San Francisco State University

Protocol Modification Form

*Please complete and submit this form and any appropriate accompanying documents to the Human and Animal Protections (HAP) via email to* [*protocol@sfsu.edu*](mailto:protocol@sfsu.edu)*. Please be advised that you may not use any modified documents until the HAP has approved the changes. Approval time depends on the nature of the modification.*

Principal Investigator Name:

Faculty Advisor Name (if applicable):

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 Adverse Event Report or Deviation Report form found in* [*Human Protections Forms*](http://research.sfsu.edu/protocol/submit_protocol/human_protections_forms.html)*.)*

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 participants currently enrolled in the study.

4. If the current participants 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.*

***\* Please note that Expedited and Non-Exempt studies require the submission of an updated Protocol.***

* 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 a CITI Certificate for the new PI;
  + submit any other documents where the PI is named.
* Add Research Assistant:
  + submit a new Protocol with 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 a CITI 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.
* submit a new Protocol reflecting the changes in the Study Design and Study Procedures section.
* Other: Please describe what documents you will change because of your modification and submit copies of them to our office.