



## **Human and Animal Subjects Procedure**

---

**Issued: January, 2008**

**Implemented: March, 2008**

### **PROCEDURE SUMMARY**

- 1) Documentation of an active protocol or exception from review must be received by ORSP before a project is activated or extended in CMS.
- 2) The Compliance Officer performs periodic checks of award folders to verify whether Human or Animal Subject documentation is active.

### **DESCRIPTION**

This procedure outlines how ORSP works with the Office for the Protection of Human and Animal Subjects (OPHAS) at SFSU 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 exception from review letter for the project from SFSU's OPHAS.

Documentation of the approved protocol or exception from review must be received by ORSP before the project is set up in PeopleSoft and expenses are charged to the award. For multi-year projects, protocols are reviewed by ORSP on an annual basis and at minimum on an annual basis by OPHAS 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 the SFSU Office for the Protection of Human and Animal Subjects website:

<http://www.sfsu.edu/~protocol>

### **ROLES AND RESPONSIBILITIES**

#### **Academic Department or Responsible Unit**

##### **▪ Principal Investigator**

- Completes the "Pre-Protocol Checklist for Use of Human and Animal Subjects in Research" and this document gives directions as to whether a protocol is required to be submitted to the SFSU Office for the Protection of Human and Animal Subjects.
- If needed, completes the documentation required by the SFSU Office for the Protection of Human and Animal Subjects, submits the protocol application, and responds to any concerns raised by the committee.
- Provides a copy of the approved protocol letter or exception from review letter from OPHAS for a sponsored project to ORSP for their files.

- Renews the research protocol and provides ORSP with a copy of the approval for renewal.

### **Office of Research and Sponsored Programs (ORSP)**

#### **▪ Proposal Specialist**

- When a proposal is brought to ORSP for processing and submission, the Proposal Specialist gives the PI the “Pre-Protocol Checklist for Use of Human and Animal Subjects in Research” to help the PI determine if a protocol is necessary.
- If a sponsor requires approval of a human or animal subject protocol before issuing an award, the Proposal Specialist is responsible for obtaining a copy of the protocol from the Principal Investigator and submitting the protocol documentation to the sponsor.
- Keeps a copy of the approval letter or exception in the proposal folder.

#### **▪ Grants Administrator (GA)**

- At the time of award set-up, the GA checks the ORSP documentation to confirm that there is a protocol and that it has received approval. If a protocol approval is missing from the ORSP documentation, or the time period of the protocol approval has expired, the GA contacts the PI and requests a copy of the new approval letter of the protocol.
- Does not set-up an account for a project with human or animal subjects without documentation of an approved and current protocol.

#### **▪ Compliance Officer**

- Conducts periodic random checks of award files to confirm that awards have an active and approved protocol letter or exception from review letter.

## **PROCEDURES**

### **OFFICE OF RESEARCH AND SPONSORED PROGRAMS (ORSP)**

#### **Proposal Specialist**

1. During the proposal development, the Proposal Specialist gives the PI the “Pre-Protocol Checklist for Use of Human and Animal Subjects in Research” to help the PI determine if a protocol must be submitted to the Office of Protection for Human and Animal Subjects. If the PI marks any items on the “Pre-Protocol Checklist for Use of Human and Animal Subjects in Research,” a protocol must be submitted to the Office for the Protection of Human and Animal Subjects.
2. The Proposal Specialist also reviews the PI Checklist to see if use of human or animal subjects has been marked by the PI. The Proposal Specialist reviews the application guidelines 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.

3. When meeting with the PI:
  - a. If the PI has not marked human and animal subjects, the OPHAS confirms with the PI that the project does not require review. The exception from review letter will be sent to the PI who should forward this information to the PS. The criteria listed on the Office of Protection for Human and Animal Subjects' website under the section "Does My Research Require Review?" may be helpful to the PI and the PS.

<http://www.sfsu.edu/~protocol/human/review-required.htm>

- b. If OPHAS has confirmed that there will be use of human or animal subjects, guide the PI to the Office for the Protection of Human and Animal Subjects website (see below) and explain that if the proposal is funded an approved protocol letter, or verification of an exception from review letter, is required before expenses can be charged to an award account.

<http://www.sfsu.edu/~protocol>

4. If a sponsor requires verification of an approved protocol before an award is issued, the PI will apply for approval (or exception from review) from the Office for the Protection of Human and Animal Subjects. The Proposal Specialist makes a copy of the approval for the proposal folder and submits the verification of the protocol to the sponsor.

#### **Grants Administrator (GA)**

1. At the time of award set-up, the GA reviews the proposal file for documentation of an approved research protocol letter or an exception from review letter. Confirms that the protocol is under a valid approval or that an exception from review is in effect.
2. If there is no approval letter or an exception from review letter from the Office of Protection for Human and Animal Subjects, the GA contacts the PI and requests a copy of the approval letter or an exception from review letter. The GA must have a currently approved protocol letter or an exception from review letter before an award account is activated for the project or for a continuation year of the project.

#### **RELATED DOCUMENTS**

- Proposal Development and Submission Procedure
- Award Set-Up Procedure
- Office for the Protection of Human and Animal Subjects Policies and Procedures