

CHAPTER TWO  
ACADEMIC AFFAIRS

260 OFFICE OF RESEARCH AND ECONOMIC DEVELOPMENT

260.1.1 Policy for Use of Human Subjects in Research

Introduction

California Polytechnic State University, San Luis Obispo, (hereafter, Cal Poly) is committed to the protection of human subjects in research and, as such, is guided by the principles set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects in Research (The Belmont Report), and is obligated by the policies of the Department of Health and Human Services (DHHS) and the Code of Federal Regulations for the Protection of Human Subjects (45 CFR 46), also known as the “Common Rule.” The actions of Cal Poly also will conform to all other applicable federal, state, and local laws and regulations regarding the conduct of research with human subjects.

To assist with this goal, the University has designated a committee, or Institutional Review Board (IRB), to review proposals for research involving human subjects and to evaluate both risk and protection against risk for those subjects, the researchers, and Cal Poly. It is the function of the IRB to:

- 1) evaluate research in terms of its compliance with ethical standards and the regulations set forth in the Federal Regulations regarding the health, welfare, safety, rights, and privileges of subjects; and
- 2) assist the investigator(s) in complying with federal, state, and local regulations, including Cal Poly policies governing research.

While individual researchers are ultimately responsible for their practices, the IRB's review is designed to provide objective input as an additional protection for the subjects. In addition, the independent review by the IRB is of benefit to those who could be held accountable for the research practices — the researchers and the University — and will seek to evaluate and minimize the potential risks for all.

260.1.1.1 Applicability of this Policy

All institutions at which research involving human subjects is carried out are required by law to have an IRB to oversee those projects when the research is supported by a federal agency. Even if the research is not federally funded, however, it is Cal Poly's policy that a review of compliance with ethical guidelines be completed on all research involving human subjects conducted at Cal Poly, including, but not limited to, research:

- conducted by or under the direction of any employee or agent of Cal Poly (including students) in connection with his/her institutional responsibilities;
- conducted by or under the direction of any employee or agent of Cal Poly using any property or facility of Cal Poly; or
- involving the use of Cal Poly's non-public information to identify or contact human subjects.

These categories encompass reviews of all off-campus research on human subjects carried out by Cal Poly faculty, staff, and students when they are conducting the research as an aspect of their roles as faculty, staff, or students of the University; and also research conducted by external investigators at Cal Poly using faculty, staff, or students as subjects. Approval from another IRB (e.g., external research partner) does not serve in lieu of review by the Cal Poly IRB under the requirements of this policy. The IRB is not responsible for reviewing research on human subjects that is conducted by a University employee or student as a function of their independent consulting work or their personal work with another institution.

#### 260.1.1.2 Definitions.

In accordance with federal guidelines for the protection of human subjects, research involving human subjects is defined as any systematic investigation of living human subjects that is designed to develop or contribute to generalizable knowledge.

Human subject is defined as a living individual, human materials, or identifiable private information about whom an investigator obtains data through interaction or intervention.

Systematic investigation is defined as an attempt to answer research questions using a methodological approach, incorporating data collection (both quantitative and qualitative) and data analysis, and permitting conclusions to be drawn.

Contributing to generalizable knowledge is defined as the dissemination and application of research findings to populations outside of the specific study population.

Human subjects research that requires review by the IRB includes, but is not limited to, faculty research, master's theses, and senior projects as well as research involving human subjects that is conducted on campus by parties not directly affiliated with the University. While the ethical principles for research are often applicable to classroom activities, demonstrations, and assignments, the IRB does not review classroom activities unless data will be collected and used in a systematic investigation that contributes to generalizable knowledge.

### 260.1.1.3 Overview of the Ethical Principles

Cal Poly's ethical guidelines for the use of human subjects in research are based on the principles and procedures outlined in the Code of Federal Regulations for the Protection of Human Subjects and the Office for Human Research Protections (OHRP) Policy and Guidance. The OHRP Policy and Guidance provides interpretation and discussion of the Federal Regulations related to the protection of human subjects. The Federal Regulations provides a common rule to be implemented across a broad spectrum of federal agencies including the National Aeronautics and Space Administration, the Environmental Protection Agency, the Consumer Product Safety Commission, the National Science Foundation, and the Departments of Agriculture, Energy, Education, Justice, Defense, Housing and Urban Development, and Health and Human Services. Cal Poly's policy is similarly intended to apply to the range of disciplines represented on campus while at the same time acknowledging the value of the ethical guidelines of individual disciplines' professional associations (e.g., the American Medical Association, the American Psychological Association, the American College of Sports Medicine, the American Association on Mental Deficiencies). Should a specific circumstance not be fully addressed by the Cal Poly policy, the Federal Regulations and the OHRP Policy and Guidance will provide the guidelines for the IRB's decision-making. The Federal Regulations will be the primary reference for the review of federally funded research.

The Federal Regulations and Cal Poly's guidelines draw heavily on the three basic ethical principles laid out in the Belmont Report, a 1979 report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. These three basic principles are: respect for persons, beneficence, and justice. Respect for persons entails treating individuals as autonomous agents who enter into research voluntarily and with adequate information (i.e., informed consent). Those with diminished autonomy, such as human fetuses (pregnant

women), neonates, children, prisoners, and individuals who are in some way incapacitated, have a right to be protected. The second basic principle, beneficence, refers to the obligation to secure the well-being of research subjects. Possible benefits should be maximized, while possible harms should be minimized. The final principle explicated in the Belmont Report is that of justice. Justice implies that both risks and benefits of research should be distributed equally across various groups. For example, the burden of serving in research should not largely fall on certain groups such as the poor or the imprisoned, while others primarily benefit from the knowledge gained from the research.

The specific ethical criteria used to evaluate research proposals are provided in the Cal Poly Procedures and Guidelines for Human Subjects Research.

#### 260.1.1.4 Authority and Assurance of Compliance

At the delegation of the Provost and Executive Vice President for Academic Affairs, the Vice President for Research and Economic Development at Cal Poly has designated the Dean of Research as the responsible Institutional Official (IO) for oversight of the university's human research protections program. Cal Poly holds a Federalwide Assurance (FWA), FWA00000342, which is granted to IRBs that register with the OHRP.

#### 260.1.1.5 IRB Membership

The Cal Poly IRB, has been established in accordance with the requirements of the current Federal Regulations, under 45 CFR 46.107.

In keeping with the Federal Regulations, the Cal Poly IRB must:

- 1) have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted under the authority of the Cal Poly IRB. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. Since the IRB may review research that involves vulnerable categories of subjects (such as children, prisoners, pregnant women, or physically or mentally disabled

persons) consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

- 2) employ nondiscriminatory selection in compliance with CSU Executive Order 1097, and all other applicable laws of non-discrimination.
- 3) include at least one member who is qualified as a scientist and one member who is qualified as a non-scientist. Both a scientist and a non-scientist member are required for quorum at all meetings convened with the full IRB.
- 4) include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- 5) ensure that no members will participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

The IRB may at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available in the IRB membership. These individuals may not vote with the IRB.

Other considerations: The IRB can have as many members as necessary for it to perform its duties effectively. The appointing authority should ensure that it does not become so large that its management becomes cumbersome.

The non-affiliated member(s) of the IRB shall be from the local community-at-large. The person(s) selected should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to the type of community from which the institution will draw its research subjects. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB.

The chair of the IRB should be a highly respected individual from within the institution, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community falls primarily on the shoulders of this individual. The IRB must be and must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.

The Chair may designate other IRB members to perform duties, as appropriate, such as reviews, signature authority, or other IRB functions.

The IRB members and the chair are appointed by the Dean of Research. IRB members who are faculty should be tenured, so as to avoid pressure or influence from more senior faculty or administrators. Due to the level of experience and relevant expertise needed to perform IRB duties, there are no term limits for IRB members, and they will continue to serve as long as they demonstrate knowledge of regulations, an understanding of the application of the ethical principles, and have time available to devote to the associated responsibilities. The Dean of Research will conduct annual reviews of the chair, IRB members, and IRB composition for compliance with Federal Regulations and Cal Poly policy and procedures, and will determine and seek action if a conclusion is made that a member's participation should be discontinued. If it is necessary to add new or replace exiting members, several methods are used to identify candidates: the existing members may be asked to provide recommendations; faculty with expertise in areas specific to the types of projects reviewed may be contacted directly; open calls will be announced via campus websites and distributed emails; interested persons may contact the Dean of Research to express interest; or the Dean of Research may identify and recruit potential members.

The IRB should meet at least once per quarter during the academic year. A list of current IRB members is available from the Office of Research and Economic Development, Bldg. 38, Rm. 154; (805) 756-1508.

#### **References for CAP 261.1.1:**

1. Date approved by the President: To be determined.
2. Effective Date: To be determined.
3. Responsible Department/Office: Office of Research and Economic Development
4. Revision History: May 24, 2006
5. Related University Policies, Procedures, Manuals and/or Documents:
  - a. [Procedures and Guidelines for Human Subjects Research](#)
  - b. [CSU Executive Order 1097](#)
  - c. [Institutional Review Board Membership](#)
6. Laws, Regulations and/or Codes of practice referred to herein or related to this policy:
  - a. [Ethical Principles and Guidelines for the Protection of Human Subjects \(The Belmont Report\)](#)
  - b. [Code of Federal Regulations for the Protection of Human Subjects \(45 CFR 46\)](#)
  - c. [Office of Human Research Protections \(OHRP\) Guidance](#)
  - d. [Regulations for IRB Membership: 45 CFR 46.107](#)