

HUMAN SUBJECTS RESEARCH

Scope of Authority

The District considers all research involving the use of humans, or data maintained by the District as being subject to federal regulations regardless of the type of research being performed or the source of funding. Here, *research* means a *systematic investigation* designed to develop or contribute to *generalizable knowledge* (per 45 CFR 46.)

It is the responsibility of the District Institutional Review Board (IRB) to evaluate each research proposal in terms of ethical standards. In particular, the board will assess if there are appropriate measures planned to maintain confidentiality, establish informed consent, and avoid any risk to individuals.

Generally, investigators should submit a research proposal to the District IRB for review if data collection involves intervention or interaction with a living human being and *any one* of the following conditions applies:

1. Collection of information that is intended to contribute to generalizable knowledge (i.e., data will be used to make inferences about persons outside the group from which the data are collected),
2. Anonymity cannot be assured,
3. Conclusions drawn from the data are intended to be published or presented at a professional meeting.

Specific Requirements

The investigator shall present to the District IRB a description of his or her research project's goals, objectives, and procedures via the District's internal research proposal form. The proposal form can be found on the District IRB website or requested from the District Research Office.

Instruction Certification

Human Research Protections/IRB training in the responsible conduct of research is essential to the maintenance of ethical standards. Each investigator associated with a research project must attach a "Certificate of Completion" for a Human Research Protections/IRB training course recognized by the National Institute for Health (NIH). Certification must have been within three years of the submission of any research proposal to the District IRB.

Permitted Research

The College of the Sequoias is not a research institution and thus does not conduct clinical trials. All data collected must involve only procedures or protocols specifically

outlined in federal regulations. Any study presenting with greater than minimal risk will most likely be subject to a full board review.

Exemptions

Some research with human subject(s) is exempt from IRB approval. Investigators who believe their research projects qualify for exemption should petition the District IRB for a Certificate of Exemption. When such exemptions are found, a Certificate of Exemption is issued by the District IRB. Though not legally required for exempt research, obtaining informed consent from participants remains a basic ethical obligation and is therefore strongly encouraged by the District IRB.

Student Assignments and Class Projects

In instances where students may be involved in course activities such as conducting surveys of District students, faculty, staff or community members, the instructor is responsible for determining whether such activity requires submission to the District IRB. The guidelines for determining the necessity of IRB submission for student projects are outlined in the District IRB Guidelines for Student Assignments and Class Projects.

Membership and Administrative Reporting

The Institutional Review Board is composed of six members. Alternates and non-voting members are also appointed, as needed.

- a. Appointed members of the District IRB will reflect the rich diversity of the campus. Members will possess levels of expertise that will assure adequate review of the research brought before it. Minimally, the committee will be composed of three faculty members appointed by the District's Academic Senate (1 Humanities, 1 Sciences, and when possible 1 Student Services), the Vice President of Academic Services or designee, and one person from the community appointed by the District President/ Superintendent. A student representative will be appointed by the Student Senate as a non-voting member. In cases where, after a good faith effort has been made, the Academic Senate or the Student Senate cannot fill appointments as described above, the IRB co-chairs may appoint members as needed. All appointments to the IRB will be reported by the Vice President of Academic Services or designee to both the Board of Trustees and the Office of Human Research Protections (OHRP), as needed or required.
- b. The IRB will be co-chaired by the Vice President of Academic Services or designee and the Office of Academic Services will be responsible for managing all administrative requirements.
- c. The Academic Senate will designate one of its faculty appointments as co-chair of the IRB.
- d. The IRB is administratively responsible for reporting to the President/Superintendent of the District.
- e. Voting members of the IRB will be appointed for a term of three years. In the event that a member is no longer able to serve, a notice must be sent to a co-chair. Non-voting members will serve for a single year. Both voting and non-voting members can be reappointed at the end of their terms, as needed.
- f. In the event of the absence of a voting member of the IRB, an alternate may cast a

vote. Members of the committee who are absent regularly, can be removed by the Vice President of Academic Services or designee before their term is complete. A replacement will be appointed by the appropriate body in the event of either a resignation or removal from the IRB.

- g. All members of the District IRB must complete training before serving on the board and at a frequency of no less than once every three years thereafter. To satisfy this requirement, members shall complete the online course entitled “Protecting Human Research Participants” or equivalent recognized by the National Institutes of Health (NIH), Office of Extramural Research. A certificate of completion will be kept on file in the Office of Academic Services.
- h. Members of the IRB are not compensated for their service.
- i. No person shall be excluded from the IRB based on gender, race, color or nation of origin.

Approved: June 19, 2013
Revised: June 5, 2014
Revised: June 8, 2020