"WHAT A PI NEEDS TO KNOW"

OEC IRB Supplementary Expectations

Draft 5/8/20

The OEC IRB expects Principal Investigators (PIs) to read and follow this set of instructions and procedures which amplify the standard OHRP requirements to reflect the OEC IRB's commitment to protecting vulnerable subjects, specifically children under 5 years of age.

Themes

1. **OEC programs and IRB scope** PIs considering research with children 5 years of age and younger must:
   a. Determine whether individuals, services, and/or data are part of OEC funded programs or part of the OEC population.
      i. E.g.) A study broadly targeting three-year-olds will not require OEC IRB review, however, a study of three-year-olds in School Readiness would require OEC IRB review.
   b. If yes, PIs must communicate with the appropriate OEC Division contact to discuss the research project's purpose, hypothesis, protocol, and impact on Division staff. It may be helpful to provide a flow chart of the process. PIs should then request an OEC letter of support for the research.

Division / Program	**OEC Contact**	**Email**
Early Care and Education	Harriet Feldlaufer	harriet.feldlaufer@ct.gov
Licensing	Debra Johnson	debra.johnson@ct.gov
Quality Improvement	Deb Flis	deb.flis@ct.gov
Home Visiting	Aileen McKenna	aileen.mckenna@ct.gov
Birth to Three	Alice Ridgway	alice.ridgway@ct.gov

   c. Before starting research activities or recruiting any OEC staff,/contractors, or grantees, PIs must:
      i. Obtain the OEC program administrator Letter of Support and IRB approval.
      ii. Include if available letters of support from community partners e.g.) child care centers
      iii. Be prepared to review and respond to approval from OEC IRB and support from the OEC program administrator to everyone involved at the program site, e.g., the Superintendent, Program director, program staff, and all families being recruited for participation.

2. Access to participants – direct/indirect, languages

   a. To protect the confidentiality of potential participants, recruitment activities cannot involve release by OEC of any child or family's contact information or program enrollment status. The PI may ask OEC to send recruitment information to potential participants, or use another method of indirect contact.
   b. The PI must ensure document translation and/or oral interpretation is available to participants who read or speak languages other than English who may be in the recruitment cohort. The translation of materials should be accessible to the population under investigation.

c. Lab Schools or other agencies that collect parental consent for photo or audio recording children as a condition of enrollment must:
    i. provide a copy of that consent document so that the OEC IRB may confirm that potential use of any recorded data extends beyond marketing and public awareness and specifically includes research uses,
    ii. Offer an opt-out provision for any parent who does not wish to allow recording of their child for the specific research study.

3. Study methodology

a. PIs conducting studies involving children and staff in a **group care setting** must:
    i. Ensure consent is obtained for all participants;
    ii. Determine how participants will be distinguished from non-participants in a manner that does not affect the behaviors being measured;
    iii. Safeguard privacy for participants as well as non-participants (which may include children and staff present);
    iv. Guarantee minimal disruption to daily routines and schedules of participants and others (non-participants and staff);
    v. Verify activities conducted for research do not interfere with the needs of participants and non-participants;
    vi. Ensure that activities conducted for research do not isolate particular participants from the larger group or regular activities;
    vii. Implement strategies to ensure that videos, photos, and/or audio recordings include only individuals who have granted written consent;
    viii. Verify that parents of child participants are informed about all aspects of the study.
    ix. Before, during and after the study period, provide information about the study to community partners for distribution to all classroom or program parents regardless of participation status.
    x. Detail plan to share study results to participants.

b. To ensure participation is voluntary, PIs must:
    i. Make participants aware of their rights under all applicable federal and state laws and regulations, and of alternative treatment options available to them during the informed consent process;
    ii. Highlight the voluntary nature of research participation and clarify that declining to participate will in no way affect their receipt of services.

c. PIs proposing investigations involving families, including situations where **both parent and child are minors**, must specify practices for obtaining consent from minor participants or their legal guardian. The following considerations should be addressed in their IRB proposal:
    i. How will they obtain consent for minors (e.g., legal guardian or grandparent)?
    ii. What is the research protocol when a parent or legal guardian is not available to provide consent for a minor? Will those minors be excluded from participation?

d. When research is conducted in a private setting:
    i. What accommodations will be made to protect participants' privacy during research interviews or other activities while others are present or may overhear the participant's responses, particularly in home settings?

ii. What measures will be taken to ensure that a parent's research activities do not negatively impact their child who may be present during research interviews/assessments with the parent/caregiver?

4. Data security and confidentiality

a. PIs Must:
   i. Delineate security procedures during travel from the field to an office, across research locations, within office, etc.
   ii. Extend security protocols to include paper files, electronic data.
   iii. Data Retention and Destruction: PIs must describe how data will be secured during and after study implementation, and how ownership may change if the PI is no longer able to ensure data security.

b. OEC Data Resources
   i. OEC Data Sources – de-identified data may be found at www.ctoec.org
   ii. OEC Data Request Form

5. Application materials –

To initiate IRB review, PIs must provide:

a. All participant interaction plans, procedures, and materials including but not limited to all surveys, data collection instruments, interview questions, recruitment materials, focus group questions and plans.
b. Grant application and award notice, as applicable
c. Statutory citation for the program involved, as appropriate (e.g., Birth to Three – IDEA, Part C)
d. Parent Rights statement in the informed consent document and recruitment protocol
e. All consent forms
f. Recruitment scripts
g. All survey instruments; drafts marked as appropriate
h. Note if consent to video or audio record is obtained universally upon program enrollment from all families, or if consent to record is only requested for potential research participants
i. Language translations for any research-related materials and whether interpretation will be provided.

I, _____, have read and agree to comply with all of the foregoing expectations.

Principal Investigator printed Name: _____

PI Signature: _____ date: _____

Principal Investigator Initials _____