emotional needs and the goals to realize improvement (see appendix C for an outline of the coding sheet to be used in the present study; Pariseau, 2011). We will also track which goals are added by consultants to the DRC that were noted as needs by the teacher, but not listed on the IEP. The occurrence of these issues may indicate that the IEP is outdated, poorly constructed, or not reflective of current behavior. These indicators will comprise an IEP quality score investigated as a moderator. Specifically, the score will be calculated as: (Alignment between needs and goals + additional targets added)/overall alignment). A score of 1 would indicate perfect alignment whereas a score below 1 would indicate discrepancy between needs and goals.

Mediators

Three key components of the DRC intervention that are central to our logic model (see figure in the introduction) will be investigated as mediators of treatment outcome. It is expected that relative to the SAU group, the children in the DRC condition will experience a more positive classroom environment, receive more consistent feedback from teachers, and experience more consistent home-based consequences for school behavior. These three variables will each have a partial mediating effect, and the sum total will fully mediate the effect on treatment outcome.

Positive Student-Teacher Interactions. The ratio of positive to negative statements issued by the teacher on the SBTR observational measure will be used as an indicator of student-teacher interactions, with classrooms that have a positive environment having a larger number (i.e., more positives than negatives) relative to those that have a negative environment (i.e., fewer positives than negatives). Prior studies have demonstrated this information can be reliably collected (Vujnovic, et al., 2014). Further, these rates of positive to negative statements can be reliably modified based on background behavioral interventions such as the DRC (Fabiano et al., 2007). This measure will be collected across SAU and DRC groups.

Teacher Feedback for Targeted Behaviors. Observers in the DRC and SAU groups will have a list of the child's DRC/ITBC targets for each of their classroom observations. Observers will record the frequency of targeted behaviors exhibited as well as the number of targeted behaviors that receive appropriate feedback from the teacher. Observers will be blind to treatment condition. This approach to recording targeted behaviors and denoting which were responded to appropriately is part of the SBTR observation system developed by our group and used successfully in a number of school settings (Fabiano et al., 2010; Pelham et al., 2007; Vujnovic, Fabiano, et al., 2014). In this case we will modify the rule violations typically observed to be the individual child's targeted behaviors. The SBTR observation system has good inter-rater reliability: in one study the mean difference between the observers on total number of challenging behaviors was .53 (SD=3.3; Range=0-12). In an early childhood setting, agreement on the appropriate acknowledgement of challenging behavior was .68 ($p<.05$). For the total challenging behaviors variable, the correlation between the two observers was .94 ($p < .001$; Fabiano et al., 2010), supporting the inter-rater reliability of the observation measure. As a measure of validity, classroom challenging behaviors were negatively correlated with class climate r=-.45 (Massetti et al., 2007). The proportion of DRC/ITBC behaviors that were exhibited by the child that received feedback from the teacher will be used as an indicator of teacher monitoring and feedback of IEP goals.

Parent-Implemented Contingency Management. Families will be contacted in the morning and will be asked what contingencies were administered in the home the prior evening based on school behavior. For the SAU group, it is expected that the answer for most contacts will be none, unless the parent/school have arranged some contingency management program. For the DRC group, it is expected that the parent will report contingencies administered within the bounds of the DRC reward program. The number of days contingent rewards were accurately provided will be considered as a mediating variable. The collection of home reward related data suggested predictive validity in a recent meta-analysis (Vannest et al., 2010) and in our Goal 2 project. In the Goal 2 project, the percent of DRCs rewarded appropriately was negatively related to frequency of disruptive behavior at the end of the school year ($r= -.53$, $p=.002$; Fabiano et al., 2010). It is expected that the repeated morning phone calls will result in increased reliability for this measure. Teachers will also ask the child the next morning what reward was received and record this for the investigators. Teacher collected data should be less susceptible to reactivity for this variable than information provided by the parent.

Treatment Integrity and Fidelity of the Intervention as Implemented

Multiple methods will be used to document treatment integrity and fidelity. To record the integrity and fidelity (Cordray & Pion, 2006; Gresham, 1989; Lane, Beebe-Frankenberger, Lambros, & Pierson, 2001; Waltz, Addis, Koerner, & Jacobson, 1993) with which the DRC intervention is implemented, multiple procedures will be used that have been previously developed (Pelham, Greiner, & Gnagy, 1998; Pelham et al., 2000). Treatment fidelity will be defined as the skill, care, and genuineness with which the intervention is implemented, and integrity will refer to the degree to which the intervention was implemented as intended.

Fidelity of Teacher Implemented Interventions. Observers will collect information each month (January to May) on teacher responses to student behavior and general classroom management techniques. These observations will include a recording of frequency counts of social reinforcement (e.g., praise statements) as well as commands and negative feedback (i.e., reprimands) directed toward the individual student across the entire school day. These frequency counts will be combined into a ratio of positive to negative statements and used as an indicator of classroom environment. After each observation, observers will also complete a post-observation inventory form. These forms will ask the observer to rate the teacher's use of social reinforcement, commands, tone of voice, and the overall classroom climate on a 7-point Likert scale. An example of this rating to be completed after the observation is in Appendix C.

Integrity of DRC/Targeted Behavior Feedback. Once per month, observers blind to treatment group assignment will spend a full school day in the child's classroom. The observer will be provided a copy of the child's DRC/ITBC and will record a frequency count of the occurrence of each targeted behavior. In addition, targeted behaviors for which the child received specific feedback from the teacher (i.e., were acknowledged; recorded on the DRC/tracking mechanism if appropriate) will also be recorded. This will yield a daily rate of target behavior occurrence, as well as the proportion of targeted behaviors that received appropriate feedback. Observers will also record the latency between the occurrence of a targeted behavior and teacher feedback regarding the behavior using a stop-watch (a decision rule of latency greater than 1 minute will be used to document "no response" to a target behavior).

For children in the DRC group, we will be able to obtain a sample of the proportion of DRC targets appropriately monitored by the teacher with feedback provided. The observer's completed DRC tracking sheet will also be compared to the DRC completed by the teacher to ascertain a sample of the accuracy of the report sent home to the parent each afternoon. This comparison will be made by the investigators/project coordinator to maintain observer blinds.

Integrity of Home Rewards for School Performance. Following each of the all-day school observations (i.e., monthly), SAU/DRC families will be

called/texted the next morning and the child and parent will be asked what contingencies were administered based on school behavior. In addition, teachers will be asked in the SAU and DRC groups about the provision of any school-based rewards. SAU parents will also be asked whether they received any feedback from the teacher regarding the child's behavior in school that day and in what form (email, DRC, etc.).

Observations for Primary Outcome	Month	Observations for Integrity/Fidelity
SBTR Completed by Observer Blind to Condition (3 total)	January	Integrity/Fidelity Observation(1 total)
N/A	February	Integrity/Fidelity Observation(1 total)
N/A	March	Integrity/Fidelity Observation(1 total)
N/A	April	Integrity/Fidelity Observation(1 total)
SBTR Completed by Observer Blind to Condition (3 total)	May	Integrity/Fidelity Observation(1 total)

In addition, for participants in the DRC group, parents will be asked each day to sign the DRC and record the reward administered, if any. Then, they will return the DRC to the teacher the next morning. This will help promote home-school communication, and was a procedure used successfully in the Goal 2 project. It is hypothesized that the phone calls to query reward administration will replicate and extend these preliminary findings. Such phone calls have been successfully implemented by our lab on other funded projects (e.g., Fabiano, et al., 2012; NIMH # R34MH078051). The interface between observations of primary outcome and observations of integrity/fidelity during the course of the study is illustrated above. Finally, parents/teachers in both groups will complete a checklist at post-treatment reporting how often they used the components of the DRC intervention (i.e., provided home reward; daily feedback).

10.3 List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).

Include copies of these documents with your submission.

Response: See description in 10.2 above. In addition, a table of measures and administration schedule is included with the submission.

10.4 Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).

Response: N/A

*10.5 Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe how these will be shared.*

Response: All subjects will have a diagnostic report generated following the intake/screening procedures sent to them for their clinical records. The report will be sent directly to the parents of the participant so that the parents can decide with whom to share it, if anyone.

*10.6 Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response: At the end of the school year, all subjects will have a treatment summary report generated following the school year sent to them for their clinical records. The report will be sent directly to the parents of the participant so that the parents can decide with whom to share it, if anyone.

11.0 Study Timelines

11.1 Describe the anticipated duration needed to enroll all study subjects.

Response: Participants will be enrolled fall of each year.

11.2 Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response: Participants will be invited to a 3-hour intake visit to have study eligibility and screening procedures completed. Participants will enroll in the study for the entire school year as random assignment and assessment/study procedures will be implemented starting in January and continued until May.

11.3 Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).

Response: All data and analyses should be completed for this study by summer 2022.

12.0 Setting

12.1 Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."

Response: University at Buffalo Site. Research activities will be conducted within the context of the Center for Children and Families (CCF) at the University at Buffalo (SUNY). The CCF is an interdisciplinary center that focuses on a tripartite mission of education, research, and service. The CCF is a research, clinical, and training facility and its goals are to advance knowledge of mental health and learning problems. It is a 12,000 square foot clinical research facility that consists of two children's classrooms (with observational windows), five clinical rooms (with observational windows), waiting rooms, a journal library, copy room, and offices. All offices are equipped with telephones and networked computers. A large number of current statistical software packages are available to researchers, and statistical consultation is available. Also, all the required assessment materials are housed in the CCF. CCF staff includes Ph.D. level faculty, graduate trainees in clinical psychology and school psychology, full-time research staff, and undergraduate trainees. Faculty from numerous departments and schools across the university are affiliated with the CCF. Located in Buffalo, the CCF is close to local schools.

12.2 For research conducted outside of UB and its affiliates, describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.

Response: A considerable amount of research activities will occur within classrooms in local school districts. Prior to engaging in any research activities within classrooms, the principal investigator will obtain a Permission to Conduct Research in Schools form from a leader in the school and/or district. These permission forms will be kept on file and submitted to the IRB during annual reviews or amendment requests.

☐ **N/A:** This study is not conducted outside of UB or its affiliates.

13.0 Community-Based Participatory Research

13.1 Describe involvement of the community in the design and conduct of the research.

NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Response:

☒ **N/A:** This study does not utilize CBPR.

13.2 Describe the composition and involvement of a community advisory board.

Response:

☒ **N/A:** This study does not have a community advisory board.

14.0 Resources and Qualifications

*14.1 Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.

Response: *Gregory A. Fabiano, Ph.D., Principal Investigator. Dr. Fabiano is Professor in the Department of Counseling, School, and Educational Psychology at the University at Buffalo, SUNY. Academic year (9 mos) salary support is requested at 20% and 20% summer salary support is requested in Years 1-4. His expertise is in the area of school-based behavioral treatments for children with ADHD, and he was principal investigator on the Goal 2 project that investigated how DRCs could be used to enhance IEP implementation as well as a Co-Investigator on the prior Adaptive Treatment study (Preliminary Study 6). Dr. Fabiano has extensive experience with classroom-based behavioral interventions in both analogue and regular school settings as well as in the measurement of classroom-based teacher and student outcomes (i.e., he was co-I on two IES Goal 5 studies). Dr. Fabiano will serve as principal investigator for this project at the Buffalo site, and he will be responsible for all research and project implementation. At the Buffalo site, he will oversee recruitment of participants, coordinate assessments, and provide supervision of research staff. During the final year of the project, he will*

participate in analyzing and interpreting the results and in writing reports and publications.

Describe other resources available to conduct the research.

14.2 Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

Response: Dr. Fabiano's time is budgeted *Academic year (9 mos) salary support is requested at 22% and 25% summer salary support is requested in Years 1-4.*

14.3 Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.

Response: Study PI (Dr. Fabiano) will be available on-call for participants throughout the study via cell-phone.

14.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response: All study staff will complete CITI training, complete UB's training for working with children and have a background check completed to ensure the appropriateness for working with children.

15.0 Other Approvals

15.1 Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).

Response: Any participating school district will complete the Permission to Complete Research in Schools form prior to any classroom visits or research conducted in the school.

☐ **N/A:** This study does not require any other approvals.

16.0 Provisions to Protect the Privacy Interests of Subjects

16.1 Describe how you will protect subjects' privacy interests during the course of this research.

NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response: During all interactions with parents, only first names will be used, not last names. When meeting with teachers, we will not tell office staff about the specific nature of our visit. All intake and follow-up appointments will occur in private, secure offices at the University at Buffalo or at private locations at the schools. Any correspondence to participant families or teachers will be mailed in sealed envelopes.

16.2 Indicate how the research team is permitted to access any sources of information about the subjects.

NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question ***does apply*** *to records reviews.*

Response: Only graduate students, direct study staff, and the principal investigator will have access to those rooms and cabinets where the data will be stored. Undergraduate research assistants will have access to the data initially for entry into a computerized database, but this will all be monitored and controlled by the graduate students, direct study staff, or principal investigator. School related data (e.g., teacher rating scales) will be obtained from the school via a Release of Information Authorization signed by the parent.

17.0 Data Management and Analysis

17.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Response: *To ensure appropriate manipulation of the independent variable the treatment integrity data described above will be collected and analyzed. The distributional characteristics of all dependent variables will be examined. If outcomes are appreciably non-normal, we will consider power transformations where appropriate. Although we expect that our cross-site and cross-cohort training efforts will mitigate the possibility of any site, cohort, or consultant differences, we will still conduct sensitivity analyses that evaluate treatment effects separately by cohort, site, and*

consultant. As the study is powered for efficacy analyses and we do not anticipate being powered to detect cohort/site/consultant effects, these analyses will emphasize effect size comparisons. To the extent that any differences are revealed, we will improve cross-site and cross-cohort training and fidelity observations, as well as to consider the inclusion of site, cohort, or consultant as additional covariates. Benjamini-Hochberg adjustments will be used throughout in order to control for the false discovery rate associated with multiple comparisons across outcomes (Benjamini & Hochberg, 1995). This strategy is implemented in SAS® using PROC MULTEST. Multiple imputation methods will be used to accommodate missing data (Allison, 2002). This strategy is implemented in SAS® using PROC MI and MIANALYZE.

Aim 1. Investigate the effectiveness of using a DRC to link the child with ADHD's IEP to daily classroom behavior.

Aim 1 will be evaluated using Analysis of Covariance (ANCOVA) models of the following form

$$y_{post} = \gamma_1 pretest + \gamma_2 DRC + \sum_{j=1}^{5} \gamma_j covariates + e_i$$

Specifically, each outcome score will be regressed on the corresponding pre-test score, a treatment indicator, and four covariates (medication status, grade level, comorbid DBD, and child gender)—the first three of which will be evaluated as potential moderators of treatment in Aim 2. Although the pretest score can be conceived as simply another covariate, it is distinguished here to emphasize the point that its inclusion results in improved statistical power relative to a repeated measures approach for evaluating treatment efficacy (Van Breukelen, 2006). Group differences on adjusted post-test scores (i.e., the significance test of γ_2) will inform the efficacy of using the DRC to enhance academic performance and behavioral outcomes beyond that associated with the routine use of IEP. Measures of primary outcome will be observations of classroom behavior and teacher ratings of academic performance. Measures of secondary outcome will include teacher ratings of symptoms and impairment related to ADHD.

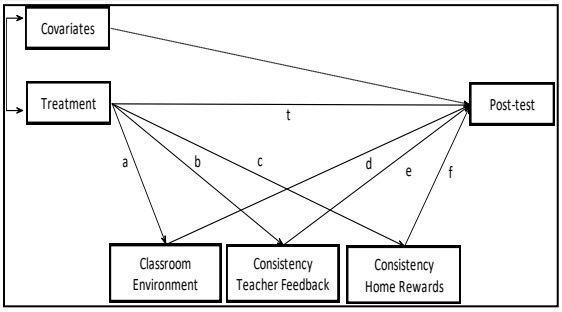
Aim 2. Investigate moderators of treatment outcome.

Aim 2 will be evaluated by extending the ANCOVA model from Aim 1 as follows

$$y_{post} = \gamma_1 pretest + \gamma_2 DRC + \sum_{j=1}^{2} \gamma_j covs + \sum_{k=1}^{3} \gamma_k moderator + \gamma_k moderator * DRC + e_i$$

Specifically, Aim 2 will extend the models estimated from Aim 1 by including three additional terms (i.e., the product of each of the three moderators—age group, comorbid DBD, IEP Quality–with the indicator of treatment). Tests of each of these three terms (i.e., $\gamma_{k1}, \gamma_{k2}, \gamma_{k3}$) will inform Aim 2. Each DRC X moderator term that is statistically significant will be probed using simple main effects (i.e., comparisons between DRC and SAU outcomes within each level of the moderator variable) in order to delineate the differential magnitude of treatment on adjusted post-test scores as a function of a given covariate (i.e., primary vs. secondary grade; ADHD only vs. ADHD+DBD; High Quality vs. Low Quality IEP).

Aim 3. Investigate mediators of treatment outcome. *Aim 3 will be evaluated using a path analytic approach for testing mediation. The path model will extend the ANCOVA models above by simultaneously estimating equations for both the post-test score and mediators. Specifically, a path model will be estimated in which post-test scores are regressed on a dichotomous indicator of treatment, covariates described above (including pre-test scores and moderators), and on three mediators, measured as aggregate variables across the treatment period, including the quality of the classroom environment (ratio of positive to negative comments direct to the target child), consistency of teacher feedback in the classroom and home-based consequences related to school behavior. Moreover, the mediators will be simultaneously regressed on the indicator of treatment. A prototypic model is depicted below. The dashed line from covariates to post-test indicates that this actually refers to a block of variables that are omitted for presentation purposes A formal evaluation of mediation comes from tests of whether the product of the coefficients relating treatment to mediators and mediators to outcomes (i.e., the indirect effects) differs from 0 (Bollen, 1987; MacKinnon, 2008). Whereas the joint test of the set of product terms (i.e., a*d = b*e = c*f = 0) provides an omnibus test of mediation, individual tests of products (i.e., a*d = 0; b*e = 0; c*f = 0) informs the contribution of each specific mediator. When combined with information regarding tests of indirect effects, the statistical significance*



of the direct effect of treatment on post-test scores informs whether partial (i.e., if the path 't' is statistically significant) or complete (i.e., if the path 't' in the figure is not statistically significant) mediation is present. All tests of mediation will be based on the use of bootstrapped standard errors, which results in better statistical power and avoids having to make potentially unrealistic distributional assumptions about the mediated effect (MacKinnon et al., 2004; Preacher & Hayes, 2008). All mediated effects will be tested using Mplus software which includes facilities for testing individual and compound sets of mediated effects, as well as the use of bootstrapped standard errors (Muthén & Muthén, 2006).

17.2 If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

Response: *We relied on our previous (N = 63), randomized study contrasting DRC and SAU conditions in order to compute effect sizes for the proposed study (see Preliminary Study 2). Results from that study indicated an effect size of approximately Cohen d = .50 (or larger) across the majority of outcomes considered. The weighted random effects effect size of between groups studies for ADHD such as this one was .74; thus we are using a conservative effect size relative to the larger literature (Fabiano et al., 2009). We also assumed that covariates (most prominently the pre-test score) would explain at least 45% of the observed variation in post-test scores (in the Goal 2 study using comparable covariates 47% of the variance for post-test scores for objective observations and teacher ratings of ADHD was explained by pre-test scores).*

Given these assumptions, Aim 1 will have power of .80 to detect effects of Cohen d = .50 with N = 71 participants. In order to estimate power for Aim 2, we assumed treatment effects of Cohen d = .4 and .6 within moderator groups (e.g., the treatment effect would be Cohen d = .4 in intermediate grades compared to Cohen d = .6 in primary grades), which, given the sampling plan that balances participants across levels of dichotomous moderators, is consistent with the marginal treatment effect of Cohen d = .50 used for Aim 1. In order to detect treatment effects as small as Cohen d = .40 (given R^2 = .45, as per Aim 1) with power of .80, N = 105 participants are necessary. Hence, the total sample size needed to power Aim 2 at .80 is adequate at N = 216 (i.e., 108 participants X 2 levels of moderator). Based on recent work by Fritz and MacKinnon (2007), the proposed total sample size of 216 will provide power of greater than .80 to detect moderate sized indirect (mediated) effects (there is no standard metric for reporting effect sizes for indirect effects). We

conclude that N=216 participants results in power of .80 or greater to address all three motivating aims. The use of modern methods for dealing with missing data (Multiple Imputation for Aims 1 and 2, Full Information Maximum Likelihood estimation for Aim 3) ensure that all N = 216 participants will contribute to each analysis.

17.3 Describe any procedures that will be used for quality control of collected data.

Response:

Treatment Integrity and Fidelity of the Consultant Activities

Consultants will partner with teachers/parents to develop DRCs based on the IEP of the participating student. Procedures for establishing DRCs are manualized (see Appendix D) and all visits with teachers and parents have a checklist that is to be completed by the consultant to ensure all procedures were implemented (see Appendix C). Further, to ensure that the consultant checklists are being completed appropriately, we will have consultants audio-record all consultant meetings, and 20% of each consultant's recordings will be evaluated for integrity to the checklists (all meetings will be recorded to prevent reactivity or positive presentation solely during selected recorded sessions). In prior work we were able to obtain permission from 100% of teachers to audiotape comparable meetings (N=89; Fabiano, Reddy, et al., 2017). To obtain information on the fidelity of consultants we will ask parents and teachers to complete an evaluation of the consultant following the final assessment through submission of a sealed envelope to a staff member uninvolved with the case to prevent reactivity. Adherence will be measured by contact logs and the collection of behavioral products (e.g., completed DRCs).

18.0 Confidentiality

A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*

*18.1 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) **and** electronic files.*

Response: All data will be immediately deidentified and stored on a secure, password protected server at the University of Buffalo. All deidentified measures will be stored in locked filling cabinets at each respective site. Data will be entered electronically into the Research Electronic Data Capture system (REDCap; project-redcap.org), a secure web application engineered for data collection purposes, or into data files on secure UB servers.

18.2 A. How long will the data be stored?

Response: The data will be kept on file for approximately 3 years following any professional publication according to the American Psychological Association guidelines. Deidentified, anonymous data will be kept in a database indefinitely.

18.3 A. Who will have access to the data?

Response: Only trained study personnel and staff will have access to the data.

18.4 A. Who is responsible for receipt or transmission of the data?

Response: Data that are collected from participants will be immediately stored electronically via REDCap, entered into data files on secure UB servers, or immediately placed into locked filing cabinets at the University at Buffalo. Only deidentified data will be available through the REDCap system. No other transmission or receipt of data will be necessary.

18.5 A. How will the data be transported?

Response: Not applicable. Recordings or study measures completed at either the University at Buffalo will stay at their respective site. Only deidentified data will be available through the REDCap system.

B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of **study specimens**.*

☒ **N/A:** No specimens will be collected or analyzed in this research. *(Skip to Section 19.0)*

18.6 B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.

Response:

18.7 B. How long will the specimens be stored?

Response:

18.8 B. Who will have access to the specimens?

Response:

18.9 B. Who is responsible for receipt or transmission of the specimens?

Response:

18.10 B. How will the specimens be transported?

Response:

19.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

19.1 Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Response: *The principal investigator will oversee and be responsible for monitoring the safety and efficacy of the trial. An annual report will be sent to NIMH outlining recruitment of participants and their demographic characteristics and how these compare to expected recruitment rates, retention rates in the project, summaries of any adverse events, and any actions taken with respect to the protocol. The study will be approved by the University at Buffalo and Florida International University Institutional Review Boards.*

All data collected will be coded with study numbers (computer-generated data, videotapes, and paper ratings) and the sheet linking study code numbers to individuals will be keep in a locked filing cabinet inside a locked room. All data entered into computer databases will use study numbers to protect the confidentiality of the participants. Data entry will be checked by an individual other than whomever entered the data, and errors will be corrected and discrepancies corrected by a supervisor

based on the original source documents. Data will be entered and screened for accuracy immediately after it is obtained, and preliminary blind analyses will be conducted immediately after each funded year to determine whether the results indicate an overwhelming treatment effect that suggests the study should be stopped, or suggests any potential unforeseen adverse effect of the behavioral parent training programs. All source documents and recordings will be kept in locked filing cabinets inside a locked room.

Experimental integrity will be ensured by the creation of program manuals, checklists and materials to ensure consistent implementation of planned manipulation components. In addition, all sessions will be video-recorded so that the principal investigator can review implementation and provide feedback as necessary. Data will be collected by research assistants who have completed the Biomedical Sciences CITI course on research ethics, and who are trained by the study investigators in the research procedures.

The safety of all participants in these proposed studies is paramount. After the initial intake interview, records will be reviewed by the principal investigator to determine the participant's eligibility for the study. Careful attention will be directed toward any potential reports of child abuse or neglect or reports of suicidal ideation or behavior on the part of the parent or child. Should child abuse or neglect be suspected, the parent will be notified that a mandated report is being made to the state child abuse hotline. Any additional actions that might be necessary to ensure the child's immediate safety will occur. Similarly, if a parent reports suicidal ideation, intent, or behavior on the part of the child or parent, the participant will not be enrolled in the study, but instead directed to mental health or psychiatric treatment, and if interested can enroll in the project once their behavior has stabilized.

19.2 Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response: See response to 19.1

19.3 Describe any safety endpoints.

Response: Safety endpoints will be the collection of endpoint data in May

19.4 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response: See response to 19.1

19.5 Describe the frequency of safety data collection.

Response: Data will be collected at intake, in January, and in May. Spontaneous reports will also be collected, documented and reviewed by the PI and the team at least weekly.

19.6 Describe who will review the safety data.

Response: Final review will be conducted by Dr. Fabiano

19.7 Describe the frequency or periodicity of review of cumulative safety data.

Response: At least weekly or more often if needed.

19.8 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response: Each year, preliminary analyses will be conducted to ensure there is no untoward effect of the DRC intervention.

19.9 Describe any conditions that trigger an immediate suspension of the research.

Response: Documentation of a significant untoward effect of the DRC.

20.0 Withdrawal of Subjects

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

*20.1 Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response: Subjects may be withdrawn due to failure to comply with study protocol, or pursuing of treatments incompatible with study procedures (e.g., home instruction).

20.2 Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response: At the end of the school year, all participants will be invited to an exit interview, complete ratings of effectiveness and satisfaction, and review study outcomes with the investigators. Recommendations for continued treatment will be provided.

20.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response: If participants withdraw from the research, any data collected up until that point will be retained. If a participant withdraws from a particular part of the protocol (e.g., declines school intervention) other procedures and assessments will continue, if the participant agrees to continued participation in other aspects of the study.

21.0 Risks to Subjects

21.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response: ***Risk:*** *Participants may experience mild and transitory psychological discomfort from completing research measures, including reporting on child emotional and behavior problems and academic difficulties.* ***Procedure:*** *Participants and their parents will be advised to ask questions of study personnel if confidentiality is of a concern, and to refrain from answering questions that cause them person distress.*

Risk: *Participants may face risk as they may experience mild and transitory psychological discomfort from changing their behaviors as part of the study interventions.* ***Procedure:*** *The centers at FIU and at UB are quite experienced at running psychosocial intervention for youth with ADHD in school and with parents. We experience very low attrition rates (under 5% from our clinical and research programs. None the less, children and parents can refuse to continue to participate in the study at any time.*

Risk: *Teachers may find the additional consultation and implementation of new strategies to be burdensome.* ***Procedure:*** *We are quite experienced in teacher consultation both in IES- and NIH-funded studies and in nonresearch work in the Buffalo and Miami-Dade schools. Our groups are well known to teaching staff, given that we provide regular inservice instruction and consultation to the districts, and we have excellent rapport with principals, teachers, psychologists/social workers, and administrators. We have had very low rates of teacher refusal to participate in the studies, and we anticipate that to continue for*

this project. Indeed, the vast majority of teachers find the consultations to be helpful in coordinating school-based supports for their students with ADHD. We will work with teachers to schedule consultations at times teachers identify as most convenient. Furthermore, consultations are intended to be collaborative and teachers' input is encouraged.. Efforts will be made to collaborate with and reengage teachers who refuse to contribute to any specific intervention or study activity.

Risk: *Randomization to the treatment arms.* ***Procedure:*** *This risk will be addressed through the informed consent/assent process, where parents and children will agree to be assigned to treatment groups. Parents and children are free to withdraw from the study at any time and are not obligated to participate in the treatment group to which they are assigned. Withdrawing from this study will not affect any future interactions or their participation any future clinical services or studies at the FIU or the UB centers.*

Risk: *Participants may experience a worsening of ADHD if ADHD medication is withheld for the study assessments.* ***Procedure:*** *Only those participants who obtain permission from the prescribing physician will have medication withheld. This is a procedure common in studies of ADHD treatment (Fabiano et al., 2010; Pelham, Wheeler, & Chronis, 1998).*

21.2 Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Response: See 21.1

21.3 If applicable, indicate ***which procedures*** *may have risks to the subjects that are currently unforeseeable.*

Response: There are no procedures included for which there are unforeseeable risks.

21.4 If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response: N/A

21.5 If applicable, describe risks to others who are not subjects.

Response: N/A

22.0 Potential Benefits to Subjects

22.1 Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

*NOTE: Compensation **cannot** be stated as a benefit.*

Response: All participants in the study will have monitoring of school-based treatments, which may help inform future treatment efforts and decisions. Participants in the DRC condition will have evidence-based interventions for ADHD (i.e., behavior therapy) delivered which may directly benefit the functioning of the participants in schools.

23.0 Compensation for Research-Related Injury

☒ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

*23.1 **If the research procedures carry a risk of research related injury,** describe the available compensation to subjects in the event that such injury should occur.*

Response:

23.2 Provide a copy of contract language, if any, relevant to compensation for research related injury.

*NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with **different language regarding research related injury**, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response:

24.0 Economic Burden to Subjects

24.1 Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

Response: Participants are responsible for providing transportation to study meetings and follow-up visits or a home visit will be arranged if preferred.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

25.0 Compensation for Participation

25.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Response: Parents and teachers will receive a $45 gift card for completing ratings at the January Baseline Assessment as well as the June endpoint assessment.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

☐ **N/A:** There is no compensation for participation. This section does not apply.

26.0 Consent Process

26.1 Indicate whether you will be obtaining consent.

NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 27.0.

☐ ***Yes*** *(If yes, Provide responses to each question in this Section)*
☐ ***No*** *(If no, Skip to Section 27.0)*

26.2 Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Response: Adult consent, child assent and parental permission will be obtained during initial intake and eligibility meetings at the University at Buffalo and Florida International University.

As we have done for other IRB-approved studies, teachers will be provided with an Information Sheet (described further below) with a packet of ratings by the consented parents of the assenting child following the parent and child's initial intake and eligibility meeting.

As teachers are asked to complete rating forms based on their observations of the child and implement the study interventions only, written consent to participate will not be obtained. This is because the child is the participant in this study, and the teacher is simply a reporter of the child's behavior and implements positive behavioral supports, which are a standard part of educational practice for students with ADHD. Instead, an Information Sheet will be provided to teachers outlining relevant sections of a typical consent form according to Section 7 of the Criteria for Approval Worksheet. This would meet the criteria of Section 1 of the Waiver of Written Documentation of Consent Checklist as:

a. The research presents no more than minimal risk and

b. The research involves no procedures for which written consent is normally required outside of the research context. The information

obtained from teachers is used to supplement other information provided by the parents of the child relevant to diagnosis and treatment of the child only, and is common in psychological and educational practice.

The teacher's refusal to complete rating forms in no way impacts the eligibility of the child or parent participant.

26.3 Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.

Response: All participants will be provided with time to read/discuss the informed consent form, and will be encouraged to take as much time as they need, up to including scheduling a follow-up appointment at a later time to prevent the participant from feeling any urgency to make an immediate decision.

26.4 Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Response: Families will be told that their participant is completely voluntary and they can discontinue at any time without any consequence. Should our procedures change in a manner that necessitates re-consent, all parents and children will be asked to re-consent or discontinue.

26.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

- *The role of the individuals listed in the application who are involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the subjects' understanding*

Response:

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects

☒ **N/A:** This study will not enroll Non-English speaking subjects.
(Skip to Section 26.8)

26.6 Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

NOTE: The response to this Section should correspond with your response to Section 6.4 of this protocol.

Response:

26.7 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-090)."

Response:

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults.
(Skip to Section 26.9)

26.8 Describe the process to determine whether an individual is capable of consent.

Response:

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 26.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 26.9 and 26.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 26.11 and 26.12).*

26.9 Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.

NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.

Response:

☒ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

26.10 ***For research conducted outside of New York State****, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response: N/A

26.11 Describe the process for ***assent of the adults****:*

- *Indicate whether assent will be obtained from all, some, or none of the subjects. If some, indicate which adults will be required to assent and which will not.*

Response: N/A

- *If assent will not be obtained from some or all subjects, provide an explanation of why not.*

Response: N/A

26.12 Describe whether ***assent of the adult*** *subjects will be documented and the process to document assent.*

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.

Response: N/A

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☐ **N/A**: This study will not enroll subjects who are not yet adults. *(Skip to Section 27.0)*

26.13 Describe the criteria that will be used to determine ***whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research*** *under the applicable law of the jurisdiction in which the research will be conducted* ***(e.g., individuals under the age of 18 years)****. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.

Response: Only consenting adults and assenting children with parental permission will be enrolled. Assent will be obtained from children 7 years of age and older as younger children are likely to be unable to provide informed assent given their developmental cognitive level.

26.14 ***For research conducted outside of New York State****, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response: N/A

26.15 Describe whether parental permission will be obtained from:

Response:

☒ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."

26.16 Describe whether permission will be obtained from individuals ***other than parents****, and if so, who will be allowed to provide permission. Describe*

your procedure for determining an individual's authority to consent to the child's general medical care.

Response: Permission will be obtained from legal guardians, including parents, but may include other adults as determined by judicial review and determination.

*26.17 Indicate whether assent will be obtained from all, some, or none of the **children**. If assent will be obtained from some children, indicate which children will be required to assent.*

Response: Assent will be obtained from all children over 7 years of age.

26.18 When assent of children is obtained, describe how it will be documented.

Response: Assent will be documented via child signature and assenter signature.

27.0 Waiver or Alteration of Consent Process

Consent will not be obtained, required information will not be disclosed, or the research involves deception.

☒ **N/A:** A waiver or alteration of consent is not being requested.

27.1 If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.

NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.

Response:

27.2 If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

28.0 Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 29.0)

28.1 Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether

and how consent of the subject will be obtained including whether or not it will be documented in writing.

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as 'verbal consent.' Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).

Response:

☒ We will be following "SOP: Written Documentation of Consent" (HRP-091).

29.0 Multi-Site Research (Multisite/Multicenter Only)

☐ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

*29.1 If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as:*

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response: This study is a multi-site study where the University at Buffalo is the lead site, and Florida International University is the subcontracted site. Both sites will obtain study approval from their respective IRBs.

29.2 Describe the method for communicating to engaged participating sites:

- *Problems*
- *Interim results*
- *Study closure*

Response: *As a multi-site project, careful attention will be provided toward consistent implementation of the protocol across both sites (e.g., see our description of treatment integrity and fidelity measures described above). Dr. Pelham and Dr. Fabiano are both experienced in multi-site collaboration. Dr. Pelham has successfully completed numerous multi-site studies including a longitudinal follow-up of young children with ADHD (e.g., Lahey, Pelham et al., 1998), an investigation of the impact of alcohol on parent-child interactions (e.g., Pelham et al., 1998), and he was a member of the steering committee for the largest multi-site study in the field of ADHD, the multi-modal treatment study for ADHD (MTA Cooperative Group, 1999). Dr. Fabiano has also participated in multi-site studies investigating time out as an intervention for children with ADHD (Fabiano et al., 2004), the development of a measure of impairment for children with ADHD (Fabiano et al., 2006), and he is Co-I on two multi-site, IES Goal 5 projects (Reddy, P.I.; #R305A080337; Chafouleas, P.I., #R324A110017). Furthermore, Dr. Fabiano and Dr. Pelham have collaborated on ADHD intervention studies for 13 years at the Buffalo site, and nearly every study has included behavioral treatments as a component of the project similar to the present project. Further, Dr. Pelham was the P.I., and Dr. Fabiano was the Co-P.I. on another IES-funded SMART trial with adaptive treatment tailoring (#R324B060045). Thus, the key personnel on the study at both sites will use a protocol for intervention that is similar to ones implemented successfully in the past (e.g., Fabiano, et al., 2010; Pelham et al., under review), and the team has a strong record of collaboration.*

For this project specifically, Dr. Fabiano will meet in person with Dr. Pelham each year in tandem with the IES investigator meeting to review data collection and management procedures, review procedures for training clinicians with the same training protocol, and meet with project personnel. Detailed manuals and protocols for all aspects of the study were written for the prior Goal 3 project, and Drs. Fabiano and Pelham will modify these for the present project. Project investigators will participate in a monthly conference call to review study procedures, prevent drift, trouble-shoot, and discuss implementation of the procedures. Finally, behavioral consultants will have weekly supervision on site. Every other week, extended supervision will be held via conference call where consultants can discuss current issues, barriers, or successful cases with supervisors and peers from both sites. This procedure will be used to prevent drift and encourage consistency across sites. To ensure reliability of the observational measure, observers will be trained using identical procedures are each site in the SBTR observational coding scheme and pass a uniform reliability assessment. A data codebook will be established

for use in data entry at both sites – monthly investigator phone calls will include a review of data entry to ensure minimal missing data across study years.

Drs. Fabiano and Pelham will enter data into databases housed on a RedCap server. The data server is backed up nightly, and it permits remote access from anywhere in the country. This server will also be available to statisticians and methodologists to review and work on methodological and statistical issues throughout the project, and it will also ensure the entire team is using verified and finalized versions of all study databases for analysis.

29.3 Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.

Response: 216 subjects total will be enrolled across sites.

29.4 If this is a multicenter study for which UB will serve as the IRB of record, and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.

Response: N/A

30.0 Banking Data or Specimens for Future Use

☒ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*30.1 If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*

NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).

Response:

30.2 List the data to be stored or associated with each specimen.

Response:

30.3 Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response:

31.0 Drugs or Devices

☒ **N/A:** This study does not involve drugs or devices. This section does not apply.

31.1 If the research involves drugs or devices, list and describe all drugs and devices used in the research, the purpose of their use, and their regulatory approval status.

Response:

31.2 Describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

Response:

If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

31.3 Identify the holder of the IND/IDE/Abbreviated IDE.

Response:

31.4 Explain procedures followed to comply with FDA sponsor requirements for the following:

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Response:

32.0 Humanitarian Use Devices

☒ **N/A:** This study does not involve humanitarian use devices. This does not apply.

32.1 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

Response:

32.2 For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.

Response: