



University Policy Statement

UPS 620.000

PROTECTION OF HUMAN PARTICIPANTS

I. OVERVIEW

A. AIM

To educate and inform faculty, staff, and employees of the University regarding the federal regulations as they pertain to the use of human participants in research and to facilitate compliance with the University's Federal-Wide Assurance on file with the Department of Health and Human Services (DHHS) Office of Human Research Protections ([FWA No. 00015384](#)).

B. DEFINITIONS

“Research” is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. [[45CFR 46.102](#) (d)].

“Non-standard instructional activity” is understood to be a course which departs from the standard and accepted instructional setting by having as an intrinsic part of the course activities which involve the rights and welfare of human participants. Such activities may proceed within or outside the classroom.

A “human participant” means a living individual about whom an investigator conducting research or non-standard instructional activity obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

“Intervention” includes both physical procedures by which data are gathered and manipulation of the participant or the participant’s environment that are performed for research purposes.

“Interaction” includes communication or interpersonal contact between the investigator and the participant.

“Private information” includes information about behavior that occurs in a contact in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the participant is or may be readily ascertained by the investigator or persons associated with the investigation) in order to obtain the information to constitute research involving human participants.

“University” includes California State University Fullerton (CSUF) and its formally recognized auxiliaries, including the CSU Fullerton Auxiliary Services Corporation (ASC), the Cal State Fullerton Philanthropic Foundation (CSFPF), and the Associated Students, Inc., California State University, Fullerton (ASI).

“Minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests to be determined by the IRB.

“IRB” means the CSUF Institutional Review Board established in accordance with and for the purposes expressed in [45 CFR 46](#) and in compliance with the University’s Federal-Wide Assurance.

“Investigator” means the person or persons in charge of a research project. The title given to such person(s) might be Researcher, Principal Investigator, Project Director, Director, or some similar title. In the case of research being conducted by graduate or undergraduate students at the University, the IRB shall require that a faculty or staff member serve as the Faculty Advisor for purposes of the policy.

“Federal guidelines” means the federal common rule established at 45 CFR 46, published in the Federal Register in 1991 and as amended in 2018 and subsequently from time-to-time, and the implementing guidelines and policies established by federal agencies that sponsor research.

C. SCOPE

This policy applies to all faculty, staff, and students under the auspices of the University as it pertains to either supervising or conducting any research or nonstandard instructional activity involving human participants, regardless of whether the participants are members of the University community; if they are using University facilities, University supports, or the University’s name; or under University agreements with external sponsors. This policy applies as described regardless of funding status, and whether or not the research is internally or federally funded. The University cannot and does not accept responsibility for research conducted in violation of University policy.

This policy recognizes that researchers not affiliated with the University may wish to engage students, faculty or staff of the University in protocols that may or may not have received IRB approval. Such outside researchers or institutions should be made aware that any arrangements to engage in research using University faculty, staff or students are independent of the IRB. Faculty members are encouraged to consult with the IRB regarding research protocol requests and at their discretion may request that an outside research protocol be reviewed by the IRB. The decision of students, faculty, and/or staff to participate in research studies as participants is up to their discretion and based upon their informed consent. University faculty and staff must adhere to the Family Educational Rights and Privacy Act (FERPA) guidelines in sharing any student level data with researchers without the student’s expressed written consent. Use of University facilities or faculty, staff, and students for the purposes of research conducted by outside researchers is independent of the IRB. Faculty members should make requests of this nature through their department or other offices as needed for University approval.

This policy does not affect any federal, state, local, or foreign laws or regulations which may otherwise be applicable, and which provide additional protections for human participants.

D. RESPONSIBILITIES

The University acknowledges and accepts its responsibilities for protecting the rights and welfare of human research participants which includes obtaining informed consent from potential human participants in research prior to their participation in studies conducted by faculty, staff, or students of the University. The University agrees to comply with both its Federal-Wide Assurance and the federal policy which governs the use of human participants in research.

Faculty, staff, and students are reminded to strictly adhere to the guidelines for human participant use as may be described in their research proposal. Any change in protocol or consent form procedure must be approved by resubmission to the IRB prior to implementation. Additionally, the Investigator is reminded to report promptly (no later than five calendar days), in writing, any unanticipated or adverse events causing risks to research participants or others.

It is the responsibility of heads of departments, programs, units, etc. to bring to the attention of their faculty, staff, and students the existence of UPS 620.000 and they are reminded of the responsibility for being informed concerning research projects involving human participants in the department.

E. INSTITUTIONAL REVIEW BOARD (IRB) FOR THE PROTECTION OF HUMAN PARTICIPANTS

The responsibility and authority for implementing and administering policies and procedures that will protect the dignity, rights and welfare of human participants shall be delegated to the IRB, subject to review by the Academic Senate and the University. The IRB shall report to the Academic Senate and University] as requested by the Senate.

The membership of the IRB and the qualifications of the members shall comply with federal policy (45 CFR 46.107, IRB Membership). The members of the IRB shall be appointed by the University President or their designee.

In addition to the membership qualification as outlined in federal policy, the IRB may also include, at any given time, the following representation:

1. Faculty from the College of Health and Human Development, the College of Communications, the School of Nursing, the Department of Kinesiology, the Department of Psychology, the Department of Sociology, and the College of Education, shall each have a representative as voting members on the Board. These representatives are to be recommended to the University President or their designee by the IRB in direct consultation with the respective units. The academic units with permanent representation will consult with the IRB and nominate an alternate member who will stand in for the permanent member if they cannot attend a full review meeting. Two or more remaining members will be appointed by the University President or their designee in consultation with the IRB, drawing on faculty or staff from departments without permanent representation who have professional competence necessary to review research activities. The terms of those appointed by the University President or their designee shall be outlined in their respective appointment letter and may be renewed annually as needed.
2. At least one student member, appointed by the IRB in consultation with the ASI, who shall serve as a non-voting member. The student member will serve for one year and may be renewed by the IRB.
3. The Director of the Student Health and Counseling Center or their designated representative who shall serve as a voting member.
4. The Director of Environmental Health and Safety or their designated representative who shall serve as a voting member.
5. The Associate Vice President for Research and Sponsored Projects who shall be a non-voting member.
6. One community representative not affiliated with the University or part of the immediate family of a person affiliated with the University who shall serve as a voting member. There should also be an alternate community representative who can stand in for the community representative.

All new appointments to the IRB for an academic year shall be made no later than September 15 of each academic year. Vacancies occurring during an academic year shall be filled by recommendations of the IRB to the University President or their designee.

The composition of the Board will be reviewed every three years by the Academic Senate in consultation with the IRB to help facilitate permanent members' representation in accordance with research initiation, adjusting the representativeness of the membership, and to ensure compliance with government regulations.

No member of the IRB may be present during a vote of a research protocol in which they affiliated as an investigator.

The members of the IRB shall select a Chair and Vice Chair from among the voting members of the IRB and in conjunction with appointment periods. Staff support to the IRB shall be provided by the Office of Research and Sponsored Projects.

For protocols requiring a full committee review, it is required that a quorum be established to review and/or vote on proposed research protocols. In compliance with federal policy, this quorum must contain at least one community member. IRB meetings are open to the public; however, the IRB utilizes a primary reviewer system to facilitate review of proposals. To expeditiously review numerous protocols at IRB meetings, researchers are encouraged to attend only if their primary reviewer has instructed them to do so prior to the meeting. Primary reviewers are encouraged to contact researchers prior the meeting to discuss concerns and/or request revisions that may be necessary to approve a protocol. Any IRB member may request that an investigator attend a meeting to discuss their protocol.

The complete operational procedures of the IRB can be viewed at http://www.fullerton.edu/doresearch/compliance/irb_cayuse.php or may be obtained upon request to the Office of Research and Sponsored Projects. Persons planning to submit an IRB application should review the most current version of these procedures.

F. REFERENCES

For guidance, concerned parties should consult (1) the *Federal Policy for the Protection of Human Subjects* as published in the *Federal Register*, June 18, 1991, and its amendments as they appear in the *Federal Register*; (2) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Biomedical and Behavioral Research*; (3) the *Nuremburg Code*; (4) American Psychological Association's Ethical Principles of Psychologists and Code of Conduct (2003, as amended in 2010, 2017); (5) The American College of Sports Medicine's "*Guidelines for Exercise Testing and Prescription*" (most recent edition); and (6) *World Medical Association Declaration of Helsinki*.

Source: Faculty Research Policy Committee

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