SUU SOUTHERN UTAH UNIVERSITY

Institutional Review Board
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Standard Operating Procedure 306 - Initial Review of Research

Scope: The following procedure describes the initial review process for human subject research proposals. All human subject research proposals are subject to review by the university's Institutional Review Board using the process outlined below. Note that additional procedures will be carried out for proposals that are referred for convened IRB review.

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

Related Procedures: SOP 302 - Researcher Ethics Training for SUU Affiliates

1. Processing Before Initial Review

a. Upon receipt, human subject research proposal submissions are reviewed by an IRB member and/or the IRB student worker for completeness to ensure necessary information for initial review has been provided.

b. Related materials are reviewed to ensure essential documents have been provided. Virtually all IRB proposals must include the IRB Proposal Form, an Informed Consent document, and CITI (researcher ethics training) certificates for all investigators. Other materials, such as survey questions or interview protocols, must be submitted as well.

c. Should the IRB proposal and related materials be deficient in any way, the IRB member and/or the IRB student worker completing processing will request the principal investigator correct and/or supply materials.

d. All IRB proposal submission materials are saved in a record organized by the principal investigator's name. Any modifications or addenda or other changes to the study become part of the IRB record file.

e. Proposals are added to the review queue for initial IRB review once all items are received and the proposal record has been created.

2. Initial Review of IRB Proposal

a. Once the proposal is complete and assigned to a reviewer, the IRB member responsible for the initial review will generate a note record for the proposal file recording essential data and correspondence concerning the proposal submission.

b. The reviewer will read the submitted IRB Proposal Form. Notes on the purpose/research questions, recruitment procedures, data collection methods, data

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analysis procedures, confidentiality/anonymity procedures, risks, benefits, and compensation, and other relevant questions, are recorded in the proposal record.

c. Supporting documentation will also be reviewed by the reviewer. Supporting documents could include the draft Informed Consent form and supportive documentation, assent forms, protocols for observations and interviews, survey questions, site letters/letters of permission, and others. Any concerns with these items will be noted in the proposal record.

d. In situations where essential information and/or documentation was omitted or unclear, or additional information and/or documentation is required to make a determination, the reviewer may request clarifications from the principal investigator by written request. Requests identify required information and/or documentation and the manner in which the information and/or documentation should be submitted to the IRB.

e. Upon review of a study's IRB Proposal Form and supporting documentation, the reviewer assigns an approval category for proposals meeting the requirements for exempt or expedited approval.

    i. When the proposal cannot be approved through an IRB exempt or expedited review category, it is referred to the IRB committee for a convened IRB review.

3. Typical Outcomes of Initial Review and Principal Investigator Notification

a. Referral to Convened IRB: The reviewer notifies the principal investigator of this outcome in writing. If the proposal 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 proposal cannot immediately be scheduled, an IRB committee member will subsequently notify the principal investigator of the date, time, and location of the proposal's convened IRB review.

b. Request for Revisions: The reviewer may request changes to the proposal and/or its supporting documentation necessary for the proposal to be approved through an exempt or expedited review category. 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 revisions are submitted, the reviewer may either request additional revisions, approve the study, or, in rare instances, refer the study to the convened IRB for review.

c. Conditional Approval: In situations in which the reviewer finds that the proposal qualifies for an exempt or expedited review category, but there is a procedural

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requirement still to be satisfied, the reviewer may issue a conditional approval. Notification of conditional approval, along with a signed conditional approval letter and IRB number, is sent via email. The approval letter will clearly identify the condition that must be met. All conditions must be satisfied and acknowledged by the IRB before recruitment and data collection activities can commence.

d. Full Approval: Once the reviewer finds that there are no outstanding concerns or issues with the proposal, and that the proposal qualifies for an IRB exempt or expedited review category, the proposal can be approved. Notification of full approval, along with an approval letter and IRB number, is sent via email. Once the principal investigator has received full approval, recruitment and data collection activities can commence.