

INSTITUTIONAL REVIEW BOARD (IRB) POLICY

The LEARN Board of Directors welcomes the opportunity to partner with individuals and organizations to conduct in-district research and surveys and to fulfill data requests that are consistent with the LEARN [Mission Framework](#) and the best interests of students, and is committed to fostering high-quality, ethical research that supports educational improvement while protecting the rights, welfare, and privacy of all human subjects—particularly students, families, and staff. This policy establishes the authority, scope, structure, and procedures of the Institutional Review Board (IRB) to ensure all research conducted under the auspices of the District meets the highest ethical and legal standards and is consistent with the District’s mission, vision, and strategic goals.

The purpose of this policy is to:

1. Ensure compliance with federal, state, and local laws governing human subjects research.
2. Provide oversight for research conducted within or on behalf of the District.
3. Protect the rights, welfare, and privacy of research participants.
4. Promote transparency, accountability, and community trust in the District’s research activities.
5. Ensure that all approved research aligns with and supports the mission, vision, and goals of LEARN

Scope of this Policy

This policy applies to all research involving human subjects that:

1. Is conducted by District employees or agents;
2. Takes place within District facilities;
3. Involves District students, staff, or data; or
4. Uses District resources in any capacity.
5. All research considered for approval must demonstrate a clear connection to LEARN’s educational mission and goals and must not conflict with the LEARN’s core values or strategic priorities.

This includes activities that may be considered “exempt” under federal regulations; all such research must still be submitted to the IRB for determination of exemption.

Definitions

1. **Human Subject** means a living individual about whom an investigator conducting research obtains data through intervention, interaction, or identifiable private information.
2. **Research** means a systematic investigation, including development, testing, or evaluation, designed to develop or contribute to generalizable knowledge.
3. **Minimal Risk** means the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life.
4. **Investigator** means any individual conducting research under District auspices, including employees, contractors, and external researchers.

Authority & Legal Compliance

LEARN's Institutional Review Board (IRB) is established under the authority of the Board to ensure the ethical and lawful conduct of research involving human subjects within the jurisdiction of the District.

The IRB shall operate in full compliance with:

Federal Regulations

- 45 CFR 46 (“Common Rule”) governing the protection of human subjects in research.
- 21 CFR Parts 50 and 56 for FDA-regulated research involving drugs, devices, or biologics.

Connecticut State Law

- C.G.S. § 19a-25 and Regulations of Connecticut State Agencies §§ 19a-25-1 through 19a-25-4, governing the protection of confidential health data and human research review.
- C.G.S. § 19a-591c, ensuring that no individual is denied the opportunity to participate in research solely due to inability to pay for medical treatment.
- C.G.S. § 1-1(d) and § 46b-150(b), defining the legal age of majority and emancipation, and applicable statutes on minors' consent to participate in research.
- State requirements for human embryonic stem cell research oversight, including compliance with Embryonic Stem Cell Research Oversight (ESCRO) procedures.

Ethical Standards

The IRB shall be guided by the Belmont Report principles of Respect for Persons, Beneficence, and Justice.

Oversight Authority

The IRB is vested with the authority to:

- Review, approve, require modifications to, or disapprove any research involving human subjects under District auspices.
- Conduct continuing review of ongoing research at intervals appropriate to the level of risk, but no less than once per year unless otherwise permitted by law.
- Observe, monitor, suspend, or terminate research not in compliance with IRB requirements, applicable laws, or that poses risk to subjects.
- Require prompt reporting of unanticipated problems, adverse events, and protocol changes.

Independence of Review

The IRB's determinations are final with respect to the approval or disapproval of human subjects research. District leadership may impose additional operational restrictions but may not approve research disapproved by the IRB.

Assurance and Registration

The District shall maintain, as required, an active Federalwide Assurance (FWA) with the U.S. Department of Health and Human Services Office for Human Research Protections (OHRP) and register the IRB in accordance with federal requirements.

Membership & Structure

Composition

The IRB shall consist of at least five members with varying backgrounds to ensure adequate review of research activities. Membership shall include:

- At least one member whose primary concerns are in scientific areas.
- At least one member whose primary concerns are in non-scientific areas.
- At least one member unaffiliated with the District and without immediate family ties to District staff.
- Additional members as needed for special expertise.

[link to IRB Guidelines}

Legal References:

20 U.S.C. § 1232g Family Education Rights and Privacy Act
CFR 45, Part 99 Family Education Rights and Privacy Act Regulations
20 U.S.C. § 1232h Protection of Pupil Rights Amendment
CFR 34, Part 98 Protection of Pupil Rights Amendment Regulations
CFR 45, Part 46 Protection of Human Subjects

Cross References:

[Policy 5153](#), Student Surveys
[Policy 5154](#), Computer Use, E-mail, and Internet
[Policy 5125](#), Student Records: Confidentiality

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