SUU SOUTHERN UTAH UNIVERSITY

Institutional Review Board
351 W University Blvd.
Cedar City, UT, 84720
irb@suu.edu

Standard Operating Procedure 501 - Modification/Addendum of Approved IRB Proposal

Scope: The following procedure describes the process to modify or add to an approved human subject research protocol. Once a human subject research proposal has been approved by the Institutional Review Board, the proposal exists as a protocol that outlines the conduct of the study. The IRB must approve any changes or additions to an approved protocol through the modification/addendum process. Researchers may not deviate from an approved protocol unless such deviations are necessary to avoid unforeseen risk(s) to research participants.

Relevant Regulations: 45 CFR 46 (specifically §46.109 & §46.111); SUU IRB Policy 6.20

Related Procedures: SOP 306 - Initial Review of Research

1. Notification of Modification/Addendum Process

a. When submitting the IRB Proposal Form, researchers must sign an acknowledgement as part of the IRB Proposal Form requiring investigators to notify the IRB of proposed changes to an approved protocol.

b. The IRB also notifies researchers in writing of the need to notify/request modifications or addendums. This notification is typically sent via email to the principal investigator and faculty supervisor (when applicable) of all approved protocols.

2. Submitting and Evaluating a Request to Modify/Add to Approved IRB Protocol

a. All changes to an approved study require completion of the IRB Modification/Addendum Form.

b. Researchers must receive approval from the IRB before implementing changes and/or additions to their study. To receive approval, researchers must complete and submit the IRB Modification/Addendum Form. Changes to investigators (e.g., a change of faculty supervisor; addition of new investigators) also require completion and submission of the IRB Modification/Addendum Form.

c. Once the IRB Modification/Addendum Form is received by the IRB, the IRB member responsible for review files the form and any supporting documentation in the IRB proposal record.

d. The reviewer reads the submitted IRB Modification/Addendum Form. Notes include a listing and description of any proposed changes or additions, along with

researcher-identified risks resulting from the changes/additions. Any concerns with these items will be noted in the study's notes record.

e. Supporting documentation will also be reviewed by the reviewer. Supporting documents should include any form or measure from the original submission that has been changed. Any concerns with these items will be noted in the notes record.

f. In situations where essential information and/or documentation was omitted, or additional information and/or documentation is required to evaluate the request, the reviewer may request clarifications from the principal investigator. The written request will identify required information and/or documentation and the manner in which the information and/or documentation should be submitted to the IRB. Once clarifications are submitted, the reviewer may request revisions or approve the request.

3. Typical Outcomes of Modification/Addendum Request and Principal Investigator Notification of Decision

a. Request for Revisions: The reviewer may request revisions to the proposed modifications or addendums. These changes may be necessary for the request to be approved. The written request via email will identify required information and/or documentation and the manner in which the information and/or documentation should be submitted to the IRB. Once revisions are submitted, the reviewer may request additional revisions or approve the study.

b. Approval: Once the reviewer finds that there are no outstanding concerns or issues with the request, and that the proposed changes to the protocol do not result in more than minimal risk to research participants, the request will be approved. The reviewer will notify the principal investigator via email of the request's approval. This message will include the approved modifications and/or addendums that are now approved for use. Once this message is received by the principal investigator, the proposed changes may be implemented in the study.

c. Referral to Convened IRB: If a modification/addendum request is judged to increase the risk of a study beyond what the IRB deems minimal risk, the request may be referred to the convened IRB for review. The reviewer will notify the principal investigator of this decision in writing. If the request can be immediately scheduled for review, the reviewer will notify the principal investigator of the date, time, and location of the convened IRB review. If the request cannot immediately be scheduled, an IRB committee member will subsequently notify the principal investigator of the date, time, and location of the request's convened IRB review.