PennState

# HRP-591 - Protocol for Human Subject Research

## Protocol Title:

Provide the full title of the study as listed in item 1 on the "Basic Information" page in CATS IRB (http://irb.psu.edu).

Smart Parents – Safe and Healthy Kids: Small RCT

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## Version Date:

Provide the date of this submission. This date must be updated each time the submission is provided to the IRB office with revisions.

July 26, 2018

## Clinicaltrials.gov Registration #:

Provide the registration number for this study, if applicable.

N/A

## Important Instructions for Using This Protocol Template:

1. Add this completed protocol template to your study in CATS IRB (http://irb.psu.edu) on the "Basic Information" page, item 7.
2. This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.
3. **Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.**
4. **For research being conducted at Penn State Hershey or by Penn State Hershey researchers only, delete the instructional boxes from the final version of the protocol prior to upload to CATS IRB (http://irb.psu.edu). For all other research, do not delete the instructional boxes from the final version of the protocol.**
5. When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the Study Submission Guide available in the Help Center in CATS IRB (http://irb.psu.edu) for using track changes.

| If you need help… | |
|---|---|
| **University Park and other campuses:**<br>Office for Research Protections Human Research Protection Program<br>The 330 Building, Suite 205<br>University Park, PA 16802-7014<br>Phone: 814-865-1775<br>Fax: 814-863-8699<br>Email: irb-orp@psu.edu | **College of Medicine and Hershey Medical Center:**<br>Human Subjects Protection Office<br>90 Hope Drive, Mail Code A115, P.O. Box 855<br>Hershey, PA 17033<br>(Physical Office Location: Academic Support Building Room 1140)<br>Phone: 717-531-5687<br>Fax number: 717-531-3937<br>Email: irb-hspo@psu.edu |

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# 1.0 Objectives

## 1.1 Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

The purpose of the proposed study is to assess the effectiveness of the addition of a single-session child sexual abuse (CSA) prevention module (*Smart Parents – Safe and Healthy Kids*) on improving parents' knowledge, attitudes, and behaviors regarding CSA prevention for parents already receiving parent-education services (e.g., The Incredible Years, Parents as Teachers, SafeCare). We hypothesize that parents who receive the parenting curriculum and the CSA prevention module will (a) demonstrate significant improvement in CSA-related knowledge, attitudes, and protective behaviors from pre-test to post-test, and (b) demonstrate higher scores on CSA-related knowledge, attitudes, and protective behaviors as compared to parents who only receive the parenting curriculum.

## 1.2 Primary Study Endpoints

State the primary endpoints to be measured in the study. Clinical trials typically have a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

The primary endpoint of this study is to deliver the intervention to enough parents such that we are powered to detect an effect (power calculations provided in section 8). The primary outcome on which we are detecting an effect is a project-developed measure specific to our intervention ('Measure_ParentAssessmentTool' in supporting documents). Additional outcomes of interest, but upon which the module is not contingent, include parental stress, perception of social support, mental health, substance use, readiness for change, and parenting behaviors.

## 1.3 Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

The secondary endpoint to be measured in the study is the degree to which the CSA module (*Smart Parents – Safe and Healthy Kids*) is implemented with fidelity. We are assessing this in three ways: parent report, provider self-report, and observation through audio recording.

# 2.0 Background

## 2.1 Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

Child sexual abuse (CSA) is a public health problem in the United States (USDHHS, 2015) and its biopsychosocial consequences are well-documented (e.g., Noll et al., 2007, 2009, 2011). Whereas evidence-based prevention efforts for physical abuse and neglect have achieved the gold standard of reducing rates of those forms of maltreatment (e.g., SafeCare; Self-Brown et al., 2012), CSA primary prevention efforts have not (Letourneau et al., 2014). While adequate school, community, and clinical treatment CSA primary prevention programs exist, evidence-based CSA prevention programs designed for direct delivery to parents do not. Parents are the chief agents of change for children and involving parents in prevention efforts significantly enhances efficacy and uptake (Mendelson & Letourneau, 2015). Targeting high-risk parents for selective prevention is especially important because at-risk parents (i.e., parents involved with child welfare) are likely to (1) experience parenting challenges such as skills (e.g., monitoring) deficits, high stress, little social support, and (2) have their own abuse

histories (Whitaker et al., 2008). This kind of environment places children at greater risk for experiencing sexual abuse, not necessarily by parents themselves, but by other adults or older children. At-risk parents are likely to create environments where children are vulnerable to perpetrators of sexual abuse (Noll, 2008).

In Pennsylvania, many of these at-risk parents are already receiving parent-education services (e.g., The Incredible Years, Parents as Teachers, SafeCare) which teach parents the fundamentals of children's healthy physical and emotional development, parent-child communication and relationship-building, as well as strategies to ensure children's physical safety. However, how to create protective environments from perpetrators of sexual abuse is not covered in any of these broader existing parent-education programs. If a brief CSA prevention module was added onto preexisting services where knowledge and skills are already being taught, then a cost-effective, efficacious, widely disseminated CSA primary prevention effort could begin to address this missing prevention piece.

In order to determine if such a prevention effort is effective, it must undergo a randomized controlled trial (RCT) that compares the hypothesized improvement in outcome among participants who receive the program to a group of participants who do not receive the intervention module. RCTs are the most rigorous way of determining whether a cause-effect relationship exists between treatment and outcome (Sibbald & Roland, 1998). An RCT is required to demonstrate that our CSA prevention program produces change in parents' knowledge, attitudes, and protective behaviors regarding CSA prevention. This change can be demonstrated due to the random allocation of participants to either the intervention or control group because randomization ensures that no between-group systematic differences could explain the cause-effect relationship of the intervention on the outcome. To date there have been no RCTs of a single-session CSA prevention module that has been added onto an existing parent-education program. The proposed study seeks to determine if a single-session CSA prevention module (*Smart Parents – Safe and Healthy Kids*) can improve parents' knowledge, attitudes, and protective behaviors regarding CSA prevention by being added onto The Incredible Years, Parents as Teachers, and SafeCare.

Implementing an evidence-based intervention necessitates that it is executed the way in which the intervention was originally designed. If an intervention demonstrated a positive effect on behavior, the only way one can be sure they can replicate that positive effect is to deliver the intervention in the exact same way. This process is known as implementing with fidelity. Fidelity monitoring may be done in a variety of approaches including participant report, provider report, or direct observation. Typically, interventions use one form of fidelity monitoring, but empirical studies often cite the importance of utilizing multiple methods of monitoring (Resnicow et al., 1998). Given that we are introducing an additive intervention approach to multiple parent-education models, assessing fidelity of our added module in two different methods is a secondary outcome of interest. We are including multiple methods of fidelity monitoring to assess if one method of fidelity monitoring (e.g., provider self-report, parent report, and direct observation) is sufficient. This has implications for reducing burden/cost in future work.

## 2.2 Previous Data

Describe any relevant preliminary data.

Data collected during an Acceptability and Feasibility trial (in approved STUDY00006402) in late 2017 informed revisions to the *Smart Parents – Safe and Healthy Kids* module, specifically pacing of the presentation of materials and adjustments for group delivery. Feedback on the content and presentation of the module was universally positive. Providers who observed delivery of the module found it "extremely beneficial to parents of kids of all ages…taught in a very practical, non-threatening way" and thought it "fits very well into the [existing parenting] curriculum." Parents who received the module reported feeling confident they could use the module and would recommend it to a friend; 100% of participating parents found the module helpful.

## 2.3 Study Rationale

Provide the scientific rationale for the research.

The *Smart Parents – Safe and Healthy Kids* module is not intended to teach parents basic foundational knowledge about children's healthy development, parent-child communication, nor how to keep children safe from general harm. Instead, the purpose of the brief behavioral intervention is to teach parents about children's healthy sexual development, parent-child communication about sexual abuse, and children's sexual safety. Programs such as Incredible Years, Parents as Teachers, and SafeCare are implemented widely, are evidence-based, and teach parents the aforementioned foundational knowledge and skills and are therefore good candidates for our additive strategy. Additionally, Incredible Years, Parents as Teachers, and SafeCare are delivered to parents via two different approaches: Incredible Years is a group-based delivery whereas Parents as Teachers and SafeCare are home visiting programs (the programs are described in greater detail below). Thus, by adding the CSA module to each of these programs, we will be able to determine the module's effectiveness across a variety of ages and implementation strategies. No previous research has been conducted on this CSA prevention module, nor has an RCT been conducted on a parent-focused CSA prevention module designed to be added onto existing parent-education programming.

**The Incredible Years (IY)** is a parent-education program for parents of children aged approximately 0–13. The Incredible Years program aims to increase positive parenting and parent-child bonding, decrease harsh discipline, increase monitoring, and improve parent-child communication. Depending on the age group of the children, 8 to 20 sessions, 2 hours in duration, are delivered to groups of approximately 10 parents. The Incredible Years has been delivered to parents from a variety of populations, including parents involved with child welfare (Webster-Stratton & Reid, 2010). In these studies, The Incredible Years' intervention effects demonstrated significant improvements in positive parenting compared to individuals who received care as usual. Further accumulated evidence over the course of decades of peer-reviewed research suggests that IY is effective in changing both children and parents' knowledge and behaviors. For example, improvements in parental attitudes and parent-child interactions have been demonstrated, as well as reductions in harsh discipline and child conduct problems in a series of RCTs (e.g., Reid, Webster-Stratton, & Hammond, 2007; Webster-Stratton, Reid, & Hammond, 2004).

**Parents as Teachers (PAT)** is a parent-education program which focuses on parent-child interaction, development-centered parenting, and family well-being (Albritton, Klotz, & Roberson, 2003). Families are eligible for PAT until the child enters kindergarten, but as the program works with a family unit the educator may continue to work with the family if there are younger children. Results from several trials suggest that PAT: detects developmental delays and child physical health problems early (Pfannenstiel & Lente-Jojola, 2011); improves children's language ability, social development and other cognitive abilities (Drotar, Robinson, Jeavons, & Kirchner, 2009; Wagner, Spiker, & Linn, 2002); decreases the achievement gap between low-income and more advantaged children at Kindergarten entry (Pfannenstiel, Seitz, & Zigler, 2003); and improves parents engagement with their child's schooling (Zigler, Pfannenstiel, & Seitz, 2008). Other findings from PAT research demonstrate improvement in parenting knowledge, attitudes, and behaviors (Pfannenstiel & Seltzer, 1989; Wagner & Clayton, 1999).

**SafeCare (SC)** is a parent-support program for parents of children 0–5 who are at-risk or have been involved with child welfare services. The program teaches parents skills in three core areas (parenting, home safety, and child health) to reduce the risk for maltreatment. Specifically, parents are taught to positively interact with their children, identify and remove potential safety hazards in the home, and to recognize and respond to children's illnesses or injuries. The program is delivered over the course of approximately 18 weeks, 6 weeks per module, 3 modules total. Decades of research have established a strong evidence-base for SC (Guastaferro & Lutzker, 2017; 2012). Most notably, in a statewide trial of more than 2,000 families, those that received SafeCare were significantly less likely to have repeat

involvement with child protective services compared to families who received services as usual and these findings remained consistent 7 years post-intervention (Chaffin et al., 2012).

Incredible Years, PAT, and SC are evidence-based parent-education programs that cover a wide range of children's ages (0–13 and 0–5, respectively) and modalities (group-based and home visiting, respectively). All three programs have demonstrated important changes in parenting knowledge, attitudes, and behaviors in high-risk (i.e., child welfare involved) parents. For this reason, IY, PAT, and SC are good candidates onto which *Smart Parents – Safe and Healthy Kids* may be added.

## 3.0 Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.). Indicate specifically whether you will include any of the following vulnerable populations: (You may not include members of these populations as subjects in your research unless you indicate this in your inclusion criteria.) Review the corresponding checklists to ensure that you have provided the necessary information.

- **Adults unable to consent**
  - Review "CHECKLIST: Cognitively Impaired Adults (HRP-417)" to ensure that you have provided sufficient information. HRP-417 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).
- **Individuals who are not yet adults (infants, children, teenagers)**
  - If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children"), review the "CHECKLIST: Children (HRP-416)" to ensure that you have provided sufficient information. HRP-416 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).
- **Pregnant women**
  - Review "CHECKLIST: Pregnant Women (HRP-412)" to ensure that you have provided sufficient information. HRP-412 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).
- **Prisoners**
  - Review "CHECKLIST: Prisoners (HRP-415)" to ensure that you have provided sufficient information. HRP-415 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).
- **Neonates of uncertain viability or non-viable neonates**
  - Review "CHECKLIST: Neonates (HRP-413)" or "CHECKLIST: Neonates of Uncertain Viability (HRP-414)" to ensure that you have provide sufficient information. HRP-413 and HRP-414 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

### 3.1 Inclusion Criteria

List the criteria that define who will be included in your study.

Parents

1. Parent or caregiver ≥ 18 years old
2. Parent or caregiver of at least one child under 13
3. Enrolled in either Incredible Years, PAT, or SafeCare parent-training program

Providers

1. 18 years or older

Provider of either Incredible Years, PAT, or SafeCare parent-training program from a site that has agreed to participate in the research and was trained in SPSHK

### 3.2 Exclusion Criteria

List the criteria that define who will be excluded in your study.

1. Parent/caregiver does not speak English
2. Parent is mandated (i.e., court-ordered) to attend parent-training program

Providers who are not implementing SPSHK.

### 3.3 Early Withdrawal of Subjects

#### 3.3.1 Criteria for removal from study

Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

1. Participant decides to withdraw from the parent-training program
2. Participant decides to withdraw at any point from the survey

Providers who decide to not deliver the module.

#### 3.3.2 Follow-up for withdrawn subjects

Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; whether and how subjects are to be replaced; the follow-up for subjects withdrawn from investigational treatment.

If a participant (parent or provider) decides to stop before the study's conclusion, a member of the research team will ask if they wish to have their information used at all; if no, we will purge their information from our database. If the participant indicates that we can use their unidentifiable information, we will retain their available survey data and remove their identifiers from the master list.

## 4.0 Recruitment Methods

### 4.1 Identification of subjects

Describe the methods that will be used to identify potential subjects or the source of the subjects. If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.
StudyFinder: If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, please indicate this in section 4.1 along with any other methods for identifying subjects. Note that information provided in this protocol should be consistent with information provided on the StudyFinder page in your CATS IRB study.

For Penn State Hershey submissions using Enterprise Information Management (EIM) for recruitment, attach your EIM Design Specification form on the Basic Information page in CATS IRB (http://irb.psu.edu). See HRP-103 Investigator Manual, "What is appropriate for study recruitment?" for additional information.

We will utilize our relationship with community partners (i.e., providers of the parent-education programs) and Children and Youth agencies to recruit provider agencies.

After obtaining provider buy-in at both experimental and control sites, we will recruit participants directly through providers at these agencies.

For experimental sites, that is those who are randomized to add the CSA module onto the existing PE program, providers will be recruited to participate in the fidelity research at the time of training in SPSHK.

### 4.2 Recruitment process

Describe how, where and when potential subjects will be recruited (e.g., approaching or providing information to potential subjects for participation in this research study).

Providers at the experimental groups who are trained to deliver SPSHK will be presented with the opportunity to participate in the fidelity research at the time of training. The trainers will read the attached recruitment script and obtain consent.
Parents who have enrolled in Incredible Years or PAT or SC will be recruited by a member of the research team at the first session of their respective parenting program; that is, before any intervention is delivered. A parent's participation in research (i.e., the surveys) does not affect their ability to participate in the original parenting program (i.e., Incredible Years or Parents as Teachers or SafeCare).

### 4.3 Recruitment materials

List the materials that will be used to recruit subjects. Add recruitment documents to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page. For advertisements, upload the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.

StudyFinder: If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, you do not need to upload a separate recruitment document for information placed on the StudyFinder site to your study in CATS IRB. Necessary information will be captured on the StudyFinder page in your CATS IRB study.

Attached is the verbal recruitment script for providers in the SPSHK training to participate in the fidelity research.
Attached to this application is the script for recruitment of parents who have signed up for Incredible Years or PAT or SC but have not yet begun sessions. Separate recruitment scripts are included for control and treatment groups.

For parents who will be asked to be recorded, a separate half-page flyer is available for the provider to use to explain why the recording is happening; the provider may choose to use this at his/her discretion.

### 4.4 Eligibility/screening of subjects

If potential subjects will be asked eligibility questions before obtaining informed consent, describe the process. Add the script documents and a list of the eligibility questions that will be used to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page.

StudyFinder: If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, any scripts (phone, email, or other) used when contacting StudyFinder participants as well as any eligibility screening questions must be added to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page.

There are no additional screening questions for providers.

We will not be asking subjects additional eligibility questions. As they are recruited by providers, we are using the eligibility criteria of the parenting program (Incredible Years or PAT or SC) as the only screener.

In other words, if they are enrolled or enrolling in either of these programs, and meet the other criteria (English-speaking, over 18, and a parent/caregiver to a child under 13) then there are no additional screening items. These eligibility criteria (and whether a parent meets them or not) will be known by the providers prior to approaching a family. If a parent receiving PAT or SC is ineligible, they will not be presented with an opportunity to participate. Incredible Years providers will conduct sessions with eligible parents for the research and separate sessions for ineligible parents.

# 5.0 Consent Process and Documentation

Refer to "SOP: Informed Consent Process for Research (HRP-090)", for information about the process of obtaining informed consent from subjects. HRP-090 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

## 5.1 Consent Process

### 5.1.1 Obtaining Informed Consent

#### 5.1.1.1 Timing and Location of Consent

Describe where and when the consent process will take place.

Providers will consent to be audio recorded for fidelity purposes at the time of SPSHK training. These trainings will occur at the agency site.

Consent will occur at the time and location of recruitment (IY: the community center or agency where the group occurs, PAT or SafeCare: the subject's home). This is prior to any delivery of intervention (i.e., parent-education program) content.

#### 5.1.1.2 Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

The researcher will stress that participation is optional to all participants (providers and parents). Potential provider-subjects will be reminded that they will receive the SPSHK training regardless of their decision to participate as a research subject (i.e., in the fidelity study). Additionally, we will make it clear that any site-level incentives provided to agencies are not dependent upon the number of providers that enroll as research subjects. Potential parent participants are also reminded that they may decline to participate in the research (i.e., surveys), but still participate in the parenting program.

### 5.1.2 Waiver or alteration of the informed consent requirement

If you are requesting a waiver or alteration of consent (consent will not be obtained, required information will not be disclosed, or the research involves deception), describe the rationale for the request in this section. If the alteration is because of deception or incomplete disclosure, explain whether and how subjects will be debriefed. Add any debriefing materials or document(s) to your study in CATS IRB (http://irb.psu.edu) on the "Supporting Documents" page. NOTE: Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure you have provided sufficient information for the IRB to make these determinations. HRP-410 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Not applicable

## 5.2 Consent Documentation

### 5.2.1 Written Documentation of Consent

Refer to "SOP: Written Documentation of Consent (HRP-091)" for information about the process to document the informed consent process in writing. HRP-091 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

If you will document consent in writing, describe how consent of the subject will be documented in writing. Add the consent document(s) to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page. Links to Penn State's consent templates are available in the same location where they are uploaded and their use is required.

Written consent will be obtained for all participants (program subjects and provider-subjects).

### 5.2.2 Waiver of Documentation of Consent (Implied consent, Verbal consent, etc.)

If you will obtain consent (verbal or implied), but not document consent in writing, describe how consent will be obtained. Add the consent script(s) and/or information sheet(s) to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page. Links to Penn State's consent templates are available in the same location where they are uploaded and their use is required. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. HRP-411 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

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.

Not applicable

## 5.3 Consent – Other Considerations

### 5.3.1 Non-English Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

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.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review the "SOP: Written Documentation of Consent (HRP-091)" and the "Investigator Manual (HRP-103)" to ensure that you have provided sufficient information. HRP-091 and HRP-103 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Due to current limitations in program materials available, only English-speaking subjects will be recruited.

### 5.3.2 Cognitively Impaired Adults

Refer to "CHECKLIST: Cognitively Impaired Adults (HRP-417)" for information about research involving cognitively impaired adults as subjects. HRP-417 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

#### 5.3.2.1 Capability of Providing Consent

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

Adults with cognitive disabilities have unique parenting circumstances that, though important, are beyond the scope of the proposed research.

#### 5.3.2.2 Adults Unable To Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual's authority to consent to research.

For research conducted in the state, review "SOP: Legally Authorized Representatives, Children and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "legally authorized representative". HRP-013 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

For research conducted outside of the 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 procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." HRP-013 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Not applicable: Adults with cognitive disabilities have unique parenting circumstances that, though important, are beyond the scope of the proposed research.

#### 5.3.2.3 Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

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

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

Not applicable

### 5.3.3 Subjects who are not yet adults (infants, children, teenagers)

#### 5.3.3.1 Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individual's authority to consent to each child's general medical care.

For research conducted in the state, review "SOP: Legally Authorized Representatives, Children and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children". HRP-013 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in 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 with the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." HRP-013 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Not applicable

#### 5.3.3.2 Assent of subjects who are not yet adults

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. When assent of children is obtained describe whether and how it will be documented.

Not applicable

## 6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See the "Investigator Manual (HRP-103)" for a list of the 18 identifiers. HRP-103 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

If requesting a waiver/alteration of HIPAA authorization, complete sections 6.2 and 6.3 in addition to section 6.1. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

### 6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

**Check all that apply:**

☒ **Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

☐ **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

☐ **Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

## 6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

### 6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

#### 6.2.1.1 Plan to protect PHI from improper use or disclosure

Include the following statement as written – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver of authorization. If the section is not applicable, remove the statement and indicate as not applicable.

Not applicable

#### 6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed. If identifiers will be retained, provide the legal, health or research justification for retaining the identifiers.

Not applicable

### 6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide an explanation for why the research could not practicably be conducted without access to and use of PHI.

Not applicable

### 6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide an explanation for why the research could not practicably be conducted without the waiver or alternation of authorization.

Not applicable

## 6.3 Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a

waiver or alteration of authorization. If the section is not applicable, remove the statement and indicate as not applicable.

Not applicable

# 7.0 Study Design and Procedures

## 7.1 Study Design

Describe and explain the study design.

This research will utilize a randomized controlled trial (RCT) design. As this research includes three parenting programs, Incredible Years, PAT, and SafeCare , three RCTs will be conducted simultaneously. Randomization will occur at the site level to reduce the potential for contamination; as such, recruited parents will not be informed of the randomization process . When sites agree to participate (i.e., be randomized) they agree to implement the evidence-based parenting program plus the added module as they would typically implement the parenting program. Although the module is not evidence-based, they are agreeing to deliver as if it were standard procedure.

This section describes the design and procedures for the three RCTs: (1) *Incredible Years RCT;* (2) *Parents as Teachers RCT* and (3) *SafeCare RCT*. However, there are commonalities between the three trials:

- There will be two groups of providers– one assigned to deliver the parenting program and one assigned to deliver the parenting program plus additional SPSHK module at the end of the last session (described below), in support of the research question.
- Parents in the control group will complete assessments at four time points: pre-parenting intervention, post-parenting intervention, one-week post parenting, and one month post-intervention.
- Parents in the experimental group will complete assessments at four time points: pre-parenting intervention, post-parenting intervention, post-module, and one month post-intervention.
- For the experimental group, fidelity monitoring procedures will also occur in sessions for each enrolled provider-subjects. Parents and provider-subjects of these sessions will each complete a fidelity assessment instrument. With the parent's permission, the provider will audio record two experimental sessions.

Different measures will be asked at specific assessment periods:

| **Measure Name (file name in supporting documents attachments)** | **Construct** | **Timing of Delivery (by Protocol Section description paragraph)** |
|---|---|---|
| Alabama Parenting Questionnaire (APQ; 'Measure_APQ.docx') | Parenting behaviors and responding to child's externalizing behaviors: subscales of Parental Involvement, Positive Parenting, Inconsistent Discipline Practices | 7.2.1, 7.2.3, 7.2.5, 7.2.6 |
| Alcohol Use Disorders Identification Test (AUDIT; 'Measure_AUDIT.docx') | Assesses alcohol consumption, drinking behaviors, and alcohol-related problems. | 7.2.1 |
| Center for Epidemiologic Studies Depression Scale (CES-D; 'Measure_CESD.docx') | Screening test for depressive symptoms and depressive disorder | 7.2.1 |

| | | |
|---|---|---|
| Drug Abuse Screening Test (DAST; 'Measure_DAST.docx') | Assesses drug use, not including alcohol or tobacco use, in the past 12 months | 7.2.1 |
| Demographics ('Measure_Demographics.docx') | | 7.2.1 |
| Interpersonal Support Evaluation List (ISEL; 'Measure_ISEL-SF.docx') | Perceptions of social support (Appraisal, Belonging, Tangible) | 7.2.1 |
| Parent Satisfaction Survey ('Measure_ParentSatisfactionSurvey.docx') | Satisfaction with added module | 7.2.5 |
| Module Assessment ('Measure_ParentAssessmentTool.docx') | Assessment of attitudes, knowledge, behavior of CSA prevention | 7.2.1, 7.2.3, 7.2.5, 7.2.6 |
| Readiness, Efficacy, Attributions, Defensiveness, and Importance Scale (READI-SF; 'Measure_READI-SF.docx') | Assessment of parent's readiness to engage in services | 7.2.1 |
| SPSHK Parent Fidelity Monitoring (experimental group only; 'SPSHK Parent Fidelity Monitoring_v3.docx') | Parent assessment of session fidelity | 7.2.4 |
| SPSHK Provider Fidelity Monitoring measure (provider-subjects only, of experimental sessions) | Provider self-report assessment of fidelity | 7.2.4 |
| SPSHK Researcher Fidelity Monitoring (of audio recorded session; 'SPSHK Researcher Fidelity Monitoring_v2.docx') | Researcher assessment of session fidelity | 7.2.4 |

*Time points and measures used*

| **Assessment Time Point** | **(Protocol Section)** | **Measures** |
|---|---|---|
| Pre-parenting Intervention Assessment | (7.2.1) | APQ<br>AUDIT<br>CES-D<br>DAST<br>Demographics<br>ISEL-SF<br>Module Assessment<br>READI-SF |
| Post-parenting Intervention Assessment | (7.2.3) | APQ<br>Module Assessment |
| One-week post parenting (control group) or Post-parenting and SPSHK Module Assessment (experimental group) | (7.2.4) | APQ<br>Module Assessment<br>Parent Satisfaction Survey<br>SPSHK Parent Fidelity Monitoring (experimental group only)<br>SPSHK Researcher Fidelity Monitoring (experimental group only)<br>SPSHK Provider Fidelity Monitoring (experimental group only) |
| One-month Follow-up Assessment | (7.2.5) | APQ<br>Module Assessment |

## 7.2 Study Procedures

Provide a description of all research procedures being performed and when they are being performed (broken out by visit, if applicable), including procedures being performed to monitor subjects for safety or minimize risks. Include any long-term follow-up procedures and data collection, if applicable.

Describe where or how you will be obtaining information about subjects (e.g., medical records, school records, surveys, interview questions, focus group topics, audio or video recordings, data collection forms, and collection of specimens through invasive or non-invasive procedures to include the amount to be collected and how often). Add any data collection instruments that will be seen by subjects to your study in CATS IRB (http://irb.psu.edu) in the "Supporting Documents" page.

### 7.2.1 Pre-parenting Intervention Assessment

Provide a description as defined above and format accordingly.

As described above, parents are recruited to participation in the research after independently signing up to participate in Incredible Years, Parents as Teachers, or SafeCare, and the agency/site providing their parenting program would have already agreed to randomization (and experimental condition providers received their training in the SPSHK module). Following consent and before any intervention has occurred, the parents will be given a paper copy of the assessment. A member of the research team will distribute surveys (identified only by a unique code—see Section 9) at the beginning of the first session to parents who have consented to participate.

The assessment is given in a booklet format. At this assessment point, parent survey booklets include the APQ, AUDIT, CES-D, DAST, ISEL-SF, READI-SF, a demographics questionnaire, and the module assessment of parents' attitudes, knowledge, and behaviors of CSA prevention (measures described above in Section 7.1). Providers in the group sessions (Incredible Years) will engage with parents who do not wish to participate separately at this time.

### 7.2.2 Parenting Intervention

Provide a description as defined above and format accordingly.

Participants complete 14 Incredible Years, 5 Parents as Teachers, or 6 SafeCare sessions, one per week for consecutive weeks. These are rough estimates of sessions as the number of sessions largely depends on parental mastery; that is, if a parent needs two sessions to get through a particular skill, the provider is trained to do that in their training of the parent-education model.

### 7.2.3 Post-parenting Intervention Assessment

Provide a description as defined above and format accordingly.

Completion of the parenting intervention is specific to each parenting program. For PAT, completion of intervention (for the purposes of our research) is at the end of the fifth foundational visit. For Incredible Years, completion of intervention (for the purposes of our research) is the penultimate session – this is the last session in which content is delivered; the final session is a celebration and graduation. For SafeCare, completion of intervention (for the purposes of our research) is at the conclusion of the parenting module (6 weeks).

Parents will be provided with another paper survey. Those who have not agreed to participate in the research will be allowed to leave. Participants will complete the APQ and Module Assessment ('Measure_ParentAssessmentTool' in supporting documents).

### 7.2.4 One-week Post-parenting (control) OR Post-parenting and Module Assessment (Experimental group)

Provide a description as defined above and format accordingly.

One-week after completing the parenting program (7.2.3), parents in the control condition that have agreed to participate in the research will be contacted by the research team to complete the third assessment, the APQ, Module Assessment ('Measure_ParentAssessmentTool'). {This will happen within a normally scheduled session of PAT or SafeCare, and will require an additional visit for the IY participants}

The week after the conclusion of event 7.2.3, providers in the experimental condition deliver the Smart Parents – Safe and Healthy Kids module to their parents. The parent and provider will complete a short survey about the content of the session. This is done each time the module is delivered to measure fidelity. Additionally, provider-participants will record any two SPSHK sessions where the participating parent(s) agree to the recording. If the parent in the individual session—or any parent in the group session—declines to be audio recorded, the SPSHK module will be delivered as usual (including the fidelity survey), but the session will not be audio recorded.

Immediately following delivery of the SPSHK module, those in the experimental group will complete the APQ, Module Assessment, and a questionnaire asking about their overall satisfaction with the module ('Measures_Parent Satisfaction Survey'). Parents will complete their fidelity assessment in addition to the Parent Satisfaction Survey ('SPSHK Parent Fidelity Monitoring') as part of their post-intervention assessment packet. As the parent fills out this form, the provider will complete the self-reported fidelity assessment ('SPSHK Provider Fidelity Monitoring_V2').

The audio recordings will be reviewed by the PSU study team using the 'SPSHK Research Fidelity Monitoring v2.1' form. The form assesses which aspects of the curriculum were delivered and to what degree (incomplete v. complete) to the family. These observations will be compared with provider self-report and parent report. Two visits will be recorded and scored for fidelity.

### 7.2.5 One-month Follow-up Assessment

Provide a description as defined above and format accordingly.

One month after 7.2.4, when intervention is complete -- the post-parenting intervention assessment for the control group and the post-module assessment for the experimental group, a member of the research team will follow up with participants using the preferred method of contact they indicated in 7.2.1 and distribute the final survey packet over email (link to an electronic version of the survey) or a hard copy through the mail with a prepaid envelope for return to Penn State. They will complete the Module Assessment and APQ.

## 7.3 Duration of Participation

Describe the duration of an individual subject's participation in the study.

Duration of participation for Incredible Years participants that is approximately 15 weeks (depending on mastery of the material), for Parents as Teachers participants that is approximately 6 weeks (depending on mastery of the material), and for SafeCare participants that is approximately 7 weeks (depending on mastery of the material). The control condition lasts the length of the parenting program in which they are participating (14 weeks for IY, depending on mastery of the material; 5 weeks for PAT, depending on mastery of the material; 6 weeks for SafeCare, depending on mastery of the material). The one week of

follow up is outside the provision of the program. Total participation extends one month beyond that to include the final follow-up assessment.

The estimated total time for a participant in the experimental condition to complete all assessments is 60 minutes; the estimated total time for a participant in the control condition to complete all assessments is 55 minutes.

Providers participation in fidelity research (i.e., self-report will be approximately 5 minutes in all sessions they deliver the SPSHK module.

# 8.0 Subject Numbers and Statistical Plan

## 8.1 Number of Subjects

Indicate the total number of subjects to be accrued.

If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

The number of subjects needed for the PAT randomized controlled trial is 124: 62 randomized to the control group, 62 randomized to the experimental group.

The number of subjects needed for the SafeCare randomized controlled trial is 124: 62 randomized to the control group, 62 randomized to the experimental group.

The number of subjects needed for the Incredible Years cluster randomized controlled trial is 280: 140 randomized to the control group, 140 randomized to the experimental group.

We expect to enroll approximately 100 provider-subjects for the fidelity research.

In total we expect to enroll 628 subjects, both parent and provider-subjects.

## 8.2 Sample size determination

If applicable, provide a justification of the sample size outlined in section 8.1 – to include reflections on, or calculations of, the power of the study.

*Parents as Teachers and SafeCare*
In a two-arm RCT, sample size is determined by power and estimated effect size. We are doing a repeated measures design (4 assessments), so this must be accounted for in the sample size calculation. Assuming a desired power of .8 and estimated effect of .45, the sample size needed to detect an effect at alpha .05 is 62 individuals per group ($N$ = 124) for each trial. That is, 124 participants for Parents as Teachers and 124 participants for SafeCare.

*Incredible Years*
Because the additive approach of our research is novel, we are relying on prior CSA prevention and general PE program research to estimate the effect size. A meta-analysis of general PE programs, from which CSA programs were excluded, found the estimated average effect size for trials including a control group to be $d$ = .3. A meta-analysis of CSA-specific prevention programs (Davis & Gidycz, 2000) reported the average effect size for a single session program to be $d$ = .59. Averaging these findings, we estimate the effect size of our module to be ***d* = .45**. The group-based delivery of IY requires the experimental design to be a cluster RCT and, as such, clustering must be considered in sample size calculation (i.e.,

participants are nested within groups). In order to calculate the required sample size for the cluster randomized trials, we used the sample size calculation equation (Equation1) for repeated measures from Heo and colleagues (2009; Equation 19, p. 385). Cluster sampling introduces a less precise estimate of parameters than simple random sampling (e.g., commonalities among participants); this increase of variance is estimated in the design effect ($2f$). Our design has repeated measures, which introduces autocorrelation ($C_f$); for our purposes we estimate this to be .7. Together, the design effect and the autocorrelation of the outcome of interest over time creates the corrected design effect ($2fC_f$), estimated to be 8.0025 for our calculation. Assuming α = .05, β = .80, 10 participants per group ($N_2$), 3 measurement occasions ($N_1$), and an effect size (Δ) of 0.45, the number of groups needed per condition ( $N_3$) is 11; this is in agreement with simulated sample sizes presented by Heo et al. (2009; Table 1). To account for participant attrition and lack of participation in research, **we will recruit 14 groups per condition such that our sample is comprised of ~ 280 participants (140 per condition)**.

**Equation 1.**

$$N_3 = \frac{2fC_f(\phi^{-1}\left(1-\frac{\alpha}{2}\right)+\phi^{-1}(1-\beta))^2}{N_2N_1\Delta_\sigma^2}$$

*Fidelity*
Other research indicates that two audio recorded sessions from 100 provider-subjects will be sufficient to answer fidelity research questions.

### 8.3 Statistical methods

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

We will be examining the effect of our module using a variety of statistical methods. Exact models to be used will be dictated by recruitment and participating sites (e.g., potentially controlling for nesting). Statistical methods considered will include simple t-tests, general linear regression models, or hierarchical regression models. We are powered for repeated measure ANOVA between factors.

## 9.0 Confidentiality, Privacy and Data Management

**For research being conducted at Penn State Hershey or by Penn State Hershey researchers only**, the research data security and integrity plan is submitted using "HRP-598 – Research Data Plan Review Form Application Supplement", which is available in the Library in CATS IRB (http://irb.psu.edu). Refer to Penn State College of Medicine IRB's "Standard Operating Procedure Addendum: Security and Integrity of Human Research Data", which is available on the IRB's website. **In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" in section 9.0 if you are conducting Penn State Hershey research and move on to section 10.**

**For all other research**, in the sections below, describe the steps that will be taken to secure the data during storage, use and transmission.

### 9.1 Confidentiality

#### 9.1.1 Identifiers associated with data and/or specimens

List the identifiers that will be included or associated with the data and/or specimens in any way (e.g., names, addresses, telephone/fax numbers, email addresses, dates (date of birth, admission/discharge dates, etc.), medical record numbers, social security numbers, health plan beneficiary numbers, etc.).

If no identifiers will be included or associated with the data in any way, whether directly or indirectly, please indicate this instead.

The provider-subjects will provide their name, email, and phone number.

The contact information sheet filled out by participants at the first assessment point asks for their name, address, phone number(s), and email. It also asks for them to identify a friend or family member we can call should we not be able to locate the participant using the information they provide. This is a method members of our team have used previously, and is the best way to prevent loss-to-follow-up. The contact sheet is necessary to ensure participants are reached for later phases of study. The master ID file and contact information sheet are the only documents linking participant ID with identifiable information. The contact information sheet will be collected immediately upon completion by a study team member, before participants fill out the surveys, and placed in a pre-paid, addressed, and sealed envelope. These will be returned to Penn State separately from other survey instruments and immediately following this session.

#### 9.1.1.1 Use of Codes, Master List

If identifiers will be associated with the data and/or specimens (as indicated in section 9.1.1 above), describe whether a master record or list containing a code (i.e., code number, pseudonyms) will be used to separate the data collected from identifiable information, where that master code list will be stored, who will have access to the master code list, and when it will be destroyed.

If identifiers are included or associated with the data as described in section 9.1.1 above, but no master record or list containing a code will be used, it will be assumed by the IRB that the investigator plans to directly link the identifiers with the data.

The research team will randomly assign a pre-generated participant ID to each participant (parent or provider). These are randomly-generated combinations of 5 digits. The project manager will be the keeper of a password-protected file stored on a secured drive that links the name to ID and a file that links name to contact information.

For providers: The consent form will be collected at the time of training and stored separately from any fidelity monitoring data. The hard copies of the consent form will be stored in a locked filing cabinet, separate from fidelity data (containing only IDs), in a locked office, in a swipe-access controlled office suite.

For parents: The consent form and contact information sheet will be collected immediately after completion and stored in a sealed envelope separately from hard copies of surveys. This will be standard practice for all study team members, whether they are PSU team members or affiliates. Upon return to University Park, hard copies of the contact sheet will be stored in a locked filing cabinet, separate from surveys (containing only unique ID codes), in a locked office, in a swipe-access controlled office suite.

Because this study involves longitudinal research requiring continued contact with subjects to maintain participation, personal contact information for enrolled participants will be retained until the study is completed, at which

point they and the master ID file will be destroyed. De-identified electronic information will be stored indefinitely.

Provider fidelity data will be submitted through REDCap. The audio file will not be saved with any identifiable information, only the provider study ID. A separate secure REDCap database will contain the provider name, email, and ID. Another REDCap database will contain the subject ID and audio files.

### 9.1.2 Storage of Data and/or Specimens

Describe where, how and for how long the data (hardcopy (paper) and/or electronic data) and/or specimens will be stored. NOTE: Data can include paper files, data on the internet or websites, computer files, audio/video files, photographs, etc. and should be considered in the responses. Refer to the "Investigator Manual (HRP-103)" for information about how long research records must be stored following the completion of the research prior to completing this section. HRP-103 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Please review Penn State's Data Categorization Project for detailed information regarding the appropriate and allowable storage of research data collected according to Penn State Policy AD71. Although the IRB can impose greater confidentiality/security requirements (particularly for sensitive data), the IRB cannot approve storage of research data in any way or using any service that is not permissible by Penn State Policy AD71.

Paper surveys will be stored in sealed and signed envelopes during transfer from the field to our secure office space. Penn State study team members will keep such envelopes securely in their possession the entire time from the field to University Park; in the event affiliate staff are collecting data without the presence of a Penn State team member, they will be provided with pre-paid envelopes to mail surveys back to Penn State immediately after the session. Paper surveys will be stored in a locked filing cabinet in a secured office in the Center for Healthy Children on the University Park campus. They will only be accessible to project staff. After surveys have been electronically entered into a database, the hardcopies will be shredded. Electronic data will be stored on a secure server on password-protected computers in locked rooms. Per regulations, electronic data will be kept for 3 years after the close of the study, after which time data will be deleted from our secure server.

Audio recordings will be done on a password-protected smartphone. After the facilitator uploads the audio recording to REDCap, the audio file will be deleted from the recording device. Audio files will be labeled with the provider's unique 5-digit ID.

After each audio recording has been listened to by the PSU research team through REDCap, the audio recording will then be moved to a storage folder on Box to be maintained along with other research records for 3 years after the closure of the study. Recordings will not be transcribed.

### 9.1.3 Access to Data and/or Specimens

Identify who will have access to the data and/or specimens. This information should not conflict with information provided in section 9.1.1.1 regarding who has access to identifiable information, if applicable.

Only members of the research team will have access to the data.

#### 9.1.4 Transferring Data and/or Specimens

If the data and/or specimens will be transferred to and/or from outside collaborators, identify the collaborator to whom the data and/or specimens will be transferred and how the data and/or specimens will be transferred. This information should not conflict with information provided in section 9.1.1.1 regarding who has access to identifiable information, if applicable.

In the event affiliate staff collect data without the presence of a Penn State team member to take immediate possession of the data, they will be provided with pre-paid envelopes to mail surveys back to Penn State immediately after the session.

### 9.2 Subject Privacy

This section must address subject privacy and NOT data confidentiality.

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

Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact with or to whom they provide personal information.

Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

Completed survey instruments (including the contact sheet) will never be left in the open, unsecured, or outside the direct control of a study team member while in the field. Surveys (and discussion) covering a wide range of topics are part of the typical implementation of these programs, and therefore providers are trained for and familiar with accounting for sensitive information. Budgetary and practical space constraints preclude our providing individual spaces or privacy screens for participants to complete surveys, but we will ensure team members know how to foster an environment of privacy (e.g., in group delivery condition: maximized space between seats, option for individuals to go into a hallway if they desire) for participants who elect to complete surveys.

Only members of the PSU research team will listen to the recordings. Headphones will be used while listening to all recordings to ensure that other individuals passing in or through the office space do not overhear. Research team members are listening for whether or not each topic area of interest was covered during the session (see 'SPSHK Researcher Fidelity Monitoring_v2.docx' in supporting documents). If there is a disclosure of child abuse or neglect, team members will follow mandated reporting guidelines and Penn State Policy AD72.

## 10.0 Data and Safety Monitoring Plan

**This section is required when research involves more than Minimal Risk to subjects.** As defined in "SOP: Definitions (HRP-001)", available in the Library in CATS IRB (http://irb.psu.edu), Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. **Please complete the sections below if the research involves more than minimal risk to subjects OR indicate as not applicable.**

### 10.1 Periodic evaluation of data

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

N/A

**10.2 Data that are reviewed**

Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

N/A

**10.3 Method of collection of safety information**

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

N/A

**10.4 Frequency of data collection**

Describe the frequency of data collection, including when safety data collection starts.

N/A

**10.5 Individuals reviewing the data**

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

N/A

**10.6 Frequency of review of cumulative data**

Describe the frequency or periodicity of review of cumulative data.

N/A

**10.7 Statistical tests**

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

N/A

**10.8 Suspension of research**

Describe any conditions that trigger an immediate suspension of research.

N/A

## 11.0 Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. For each potential risk, describe the probability, magnitude, duration, and reversibility. Consider all types of risk including physical, psychological, social, legal, and economic risks. If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. If applicable, describe risks to others who are not subjects.

Please keep in mind that loss of confidentiality is a potential risk when conducting human subject research and should be addressed as such.

There are no foreseeable risks to research participants beyond those of everyday life. The topic of the module, prevention of sexual abuse, is potentially uncomfortable, but this is addressed in the curriculum. Specifically, providers are trained to respond to any feelings of discomfort by trying to address those feelings directly. We will follow each participating site's protocol for referral to services (e.g., trauma therapy) and for reporting any disclosures of abuse during sessions. These are typical elements of the parenting program in typical implementation.

The other potential risk is a loss of confidentiality. We will make every effort to reduce this risk, and participants will be informed of their rights to confidentiality. To minimize this risk, the Survey Team follows all procedures related to data confidentiality. Participant names will not be recorded nor linked to their individual responses, and data collected from the survey will not have names or other personally identifiable information attached to it. All data are stored on secured servers in locked rooms on password-protected computers, and only members of the research team will have access to the data.

In the event of a disclosure of child abuse by a participant, or if a Study Team member suspects child abuse has occurred, a report will be made to the Pennsylvania Department of Human Services ChildLine, the County Children and Youth agency, and to Penn State's internal reporting mechanism (ad72@psu.edu), in accordance with Penn State Policy AD72. Because such action is a potential risk of participation, subjects will be informed during the consent process of the Study Team's obligation as mandated reporters.

For parents in an Incredible Years group, the potential inconvenience of a longer-than-usual first session is mitigated by their being compensated for their time with free childcare and dinner. Individuals who choose not to participate in the research by completing surveys will have the opportunity to spend time speaking with the other provider building rapport.

A subject might be uncomfortable knowing that someone might hear and recognize their voice. Participants being interviewed in-home might be uncomfortable knowing that other people in the home or discussions with other members in the home might be recorded. No individual (study subject or otherwise) will be audio recorded without their permission/knowledge. If other family members will be present and do not wish to be recorded, either they should be asked to leave the room during the session or the recording not happen.

**12.0 So as to mitigate risk, the audio recordings will not be shared outside of the PSU research team and will be stored in a secure PSU-approved location. Participants will be reminded of this at the time of recording.**

## Potential Benefits to Subjects and Others

### 12.1 Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 14.0.

Parents in the treatment condition who participate in this research will learn skills on how to keep their children safe from victimization. There is no benefit to participants in the control condition.

### 12.2 Potential Benefits to Others

Include benefits to society or others.

Results of this research will inform revisions to a curriculum that will eventually be disseminated to at-risk parents.

## 13.0 Sharing Results with Subjects

Describe whether results (study results or 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 physicians) and if so, describe how it will be shared.

Results will not be shared with subjects. We will share the aggregated, de-identified data with participating sites who may choose to share it with their clients.

## 14.0 Subject Stipend (Compensation) and/or Travel Reimbursements

Describe the amount and timing of any subject stipend/payment or travel reimbursement here. If there is no subject stipend/payment or travel reimbursement, indicate as not applicable.

If course credit or extra credit is offered to subjects, describe the amount of credit and the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered.

If an existing, approved student subject pool will be used to enroll subjects, please indicate as such and indicate that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

Providers are not compensated for their participation in the audio recordings. Parents do not receive anything additional for participating in sessions that are audio recorded.

Participants of all parent-education (PE) programs are incentivized for their completion of each aspect of the research and can earn up to a total of $50 for completing surveys at all four time points. The experimental group participating in IY is also compensated with one additional session's worth of dinner and childcare during their participation in the SPSHK module (this is a typical element of Incredible Years implementation; we are including it in the delivery of our added module so that it has all of the characteristics of a typical IY session).

| | | Amount |
|---|---|---|
| T1 | Pre-PE | $10 |
| T2 | Post-PE | $10 |
| T3 | One-week post PE (Control) / Post-CSA (experimental) | $10 |
| T4 | Follow-up | $20 |
| | **Total** | **$50** |

*NOTE: PE = Parent Education (e.g., Incredible Years, Parents as Teachers, or SafeCare)*

## 15.0 Economic Burden to Subjects

### 15.1 Costs

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

There are no costs to subjects because of participation in the research.

### 15.2 Compensation for research-related injury

**If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.**

**If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:**
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

**For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written - DO NOT ALTER OR DELETE:**
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

Not applicable

# 16.0 Resources Available

### 16.1 Facilities and locations

Identify and describe the facilities, sites and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator's experience conducting research at these locations and familiarity with local culture.

This is an applied research project. The setting for all study procedures are naturally occurring in the homes of parents enrolled in parent-training programs (PAT or SC) or at group spaces for the community-based organizations (IY). A complete list of locations and facilities is not possible.

### 16.2 Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.

We are working within the existing sites who already provide these parenting services. In addition, both models are well supported by agencies across the Commonwealth. We do not expect any problem in recruiting the required number of subjects, and have factored in ample time.

### 16.3 PI Time devoted to conducting the research

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Please consider outside responsibilities as well as other on-going research for which the PI is responsible.

The PI (Guastaferro) has .6FTE devoted to this project, which is ample time to conduct and complete the research.

### 16.4 Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subject might need as a result of their participation in the study, if applicable.

We will rely on the providing agencies to utilize the psychological resources they already have in place. If an agency does not have an existing document (though they should), we will work with them to create one. If said existing document does not include information for statewide and/or national hotlines (e.g., United Way Crisis Helpline (211)), we will supply participants with that information as well.

### 16.5 Process for informing Study Team

Describe the training plans to ensure members of the research team are informed about the protocol and their duties, if applicable.

Study Team members housed at Penn State have extensive training in the protection of human subjects and appropriate, ethical research. The team holds regular meetings to discuss the implementation and research protocols, survey instruments, and their specific duties.

The PSU research team members will provide a training day for all providers who will implement the module and consent participants. The implementation and research protocols will be explained, reviewed, and modeled. Each person who will obtain consent and explain procedures will practice in a role-play format supervised by the PI prior to entering the field.

## 17.0 Other Approvals

### 17.1 Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from cooperating institutions, community leaders, schools, external sites, funding agencies).

Agencies that implement Incredible Years or PAT or SafeCare parent-training programs will be approached by mail, email, and/or phone call and invited to participate in the study. Presentations or webinars will be made available to provide more information should agencies desire. Facilitators (i.e., the individuals who actually implement the programs with parents) will then be recruited and then randomized to either (a) business-as-usual implementation of their respective program or (b) implementation of their respective program and the additional, one-session CSA module. As we recruit sites to participate we will ask about their required approvals. At this time, no site that has agreed to participate has an external approval process. All they require is a letter from the PSU IRB saying this research is approved.

As a site is recruited, a document agreement will be acquired from someone in an oversight position who has a decision-making capacity over potential subjects.

### 17.2 Internal PSU Committee Approvals

**Check all that apply:**

☐ Anatomic Pathology – Hershey only – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of HRP-902 - Human Tissue For Research Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.

☐ Animal Care and Use – All campuses – Human research involves animals and humans or the use of human tissues in animals

☐ Biosafety – All campuses – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

☐ Clinical Laboratories – Hershey only – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes, but are no longer needed for clinical use. Upload a copy of HRP-901 - Human Body Fluids for Research Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.

☐ Clinical Research Center (CRC) Advisory Committee – All campuses – Research involves the use of CRC services in any way.

☐ Conflict of Interest Review – All campuses – Research has one or more of study team members indicated as having a financial interest.

☐ Radiation Safety – Hershey only – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of HRP-903 - Radiation Review Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.

☐ IND/IDE Audit – All campuses – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

☐ Scientific Review – Hershey only – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Hershey Cancer Institute Scientific Review Committee is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website at: http://www.pennstatehershey.org/web/irb/home/resources/investigator

## 18.0 Multi-Site Research

If this is a multi-site study (i.e., the study will be conducted at other institutions each with its own principal investigator) and you are the lead investigator, describe the processes to ensure communication among sites in the sections below.

### 18.1 Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site's IRB of record). Describe the process for communication of problems with the research, interim results and closure of the study.

N/A

### 18.2 Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

N/A

### 18.3 Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

N/A

### 18.4 Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

N/A

### 18.5 Audit and Monitoring Plans

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

N/A

## 19.0 Adverse Event Reporting

### 19.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

## 20.0 Study Monitoring, Auditing and Inspecting

### 20.1 Auditing and Inspecting

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

## 21.0 Future Undetermined Research: Data and Specimen Banking

If this study is collecting identifiable data and/or specimens that will be banked for future undetermined research, please describe this process in the sections below. This information should not conflict with information provided in section 9.1.1 regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly).

### 21.1 Data and/or specimens being stored

Identify what data and/or specimens will be stored and the data associated with each specimen.

N/A

### 21.2 Location of storage

Identify the location where the data and/or specimens will be stored.

N/A

### 21.3 Duration of storage

Identify how long the data and/or specimens will be stored.

N/A

### 21.4 Access to data and/or specimens

Identify who will have access to the data and/or specimens.

N/A

### 21.5 Procedures to release data or specimens

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

N/A

### 21.6 Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

N/A

## 22.0 References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

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