**State of Connecticut Office of Early Childhood**

**Institutional Review Board (IRB)**

Name of P.I.:       page       of       total pages

**Application for OEC IRB Review of Research**

*For IRB Use only*

*Date Received: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Application #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Approval Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ End Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*IRB Authorized Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Notice Sent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

1. **General Information**

Request Date:       Total # of pages submitted:

Project Start Date:       Expected end date:

Title of Project:

Funding Source:

 *Please attach your grant application and award notice.*

IRB of record: OEC       Other:

If a Reliance Agreement is requested, please submit an OEC IRB Reliance Agreement Request and check here:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator (or major advisor, if student project): *Attach resumé or vitae*

Department, university, hospital, or agency affiliation:

Mailing Address:

E-mail:       Phone:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Co-Investigator(s) or student advisee: *Attach resumé or vitae*

Department, university, hospital, or agency affiliation:

Mailing Address:

E-mail:       Phone:

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1. **Research Study Personnel**
2. Please list all research study personnel and indicate for each:
* Name and title (e.g., professor, director, research assistant)
* Completion date of Human Subject Protection Training (HSPT) (e.g., CITI)
* Role: (P) contact with Participants; (R) records/data handling; (O) other
* Affiliation: university/agency name

|  |  |  |  |
| --- | --- | --- | --- |
| *Name/title* | *HSPT completion date* | *Role(s)**P – R - O* | *affiliation* |
|       |       |       |       |
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It is the responsibility of the Principal Investigator to ensure rigorous training of, and full adherence to, human subject protections by all research personnel.

1. **Conflict of Interest**

Please indicate which staff, if any, have a financial interest related to this research and describe:

Please indicate which staff have any other conflict of interest related to this research and describe:

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1. **Project Description**
2. What is your hypothesis?

1. Please describe the specific aims and long-term objectives of this study.

1. Why is this research important? How will the results contribute to better services or improved understanding of the topic?

1. Provide a description of the experimental design and how it addresses your research goals.

1. How will you collect the research data?

[ ]  Survey – *Please attach a copy of all survey instruments*

[ ]  Records review

How will you request/obtain the records?

[ ]  Direct interpersonal interaction at:

 [ ]  Community location [ ]  Research agency office

 [ ]  Individual’s home [ ]  Individual’s school or child care setting

[ ]  Individual’s place of employment

[ ]  Individual’s usual daytime activity setting

[ ]  Other *(please describe)*

1. Will a participant be expected to have more than one research encounter?

[ ]  Yes or [ ]  No

If Yes, please describe the number of visits, any change in the nature of participation across the duration of the study, and the timelines involved.

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1. How will data analyses be completed?

1. How do you plan to disseminate your findings? *(please check all that apply)*

[ ]  Dissertation defense

[ ]  Internal academic departmental meetings or Grand Rounds

[ ]  Publication in peer-reviewed journal

[ ]  Poster or presentation at professional meetings

[ ]  Other *(please describe)*

1. **Interface with the CT Office of Early Childhood**
2. Does this project involve the cooperation of OEC administration?

[ ]  No [ ]  Yes *(describe):*

List the OEC Staff, Division(s), or program involved:

Attach letters of support.

1. Does this project involve the cooperation of any OEC funded or operated agencies/programs?

[ ]  No [ ]  Yes *(describe):*

List the agency(s) involved:

Include letters of support.

**NOTE:** *IRB approval does not constitute OEC individual or program agreement to participate in this research. Letter(s) of support must be requested separately and attached.*

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1. Does this project involve access to: *(please mark all that apply)*

[ ]  records of individuals (e.g., enrollment, program attendance, etc.)

[ ]  group records (e.g., ABC classroom attendance records)

[ ]  de-identified data or records

[ ]  individual participant interactions

[ ]  face-to-face [ ]  phone [ ]  email [ ]  mail [ ]  virtual platform [ ] other

[ ]  group participant interactions

[ ]  face-to-face [ ]  virtual platform [ ]  email [ ]  mail [ ] other

[ ]  individual’s family members (e.g., parent or sibling)

[ ]  individual’s medical or community providers or records

[ ]  agency staff: [ ]  public employees or [ ]  private/contracted agency employees

1. Are the data collected via: *(please mark all that apply)*

[ ]  Survey [ ]  Video recording analyses

[ ]  Records review [ ]  Audio recording analyses

[ ]  Passive Individual Observation only – no direct interaction

[ ]  Passive Group Observation only – no direct interaction

[ ]  Direct interpersonal interaction at:

 [ ]  Community location [ ]  Research agency office

 [ ]  Individual’s home [ ]  Individual’s school or child care setting

[ ]  Individual’s usual daytime activity setting other than school or child care

[ ]  Other *(please describe)*

**NOTE:** *Researchers may not have 1:1 interactions with a child without another adult present (e.g., parent or program staff member)*.

1. Does the project involve the use of FDA regulated products or devices?

[ ]  No

[ ]  Yes: [ ]  Drug IND # and name:

 Sponsor:

[ ]  Device IDE # and name:

 Sponsor:

1. List all procedures, both experimental and non-experimental, that involve human subjects. Describe alternate procedures that are available for each or indicate N/A (not applicable).

 *Research Procedure/Treatment Alternate Procedure/Treatment*

*Experimental*

*Non-Experimental*

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1. **Human Subjects**
2. Indicate the type, number and age range of human subjects that best fit the study population(s) to be recruited:

 *Type number age range male/female, if relevant*

[ ]  Infants

[ ]  Children

[ ]  Pregnant Women

[ ]  Incarcerated Adults

[ ]  Adolescents

[ ]  Adults (non-relatives)

[ ]  Parents/Guardians

[ ]  Siblings

[ ]  Other family members

[ ]  OEC employees

[ ]  Private provider agency

employees

[ ]  Others *(please describe)*

1. Describe any notable characteristics of the research participants (e.g., English language literacy/fluency, race, ethnicity, program enrollment, custody or health status, etc.). Describe how these characteristics will be assessed, e.g., participant self-report.

1. Describe the rationale for inclusion of special classes of human subjects (e.g., pregnant women, minors, children, elderly, prisoners, people who may have difficulty understanding and consenting to participate).

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1. List specific eligibility criteria for subjects, including those criteria that would exclude otherwise acceptable subjects.

Inclusion criteria:

Exclusion criteria:

1. Describe how subjects will be recruited. Attach copies of all recruitment materials and recruitment scripts:

1. From whom will you seek informed consent? *(check all that apply)*

[ ]  Participant [ ]  Parent or guardian [ ]  Foster parent

[ ]  Legally-appointed representative [ ]  Other:

1. In which languages will you seek informed consent? *(check all that apply)*

[ ]  English [ ]  Spanish [ ]  ASL [ ]  Others:

1. For languages other than English, how did you assure that the translation is valid, and that your interpreters are qualified?
2. Describe your process for ensuring fully informed consent and - if applicable - assent, including safeguards for potentially vulnerable people who may be recruited. *(Assent usually implies cooperation from participants who may not be able to give* *consent themselves, e.g., children.)*

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1. **Risks to Human Subjects**
2. Clearly state all potential risks associated with the proposed procedures.

Physical: [ ]  No [ ]  Yes *(describe)*

Psychological: [ ]  No [ ]  Yes *(describe)*

Social: [ ]  No [ ]  Yes *(describe)*

Vocational/Professional: No [ ]  Yes *(describe)*

Legal: [ ]  No [ ]  Yes *(describe)* No [ ]  Yes *(describe)*

Chemical/Drug toxicities: [ ]  No [ ]  Yes *(describe)*

Participant Costs incurred: [ ]  No [ ]  Yes *(describe)*

Participant Loss of wages: [ ]  No [ ]  Yes *(describe)*

Participant mileage or transportation fees: [ ]  No [ ]  Yes *(describe)*

Loss of eligibility for services or program enrollment: [ ]  No [ ]  Yes *(describe)*

Other:

1. Describe procedures to minimize or eliminate each potential type of risk described above.

1. Describe the benefits, if any, to the participant for their consent to participate.

1. Will there be financial, product, or service incentive(s) for participation?

[ ]  Yes [ ]  No

If yes, describe type of incentive(s). (e.g., children’s book, gift card, developmental evaluation)

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4A. Indicate timing of incentive distribution.

[ ]  Upon agreeing to listen to the project description

[ ]  Upon signing informed consent

[ ]  Upon withdrawal of consent prior to completion of research encounter

[ ]  Upon completion of first/only research encounter

[ ]  Upon completion of final research encounter

4B. Will children whose parents declined to participate witness the incentive being enjoyed by other child participants in their classroom? [ ]  No [ ]  Yes

If yes, describe methods you will use to prevent non-participant children from feeling left out, jealous, or “less than” those children who participated and received the incentive.

4C. How will you distribute the incentive(s) to each qualifying participant?

[ ]  direct, in person delivery [ ]  email

[ ]  mailed to participant’s home [ ]  mailed to participant’s work place

[ ]  Other

1. **Data Management and Security**
2. Identify all records or data you will request from OEC offices, provider agencies, or families for individually identifiable living human subjects. Attach OEC IRB form, “Protected Health Information/Personally Identifiable Information and Assurances”.

1. Describe your procedures to assure confidentiality during all data collection activities(s), particularly when data are collected with others nearby.

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1. Describe your procedures to assure confidentiality of all research records (e.g., physical, photographic, electronic).

1. Describe the secure handling procedures for transfer of data across research partners.

1. Describe the secure handling procedures for transfer of data across physical locations, i.e., during travel from data collection site to research office:

1. Specify the ownership of all data sets. If different parties own specific subsets of data, list in detail.
	1. CT Office of Early Childhood
	2. Principal Investigator
	3. Co-Investigator or student advisee
	4. Research contractor:
	5. Funding source:
	6. Other:
2. Specify the timeframe and expected method of data set destruction by each owner.

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1. **Signatures and Assurance of Continuous Compliance with Regulations**

**Regarding the Use of Human Subjects**

1. I have read the OEC IRB supplementary expectations document entitled, “What a PI Needs To Know” and have addressed each of the issues identified therein in this application for approval.

\_\_\_\_\_\_ Initial       Date

1. I will report all changes to the approved procedures for obtaining consent or assent of subjects, any increase in the risk of physical, psychological or social injury, or any unanticipated problems involving risk to subjects or others. I shall report such changes to the Chair of the OEC IRB in writing within five business days.

\_\_\_\_\_\_ Initial       Date

1. I will report to the IRB Chair, within five business days of occurrence, all unanticipated adverse events, whether or not OEC has ceded reliance to another IRB. These are defined as any experience or reaction related to the conduct of the research that is not identified or outlined in the research procedure and the informed consent form. I will include descriptions of any change in the nature, severity, or frequency of the adverse experience or reaction, and/or any unanticipated problem associated with the conduct of the research related to the level of risk to the participant.

\_\_\_\_\_\_ Initial       Date

1. I will report serious adverse events including, but not limited to those that result in death, are life threatening or potentially life threatening, result in disability, result in hospitalization or other significant treatment, or other event deemed to be serious by the investigator in writing to the IRB Chair within 24 hours, whether or not OEC has ceded reliance to another IRB. Immediate notification is required in the case of participant deaths. If reported by phone, a written report must follow within three business days.

\_\_\_\_\_\_ Initial       Date

1. I will forward a final report to the IRB upon completion of the research project. I understand that the research is considered completed when the following applies: (1) no additional participants are being enrolled, (2) all interventions with human participants have ended, (3) data analysis is complete, and (4) all other research related activity has ended.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 *Principal Investigator (or major advisor, if student project)*

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 *Co-Investigator or student*

**Note:** Print this page, initial and sign in **blue** ink where indicated to affirm your agreement. Electronic signatures are not accepted. Scan and email all materials to oec.irb@ct.gov.