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Use of Human Subjects in Research at SF State

Source Committee: Academic Policies Committee

Unit(s) Responsible for Implementation: *Office of Research and Sponsored Programs*

Consultations: *AVP for Research, Institutional Review Board*

History

Version	Approved	Revisions(s)
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1	04/23/2020	Original; Replaces in whole #S15-004. Addresses changes in Federal policy, sets out actions in cases where the policy is violated. Pulls out procedural information into a Guidebook and the IRB website.
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Rationale

This document sets forth the policies and procedures for the protection of human subjects in research, development, and related activities conducted at, or sponsored by, San Francisco State University (SFSU). It also serves to implement the specific requirements of the United States Department of Health and Human Services (HHS) (45 Code of Federal Regulations Part 46, known as Common Rule, as revised FR 40, 11854-58, March 13, 1975; FR 40, 33528-30, August 8, 1975; FR 43, 1758, January 11,

1978; and FR 46, 8366-8392, January 26, 1981, FR 48, 9269, March 4, 1983, and FR

48, 9818, March 8, 1983, June 19, 2018). This statement supersedes all previous university policy statements governing the protection of human subjects.

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Policy

1.0 Introduction

This policy sets out the requirements for faculty, students, and staff carrying out research, development, and related activities involving human subjects and conducted at, or sponsored by, San Francisco State University (SFSU). The latest Guidebook and Office of Research and Sponsored Program's Human and Animal Protections website (now available at <https://research.sfsu.edu/protocol>) for the Institutional Review Board contains relevant information for researchers planning on work with human subjects and for members of the IRB.

1.1 Definitions

- *Common Rule.* The Common Rule is a federal policy covering research on human subjects that applies across federal agencies. It includes requirements for compliance with human subject protections by research institutions and lays out requirements for Institutional Review Board operations, how researchers should obtain and document informed consent of research subjects, and additional protections for vulnerable populations.
- *Belmont Principles.* From the Belmont Report, which outlined the case for appropriate research behavior, the Belmont Principles include Respect for Persons, Beneficence, and Justice. Together, they emphasize respect for all involved in research, maximizing benefits and minimizing possible harm during the research process, and working to achieve fairness and equal treatment.

2.0 Applicability of this Policy

It is campus procedure to apply the Common Rule to all research on campus with few deviations from the Common Rule, such as for research sponsored by an entity that has not adopted the Common Rule. Any deviations from the Common Rule will be identified with a justification for why the Common Rule is not being applied, and the campus's procedure for ensuring the equivalent protection of human subjects is in accordance with the Belmont principles of autonomy, beneficence, and justice (see IRB Guidebook and website, currently at <https://research.sfsu.edu/protocol>).

The University's assurance document was last revised in 2018 to reflect changes in HHS regulations according to the Final Rule published in the Federal Register on January 19, 2017. Effective January 21, 2019, all initial submissions of human subjects research that is funded by a federal or other agency that has adopted the Common Rule will be reviewed according to the Final Rule. All human subjects research studies that were approved prior to January 21, 2019, will follow the pre-Final Rule regulations until expiration or closure.

This policy gives paramount weight to the protection of human subjects in research on the basis of ethical considerations outlined below. In addition, the policy reflects the legal requirements that apply to research. This policy applies to the review of research involving human subjects. SFSU is considered to be engaged in research if such research meets any of the following criteria; it:

- Is conducted on San Francisco State University campus premises
- Utilizes San Francisco State University facilities or resources
- Is conducted by SFSU employees (faculty and staff), students or other persons affiliated with SFSU and involves obtaining informed consent for the collection or analysis of individually identifiable data and analysis of such data
- Is conducted under the auspices of the SFSU Sponsored programs or SFSU auxiliaries

If SFSU is considered to be 'engaged' in research (as defined in 45CFR46.101), it triggers either the need for a SFSU IRB review, operating according to the content of this policy, or entering into an agreement with another engaged institution whose IRB will review the research. All questions regarding the engagement of research and reliance agreements should

be directed to the Office of Research & Sponsored Programs.

3.0 Authority and Assurance of Compliance

The Office of Research & Sponsored Programs and the all-university, Institutional Review Board (IRB) reports to the Associate Vice President for Research and Sponsored Programs. The Associate Vice President is designated the Institutional

Official by the President of the University to ensure compliance with this policy for the protection of rights and welfare of human subjects in research. The IRB convenes a full committee meeting once a month, or as needed, to review SFSU research proposals that involve human subjects and greater than minimal risk, or those that involve vulnerable populations.

The determination of which review category is pertinent in each case is made by the office staff in consultation with the IRB Chair or a designee of the Chair. The SFSU IRB adheres to local, state, and federal regulations governing the protection of human subjects in research. Researchers on all university research projects that involve human subjects and involve faculty, staff, or students are expected to contact the human and animal protections unit (HAP) in the Office of Research & Sponsored Programs for consultation before proceeding with their research project. The Institutional Review Board (IRB) shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under 45CFR46.104 for which limited IRB review is a condition for exemption.

4.0 Institutional Review Board

The Institutional Review Board (IRB) is a standing administrative committee of the University. The IRB is administratively responsible to the Associate Vice President for Research and Sponsored Programs. Membership on the board is for a three-year, renewable term unless the member requests to terminate their membership on the board before their term ends. The IRB is composed of members representing the University faculty, staff, and local community. Membership includes at least one individual whose primary concerns are in the non-scientific areas and at least one member not otherwise affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution. The faculty members must represent a variety of disciplines representative of the research reviewed.

4.1 Selection/Appointments

The IRB Chair or IRB Administrator will confirm that IRB membership is in compliance with regulations (46.107). If an additional member(s) is needed, several methods are used to identify candidates. The existing members may be asked to provide recommendations to the Chair. Department Chairs may be contacted to suggest faculty who are available and interested. Faculty who are active in the research community may be contacted directly to discuss service to the committee.

The Associate Vice President for Research and Sponsored Programs, in consultation with the Dean of Graduate Studies, shall appoint committee members with the concurrence of the Executive Committee of the Academic Senate for three-year terms.

Representatives of Office of Research and Sponsored Programs shall be ex-officio members without a vote, except the IRB Administrator may be appointed as an alternate non-scientist member of the board.

Reappointment may occur on an annual basis.

4.2 Alternate Member

An alternate member may be appointed to the Committee to serve in the absence of a member. Alternate members shall be appointed in the same manner as primary voting members and shall only be counted towards quorum when the primary voting member is absent.

4.3 Training

IRB members must attend new member orientation prior to beginning their service on the IRB and complete the CITI (Collaborative Institutional Training Initiative) course, including the elective IRB member modules. They will also participate in initial and continuing education by reviewing relevant materials on issues, regulations, and guidance concerning human subjects protections, to be disseminated by the IRB Coordinator. IRB members will be familiar with the Code of Federal Regulations (45 CFR 46) (<http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>), the Belmont Report

(<http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>) and with this IRB policy document. IRB members are also periodically notified of events such as lectures, workshops, and conferences related to human research protections occurring locally and nationally.

4.4 Chair and Associate Chair

The committee will elect a Chair and an Associate Chair annually in consultation with the Associate Vice President for

Research and Sponsored Programs. To be nominated for the Chair position, the member must have served on the IRB for at least one year and have sufficient expertise in the use of human subjects for research at SFSU. The Chair and Associate Chair should come from different disciplinary backgrounds.

The responsibilities of the Chair and Associate Chair are defined in the IRB Guidebook and published on the IRB website (https://research.sfsu.edu/protocol/about_committee).

4.5 Committee Rules

The IRB meets a minimum of once a month. The schedule of meetings and deadlines for submission of protocols is to be added to an agenda that must be posted on the IRB website at the start of the academic year. If an emergency meeting is necessary in order for the IRB's actions to conform to any aspect of HHS policy or if extra meetings are necessary to accommodate and review a high number of protocols, the IRB chair will call such a meeting.

A quorum of the IRB is defined as a majority of the total membership. In order for official committee business to be conducted, a quorum must be present. In order to review proposed research, the quorum must include at least one member whose principal concerns are in non-scientific areas. Research must be approved by a majority of those members present at the meeting. Any action taken without a quorum present that requires a vote is considered invalid (45 CFR 46.108(b))

5.0 IRB Records

The Office of Research and Sponsored Programs maintains the current IRB membership roster, documentation of reviews, IRB minutes, and IRB correspondence.

Paper and electronic records required by 45 CFR 46 are fully accessible to the IRB and are stored for at least 3 years after the completion of the research.

6.0 Enforcement

Any unanticipated problems, deviations from previously approved protocol, violations involving risk to subjects or others must be reported immediately to the IRB by the researcher. The principal investigator is responsible for reporting these to the IRB in a timely manner.

6.1 Non-Compliance

Any serious or continuing non-compliance by research investigators will be reported to the Associate Vice President for Research and Sponsored Programs, as will any information concerning possible injuries to subjects or unanticipated problems involving risks to subjects. It is the responsibility of the Associate Vice President for Research and Sponsored Programs, as Institutional Official, to forward to Office of Human Research Protections (OHRP) in the Department of Health and Human Services (HHS) appropriate reports on such matters.

Researchers who have been found in violation of IRB Policies by the Associate Vice President of Research shall have their next two protocols undergo full Committee review by the IRB, even if they would normally be exempt or undergo expedited review.

6.2 Suspension or Termination of the IRB Approval of Research

The 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 subjects. Any suspension or termination of approval shall include a statement of the reasons for the action and shall be reported promptly to the investigator, appropriate officials, the funding agency, and to OHRP-HHS.

Approved by the San Francisco State 04-07-2020

Signed Memo:
S20-286
