STATE OF CONNECTICUT
OFFICE OF EARLY CHILDHOOD

Connecticut Administered State-Funded Program
General Policy A-04

Requirements for Conducting Research Involving OEC-Funded Programs

X OEC Early Start CT Programs
X OEC Smart Start CT Programs

The Office of Early Childhood (OEC) understands the importance of conducting research to improve Early Care and Education (ECE). Research may involve children (or their families) in programs whose services are funded in part or in full through OEC. Researchers may request to visit or observe ECE programs or may request to interact with the children enrolled and their families. OEC is committed to the protection of all families, staff, and children served in OEC-funded programs.

This policy covers all research conducted in ECE programs which are funded in full or in part by OEC.

POLICY

When a program is invited to promote or participate in a research study involving families, children, or staff, or is asked to provide any information for research purposes, the program must request confirmation that this research has been reviewed by an Institutional Review Board (IRB). No research-related activities should begin until this information has been provided to the program director.

An individual's participation in research is voluntary. Even if a program agrees to participate, no staff or family member is required to do so. If a child shows, with words or behavior, that he or she does not want to participate, that child shall not participate, even if the parent has consented to their child's involvement. Both parental consent and a child's willing participation (often referred to *assent*) must be confirmed. Any questions should be brought to the attention of the researcher.

Background Information

Most large educational institutions have their own IRBs which are responsible for reviewing proposed research. These IRBs review studies that involve human subjects to ensure that the research is completed in a safe and responsible manner. The IRB applies federal criteria to determine if further review is required, if a study is or is not approved, or if it is exempt from review.

Projects that do not collect Personally Identifiable Information (PII), involve minimal time, and provide detailed information about how data will be used are exempt from IRB review. An anonymous survey is one example of such research.

Research that requires direct interaction between researchers and children or families, or studies that involve sharing personal information, may require further review. The IRB evaluates these studies and their protocols to ensure that any risks to participants are sufficiently controlled.

Confirmation of IRB review should contain:

1. the name of the IRB
2. the study's IRB number
3. the results of the IRB review, and
4. the research period.

Any researcher requesting that a program director distribute recruitment materials (such as information about the study or permission slips to participate) or provide access to PII, Personal Health Information (PHI), or contact information of participants shall provide documentation of IRB approval or exemption. Programs must follow their own policies and procedures safeguarding PII and PHI.

OEC Research and Evaluation

OEC may collect data about programs, staff, families, and children in OEC-funded programs. Please refer to the information below for specific examples and reach out to your OEC program manager for further clarification.

- When data is collected for OEC program evaluation or planning purposes, programs are required to participate and to provide the information requested.
- OEC may engage a research partner to conduct research involving programs or services. If participation is expected, OEC will share information with families about these research activities, including whether participation is voluntary, any details about IRB exemption or approval, who is conducting the research, and how consent and assent to participate will be evaluated.
- OEC may provide a letter of support or share information about a research study that would further knowledge in the field of ECE. An OEC letter of support does not mean that an IRB exemption or approval has been granted or that participation in the research study is required.

DEFINITIONS

I. **Institutional Review Board (IRB):** a committee charged with protecting the rights and welfare of human subjects participating in research studies; reviews and monitors research plans, including protocols and instruments, for risks to human participants.[1]

II. **Personally Identifiable Information (PII):** information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual.[2]

III. **Protected Health Information (PHI**): Individually identifiable health information including demographic information that is collected from an individual, and:

(a) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
(b) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
(c) that identifies the individual; or
(d) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.[3]

IV. **Program Evaluation:** An assessment of the effectiveness of a program.[4]

V. **Research:** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.[5]

In the unlikely event that any provision of this General Policy is found to be inconsistent with any contract or grant provision, the contract or grant shall govern.

For further information concerning this GENERAL POLICY please contact your OEC Program Manager or visit https://www.ctoec.org/contact-us/

[1] https://opa.hhs.gov/sites/default/files/2020-07/opa-tip-sheet-irb.pdf
[2] https://www.hhs.gov/answers/hhs-administrative/what-is-pii/index.html
[3] https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html#statutory
[4] https://aspe.hhs.gov/topics/data/evaluation/program-evaluation
[5] https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html