**PennState**

### HRP-591 - Protocol for
### Human Subject Research

**Protocol Title:**
Early Childhood practitioner's knowledge and attitudes regarding reporting child abuse/neglect: iLookOut-Phase III

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**Important Instructions for Using This Protocol Template:**
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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.**
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## 1.0    Objectives

### 1.1    Study Objectives
The following objectives are ongoing from  STUDY00001243 previously approved by the IRB:

(1) To evaluate the effectiveness of the eLearning Module (iLook Out for Child Abuse) created to train and inform childcare providers (CCPs);

(2) To identify CCPs' current knowledge and attitudes regarding child abuse and its reporting;

(3) To evaluate the impact of an online educational program on CCPs' knowledge, attitudes, and patterns of decision-making regarding suspected child abuse and its reporting;

(4) To explore the factors influencing the impact of an online educational program on CCPs' knowledge and attitudes regarding suspected child abuse and its reporting.

Study Objectives unique to the new study:
(1) To evaluate the impact of *iLookOut* on the incidence of "High Yield" reports of suspected child abuse. A high yield report is defined as a report for which: child abuse was confirmed or social services were recommended by the State for the child/family.

(2) To evaluate the impact of *iLookOut* on the costs to the state from "low yield" childcare provider reports of suspected child abuse.

(3) To be conducted with Childcare providers (CCPs) in the state of Maine.

(4) To evaluate the effectiveness of after learning "pings" on learner retention.

### 1.2    Primary Study Endpoints
Primary Outcomes are 1) child abuse confirmation rates among CCP-reported cases of suspected child abuse; 2) rates of social services recommended for children/families who were reported for suspected abuse; and 3) costs associated with intake by the State and investigation of reports of suspected abuse in which child abuse is not confirmed and no social services were recommended.

### 1.3    Secondary Study Endpoints
Secondary outcomes are 1) changes in the number of CCP reports of suspected abuse; 2) number of CCPs in each study arm who complete *iLookOut* and Standard training; 3) CCP knowledge and attitudes regarding suspected child abuse and its reporting; and 4) CCPs' evaluation of the *iLookOut* and Standard training.

## 2.0    Background

### 2.1    Scientific Background and Gaps
1) children <5 years-old are particularly vulnerable to being abused; 2) despite being uniquely positioned to detect and report suspected abuse in young children, childcare providers (CCPs) currently identify and report less than half of 1% of substantiated cases of child abuse; 3) CCPs are not adequately prepared to identify at-risk children and protect them from abuse; 4) reports of suspected abuse from CCPs are less likely to be substantiated (compared to other mandated reporters); 5) evidence-based interventions are needed to help CCPs better serve their crucial role

in child protection; and 6) online interventions have particular advantages for standardization, easy dissemination, follow-up reinforcement, and tracking of outcomes.

### 2.2 Previous Data

Two previous studies were completed. The first was a field study that was completed with 60 Penn State Harrisburg undergraduate students majoring in early childhood education to pilot a draft of the present study's pre-/post-assessment instrument. A subset of the pre-/post-assessment's knowledge items were subsequently pilot-tested with CCPs actively employed at area childcare facilities.

The second study was a randomized controlled trial involving 735 CCPs in Pennsylvania, which demonstrated that participants who completed the *iLookOut* learning module: 1) had significant improvements in knowledge, compared to baseline; 2) showed significant changes (in the expected direction) in their attitudes toward child abuse and its reporting, compared to baseline; and 3) reported high satisfaction with the learning program.

Additionally, there is an ongoing "open enrollment" trial in which >10,000 CCPs in Pennsylvania have completed the *iLookOut* learning module. To date, the results are almost identical to the previous randomized controlled trial of *iLookOut*.

### 2.3 Study Rationale

The purpose of the present study is to examine whether (compared to Standard mandated reporter training, and also Control –i.e., no intervention), *iLookOut* affects the actual reporting behavior of CCPs.

## 3.0 Inclusion and Exclusion Criteria

### 3.1 Inclusion Criteria
1) **Childcare providers** (**CCPs**) in the state of Maine
   a. "**CCP**" refers to the various childcare professionals and others who work with young children, including teachers, aides, therapists, administrators, support staff, volunteers, and others.
2) CCPs who work (paid or volunteer) at a licensed childcare establishment in Maine.
3) ≥18 years of age

### 3.2 Exclusion Criteria
1) CCP working in a non-licensed facility
2) <18 years of age

### 3.3 Early Withdrawal of Subjects

#### 3.3.1 Criteria for removal from study
Participants will only be included in study analysis if they complete the online training post-test. Data from CCPs who do not complete the online training post-test will be excluded from analysis, except for the purposes of identifying factors correlated with non-completion of the learning program. CCPs who report that they are <18 years of age also will be excluded from study analysis.

### 3.3.2 Follow-up for withdrawn subjects
There will be no specific follow-up with CCPs who do not complete the online training and/or express that they do not wish to participate.

## 4.0 Recruitment Methods

### 4.1 Identification of Subjects
The study team will work with the state of Maine to get a list of all currently licensed facilities in the state of Maine directly before the study begins. This list will be updated by the state of Maine at various time-points throughout the study.

Childcare facilities along the I-95 corridor in southern Maine will be randomized to 3 study arms: *iLookOut*, Standard, and Control. Any childcare facility within the recruitment area will have an equal chance of being in each study arm. Those randomized to the *iLookOut* and Standard arms will be contacted by the study team to complete online training during years 2, 3, and/or 4 of the study, while those in the Control Arm will only be contacted beginning in the Spring of 2020 to complete the *iLookOut program*.

Directors of the childcare facilities will be provided with cards to distribute to their staff (uploaded as iLookOut- Recruitment Individual Access Cards), which will provide access to the online training (*iLookOut* or Standard) to which their childcare facility has been randomized. Additionally, brief questionnaires will be distributed at the end of years 2, 3, 4, and 5 to all childcare facilities groups (*iLookOut,* Standard, and Control*)* to learn about CCP exposure to the various mandated reporter trainings.

During year 3 of the study, individual child care providers who have already completed the Standard Maine training as a part of the standard group will be sent a message letting them know that the *iLookOut* training is now available in their training home page. Individual learners who have previously been engaged in the *iLookOut* training or the *iLookOut* advanced training pinging program will be sent an individual email letting them know that the program has returned (iLookOut Email Recruitment Communication ALL)

In the spring of 2020, the *iLookOut* learning module will be publicly available to CCPs who have access to a program license number throughout the state of Maine. In the summer of 2021, *iLookOut* will be available to all licensed and non-license CCPs throughout the state of Maine. The program will be publicly listed as a Maine mandated reporter training for CCPs in Maine and on CCP professional development lists.

After the October 2021 submission, learners who selected that they would participate in future research during program registration and completed the *iLookOut* Core Mandated Reporter training will be sent a one-time follow-up REDcap survey. The survey will be offered through December 2021.

### 4.2 Recruitment Process
Early childhood groups in Maine such as Maine Roads to Quality (MRTQ), Child Abuse and Neglect Councils, Home childcare alliance, and other similar groups may share approved Email and blanket messaging throughout the study with child care providers in our catchment area. The language that early childhood groups may use is included in the Community Group Support Language and Email.

The *iLookOut* project has developed a website ([www.ilookoutproject.org](www.ilookoutproject.org)) and a Facebook page as a way to inform colleagues and community groups about the study. The website and Facebook page is publicly available, and it is included in study team email signatures and could be shared by community groups; therefore, it may be viewed by potential participants. Approved Facebook posts may be placed into Facebook ads.

Any information created by the *iLookOut* team will be posted to our Facebook page will be submitted to the IRB for approval before posting. If the *iLookOut* team is sharing information from a community partner, we will use one of a few pre-approved postings and share the information from our community partner or other relevant organization.

Once active enrollment has ended, the *iLookOut* program will remain publicly available to all CCPs in the state of Maine. It will be listed on various CCP websites and listservs as training opportunities for mandated reporter and professional development credit.

Those randomized to the *iLookOut* and Standard arms will be contacted by a study team member to complete an online training during years 2, 3, 4 and/or 5 of the study, while those in the Control Arm will only be contacted beginning in the spring of 2020 to complete *iLookOut*.

Directors/owners of licensed child care facilities in the state of Maine will be sent a mailing with information about the study. Additionally, the directors/owner will receive an email contact (included in uploaded iLookOut- Recruitment Email Communications ALL) The study team will also contact the center director by phone. If requested during a phone conversation, the study team will visit the center in-person to answer questions.

The study team will contact the center director/owner by phone to ask if s/he would like additional information and/or in-person contact. If the study team is not able to make contact during the initial phone call (using the previously approved iLookOut- Phone Script), an email will be sent to directors/owners with emailed content that is similar to the phone script. This email has been included in the 11-22-17 revision of the *iLookOut* email communication document (ALL).

If the director/owner does not respond to the initial email and/or call, the study team will continue to re-send the recruitment email 1 time per week for up to 8 months. Follow-up phone calls will be made monthly for up to 8 months. One phone call per month will be followed-up with the follow-up email included in the 11-15-17 revision of the *iLookOut* communication document (ALL). If the director, owner, or other primary staff member indicates they no longer wish to be contacted by the study team, all contact with that site will stop.

If a director/owner has indicated that they would like to offer the *iLookOut* program to the staff at their program, but they have not completed the training, once monthly calls and emails

During study year 3, standard sites who have not completed the standard training will still be contacted to complete the *iLookOut* arm of the study - unless the site has explicitly stated that they no longer wish to be contacted by the study team. The *iLookOut* training is an entirely different training from the standard Maine version, and it is a new opportunity for child care providers to receive additional professional development credit than the previously offered Maine Standard state training.

Centers in the standard arm of the study will receive a second mailing that will include the information sent to the iLookOut arm during year 2.

During year 3 of the study, individual child care providers who have already completed the Standard Maine training as a part of the standard group will be sent a message letting them know that the *iLookOut* training is now available in their training home page. Individual learners who have previously been engaged in the *iLookOut* training or the *iLookOut* advanced training pinging program will be sent an individual email letting them know that the program has returned (Learner Messages). A learner will receive one of these messages weekly for up to 6 months. At the point a learner re-engages with the program, this message will stop. If a learner indicates they no longer wish to be contacted by the study team, all contact with that site will stop.

Beginning in the spring of 2020,, centers in the control arm will receive a information by email or mail asking them to complete the *iLookOut* program. During year 4 will be the first time control group centers are recruited to complete a learning program for this study. Emails will be sent out 1 time per week to center owners/directors and phone calls will be made 1 time per month. Centers randomized to the iLookOut or Standard arms that have not yet completed the *iLookOut* training will be contacted 1 time per week by email and 1 time per month by phone. This communication will continue for 8 months –unless the center requests that we no longer contact them.

Individuals from the control arm who have asked to be notified when the program is available in their area will be emailed directly 1 time.

The study mailing sent to directors/owners of the childcare facilities will include cards (upon request) and/or handouts to distribute to their staff, which will provide information about accessing the online training to which their childcare facility has been randomized. In addition to contact by a study team member, directors of the childcare facilities will receive handouts and other information about enrolling in the study, which will be sent by the study team, as well as various groups in Maine that provide educational resources to CCPs.

Additionally, brief questionnaires (uploaded as Maine End- of Year Survey) (about CCPs' exposure to various mandated reporter trainings) will be distributed at the end of year 2 to all child care programs in our study catchment area. This includes *iLookOut,* standard, and control arms. This survey will be sent out to the Maine Roads to Quality (MRTQ) email list using a RedCap link. MRTQ is the group who oversees child care professional development in the state of Maine. MRTQ will not have access to any iLookOut data; they will simply distribute an iLookOut approved e-mail and RedCap link. All data will go directly into the Penn State RedCap system. MRTQ has a comprehensive list of all child care providers in the state of Maine- including those in all arms of our study (iLookOut; Standard; & Control). This will give us an idea of bleed across all child care providers in the state of Maine.

A one-time follow-up REDcap survey will be sent out only to learners who have selected that they are willing to be contacted for future research. This one-time survey and a new summary of research will be sent through email and REDcap email tools upon IRB approval for the October 2021 submission. The survey will be offered through December 2021.

**4.3    Recruitment Materials**

A mailed packet will be provided to directors of the childcare facilities in the iLookOut and Standard arms, which will include a summary explanation of research, a welcome letter dependent on the study group, a study brochure (uploaded as iLookOut- Brochure), and a handout with program license number (Uploaded as iLookOut handout).  The following documents may be sent on a requested or as needed basis: cards that explain how to access the online training (uploaded as iLookOut- Recruitment individual access cards) and *Frequently Asked Questions* handouts depending on the group randomized that further explain the nature and purpose of the study.  In addition, directors and owners will receive an email about the iLookOut research project.  In addition to an electronic copy of the previously mentioned materials, this email will include director talking points. Please see appendix 3 for a list of recruitment materials sent to each group. The documents provided to the child care director/owner can be distributed to staff and volunteers as the director/owner sees fit.  Childcare facilities in the *iLookOut* and Standard arms will receive recruitment materials from the study team during years 2, 3, 4, and 5of this project.  Those in the Control Arm will ONLY receive an end of the year survey (uploaded as Maine End-of Year Survey) and summary explanation of research in year2 participants will receive recruitment materials from the study.  Due to the release of the program to all child care providers in the spring of 2020, year 3 and year 4 end of year surveys will not be distributed.   In the spring of 2020, , *iLookOut* training will be made available to all CCPs in the state of Maine completion of the *iLookOut* training will still meet State requirements for mandated reporter training, and will give CCPs professional development.

Early childhood groups in Maine such as Maine Roads to Quality (MRTQ), Child Abuse and Neglect Councils, Home childcare alliance, and other similar groups may share approved Email and blanket messaging throughout the study with child care providers in our catchment area. The language that early childhood groups may use is included in the Community Group Support Language and Email.

The *iLookOut* project has developed a website ([www.ilookoutproject.org](www.ilookoutproject.org)) and Facebook page as a way to inform colleagues and community groups about the study.  The website and Facebook page is publicly available, and it is included in study team email signatures and could be shared by community groups; therefore, it may be viewed by potential participants.  Approved Facebook posts may be used in Facebook ads.

Any information created by the *iLookOut* team will be posted to our Facebook page will be submitted to the IRB for approval before posting.  If the *iLookOut* team is sharing information from a community partner, we will use one of a few pre-approved postings and share the information from our community partner or other relevant organization.

All materials referenced in this section have been included in this submission or previously reviewed.

The one-time follow-up REDcap survey will be sent upon approval of the October 2021 submission- December 2021 using email recruitment and REDcap tools (included in this submission as Follow-up Survey Communication).  Learners will receive one email per week until the survey is completed for ~4-6 weeks.

**4.4    Eligibility/Screening of Subjects**
No specific eligibility or screening questions will be used for this study.  However, participants will be informed that they must be ≥18 years of age to participate in the study, and participants will be informed that by completing the online training they are certifying that they are ≥18 years

old. If an individual identifies him- or her-self as <18 years old and still completes the online training, their data will be excluded from any research analysis.

The one-time follow-up RedCap survey sent out upon approval of the October 2021 submission will include only individuals who completed iLookOut Core mandated reporter training and indicated in program registration that they were willing to be contacted for future research. If the participant has indicated or indicates that they do not want to be contacted by our research team, they will not be sent the survey or survey communication will be discontinued upon request.

## 5.0 Consent Process and Documentation
### 5.1 Consent Process

#### 5.1.1 Obtaining Informed Consent

##### 5.1.1.1 Timing and Location of Consent
While all owners/directors of childcare facilities asked to complete *iLookOut* or Standard training will receive a copy of the summary explanation of research in the recruitment packet, to ensure that all participants receive it individual CCPs will receive the summary explanation online.

Upon accessing the website, participants will be asked to provide their name and email address. After this, an authentication process must be completed to ensure that the individual is a real person and not a computer attempting to gain access to the website. For security and validity purposes, it is important this process be completed first.

After successfully clicking on the authentication link and completing the registration process, a summary explanation of research will appear. The summary explanation will inform potential participants that choosing to proceed with the online training constitutes consent for their data to be collected. Individuals not wishing to participate need not proceed to the online training, and it will be made clear that participants may stop at any time.

The one-time follow-up survey sent upon approval of the October 2021 submission- December 2021 will send participants electronic/email communication (included in the submission) with a summary of research.

##### 5.1.1.2 Coercion or Undue Influence during Consent
Child care facility directors/owners can indicate that they do not want the study team to contact the center and/or child care staff at any time during the study.

Individual participants can choose to proceed (or not proceed) with the online training (*iLookOut* or Standard), and members of the research team will not individually contact CCPs to influence their decision to participate. The *iLookOut* team will stop individual learner communication upon request.

The *iLookOut* staff will respect any request of a director or owner to stop all contact with a child care program.

**5.1.2 Waiver or alteration of the informed consent requirement**
Implied consent will be obtained by providing the participant with a summary explanation of research, which will inform the participant that by continuing with the online training they are agreeing to the terms of the study outlined in the summary. A summary explanation of research is necessary for this research study, as the training is completed completely online at the time and choosing of the participant.

**5.2 Consent Documentation**

**5.2.1 Written Documentation of Consent**
Participants will not complete consent in writing; instead, participants will be asked to provide implied consent during the online registration process.

**5.2.2 Waiver of Documentation of Consent (Implied consent, Verbal consent, etc.)**
Participants will be asked to provide implied consent for research. A summary explanation for research will be provided to participants online prior to starting the online training. Within the summary, participants will be informed that they are providing implied consent for research by completing the online training.

This research study does not provide any additional risk beyond what is typically encountered in daily life.

**5.3 Consent – Other Considerations**

**5.3.1 Non-English Speaking Subjects**
The online training was designed only for individuals who speak English; therefore, non-English speakers will not be able to complete the online training at this time.

**5.3.2 Cognitively Impaired Adults**
**5.3.2.1 Capability of Providing Consent**
Individuals completing the online training are required to read the instructions and complete registration prior to receiving the summary explanation of research document. Progression to this point in the online training will provide evidence of capability to consent.

**5.3.2.2 Adults Unable To Consent**
Only those individuals capable of understanding the instructions will proceed, which itself will provide evidence of the capacity to provide informed consent.

**5.3.2.3 Assent of Adults Unable to Consent**
This section does not apply.

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

**5.3.3.1 Parental Permission**
Participants will be asked not to complete this research study unless they are 18 years of age or older. If a CCP under 18 completes disregards the

warning or completes the module solely for certification purposes, the data from that participant will be excluded from analysis.

**5.3.3.2 Assent of subjects who are not yet adults**
Participants will be asked not to complete this research study unless they are 18 years of age or older.  If a CCP under 18 completes disregards the warning or completes the module solely for certification purposes, the data from that participant will be excluded from analysis.

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

**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**

NOT APPLICABLE:  While this study does use private information (i.e. name, email address, and  registration ID number), participants in this study are NOT medical center patients.  Patients will not be recruited from the medical center and no health information will be used in this study.

**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**
Not applicable

**6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers**
Not applicable

**6.2.2** **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**
Not applicable

**6.3    Waiver or alteration of authorization statements of agreement**
Not applicable

# 7.0    Study Design and Procedures

**7.1    Study Design**
This 5-year study will use a randomized controlled trial design to evaluate the efficacy of an innovative educational intervention, *iLook Out for Child Abuse (iLookOut)*, for improving childcare provider (CCP) reporting of suspected child abuse. Year 1 is devoted to establishing necessary infrastructure and completing development of study materials.

During Year 2, childcare facilities in the state of Maine will be randomized to *iLookOut*, Standard, or Control arms.  CCPs in the Standard arm will be recruited to complete Maine's existing online mandated reporter training, read 4 brief articles, and answer 1 question for each article (needed to receive 1 hour of professional development credit).  CCPs in the *iLookOut* arm will be asked to complete *iLookOut* (which includes follow-up engagement activities), and those in the Control arm will not be recruited to complete any training.  At the end of year 2, participants in all groups will be asked to complete an end-of-the year survey.  A separate summary explanation of research will accompany this survey.

During Year 3, CCPs in both the *iLookOut* and Standard arms will be recruited to complete *iLookOut* (which includes follow-up engagement activities), and those in the Control arm will not be recruited to complete any training.

In the spring of 2020, CCPs in all three study arms will be recruited to complete *iLookOut* (which includes follow-up engagement activities- pinging).

This sequential enrollment to receive the target intervention (*iLookOut*) is a uni-directional crossover design referred to as a "stepped wedge design."  This study design will allow the research team to examine both the immediate effect of *iLookOut*, as well as its effect over time.

In the spring of 2020, *iLookOut* will be made available (free-of-charge) to all CCPs in Maine, and outcomes data will continue to be collected for analysis.  Child care license numbers will continue to be collected.  This will allow the study team to continue separating the data by study arms (iLookOut, Standard, Control, and All other CCPs in Maine) without limiting the access to the mandated reporter program.

To estimate uptake/penetrance of the *iLookOut* and Standard training in each arm, surveys (uploaded as Maine End-of Year Survey) will be administered at the end of year 2, asking if individuals have heard of either training, and if they completed either training.  This will be identified with the center licensing number, but it will not ask the individual participant for any private information.

Data from Maine's *Office of Children and Family Services* will be used to compare baseline and post-intervention outcomes for each of the 3 study arms, and over time.  In this examination of reporting behaviors of CCPs, the **Primary Outcomes** are 1) child abuse confirmation rates among CCP-reported cases; 2) rates of social services recommended by the State for children/families who were reported; and 3) costs associated with intake and investigation of reports in which abuse was not confirmed *and* no social services were recommended. **Secondary Outcomes** are 4) changes in the number of CCP reports of suspected abuse; 5) number of CCPs in each study arm who complete *iLookOut* and Standard training; 6) CCP knowledge and attitudes regarding reporting suspected child abuse; and 7) CCPs' evaluation of the *iLookOut* and Standard training.  8) the impact of after learning engagement actives "pinging" on knowledge retention.

## 7.2    Study Procedures

### 7.2.1    Pre-Registration
During the randomization phase (years 2-3), the center director/owner will be asked to indicate if they would like to be contacted by the study team during an initial recruitment email.

In the spring of 2020the study will be available to the entire state of Maine.  The study team will continue to recruit center directors/owners by sending an initial recruitment email and mailing.  Center license numbers will continue to be collected, so the study team can continue to analyze data by study arm.  Previously mentioned community partners –like Maine Roads to Quality and Maine Office of Children and Families- may also distribute information about the iLookOut training widely.

### 7.2.2    Recruitment

Prior to accessing the online training, childcare facilities in selected areas of Maine will be randomized to receive *iLookOut*, Standard training, or Control.  CCPs in facilities randomized to receive *iLookOut* will be recruited during Years 2-5 to complete the *iLookOut* online training included in this submission.  CCPs in facilities randomized to the Standard arm initially will be recruited during Year 2 to complete Maine's current online child abuse training, and then during Years 3-5 will be recruited to complete *iLookOut*.  CCPs in facilities randomized to the Control arm will not be recruited to complete any training during Years 2-3, but then will be recruited beginning in the spring of 2020 (during Years 4 and 5) to complete *iLookOut*.

To accomplish recruitment goals, study staff will send mailings, call, and/or meet with Directors of childcare facilities and provide recruitment packets appropriate for the group to which that childcare facility was randomized.  This packet will include a summary explanation of the research, responses to frequently asked questions, fliers for the study, a study brochure, a study handout, and recruitment cards (optional) that will explain how CCPs in that facility can access the designated online training (the uploaded names of the documents used for each group can be found in appendix 3).  Study staff will follow-up with the childcare facility Directors/owners periodically to address questions and/or other issues related to the study, including ensuring that CCPs who completed the training have received their certificates documenting hours of earned professional development credit.

Beginning in the spring of 2020 years 4 & 5), *iLookOut* will be available to the entire state of Maine, and Maine's Office of Child and Family Services may choose to promote or advertise the training separate from this study. Centers originally randomized to iLookOut, Standard, or Control will continue to be recruited by center. As in Years 2-4 of the study, CCPs who choose to complete *iLookOut* will be asked to complete the registration, pre-test, post-test, and evaluation, and will be provided a summary explanation of research, their participation, as well as data collection and use.

### 7.2.3 Registration and Learning Module

Because the study team will talk primarily with childcare facility directors/owners/administrators responsible for maintaining staff training, consenting must take place as a part of the study's online registration process. This will ensure that all study participants taking the online training receive the same standard summary explanation of research.

Participants will begin registration by providing the center's state license number, their name, and email address. The center state license number is required because center staff are randomized to the standard, iLookOut, or control training arms based on the center's licenses number. Then, participants will activate their online account through the link provided to them via email. After authentication and registration has been completed, participants will be provided with a summary explanation of research, and participants will continue to complete the registration process and collection of demographic data. Participants will then be asked to complete the pre-assessment. All participants will then be asked to complete the online training, followed by the post-assessment, followed by an evaluation of the online training. This can be completed at one time point or at various time points, at the discretion of the participant.

After the participant completes the online training, the host of online training will store the research data and provide documentation necessary for participants to receive professional training credit and appropriate state credit for mandated reporter training.

### 7.2.4 Post-training "Pinging"

**NOTE: This portion of the project will be taken down for redevelopment on a new platform between October 1st. 2018 and spring of 2019. Learners will not have any access to this portion of the program during this time. All other aspects of the project will remain fully functional as described in this protocol. Currently engaged learners and those who complete the *iLookOut* program by September 28th will be offered an opportunity to complete after learning pinging modules 1-53 before October 1st. Learners will be able to pick-up where ever they left off in the after learning pinging program in the Spring of 2019.**

During registration, CCPs randomized to receive *iLookOut* will be informed that they can receive additional educational resources via a web-based App that can be downloaded to a cell phone or tablet or accessed online using a computer. This process of providing follow-up education is called ping-ing, and the individual notifications "pings." After the initial online training is complete, participants will be asked to sign-in to the online or App-based program to receive a training certificate. Post-training pinging will only occur for participants after they have completed the *iLookOut* child abuse training. Child care providers in Maine do not standardly receive Pings or after-training resources.

In this study, participants completing the *iLookOut* program can opt out of receiving these pings by contacting study staff or following directions provided on how to stop further pinging. Participation in pinging will not affect future use of the learning program discussed elsewhere in this submission.

CCPs may receive weekly messages per, whose content will include updates, supplementary training materials, practical resources, questions/quizzes, games, videos, resources, etc. Each week learners will be asked to complete approximately 3-6 activities within the pinging program for up to 3 years. The actual pings may evolve throughout the study –based on what the research team learns about the efficacy of different kinds of pinging. Pinging content will be developed 3 months in advance of use. The first 3 months of content and screen shots of the activities will be provided in this submission on or before have been included in this submission. This process will be a part of the actual training, and a vital piece to continuing and improving the online learning process. CCPs may opt out of receiving these pings at any time.

To allow for learner flexibility, learners will be asked to choose if they would like to receive the pinging content over the course of a 2 month, 4 month, or 6 month time period. Learners can change this setting at any time, and they are able to extend this time. This can be seen by click on the *gear* settings option beside the advanced training 1 or 2 courses on the *iLookOut* demo program.

Learners will also be able to select a theme to complete the course in. These themes can also be seen by clicking on the *gear* settings option beside the advanced training 1 or 2 courses. These themes include: a space adventure, an underwater adventure, a farm theme, a bake-a-cake theme, and a movie theater theme. Learners can also change their theme throughout the program.

Learners who do not engage in the *iLookOut* Advanced Training 1 program for a period of 4 months or more after completing the *iLookOut* core training will be asked to complete the *iLookOut* post-test (iLookOut Learning Module Pre- and Post- test) again. This provides the study team with an updated base-line of knowledge upon re-entry into the Advanced Training 1 program. All *iLookOut* advanced training users who have not completed Advanced Training 1 at program re-launch in April 2019 will be asked to re-take this knowledge test. In the demo, it can be seen in the tile, *iLookOut* training check, and this box will only appear for learners who have not engage in the *iLookOut* Advanced Training 1 program in 4 months. Learners will also be asked to complete the *iLookOut* post-test (iLookOut Learning Module Pre- and Post- test) after completing the *iLookOut* Advanced Training 1 course. This test will not be administered after Advanced Training 1 is complete.

At the end of each course, learners will receive an *iLookOut* badge and additional professional development credit.

Learners who complete the *iLookOut* course will have the option of adding an *iLookOut* flag to their conference name tag at conferences and similar events in Maine that child care providers frequently attend (*Optional: iLookOut Conference Training Badge/Flag*). *iLookOut* flags will be left at a table for child care providers to pick up. Completion of *iLookOut* will not be verified. There will be a sign or individual who simply says if an individual completed the *iLookOut* training they may take a flag. Again, no verification will be required.

The *iLookOut* after learning program mentioned in the paragraph above will be temporarily taken down between October 1st 2018- Spring 2019. This program will temporarily be down while we re-develop this learning content on a new platform with a different developer. Learners who are actively engaged in the after-learning program or learners who complete the *iLookOut* learning program during this time will have the opportunity to complete 1 year of after-learning activities (Modules 1-53) between August 7th- October 1st. We will notify learners of this opportunity by replacing the standard, weekly *iLookOut After-Learning (pinging) email messages* with the *iLookOut Open Access Email* included in this submission. The *iLookOut Open Access Email* will be sent out weekly between August 7th-October 1st.

The *iLookOut* learning program will remain active during this time. Once the *iLookOut* after learning program is fully functional on the new platform in Spring of 2019 all current learners will be notified, and they will be able to pick-up in the after-learning program where they left off. Each transition will require a new IRB submission to approve new language to keep learners informed.

### 7.2.5 Post-training Data Collection

Over the course the study, the state of Maine will provide the research team de-identified aggregate data on CCP reports of suspected abuse, including: the number of reports; their outcomes (confirmed vs. unfounded); kinds of abuse identified; whether social services were recommended (and what kind); and whether the CCP making the report completed any training on child abuse (and if so, which).

To identify which CCP report data need to be examined for the research study, intake workers at Maine's Office of Child and Family Services (OCFS) will ask all individuals making a report whether they have worked (paid or volunteer) at a childcare facility since Aug. 1, 2017. Those who answer "yes" will then be asked whether they completed any training on child abuse, and if so which. Responses to these questions will then be entered into a separate data field within Maine's Automated Child Welfare Information System, which then can be queried to create the de-identified aggregate reports mentioned above.

As a back-up to ensure that participants in the *iLookOut*, Standard, and control arms are not missed, the names of CCPs who make reports of suspected abuse will also be cross-checked against the names of CCPs who have completed the *iLookOut* and Standard online trainings used in the research study. Child Care providers will be informed that some registration information will be used to verify and connect various data sets including: learning module data, pinging data, and data from Maine's child abuse reporting system. The connecting information will be kept as a code book and destroyed after all data are connected. Because the vast majority (>99%) of CCPs do not report suspected child abuse during any given year, there is no expectation that a given individual who completes the *iLookOut* or Standard training will report suspected abuse. As such, it will *not* be seen as a red flag that a given study participant did not make a report.

**7.2.6    End-of-Year Survey (DISCONTINUED Uploaded as Maine End- of Year Survey)**

In addition to data collection associated with the *iLookOut* and Standard online trainings, research staff will distribute surveys at the end of Year 2 to CCPs in all three arms of the study to evaluate penetration of the study interventions.  These brief surveys will be sent out to the Maine Roads to Quality (MRTQ) email list using a RedCap link.  MRTQ is the group who oversees child care professional development in the state of Maine.  MRTQ will send out the end-of-year survey link and end-of-year survey message 1 time per week for up to 4 weeks.

MRTQ will not have access to any iLookOut data; they will simply distribute an iLookOut approved e-mail and RedCap link.  All data will go directly into the Penn State RedCap system.  MRTQ has a comprehensive list of all child care providers in the state of Maine- including those in all arms of our study (iLookOut; Standard; & Control).  This will give us an idea of bleed across all child care providers in the state of Maine. The survey will ask for the participant to provide the childcare facility license number that they used to complete training.  This number is not personally identifiable and only identifies a childcare facility.   The survey will not include (nor request) any personally identifying information.  These surveys will ask whether the individual has heard of, and/or completed, the *iLookOut* and/or Standard online trainings.

Note that control group participants do not receive any training or research study contact in years 2-3, except for the end-of-year survey. Learners will receive a separate summary explanation of research (uploaded as Summary Explanation of Research to Accompany End of the Year Survey) to accompany this survey.  This summary explanation will be provided at each time point the survey is provided.

**7.2.7    One-time Follow-up Survey**
A one-time follow-up survey will be sent out to learners who have completed the *iLookOut* Core training at the time the survey is being sent out.  This will not impact ongoing completion of the *iLookOut* programs.  The follow-up survey will populate different questions based on where the *iLookOut* learner is within the *iLookOut* programs. The survey will account for 1) *iLookOut* Core completion ONLY 2) Starting *iLookOut* Advanced Training pinging or 3) Completing at least one *iLookOut* Advanced Training pinging course.  The survey is designed to ask the learner questions that are relevant to their experience without asking unnecessary questions.

This survey is estimated to take ~20-30 minutes, and learners will be able to complete the survey at their own pace.  The survey will ask learners to provide additional information on their experiences completing core training and post-training pinging.  The survey purposes to learn more about the barriers learners face wen completing ongoing training. Learners will have 4-6 weeks from the first recruitment email to complete the survey.

**7.3    Duration of Participation**
CCPs who chose to participate will be randomized to complete either *iLookOut* or the Standard online training.  Those asked to complete *iLookOut* may complete the training in one sitting, or over multiple sittings, while those asked to complete the Standard training will need to do so in one sitting.  <u>For *iLookOut*</u>, it is expected that most participants will take 5-10 minutes to complete registration, 10-15 minutes to complete the pre-assessment; 90-120 minutes to complete the training itself; 10-20 minutes to complete the post-assessment; 20-30 minutes to

review the resource materials provided; and 5 minutes to complete the evaluation of the training. <u>For the Standard training</u>, it is expected that most participants will take 5-10 minutes to complete registration, 10-15 minutes to complete the pre-assessment; 30-60 minutes to complete the training itself; 10-20 minutes to complete the post-assessment; and 5 minutes to complete the evaluation of the training. Those who complete the standard training in year 2 of the study will be asked to complete the *iLookOut* training in year 3 of the study.

CCPs who complete *iLookOut* will receive weekly after-learning messages (or "pings") (via App and/or email), whose content will include updates, supplementary training materials, practical resources, questions/quizzes, etc. It is anticipated that these pings will take 1-5 minutes to read and/or respond to, and will occur with variable frequency after completion of *iLookOut*. CCPs may opt out of receiving these messages at any time. This pinging information will only be sent to participants who have completed the *iLookOut* program. Child care providers will not receive "pings" without completing the *iLookOut* program, and will be told that the *iLookOut*App will allow them to receive pings (i.e., updates, additional educational materials, and brief questions) after completing the *iLookOut* training. Because the term "pinging" is only used in specific learning gamification circles, our research population is not likely to be familiar with this term, and hence the term is not referenced in the materials shared with CCPs.

The *iLookOut* after learning program mentioned in the paragraph above will be temporarily taken down between October 1st 2018- Spring 2019. This program will temporarily be down while we re-develop this learning content on a new platform with a different developer. Learners who are actively engaged in the after-learning program or learners who complete the *iLookOut* learning program during this time will have the opportunity to complete 1 year of after-learning activities (Modules 1-53) between August 7th- October 1st. We will notify learners of this opportunity by replacing the standard, weekly *iLookOut After-Learning (pinging) email messages* with the *iLookOut Open Access Email* included in this submission. The *iLookOut Open Access Email* will be sent out weekly between August 7th-October 1st.

The *iLookOut* learning program will remain active during this time. Once the *iLookOut* after learning program is fully functional on the new platform in Spring of 2019 all current learners will be notified, and they will be able to pick-up in the after-learning program where they left off. Each transition will require a new IRB submission to approve new language to keep learners informed.

A learner who participants in the *iLookOut* course and pinging program could participate in the study for more than 4 years.

The one-time follow-up survey will be sent to learners who agree to participate in future research and completed the iLookOut Core mandated reporter training. They will be sent a survey invitation over a ~ 4-6 week period after IRB approval, and it will take ~20-30 minutes to complete all questions in the survey.

## 8.0 Subject Numbers and Statistical Plan

### 8.2 Number of Subjects
Efforts will be made to recruit ~4,500 CCPs during Years 2, 3, 4, and 5 of the study, and it is expected that ~84 CCPs reports of suspected child abuse will be needed for successful analysis. However, because the exact number of paid and volunteer staff at childcare facilities is not known, it is difficult to determine how many individuals may choose to participate in the study.

In the spring of 2020, CCPs throughout Maine will have access to *iLookOut*, which may result in additional numbers of research participants.

**8.3    Sample Size Determination**
In the spring of 2020, *iLookOut* will be made available to all CCPs in Maine.  Therefore, while we will actively recruit ~4,500 CCPs in the targeted study area to participate during the grant period, we also will collect data from additional CCPs who choose to register and complete the *iLookOut* outside of the catchment area.  As such, there is no official limit at this time for the number of CCPs who may participate in the study.

Sample size estimation for the number of needed reports is based on multivariate analysis of variance (MANOVA) for the 4 repeated measurements of the 2 primary dependent variables, and using the historical data in the past 5 years from Maine (see Appendix 4.7). Assuming a medium effect size of 0.33111 with regard to MANOVA analysis of the repeated measurements, at alpha level of 0.05, to obtain a statistical power of 80% to detect the effect of intervention and time, 22 reports from each of the 3 arms (66 total), are needed annually. Given the nature of social/behavior research, a conservative drop-off rate of 20% will be expected (to account for CCPs recruited to the study, but who leave before outcomes are measured at year's end). This results in a final sample size estimation of 84 (= 66 ÷ 0.8) in total (28 reports per arm).

**8.4    Statistical Methods**
The primary statistical analysis will be the analysis for repeated measurement of the 2 primary dependent variables as defined in the Specific Aims, using the arm and time as the 2 primary independent variables, through MANOVA. According to recent literature on the stepped wedge design, the common linear mixed model (LMM) will be utilized instead of the generalized estimating equations (GEE) or generalized linear mixed models (GLMM), given that the 3 arms have equal size. We will use the PROC MIXED software, version 9.4, including modeling the polynomial trends over time and comparisons of the 2 primary dependent variables among the 3 groups at different time points.

Additional analyses will be performed to explore the relationship between the primary dependent variables and the covariates, using appropriate statistical analyses (e.g., ANCOVA, t-test, non-parametric tests, chi-square, etc.), whose choice will depend upon study outcomes data and their distribution. However, the results from these additional analyses should only be interpreted as exploratory (not confirmatory) because the sample size estimation is not based on these covariates, and therefore these analyses may not have enough power to detect any meaningful effect for these covariates.

Moreover, since individual level data will be collected (e.g., CCPs' knowledge and attitude scores), additional analyses of these data also will be performed (e.g., t-test, chi-square, ANOVA, non-parametric tests, and psychometric analyses), again based upon the data and their distribution –with the results likewise interpreted as exploratory. The same analytic approaches will be applied to the data on Report Rate, Confirmation Rate, Social Service Rate, and Cost data, as for the supplementary analyses.

# 9.0    Confidentiality, Privacy and Data Management
**9.2    Confidentiality**

**9.2.6 Identifiers associated with data and/or specimens**
See the Research Data Plan Review Form

**9.2.6.1 Use of Codes, Master List**
See the Research Data Plan Review Form

**9.2.7 Storage of Data and/or Specimens**
See the Research Data Plan Review Form

**9.2.8 Access to Data and/or Specimens**
See the Research Data Plan Review Form

**9.2.9 Transferring Data and/or Specimens**
See the Research Data Plan Review Form

**9.3 Subject Privacy**
Every participant will be assigned a unique participant ID number when registering for the *iLookOut* or Standard online training. This will link individual names to contact information (necessary to verify completion, appropriate certificate and professional development credit, and send pings), and will allow for cross-checking with Maine's Automated Child Welfare Information System to identify which research arm CCPs who reported suspected abuse were enrolled in (if any).

# 10.0 Data and Safety Monitoring Plan

**10.2 Periodic evaluation of data**
This section does not apply at this time.

**10.3 Data that are reviewed**
This section does not apply at this time.

**10.4 Method of collection of safety information**
This section does not apply at this time.

**10.5 Frequency of data collection**
This section does not apply at this time.

**10.6 Individuals reviewing the data**
This section does not apply at this time.

**10.7 Frequency of review of cumulative data**
This section does not apply at this time.

**10.8 Statistical tests**
This section does not apply at this time.

**10.9 Suspension of research**
This section does not apply at this time.

**11.0    Risks**

The study poses no risk beyond those encountered in everyday life, nor does participation impose ay expectations (professional, legal, or otherwise) not already incumbent on child care professionals.

Participants may experience psychological discomfort due to the subject matter, though efforts will continue to be made to minimize this discomfort.  There is no violence nor graphic images in *iLookOut*, and all scenarios and language are carefully constructed to reduce any potential discomfort.

There is a risk of loss of confidentiality if participant information is obtained by someone other than the study team or the host of the online training.  Precautions will be taken to prevent this from happening.

For subjects who have elected to receive after-training contact through an App and/or online, we are including the following in the Summary Explanation of Research:
"It is illegal in the state of Maine to text while driving.  It is also dangerous to pay attention to your cellular phone while driving, walking, or doing any activity that requires your attention. You should continue to exercise good judgment on this while participating in this study."

**12.0    Potential Benefits to Subjects and Others**

**12.2    Potential Benefits to Subjects**
Successfully completing the online training that is part of this research study will provide participants with education about child abuse and their responsibilities as mandated reporters, as well as appropriate professional development credit.

**12.3    Potential Benefits to Others**
To the extent that *iLookOut* is effective in improving participants' awareness and knowledge, participants will be better prepared to take the appropriate steps to identify and report children at risk for child abuse –which would benefit society as a whole.

To the extent that *iLookOut* causes an increase in high quality reports of child abuse and better use of limited resources for investigating child abuse reports, other states and society as a whole may benefit from implementing similar training.  A reduction in low quality reports also may reduce psychological burdens experienced by families who are incorrectly reported.

**13.0    Sharing Results with Subjects**

Upon successful completion of the online training, participants would learn the results of their responses on the post-assessment tool.  We anticipate that aggregate results will be published, and generally available to the public. Participants will also be able to share any course completion certificate with their program owner or director; however, the participant will not be able to share their specific score.  If the learner desires to share their completion certificate(s) or badges with an outside source, they will be required to send the information to the source.

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

Participants will not be provided with a monetary stipend or compensation beginning in the spring of 2021.  .

**15.0    Economic Burden to Subjects**

### 15.2 Costs
There will be no costs to childcare facilities or CCPs associated with this project.  The *iLookOut* and Standard online trainings are provided to learners for free.

### 15.3 Compensation for Research-related Injury
There is no reasonable expectation that participation in this research will result in any form of injury.  That said, 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.

## 16.0 Resources Available

### 16.2 Facilities and Locations
This study will occur in the state of Maine.  CCPs will participate in the online training from their place of employment, their home, or location for public internet use (e.g., Library).  While the PI has not conducted a project in the state of Maine, the PI and study team have conducted two other projects using a similar version of the *iLookOut* learning module, and the study team has an excellent working relationship with Maine's Office of Child and Family Services, which oversees both the provision of continuing education to CCPs and child abuse reporting in the state of Maine.

### 16.3 Feasibility of Recruiting the Required Number of Subjects
The study team will have access to contact information for all registered child facilities (centers, home-based, Head Start, and other registered childcare facilities) in the state of Maine.

### 16.4 PI Time Devoted to Conducting the Research
Benjamin H. Levi, MD, PhD will continue to devote the time and attention required for managing this research project.

### 16.5 Availability of Medical or Psychological Resources
Medical and psychological resources can be obtained at the Penn State Hershey Medical Center or some other healthcare facility; however, this will be at the cost of the participant or the participant insurance.  At this time, it is not anticipated there will be any need for medical or psychological resources due to participation in this study.

### 16.6 Process for informing Study Team
Routine study meetings, emails, and phone calls.

## 17.0 Other Approvals

### 17.1 Other Approvals from External Entities
We have received approval from the state of Maine to conduct this project, and we will be working closely with Maine throughout the project.  The state of Maine has signed an MOU with the Penn State Hershey agreeing to work with the study team to meet the needs of the research project, including data collection.

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During the Spring of 2020, the study will be available to the entire state of Maine.  At this time, the study team will continue to collect program license numbers, so data can be analyzed by

assigned study arms. Study arms will continue to be recruited by center director/owner. However, community partners previously mentioned- like Main Roads to Quality, Maine's Office of Children and Families, and other CCP organizations in Maine- may broadly distribute information about the iLookOut program throughout the state.

**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 the Use of Human Tissue For Research Form on the "Supporting Documents" page in CATS IRB. This form is available on the IRB website at: http://www.pennstatehershey.org/web/irb/home/resources/forms

☐  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).

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

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

☐  Radiation Safety – Hershey only – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload the Radiation Review Form on the "Supporting Documents" page in CATS IRB. This form is available on the IRB website at: http://www.pennstatehershey.org/web/irb/home/resources/forms

☐  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**

Though this study takes place in Maine, Dr. Benjamin Levi will be the only PI for this study, and the Maine site will be the only site of the research.  Therefore, this section does not apply.

**18.1    Communication Plans**
This section does not apply.

**18.2    Data Submission and Security Plan**
This section does not apply.

**18.3    Subject Enrollment**
This section does not apply.

**18.4    Reporting of Adverse Events and New Information**
This section does not apply.

**18.5    Audit and Monitoring Plans**
This section does not apply.

**19.0    Adverse Event Reporting**

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

The data collected as part of this research study will only be used for the purposes and objectives described in this protocol and for the purpose of evaluating and/or improving education, and/or interventions related to child abuse.  No specimens are collected as part of this research.

**21.1    Data and/or specimens being stored**
Not applicable

**21.2 Location of storage**
Not applicable

**21.3 Duration of storage**
Not applicable

**21.4 Access to data and/or specimens**
Not applicable

**21.5 Procedures to release data or specimens**
Not applicable

**21.6 Process for returning results**
Not applicable

**22.0 References**

B Mathews, C Yang, EB Lehman, C Mincemoyer, N Verdiglione, BH Levi, Educating Early Childhood Care and Education Providers to Improve Knowledge and Attitudes about Reporting Child Maltreatment: A Randomized Controlled Trial, PLOS One (*in press*).

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Crowell K, Levi BH. Mandated Reporting Thresholds For Community Professionals. Child Welfare. 2012;91(1):35-53.

Levi BH, Crowell K. Child Abuse Experts Disagree About The Threshold For Mandated Reporting. **Clinical Pediatrics**. 2011;50(4):321-9.

Levi BH, Portwood S. Reasonable Suspicion of Child Abuse: Finding a Common Language, J. Law and Medicine. 2011;39(1):62-69.

**23.0 Appendices**

**23.1 Appendix 1: Learning Objectives for *iLook Out for Child Abuse***

After completing *iLook Out for Child Abuse* childcare providers should be able to:

1. Understand and recognize possible child abuse, including:
   - What does and does not constitute child abuse
   - How and where abuse occurs
   - Risk factors for abuse
   - Signs and symptoms of abuse
   - Consequences of abuse
   - Strategies and resources for responding to suspected abuse

2. Understand your responsibilities as a mandated reporters of suspected abuse, including:
   - Legal responsibilities as a mandated reporter
   - Steps for carrying out these responsibilities
   - Consequences of failing to report suspected abuse

– legal immunity so long as a report is made in good faith

3. Become empowered and motivated to protect children who are at risk for abuse, including:
   – What to do when there are barriers to reporting suspected abuse
   – How to initiate a dialogue with colleagues about concerns involving child abuse

## 23.2    Appendix 2: Explanation of "Ping-ing"

Originally (and technically), to "ping" someone (or their computer) involved sending a test unit of data that would generate a return message, allowing the sender to measure the lag time between sending and retrieving data.  As such, the term "PING" originally stood for "Packet Inter-Network Groper," and was intended to mimic the term submarine operators used to indicate a returned sonar pulse.

Over the past decade, the term "ping" has evolved to also mean "getting the attention of" or "to check for the presence of" another party online.  Forms of ping-ing include tweets, Facebook alerts, and other instant messaging that provide updates, reminders, and queries.  Some pings simply convey information, while some have response-options for the recipient to select, and others provide web-links to videos, download-able documents, or interactive activities.

There are multiple commercial services that allow individuals, businesses, and other groups to send out both generic and tailored pings to specified individuals.  Typically, pings are sent to smart-phones or other mobile technology, but they can also be sent to emails or other computer-based addresses.

We have contracted with the company CAIT to use ping-ing technology to send prompts to childcare providers (after they have completed *iLook Out for Child Abuse*) to both reinforce learning and provide opportunities for real-time interactive engagement that follows on the goals and learning objectives of the intervention.

## 23.3    Appendix 3: iLookOut documents/Materials by group (i.e. iLookOut, Standard, Control)

### *iLookOut* Study Group:
**Year 2: (COMPLETED 2018)**
Recruitment Mailing Inludes  (initially sent in study YR 2 Fall 2017):
- Summary Explanation of Research
- OCFS Endorsement Letter
- *iLookOut* Welcome Letter *iLookOut* Arm (Center Based) OR *iLookOut*- Welcome Letter *iLookOut (*Home Care ONLY)
  - Note: This is dependent on the type of child care center
- *iLookOut* Brochure
- *iLookOut* Recruitment Handout with License Number
- *iLookOut* individual Access Cards
- *iLookOut*- FAQ 1 pg Handout
- *iLookOut*- Pinging FAQ Handout
- *iLookOut*- FAQ 5 pg Program Owner/Manager FAQ

Recruitment Email(s) with Attachments (initially sent in Study YR 2 Fall 2017):
- Summary Explanation of Research
- *iLookOut*- Recruitment Email Communication (ALL)
- *iLookOut*- Recruitment Handout
- *iLookOut*- Director Talking Points

- *iLookOut* individual Access Cards
- *iLookOut* Welcome Letter *iLookOut* Arm (Center Based) OR *iLookOut-* Welcome Letter *iLookOut (*Home Care ONLY)
  - Note: This is dependent on the type of child care center
- *iLookOut- FAQ 1 pg Handout*
- *iLookOut-* Pinging FAQ Handout
- *iLookOut- FAQ 5 pg Program Owner/Manager FAQ*
- Program Recruitment Survey (with Branching Logic) AND RedCap PDF- Program Recruitment Survey * Note this is the same survey with 2 REDCap viewing options)

Phone Recruitment (initially Study YR 2 Fall 2017):
- *iLookOut-* Recruitment Phone Script
- *iLookOut-* Check in Phone Script

Content/Screen shots included in the *iLookOut* online Learning program (initially open for *iLookOut* group in YR2 Fall 2017):  *Note- Learners will be exposed to these items online at demo.ilookoutmaine.org and www.ilookoutmaine.org .  You can view these items online as they are intended by using the instructions included in the "Memo to the IRB  re. Learning Module."
- Summary Explanation of Research
- *iLookOut-* Learning Module Screen Shots
- *iLookOut:* Phase III Video and Training Script (this includes the text used to create training videos and layout of training)
- Learning Module Handouts (provided throughout training)
- *iLookOut-* Certificate of Completion
- *iLookOut* Measures included in the online learning program uploaded as:
  - *iLookOut* Learning Demographics
  - *iLookOut-* Learning Module Pre and Post Test
  - *iLookOut-* Learning Module Evaluations

After learning (pinging) content/screen shots (Can be sent/accessed by *iLookOut* group after completing the *iLookOut* program through the end of the study)
 *Note- Learners will be exposed to these items using the *iLookOut App* or the website associated with the *iLookOut app.*  You can view these items online as they are intended by using the instructions included in the "Memo to the IRB re. After-Learning Engagement (pinging)."  These items will be sent from the time of learning module completion until the study ends or the participant requests to stop receiving after-learning content.
- *iLookOut* Certified Badge (provided after training completion)
- After-learning (pinging) email messages
- After-learning (pinging) App messages
- *iLookOut-* After-learning (pinging) Activity screen shots
- *iLookOut-* After- learning (pinging) content modules 1-12
- *iLookOut-* Phase III After Packet Vignettes

**Throughout Study:**
End-of Year Survey (Sent once per year at the end of Year 2)
- Summary Explanation of Research to Accompany End of Year Survey
- Maine End- of Year Survey

**Year 3- 5: (SPRING 2019- Fall 2021)**

Continued After-learning pinging contact and continued enrollment of child care providers and volunteers who are new to centers in the *iLookOut* group and/or haven't completed *iLookOut* by using approved recruitment materials.

For Programs that have not yet completed *iLookout* or have new staff:
Recruitment Mailing Includes (initially sent in study YR 3 Spring 2019):
- Summary Explanation of Research
- OCFS Endorsement Letter
- *iLookOut* Welcome Letter *iLookOut* Arm (Center Based) OR *iLookOut-* Welcome Letter *iLookOut (*Home Care ONLY)
  - Note: This is dependent on the type of child care center
- *iLookOut* Brochure
- *iLookOut* Recruitment Handout with License Number
- *iLookOut* individual Access Cards (Optional/Upon Request)
- *iLookOut-* FAQ 1 pg Handout

Recruitment Email(s) with Attachments:
- Summary Explanation of Research
- *iLookOut-* Recruitment Email Communication (ALL)
- *iLookOut-* Recruitment Handout
- *iLookOut-* Director Talking Points (Optional/Upon Request)
- *iLookOut* individual Access Cards (Optional/Upon Request)
- *iLookOut* Welcome Letter *iLookOut* Arm (Center Based) OR *iLookOut-* Welcome Letter *iLookOut (*Home Care ONLY)
  - Note: This is dependent on the type of child care center
- *iLookOut- FAQ 1 pg Handout*

Phone Recruitment (initially Study YR 3 Fall 2018):
- *iLookOut-* Recruitment Phone Script
- *iLookOut-* Check in Phone Script

Content/Screen shots included in the *iLookOut* online Learning program (initially open for Standard group in YR3 Fall 2018): *Note- Learners will be exposed to these items online at demo.ilookoutmaine.org and www.ilookoutmaine.org . You can view these items online as they are intended by using the instructions included in the "Memo to the IRB re. Learning Module."
- Summary Explanation of Research
- *iLookOut-* Learning Module Screen Shots
- *iLookOut:* Phase III Video and Training Script (this includes the text used to create training videos and layout of training)
- Learning Module Handouts (provided throughout training)
- *iLookOut-* Certificate of Completion
- *iLookOut* Measures included in the online learning program uploaded as:
  - *iLookOut* Learning Demographics
  - *iLookOut-* Learning Module Pre and Post Test
  - *iLookOut-* Learning Module Evaluations

After learning (pinging) content/screen shots (Can be sent/accessed by Standard group after completing the *iLookOut* program in YR 3 through the end of the study)
 *Note- Learners will be exposed to these items using the *iLookOut App* or the website associated with the *iLookOut app.* You can view these items online as they are intended by using the instructions

included in the "Memo to the IRB re. After-Learning Engagement (pinging)." These items will be sent from the time of learning module completion until the study ends or the participant requests to stop receiving after-learning content.

- *iLookOut* Certified Badge (provided after training completion)
- After-learning (pinging) email messages
- After-learning (pinging) App messages
- *iLookOut-* After-learning (pinging) Activity screen shots
- *iLookOut-* After- learning (pinging) content modules Year 1
- *iLookOut-* After- learning (pinging) content modules Year 2 (Modules 1-3)

**Throughout Study:**

End-of Year Survey (Sent once per year at the end of Year 2)

- Summary Explanation of Research to Accompany End of Year Survey
- Maine End- of Year Survey

**Standard Study Group:**
**Year 2: (COMPLETED 2018)**

Recruitment Mailing Includes (initially sent in study YR 2 Fall 2017):

- Summary Explanation of Research
- OCFS Endorsement Letter
- *iLookOut* Welcome Letter Standard Arm Only
- *iLookOut* Recruitment Handout with License Number
- *iLookOut* individual Access Cards
- *iLookOut-* FAQ 1 pg Handout
- *iLookOut-* FAQ 5 pg Program Owner/Manager FAQ

Webinar and Recruitment Email(s) with Attachments (initially sent in Study YR 2 Fall 2017):

- Summary Explanation of Research
- Webinar Handout
- *iLookOut-* Recruitment Email Communication (ALL)
- *iLookOut-* Recruitment Handout
- *iLookOut* individual Access Cards
- *iLookOut* Welcome Letter Standard Arm Only
- *iLookOut- FAQ 1 pg Handout*
- *iLookOut- FAQ 5 pg Program Owner/Manager FAQ*
- Program Recruitment Survey (with Branching Logic) AND RedCap PDF- Program Recruitment Survey * Note this is the same survey with 2 REDCap viewing options)

Phone Recruitment (initially Study YR 2 Fall 2017):

- *iLookOut-* Recruitment Phone Script
- *iLookOut-* Check in Phone Script

Content included in the online Standard learning program (initially open for *standard* group in YR2 Fall 2017): *Note- Learners will be exposed to these items online at demo.ilookoutmaine.org and www.ilookoutmaine.org .

- Summary Explanation of Research

- Standard Maine Child Abuse Training
- Standard- Certificate of Completion
- Measures included in the online learning program uploaded as:
    - *iLookOut* Learning Demographics
    - *iLookOut*- Learning Module Pre and Post Test
    - *iLookOut*- Learning Module Evaluations

**Throughout Study:**
End-of Year Survey (Sent once per year at the end of Year 2)
- Summary Explanation of Research to Accompany End of Year Survey
- Maine End- of Year Survey

**Year 3 (BEGINNING APRIL 2019)**
Recruitment Mailing Includes (initially sent in study YR 3 Spring 2019):
- Summary Explanation of Research
- OCFS Endorsement Letter
- *iLookOut* Welcome Letter *iLookOut* Arm (Center Based) OR *iLookOut*- Welcome Letter *iLookOut (*Home Care ONLY)
    - Note: This is dependent on the type of child care center
- *iLookOut* Brochure
- *iLookOut* Recruitment Handout with License Number
- *iLookOut* individual Access Cards (Optional/Upon Request)
- *iLookOut*- FAQ 1 pg Handout

Recruitment Email(s) with Attachments (initially sent in Study YR 3 Spring 2019):
- Summary Explanation of Research
- *iLookOut*- Recruitment Email Communication (ALL)
- *iLookOut*- Recruitment Handout
- *iLookOut*- Director Talking Points (Optional/Upon Request)
- *iLookOut* individual Access Cards (Optional/Upon Request)
- *iLookOut* Welcome Letter *iLookOut* Arm (Center Based) OR *iLookOut*- Welcome Letter *iLookOut (*Home Care ONLY)
    - Note: This is dependent on the type of child care center
- *iLookOut- FAQ 1 pg Handout*
Phone Recruitment (initially Study YR 3 Fall 2018):
- *iLookOut*- Recruitment Phone Script
- *iLookOut*- Check in Phone Script

Content/Screen shots included in the *iLookOut* online Learning program (initially open for Standard group in YR3 Fall 2018): *Note- Learners will be exposed to these items online at demo.ilookoutmaine.org and www.ilookoutmaine.org . You can view these items online as they are intended by using the instructions included in the "Memo to the IRB re. Learning Module."
- Summary Explanation of Research
- *iLookOut*- Learning Module Screen Shots
- *iLookOut:* Phase III Video and Training Script (this includes the text used to create training videos and layout of training)
- Learning Module Handouts (provided throughout training)
- *iLookOut*- Certificate of Completion
- *iLookOut* Measures included in the online learning program uploaded as:

- o *iLookOut* Learning Demographics
- o *iLookOut*- Learning Module Pre and Post Test
- o *iLookOut*- Learning Module Evaluations

After learning (pinging) content/screen shots (Can be sent/accessed by Standard group after completing the *iLookOut* program in YR 3 through the end of the study)
 *Note- Learners will be exposed to these items using the *iLookOut App* or the website associated with the *iLookOut app.* You can view these items online as they are intended by using the instructions included in the "Memo to the IRB re. After-Learning Engagement (pinging)." These items will be sent from the time of learning module completion until the study ends or the participant requests to stop receiving after-learning content.

- *iLookOut* Certified Badge (provided after training completion)
- After-learning (pinging) email messages
- After-learning (pinging) App messages
- *iLookOut*- After-learning (pinging) Activity screen shots
- *iLookOut*- After- learning (pinging) content modules Year 1
- *iLookOut*- After- learning (pinging) content modules Year 2 (Modules 1-3)

**Throughout Study:**
End-of Year Survey (Sent once per year at the end of Year 2)
- Summary Explanation of Research to Accompany End of Year Survey
- Maine End- of Year Survey

**Year 4- 5:**
Continued After-learning pinging contact, continued enrollment of child care providers and volunteers who are new to centers in the *Standard* group and/or haven't completed *iLookOut*.

**Throughout Study:**
End-of Year Survey (Sent once per year at the end of Year 2)
- Summary Explanation of Research to Accompany End of Year Survey
- Maine End- of Year Survey

**Control Study Group:**
**Years 2-3:**
No direct recruitment contact or recruitment materials sent

**Throughout Study:**
End-of Year Survey (Sent once per year at the end of Year 2)
- Summary Explanation of Research to Accompany End of Year Survey
- Maine End- of Year Survey

**Year 4:**
Recruitment Mailing Includes (initially sent in study YR 4Spring 2020):
- Summary Explanation of Research
- OCFS Endorsement Letter
- *iLookOut* Welcome Letter *iLookOut* Arm (Center Based) OR *iLookOut*- Welcome Letter *iLookOut (*Home Care ONLY)
  - Note: This is dependent on the type of child care center

- *iLookOut* Brochure
- *iLookOut* Recruitment Handout with License Number
- *iLookOut* individual Access Cards (Upon Request/Optional)

*iLookOut*- FAQ 1 pg Handout (Upon Request/Optional)

Recruitment Email(s) with Attachments (initially sent in the spring of 2020)):
- Summary Explanation of Research
- *iLookOut*- Recruitment Email Communication (ALL)
- *iLookOut*- Recruitment Handout
- *iLookOut*- Director Talking Points (Optional/upon request)
- *iLookOut* individual Access Cards (Optional/upon request)
- *iLookOut* Welcome Letter *iLookOut* Arm (Center Based) OR *iLookOut*- Welcome Letter *iLookOut (*Home Care ONLY)
  - Note: This is dependent on the type of child care center
- *iLookOut*- *FAQ 1 pg Handout* (Optional/upon request)

Phone Recruitment (initially in the spring of 2020):
- *iLookOut*- Recruitment Phone Script
- *iLookOut*- Check in Phone Script

Content/Screen shots included in the *iLookOut* online Learning program (initially open for Control group in Spring 2020): *Note- Learners will be exposed to these items online at demo.ilookoutmaine.org and www.ilookoutmaine.org . You can view these items online as they are intended by using the instructions included in the "Memo to the IRB re. Learning Module."
- Summary Explanation of Research
- *iLookOut*- Learning Module Screen Shots
- *iLookOut:* Phase III Video and Training Script (this includes the text used to create training videos and layout of training)
- Learning Module Handouts (provided throughout training)
- *iLookOut*- Certificate of Completion
- *iLookOut* Measures included in the online learning program uploaded as:
  - *iLookOut* Learning Demographics
  - *iLookOut*- Learning Module Pre and Post Test
  - *iLookOut*- Learning Module Evaluations

After learning (pinging) content/screen shots (Can be sent/accessed by control group after the Spring of 2020))
 *Note- Learners will be exposed to these items using the *iLookOut App* or the website associated with the *iLookOut app.* You can view these items online as they are intended by using the instructions included in the "Memo to the IRB re. After-Learning Engagement (pinging)." These items will be sent from the time of learning module completion until the study ends or the participant requests to stop receiving after-learning content.
- *iLookOut* Certified Badge (provided after training completion)
- After-learning (pinging) email messages
- After-learning (pinging) App messages
- *iLookOut*- After- learning (pinging) content modules Year 1
- *iLookOut*- After- learning (pinging) content modules Year 2 (modules 1-3)
- *iLookOut*- Phase III After Packet Vignettes

**Throughout Study:**

<u>End-of Year Survey (Sent once per year at the end of Year 2)</u>
- Summary Explanation of Research to Accompany End of Year Survey
- Maine End- of Year Survey

**Year 5:**

Continued After-learning pinging contact,  and continued enrollment of child care providers and volunteers who are new to centers in the *iLookOut, standard, or control* groups and/or haven't completed *iLookOut*.

**<u>After Year 5:</u>**

The *iLookOut* program will remain available to licensed and non-licensed child care programs across the state of Maine.