



## University Policy Statement

### UPS 620.000

## PROTECTION OF HUMAN PARTICIPANTS

### I. OVERVIEW

#### A. **AIM**

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

#### B. **DEFINITIONS**

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which 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 investigator and 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 which 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 for obtaining the information to constitute research involving human participants.

“University” includes California State University, Fullerton and its formally recognized auxiliaries, including the California State University, Fullerton Auxiliary Services Corporation (ASC), the California State Fullerton Philanthropic Foundation (CSFPF), and the Associated Students, Inc. (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 1998 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 CSUF 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 accepts the responsibilities of Section I-D and I-E below only if appropriate University policies are followed, including approval by designed administrators and the Institutional Review Board (IRB). The University cannot and does not accept responsibility for research conducted in violation of University policy.

This policy recognizes that researchers not affiliated with CSUF 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 CSUF faculty, staff or employees are independent of the IRB. Faculty members are encouraged to consult with the CSUF IRB regarding research protocol requests and at their discretion may request that an outside research protocol be reviewed by the CSUF IRB. Use of CSUF facilities or faculty, staff and students for the purposes of research conducted by outside researches is independent of the CSUF IRB. Faculty members should make requests of this nature through their department or other offices as needed for CSUF 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 employees of 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 employees are reminded to adhere closely 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 CSUF IRB prior to implementation. Additionally, the principal investigator is reminded to promptly report (immediately or within at least five days), in writing, any unanticipated or adverse events causing risks to research subjects 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 this policy and are reminded of the responsibility for being informed concerning research projects involving human participants in the department. Department chairpersons and Faculty Advisors are reminded to review protocols of such investigations as often as needed to ensure that the project is being conducted in compliance with our institution and with DHHS regulations.

**E. INSTITUTIONAL REVIEW BOARD 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 annually and as required 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 President.

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

1. The College of Health and Human Development, the School of Nursing, the Department of Kinesiology, the Department of Psychology, and the Department of Sociology shall each have a permanent representative as voting members on the Board, representatives to be recommended to the President by the respective units. The two or more remaining members will be appointed by recommendations from the Academic Senate to the President, 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 President shall be outlined in their respective appointment letter and may be renewed annually as needed.
2. At least one student member, appointed by the ASI, who shall serve as a non-voting member.
3. The Director of the Student Health and Counseling Center or his/her designated representative who will serve as a voting member.
4. The Director of Environmental Health and Instructional Safety or his/her designated representative who will serve as a voting member.
5. The Associate Vice President for Graduate Programs and Research who will 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 will serve as a voting member.

All new appointments to the IRB for an academic year shall be made no later than by September 15 of each academic year. Vacancies occurring during an academic year shall be filled by Academic Senate appointment or designated departments in order to maintain permanent membership representation.

The composition of the Board will be reviewed every three years by the Academic Senate 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 sit in during a vote of a research protocol in which he/she has a vested interest.

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 Institutional Review Board shall be provided by the Office of Graduate Programs and Research.

For protocols requiring a full committee review, it is required that a quorum be established in order 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 in order to facilitate review of proposals. In an effort 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 in order to approve a protocol. Any IRB member may request that a principal investigator attend a meeting to discuss his or her protocol.

The complete operational procedures of the IRB can be viewed at <http://fullerton.edu/research/research-compliance/irb/forms.asp> or may be obtained upon request to the Office of Graduate Programs and Research. Persons planning to submit an IRB application should review the most current version.

#### **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) the American Psychological Association's *Ethical Principles in the Conduct of Research with Human Subjects* (1973, as amended); (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*.

## **II. REVIEW OF RESEARCH ACTIVITIES**

### **A. OVERVIEW**

The IRB shall review all proposals or plans for research activities involving minimal or greater risk to human participants prior to collecting data. The IRB shall evaluate the proposed research for the purpose of establishing compliance with the provisions of this document.

On the basis of this review, the IRB has the authority to approve or disapprove a project. The IRB will furnish the investigator with written notification of its decision.

If a proposal is disapproved, the reason(s) for disapproval shall be supplied in writing to the investigator. The investigator may request to attend a meeting of the IRB to discuss the reasons that a proposal was denied or may respond in writing to the IRB's decision.

The IRB has the authority, as it shall deem necessary to ensure that the activity is being properly conducted, to review approved activities involving human participants. The IRB shall review each approved project no less frequently than once a year, and it may have one or more members of the IRB observe, or have a third party observe, the consent process and the research.

There are many projects in which research with human participants is not initially anticipated but undertaken later. Initial approval of such a project by other University reviewers or by external sponsors does not constitute formal approval of the use of human participants. The review and approval of the IRB must be obtained before data collection involving the use of human participants in research commences. The IRB and the Office of Graduate Programs and Research are responsible for coordinating such formal assurances as may be requested by federal sponsors under federal policy.

Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the University. However, those officials may not approve the research if it has been disapproved by the IRB.

**B. EXEMPT RESEARCH**

Exemption from review may be granted to research activities according to the specifications of federal policy (45 CFR 46.101 (b)). *It is important to keep in mind that the term “exempt” does not indicate that a research project is exempt from the entire IRB process. Rather, an exempt review means that the project is exempt from a full committee review.*

Exemption from full committee review is ultimately determined by the IRB, not the investigator. If there is any doubt, the investigator should obtain a finding of exemption from the IRB rather than presume exemption. Any member of the IRB may require that a formal application be filed for a project that might otherwise appear to meet the conditions for exemption. Investigators who are not sure of the applicability of the regulations to their projects should apply for exempt status.

**C. EXPEDITED REVIEW**

1. Research projects involving only minimal risk may be handled by an expedited review process (Section C.2. below). The expedited review may be used in the cases suggested in federal policy (45 CFR 46.110).
2. An expedited review shall be conducted by the chair or one or more of the IRB members designated by the chair to conduct the review. The IRB member(s) conducting the expedited review may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. The standards applied in an expedited review shall be the same as for a full review, specified in Section II. D below. The reviewer(s) shall refer any research proposals which the reviewer(s) would have disapproved to the full committee for review. The reviewer(s) may also refer research proposals to the full committee whenever the reviewer(s) believe that full committee review is warranted. When the expedited review procedures are used, the IRB chair or member(s) conducting the review shall inform the IRB members of the proposals which have been approved under the procedure. On request by any member of the IRB, an activity, which has been approved under the expedited procedure, shall be reviewed by the IRB in accordance with nonexpedited procedures.
3. An expedited review may also be conducted for continuing review of research previously approved by the convened IRB where the research is permanently closed to the enrollment of new participants, all participants have completed all research-related interventions and the research remains active only for long-term follow-up of participants, or where no participants

have been enrolled and no additional risks have been identified, or where the remaining research activities are limited to data analysis.

4. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, where the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified may also be expedited.

In order to approve a research project by expedited review, the IRB shall determine that the strictest of the standards for approval under federal policy, University policy, and sponsor policy are met.

#### **D. FULL IRB REVIEW**

Research not meeting the criteria for exemption or expedited review shall require review at a convened meeting of the full IRB. Full review of the IRB requires that a majority of members of the IRB be present; approval of project requires a majority of those present.

In order to approve a research project by full review, the IRB has the authority ([45 CFR 46.109](#)) to determine that the strictest of the federal standards for approval are met ([45 CFR 46.111](#)). Other related University and/or sponsor policy may apply.

#### **E. DEPARTMENTAL REVIEW PROCESS**

Five University units including the College of Health and Human Development, the Department of Kinesiology, the School of Nursing, the Department of Psychology, and the Department of Sociology, have a “permanent” member on the IRB. For this reason, these units are entitled to a Departmental Review Process that allows them to administratively review IRB proposals and forward proposals, along with their comments and recommendations, to the Chair of the IRB. The Departmental Review Process does not replace approval by the IRB and investigators should note that this is a screening process used to facilitate a timely review of their protocols. The most recent CSUF application form must be used and collection of data should not commence until the IRB has approved the protocol. An advantage for the department review process is that the reviewer of the proposal, instead of being arbitrarily assigned, is always the IRB member who represents that investigator’s particular unit. This process applies only to exempt and expedited research where risk to the human participants is minimal. If it is decided that the research qualifies as exempt or expedited, the application along with any comments are forwarded to the Regulatory Compliance Coordinator (RCC) of the IRB. The RCC catalogs the application and forwards it along with the comments to the IRB Chair for final approval. Upon final approval, the IRB Chair sends an approval notice along with any stamped/approved consent forms for use in the study. If the application does not qualify as exempt or expedited, the investigator will be notified and the protocol will be placed on the agenda for full committee review. Investigators are encouraged to keep in mind the submission deadlines for full committee protocols which can be found at [CSUF Homepage-IRB Forms](#) [<http://fullerton.edu/research/research-compliance/irb/forms.asp>]

In pursuit of an equitable workload, it is expected that those units that submit significant numbers of IRB protocol applications annually, will request that a member of that unit be appointed to the IRB. This “appointed” member, who serves a term of two years, is then eligible to operate a Departmental Review Process within that unit. Any unit without representation on the IRB is not entitled to a Departmental Review Process and must submit all IRB applications (exempt, expedited and full) to the Regulatory Compliance Office of the IRB for review.

## **F. REQUIREMENTS FOR INFORMED CONSENT**

Ethical practice requires the investigator to inform the participant of all features of the research that reasonably might be expected to influence willingness to participate and to explain all other aspects of the research about which the participant inquires.

Research investigators are responsible for obtaining informed consent from human participants in accordance with federal policy prior to collection of data and for maintaining appropriate documentation of informed consent.

### **1. Legally Effective Informed Consent**

Unless otherwise waived by the IRB, research investigators are responsible for ensuring that legally effective informed consent shall meet the requirement of federal policy (45 CFR 46.116). The IRB may impose further requirements it deems necessary under the circumstances.

### **2. Minimum requirements for Written Informed Consent**

The requirements for the content of written informed consent, and the authority of the IRB to alter or waive those requirements, shall be as specified in the federal policy (45 CFR 46.117) and can also be found at CSUF Homepage-IRB Forms [http://fullerton.edu/research/research-compliance/irb/forms.asp]

### **3. Applicability of Other Laws**

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

### **4. Emergency Medical Leave**

Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable federal, state, or local law.

### **5. Retention of Consent Form**

Research investigators are responsible for placing the consent documents signed by human research participants in a repository approved by the IRB and/or per their department's guidelines. Completed informed consent forms should be kept by the investigator for no less than a minimum period of one year, unless otherwise specified by investigator.

## **G. EVALUATION OF LEGAL QUESTIONS**

If any reviewing body or individual believes that the proposed activity violates any law, may possibly violate any law, or may otherwise contain some significant legal issue, relevant activity description shall be submitted to the appropriate legal counsel at the Chancellor's Office for evaluation.

## **H. ENFORCEMENT**

The IRB shall report to the Vice President for Academic Affairs any projects that fail to protect the rights or welfare of participants and may recommend project suspension or termination. The Office of the Vice President for Academic Affairs shall be responsible for enforcement of the recommendations of the IRB. Any researcher demonstrating persistent or serious disregard of the IRB, especially including any serious harm to human participants resulting from disregard of the IRB, shall be subject to disciplinary action.

For projects sponsored by the Federal government, the IRB shall itself have the authority to suspend or terminate approval of research or nonstandard instructional activity that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to

participants, as provided in federal policy ([45 CFR 46.113](#)). Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate University officials, and the sponsoring agency.

The IRB, CSUF RCC, the study sponsor, and other state or federal regulatory entities may have access to any data collection or records being conducted as research sponsored by monitoring purposes. These same parties shall have authority to observe or have a third party observe the consent process and the research.

## **I. THE INVESTIGATOR**

### **1. Responsibilities**

The primary responsibilities for assuring protection when human participants are involved in research rests with the investigator. Faculty advisors are responsible for ensuring that graduate students listed as principal investigators are informed and aware of IRB requirements and the federal regulations that govern participation of human subjects in research.

For any research project approved by the IRB the investigator has the responsibility for bringing to the IRB's attention any request for approval of proposed procedural changes prior to implementation and to report any problems which emerge in the course of the activity which are related to the welfare of the participants. Adverse events resulting from participation in the protocol and/or any unforeseen problems or situations should be reported immediately but no later than five days by the investigator to the IRB.

The investigator is responsible for maintaining the signed consent forms for the human participants involved in the projects according to the IRB specifications.

### **2. The Project Application**

The basis for review of research projects involving human participants will be a project application submitted by the investigator, on the most current forms specified by the IRB. The project application will require at least the following information and documentation. The IRB may, at its discretion, require additional information as needed in order to approve a research protocol.

- (a) The title of the proposed research project.
- (b) The name(s) and title(s) and signature(s) of the principal investigator(s). If the principal investigator is a student, give the name and title of the faculty sponsor or appropriate staff sponsor as co-investigator.
- (c) The location of the activity and the projected dates for its commencement and completion.
- (d) The objective, scientific rationale, and expected benefits of the project.
- (e) The nature of the investigation to be performed on the participants.
- (f) Any special training required of the investigator to conduct this project.
- (g) The number and relevant characteristics of the proposed participants.
- (h) The protocol (procedures) for the project.



- (i) The potential risks to the health, safety, dignity, rights and welfare of the participants.
- (j) The proposed safeguards against these risks.
- (k) Potential benefits to the participants.
- (l) The procedures for obtaining informed consent from the participants and a copy of any required consent forms.
- (m) Procedures for debriefing research participants, if applicable.
- (n) The proposed procedures for recruiting and selecting participants.
- (o) The proposed financial sponsor of the project and/or any conflicts of interest which may exist between the investigator, co-investigator and the financial sponsor.

The required application forms shall be maintained and made available by the Office of Graduate Studies and Research, subject to approval of the IRB.

## **J. IRB RECORDS**

1. The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:
  - (a) Copies of all research proposals reviewed, scientific evaluation, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants;
  - (b) Minutes of IRB meetings;
  - (c) Records of continuing review activities;
  - (d) Copies of all correspondence between the IRB and the investigators;
  - (e) A list of all IRB members as required by federal guidelines (45 CFR 46.107);
  - (f) Written procedures which the IRB will follow;
  - (g) Statements provided to participants concerning significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation.
2. The records required by this policy shall be retained for at least three (3) years from the most recent IRB approval date. All such records shall be accessible for inspection and copying by authorized federal or University representatives at reasonable times and in a reasonable manner.

### **III. REVIEW OF NON-STANDARD INSTRUCTIONAL ACTIVITIES**

#### **A. RESPONSIBILITIES**

1. The responsibility for informing each student of the potential risks in such non-standard instruction activities lies with the instructor.

Each student shall be informed in writing during the first week of class of the potential risks involved in such activities and should be encouraged to pursue possible alternatives with the instructor if the risks appear excessive. The provision of information to the students shall be comparable in content and procedure to the provision of informed consent to research participants specified in Section II. F. above.

2. The responsibility for providing properly maintained and supervised equipment rests with the department offering such courses. The responsibility includes the provision of personnel properly trained to operate any necessary equipment, as well as able to operate any emergency equipment necessary in case of an accident. It is expected that all departments will provide, in advance, adequate emergency preparations.

#### **B. PROCEDURES**

The instructor shall file an application for approval of the non-standard instructional activity with the IRB not less than annually. The IRB shall review the activity by the same standards applicable to research projects in Section II above.

Academic Senate Approved Revisions 3-7-13  
President signed 4-26-13

**EFFECTIVE DATE: April 26, 2013**  
**Supersedes:** UPS 420.103 dated July 7, 2006  
and ASD 13-24