



## UNIVERSITY OF CALIFORNIA, SAN DIEGO HUMAN RESEARCH PROTECTIONS PROGRAM

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### Submitting an Amendment/Modification to a Research Plan (Protocol)

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#### A. GENERAL INFORMATION

All modifications/changes in a project must be received and approved by the Institutional Review Board (IRB) *before* they are initiated except where necessary to eliminate apparent immediate hazard to the subject. Requests for approval of modifications/changes may be submitted at any time by the Principal Investigator (PI) during the active, approved period of a study.

The initial determination as to whether a modification is major or minor is the responsibility of the PI, who assesses the degree of change in procedures and risks. However, the acceptance of the determination rests with the IRB. The modification is reviewed by the IRB professional staff and a determination of whether full IRB review is necessary is made.

If the submission does not provide sufficient information for appropriate review, it will be considered incomplete, and no further review of the submission will be done. The incomplete submission may be returned to the PI or a letter to the PI may be provided requesting additional information.

“Major” modification requests are reviewed through the full Committee review process. Major modifications may impact on the risk/benefit ratio in the study. Examples of modifications that are typically considered to be major in nature include escalation in the drug(s) dosage(s), the introduction of an additional drug(s); new risk information and/or changes in risk to subjects; changes in inclusion/exclusion criteria; significant changes in study design and the addition of a new invasive procedure.

Federal guidelines include that “An IRB may use the expedited review procedure to review... (2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.” [45 CFR 46.110(b)(2)]. The review will be carried out by the IRB Chair, or his/her designee(s) from members of the IRB. If the Chair or designee believes that the "minor" modification is too substantive to receive this type of review, the submission will be referred for full IRB review. Minor modifications that *may* receive expedited review include minor changes in recruitment materials/procedures; correction of typographical and grammatical errors or editorial revisions that do not change the meaning of the study document; change in compensation for participation if not considered to be coercive; addition of new study site; and translations of materials previously reviewed and approved by the IRB.

Changes in study sites or investigators or additions must also be reported to the IRB and may receive expedited review. These requested changes involve sending a cover letter, revised application face page, and may involve revised Research Plans and consent documents. In the case of a change in the PI, the investigator who holds the approval should sign the cover letter, and a letter indicating acceptance of the role and responsibilities PI signed by the individual who

will become the PI must also be provided. A revised application face sheet reflecting the change in PI that is signed and dated by the incoming PI and Department Chair must also be provided. For protocols involving investigational drugs or devices, an amendment or protocol change intended to eliminate an apparent immediate risk or danger to participants may be implemented immediately provided the FDA is subsequently notified by protocol amendment and the reviewing IRB is notified in accordance with 21 CFR 56.104(c). The amendment must undergo full IRB review at the earliest opportunity.

**A modification is given approval only to the overall study expiration date that was received at the most recent initial or renewal approval.**

## **B. SPECIFIC SUBMISSION REQUIREMENTS**

### **1. Cover Letter**

This letter must contain the project number, title, name of principal investigator, and **should specifically state that an amendment/modification is being requested.** The letter should clearly explain what the modification is, why it is being requested, and any potential changes to risks to subjects, risk/benefit ratio, risk management procedures, etc. If revisions have been made to study documents, the cover letter must provide an outline of those revisions as well as why those revisions are being made.

### **2. An updated Application Face Sheet, as appropriate**

The copy of the revised application face sheet should indicate its IRB number, specifically stating that it is an amendment/modification, and updating all other information from the previous submission, as appropriate. The application face sheet must be signed by the PI. If a change in the study PI is being requested, a revised application face sheet reflecting the change in PI that is signed and dated by the incoming PI and Department Chair must be provided..

### **3. Revised Research Plan (UCSD IRB Protocol), if applicable**

Two copies of a revised Research Plan are required if revisions have been made to this document. One copy must include the entire revised Research Plan **with all the revisions highlighted** either by **BOLDING** OR printing the changes in **UNDERLINED** and one “clean” copy. This is only required if there are revisions to any of the items Research Plan.

### **4. Revised Consent/Assent Form(s)**

The revised consent/assent form(s) should be clearly labeled as such and the revisions **must be highlighted**, either by **BOLDING** or printing the changes in **UNDERLINED** so all changes can be easily distinguished. As all consent/assent forms are stamped by HRPP once they have been approved, a clean copy of the revised consent/assent **with space in the upper left hand corner** of the first page for the stamp must be submitted as well.

## **5. Addition of Minors**

The addition of minors to a protocol requires review by full Committee. This also requires the addition of a parental consent, adolescent assent (for children age 13-17 years) and child assent (for children aged 7-12 years). The cover letter should also clearly describe specific risks, risk/benefit, and risk-management procedures in regards to the addition of the minor participants. If this study involves VA resources, please contact the VA R&D Administration directly regarding special requirements.

## **C. FURTHER INFORMATION**

For further information or clarification regarding modification of a research plan, please call the HRPP Office at (858) 455-5050. All completed materials should be forwarded to the HRPP Office, mail code 0052 or uploaded to the existing project number on the HRPP website at <http://irb.ucsd.edu>.