

## **Institutional Review Board Policy**

The United States Department of Health and Human Services Code of Federal Regulations Title 45, Part 46 states that the Institutional Review Board (IRB) shall establish "a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or cosponsored by the institution." In accordance with this mandate, the California State University, Dominguez Hills IRB has institutional responsibility for:

1. Assurance of protection of human subjects involved in research or related activities;
2. Assurance that the University fulfills its federally mandated and ethical obligations relative to the protection of human subjects; and
3. Maintenance of practices and procedures for protection of human subjects which are, at a minimum, in accord with applicable regulations of funding and regulatory agencies.

The IRB has the authority to review, approve, not approve, or require changes in research or related activities involving human subjects, as well as deal with issues of noncompliance. Officials of the institution may further review proposals, but "those officials may not approve the research if it has not been approved by an IRB (45CFR46.112)."

The Board is appointed by the President after consultation with various administrators. The membership composition of the Board is kept consistent with federal regulations and must include faculty representatives. Chairpersons, ex officio members, and community members of the Board are designated by the President. Board members with other than ex officio status normally shall have staggered three-year appointments. The Board reports to the President through the Associate Vice President for Academic Affairs and Dean of Graduate Studies. The Vice President for Academic Affairs serves as the designated institutional official on the United States Department of Health and Human Services Single or Multiple Project Assurances. The Office of Research and Funded Projects is responsible for support in managing individual proposal reviews; assisting in policy development, agency liaison, federal record keeping and reporting; handling allegations of noncompliance, and assisting the institution in responding to new federal initiatives affecting the ethical conduct of research.

Any undertaking in which a University administrator, faculty, staff, or student investigates and/or collects data on human subjects for research or related activities may be construed as "involving human subjects." It is the responsibility of each investigator to seek review by the Institutional Review Board for any proposed study involving human subjects prior to initiation of the project and collection of data. Also, it is the responsibility of each investigator to ensure that research is implemented and records maintained in accord with California State University, Dominguez Hills IRB procedures.

The specific responsibilities of the California State University, Dominguez Hills Institutional Review Boards are to:

1. Review all research projects (or related activities) using human subjects, that involve or are conducted by the university community.
2. Recommend appropriate action on these projects within the guidelines set forth by the applicable federal granting and regulatory agencies and California State University, Dominguez Hills IRB policy;
3. Review all proposed changes in previously approved research studies and recommend appropriate action on these changes within the guidelines set forth by the applicable federal granting and regulatory agencies and California State University, Dominguez Hills IRB policy;
4. Conduct continuing review of previously approved research projects at intervals appropriate to the degree of risk, but not less than once per year;
5. In accordance with federal guidelines, the IRB will handle reports of unanticipated problems and allegations of noncompliance concerning protection of human subjects regulations and, in cases where corrective action is needed, issue appropriate sanctions including but not limited to requesting minor changes, determining data collected cannot be used for publication, disqualifying investigators from conducting research involving human subjects at the University, and recommending to University administration that further administrative action be taken. "An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subject (45CFR46.113)";
6. Advise appropriate University officials of current federal regulations or proposed changes in federal regulations pertaining to the protection of human subjects, and advise on University policy development and regulation changes which will best insure the rights and welfare of human research subjects;
7. Recommend to the President the constituencies to be represented on the Institutional Review Board; and
8. When participating in a cooperative project with another entity, enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements in accord with guidelines set forth by the applicable federal granting and regulatory agencies and California State University, Dominguez Hills IRB policy.
9. Provide an annual report on IRB activities to the Academic Senate and to the Associate Vice President for Academic Affairs.

IRB meetings may be regularly scheduled or held upon call of the chairperson(s). Copies of the University's existing approved Single or Multiple Project Assurance(s) of Compliance with United States Department of Health and Human Services Regulations for Protection of Human Research Subjects and other educational materials are available in the Office of Research and Funded Projects.