



Procedure for ORSP Projects Involving Human Participants or Animal Subjects

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SUMMARY

Documentation of an active protocol or exemption must be received by ORSP before a project is activated or extended in CFS.

DESCRIPTION

Human and Animal Protections (HAP) at San Francisco State University (SF State) supports the work of the Institutional Review Board (IRB) and the Institutional Animal Care and Use Committee (IACUC). The IRB and the IACUC are charged with protecting the safety and welfare of humans and animals used in research at or in conjunction with this SF State. The committees do not expect research to be free from risk, but do expect the investigator to be aware of the risks, to minimize risk when possible, and to take appropriate precautions when necessary.

This document outlines how ORSP Grant Administrators work with HAP staff to document that a research protocol for a sponsored project has been reviewed and approved. If a project uses human or animal subjects, the PI must obtain approval for the research protocol or an exemption notification for the project from SF State's HAP. Documentation of the approved protocol or exemption must be received by ORSP before the project is activated in PeopleSoft and expenses are charged to the award. For multi-year projects, protocols are reviewed by HAP on an annual basis for the duration of the project period.

For further information on the documentation needed to apply for a protocol, the role of the Institutional Review Board, the approval process, and federal regulations regarding Human and Animal Subjects, please visit <http://research.sfsu.edu/protocol>.

ROLES AND RESPONSIBILITIES

Principal Investigator (PI)

- When submitting the online PI Checklist form (to indicate intention to submit a proposal), indicates whether their proposed research will involve humans or animals
- If needed, completes the documentation required by HAP, submits the protocol application, and responds to any concerns raised by the committee

HAP

- The Office is organized into two Institutional Review Boards and one Institutional Animal Care and Use Committee that review all protocols at SFSU for compliance with federal regulations
- Reviews each protocol and either exempts the protocol from full IRB review, approves, or denies the protocol. The committee also maintains documentation of each approved protocol.

- Corresponds with the GA before a proposal is submitted or funded by the agency to provide Just-In-Time approval of the protocol prior to funding being released.
- When requested, provides a copy of the approved protocol or exemption notification for a sponsored project to the appropriate ORSP GA.

ORSP Grant Administrator (GA)

- If a sponsor requires approval of a human or animal subject protocol before issuing an award, the GA is responsible for obtaining a copy of the protocol from HAP and submitting the protocol documentation to the sponsor
- Keeps a copy of the approved protocol in the proposal folder
- At the time of award set-up, the GA confirms that there is a protocol and that it has received approval. If a protocol is missing from the ORSP documentation, or the time period of the protocol has expired, the GA contacts the PI and requests a copy of the new approved protocol.
 - The GA does not set-up an account for a project with human or animal subjects without documentation of an approved and current protocol.

PROCEDURE

- The GA reviews the PI Checklist to see if use of human or animal subjects has been marked by the PI
- The GA reviews the application guidelines for the indicated funding opportunity, or contacts the program officer (if applicable) and determines when documentation of an approved protocol for human or animal subjects is required:
 - At the time of proposal submission
 - Before funds are awarded, e.g. NIH Just in Time Documentation
 - Before an award account is created
- When coordinating proposal development with the PI:
 - If the PI has not marked human and animal subjects, the GA confirms that the project does not require committee review. If there is any uncertainty, the GA directs PI to use the [Does My Project Require Review?](#) section of the HAP website
 - If the PI has confirmed that there will be use of human or animal subjects, the GA directs the PI to the [HAP website](#) and explains that if the proposal is funded an approved protocol, or verification of an exempt status, is required before expenses can be charged to an award account.
- If a sponsor requires verification of an approved protocol before an award is issued, the PI will apply for approval (or exemption) from HAP. The GA makes a copy of the approval for the proposal folder and submits the verification of the protocol to the sponsor.
- At the time of award set-up, the GA reviews the proposal file for documentation of an approved research protocol or an exemption notice. Confirms that the protocol is under a valid approval or that an exemption is in effect.
- If there is no approved protocol or an exemption notice from the Office of Protection for Human and Animal Subjects, the GA contacts the PI and requests a copy of the approval or exemption. The GA must have a currently approved protocol or exemption notice before an award account is activated for the project or for a continuation year of the project.