

San Francisco State University
Institutional Review Board for the Protection of Human Subjects

APPLICATION FOR RENEWAL OF PROTOCOL APPLICATIONS

All research projects employing human subjects must be renewed before the expiration date stated in the approval letter from the Office for the Protection of Human and Animal Subjects. All approvals are for a maximum of twelve months. Be sure to allow adequate time for review to take place (up to 12 weeks). **NO EXTENSIONS CAN BE GRANTED.**

To renew a protocol the researcher must provide an Annual Report (format given below) AND a new Protocol Approval Form (available at www.sfsu.edu/~protocol), along with any revisions or amendments to the original protocol, as required by the research. Every three years a current, complete protocol must also be submitted.

ANNUAL REPORT

1. Principal Researcher:

Name:
Position: (Professor, M.A. thesis student, etc.):
Faculty Department:
Student Home Address:
Daytime Telephone Number:
Project Title:

**2. Student Thesis Advisor / Faculty Supervisor (if applicable):
and Faculty University Telephone Number:**

3. Subjects

- a) **Total approved sample size:**
- b) **Total number of participants consented and enrolled to date:**
- c) **Number of subjects who participated in the past year:**
- d) **Number of subjects who withdrew voluntarily in the past year:
Include why they withdrew, if known:**
- e) **Number of subjects who were dropped by the researcher for any reason in
the past year: Why were they dropped?**

4. Provide a summary of research progress during the past year. Provide a copy of a grant progress report, abstract, publication, conference presentation, etc. if possible. If these are not available, provide a preliminary analysis of any data obtained or a summary of preliminary findings.

5. Summarize any unforeseen or unanticipated problems or adverse events that occurred during the past year. Include a description of the measures taken as a consequence of and any changes in the risks and benefits that occurred due to these events. State whether the attached protocol application incorporates these measures.

6. Summarize all modifications (amendments, revisions) made to the original protocol during the past year not already mentioned in the answer to Question #5. Include any proposed modifications to the protocol (see Modifications). Include any changes in the risks and benefits that occurred due to these modifications.

7. Summarize recent literature or other information that may affect the risks or benefits associated with this research.

8. If any new research personnel have been added who will have contact with subjects or their personal information, include their names, qualifications, training, and a copy of their NIH on line human subjects course completion certificates.

9. Describe any changes to internal or external funding of this research as well as any projected change to the expenses for the forthcoming research period.

Attach the Protocol Approval Form AND any requested materials. For a third renewal, also submit a copy of the complete protocol packet with all changes incorporated. (We can approve protocols for a total of three years before we need a new protocol submission. This includes the original approval period of one year, plus two renewals.)