

San Francisco State University Protocol Modification Form

Please complete and submit this form and any appropriate accompanying documents to the Human and Animal Subjects Office, via our Grad Stop box at ADM 250, via fax at 415-405-2474, or via email to protocol@sfsu.edu. Please be advised that you may not use any modified documents until the IRB Office has approved the changes. Approval time depends on the nature of the modification.

Principal Investigator Name:

Protocol Review Status (exempt, non-exempt, expedited):

Study Title:

Protocol # (for non-exempt or expedited):

1. Please describe the changes you want to make and why.

(If this Modification is being requested due to an adverse or unanticipated event, please also submit an Unanticipated/Adverse Event Report from our Forms and Templates page www.sfsu.edu/~protocol/human/forms.htm.)

2. Please describe why, in your opinion, these changes will or will not introduce any new risks to the participants.

3. Please explain how these changes affect subjects currently enrolled in the study.

4. If the current subjects will be affected, please explain how they will be notified of these changes.

5. What type of modification would you like to make? *Please check all that apply and submit the corresponding documents; please **highlight/underline/or bold** changes for ease of review.*

Change Principal Investigator:

- submit a new Protocol Approval Form (PAF) with the appropriate signatures;

- submit an updated Qualifications section;
- submit a new Informed Consent with updated Background and Contact Information sections;
- submit an NIH Certificate for the new PI;
- submit any other documents where the PI is named.
- Add Research Assistant:
 - submit a brief statement that includes the new RA's qualifications and any pertinent training he or she has received to aid in your research;
 - submit an NIH certificate for each new RA.
- Change Number of Participants:
 - submit a new Protocol reflecting the changes in the Participant Population section.
- Change Inclusion/Exclusion Criteria:
 - submit new Protocol reflecting the changes in the Participant Population section;
 - submit new Recruiting Script(s);
 - submit new Informed Consent/Assent documents reflecting the changes.
- Change Recruiting Methods:
 - submit a new Protocol reflecting the changes in the Participant Population section;
 - submit new Recruiting Materials as appropriate
- Change Research Procedures:
 - submit both a new Protocol and new Informed Consent/Assent documents reflecting these changes in the Procedures sections.
- Change Survey or Interview Questions:
 - submit a copy of the new survey or interview questions.
- Other: Please describe what documents you will change because of your modification and submit copies of them to our office.