Children's Hospital of Philadelphia

Informed Consent Form

Study Title: **Promoting Implementation of Behavioral Classroom Interventions for Children with ADHD in Urban Schools: A Pilot Test, Aim 3**

Version Date: 12/1/23

Consent Name: Teacher Consent Form

Principal Investigator: Gwendolyn Lawson Telephone: (267)-426-6612

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the study doctor and other research staff.

Study Overview

This study aims to pilot test a resource package of implementation strategies, also referred to as a "toolkit" to support teacher use of behavioral classroom management interventions. You are being asked to take part in this research study because you are a K-5 teacher in the School District of Philadelphia.

The purpose of this study is to find out if the Positive Behavior Management Toolkit effects teacher use of positive behavior management practices and/or impacts outcomes for students with elevated levels of hyperactive, impulsive or inattentive behavior.

If you agree to take part, your participation will last for approximately 12-15 weeks and will involve nominating two students in your class who show hyperactive, inattentive, or impulsive behaviors, and contacting their parents/guardians to see if they would be interested in participating in the study. If the child's parent/guardian consents to their participation, you will be asked to complete questionnaires about these two students. You may also be asked to use the Positive Behavior Management Toolkit during your normal teaching schedule over the course of approximately 8 weeks. As a participant in the research you will:

- Complete a demographic questionnaire at the beginning of the study, and questionnaires about your classroom management practices at the beginning, middle, and end of the study
- Nominate two students in your class who show inattentive, hyperactive, or impulsive behaviors and fill out a screening form about these students (without providing identifying information)

- Contact the students' parents/caregivers to see if they would be interested in learning more about the study
- Complete measures about these students' behaviors in the classroom and academic performance at the beginning, middle, and end of the study
- You may be given a Positive Behavior Management Toolkit to try out with the two selected students over the course of approximately 8 weeks
    - This may involve brief meetings with a toolkit "guide", classroom observations, and use of other resources
    - You will be able to opt-in or opt-out of receiving reminder text messages as part of the Toolkit
    - You will have the option to follow an Instagram account that contains additional resources as part of the Toolkit

The main risk of this study is the possibility of any discomfort you may feel in trying new or different classroom management strategies, or reflecting on your teaching practice. It is also possible that the selected students do not respond well to the classroom management practices you use during your use of the toolkit. However, you do not have to use or do anything from the toolkit that makes you uncomfortable or that you do not wish to use.

You may benefit from receiving extra support during your time using the toolkit and/or learning new classroom management strategies. In addition, your students may benefit from the classroom management strategies you use with support of the toolkit. You will also be part of testing a toolkit for teachers that, if found to be effective, may be broadly disseminated to support teachers and students on a large scale.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

Please see below for additional details about the study.

How many people will take part?

About 30 teachers and 60 children will take part in this study.

What is involved in the study?

This is a randomized controlled trial, which means that you will be randomly assigned to one of two groups: a group that receives and uses the Positive Behavior Management Toolkit, or the group that receives support as usual.

What are the study procedures?

Experimental Procedures:

Positive Behavior Management Toolkit: If you are randomly assigned to the Toolkit group, you will be asked to use the Positive Behavior management Toolkit during your normal teaching schedule for approximately eight weeks. This includes

receiving and engaging with various resources and meeting with a toolkit "guide" approximately 3-4 times to set goals and problem solve classroom management challenges. If you are randomly assigned to the group that receives support as usual, you will receive access to the Toolkit (but not the support meetings) after you have finished participating in the study.

Routine Clinical Trial Procedures

Regardless of which group you are assigned to, you will nominate two students from your classroom, about whom you have concerns about inattentive, hyperactive, or impulsive behavior, and complete a screening measure about those students. If a students' parents/guardians consent to enroll them in the study, the students' caregivers will receive brief parenting resources to thank them for participating (regardless of which group you are randomly assigned to). Regardless of which group you are assigned to, you will be asked to complete:

a) Questionnaires about the two students in your class who have enrolled in the study. These questionnaires will include questions about each students' behaviors and academic performance. You will be asked to complete them at the beginning and end of the study.

b) Questionnaires about your teaching practices: These questionnaires will include questions about yourself and your teaching practices. You will be asked to complete them at the beginning, middle, and end of the study.

c) Classroom Observations: a member of the study team will observe in your classroom at the beginning, middle, and end of the study.

Visit Schedule

The table below provides a brief description of the purpose and duration of each study visit. The visits listed in the table below will take place regardless of whether you are randomly assigned to receive the Positive Behavior Management Toolkit or to the waitlist condition. In addition to the visits listed in the table, if you are assigned to the Positive Behavior Management Toolkit condition, you will have a biweekly, 20-minute meeting with the "Toolkit Guide" who will support you in using the Toolkit.

Visit	Purpose	Main Procedures	Duration
Visit 1	Informed Consent, Screening	-Ask any questions you have, give informed consent, fill out baseline questionnaires about yourself -Fill out a brief questionnaire for two students (with no identifying information) in your class who show inattentive, impulsive, or hyperactive behaviors	Approximately 40-60 minutes
Visit 2	Baseline Data Collection	-Classroom Observation: A member of the study team will observe in your classroom during your regular activity	Approximately 20-40 minutes completing questionnaire;

		-Complete questionnaires about the two students from your class who enroll in the study.	Classroom Obseration will occur during regular instruction at a time convenient for you and will not require any time from you
Visit 3	Midpoint Data collection	Classroom Observation: A member of the study team will observe in your classroom during your regular activity Midpoint Questionnaires: Complete questionnaires about your teaching practices.	Approximately 20-30 minutes completing questionnaire; Classroom Observation will occur during regular instruction at a time convenient for you and will not require any time from you
Visit 4	Endpoint Data Collection	Classroom Observation: A member of the study team will observe in your classroom during your regular activity Endpoint Questionnaires: Complete questionnaires about your teaching practices, and about the two students from your class who enrolled in the study.	Approximately 40-60 minutes

What will be done with my data during this study?

During the study, we will collect data via the questionnaires you complete and data collected during classroom observation. By agreeing to participate in the study, you agree to give this data to CHOP for research purposes.

Will I receive any results from the tests done as part of this study?

You will not receive any results from the data collected as part of this study.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

Risks associated with study participation: There is minimal risk associated with this study. The possible risks include:

- Discomfort you may feel when reflecting on your classroom management practice or trying new approaches to classroom management
- Your students may have a negative reaction to new or different classroom management practices that you use

Are there any benefits to taking part in this study?

You might benefit by receiving extra support in your classroom management practice, However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study. The knowledge gained from this research may help researchers determine if the Positive Behavior Management Toolkit is feasible for teachers.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. You will need to use the toolkit to the best of your ability, and keep all study appointments.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled. Your decision or refusal to work on this study will not be shared with your supervisors, although if study activities take place in the school building, it is possible that supervisors may be able to observe which teachers do and do not receive visits from the study team. Your decision or refusal to work on the study will not affect your employment within your school or your relationship with Children's Hospital of Philadelphia.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

If you withdraw from the study for any reason, we will not longer collect data about the students enrolled in your class, and you will no longer receive support through the toolkit. The study team will notify the parents/guardians of your participating students to inform them that they are no longer enrolled in the study.

Can the study doctor take you out of the study early?

The study doctor may take you off of the study if:

- The study is stopped.
- You cannot meet all the requirements of the study.
- The study team is concerned that the intervention is causing harmful effects.

What choices do you have other than this study?

There are options for you other than this study including:

- Receiving support for classroom management as you usually do.

What about privacy and confidentiality?

We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. People from oversight agencies and organizations such as the Department of Health and Human Services or the Office for Human Research Protections may also look at your study records.

The results of this study may be shown at meetings and published in journals to inform other researchers and health professionals. We will keep your identity private in any publication or presentation.

By law, CHOP is required to protect your private information. The investigator and staff involved in the study will keep your private information collected for the study strictly confidential.

We will not be collecting any information about your students from student education records; nor will we be collecting any information about you from your school's records or files. The School District of Philadelphia will not have access to information about you from this study, with the only exceptions to this being if a mandated report is required (this would occur in cases of suspected child abuse or neglect) or if concerns about harm to self or others arise). If a mandated report were to be required or concerns about harm to self or others arise, this may involve communication with your child's school. Other than these exceptions, school district staff will not have access to you or your students' information from the study.

Additionally, if you are given the teacher toolkit during the study, you will have the option to follow a study Instagram account as one way to engage with resources in the toolkit. This is completely optional. If you choose to follow this account, your personal Instagram account information would be visible to other individuals who follow the study account, who may infer that you are participating in the study. If you choose to follow the study Instagram account, you understand that this limits the study staff's ability to protect your confidentiality in this regard. You are not required to follow the study Instagram account and you may un-follow the account at any time.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your data could be shared for:

- other scientific research;

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institute of Health (NIH) may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Financial Information

Will you be paid for taking part in this study?

- Teachers will be paid in the form of a ClinCard for their time and effort.
- Teachers will receive a $70 ClinCard for completing baseline measures ($30 for self-report measures, and $20 for each of two teacher-report measures), $30 for completing midpoint measures, and $70 for completing end point measures ($30 for self-report measures, and $20 for each of two teacher-report measures). Teachers will also be compensated $10 for completing screening measures, and $10 for contacting parents/guardians of each nominated student for up to 5 students.
- If you receive payment using a bankcard, the bank will have access to some personal information in order to process your payment. The bank will not have access to any medical information.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

Please ask Dr. Lawson if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about this study or how your data are going to be used, call the study doctor, Dr. Gwen Lawson at (267) 426-6612.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What will be done with my data when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of CHOP. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Consent to Take Part in this Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

As explained in this consent form, if you are assigned to the Positive Behaivor Management Toolkit condition, you will have the option to receive reminder text messages and/or to follow the study Instagram account. These are both optional, and you may stop them at any time. Please indicate below if you opt in or out of these aspects of the study.

Reminder Text Messages:

- ☐ I opt IN
- ☐ I opt OUT

Following the study Instagram account:

- ☐ I opt IN
- ☐ I opt OUT

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study.

Name of Subject	
Signature of Subject	Date