

## **Standard Operating Procedure 205 - Approval and Revision of Standard Operating Procedures**

**Scope:** This procedure outlines the process for establishing and revising the Institutional Review Board's Standard Operating Procedures.

**Relevant Regulations:** [45 CFR 46](#) (specifically [§46.108](#)); SUU IRB Policy [6.20](#)

**Related Procedures:** [SOP 201 - IRB Meetings, Quorum, and Voting](#)

### **1. Background**

- a. Standard operating procedures outline the specific processes the university IRB uses across all of its basic functions, including the review of research.
- b. These procedures will be developed by the university IRB committee to address regulatory requirements of the federal government for written procedures.
- c. Additional procedures may be developed to communicate to the university community IRB processes.
- d. Standard operating procedures should be developed in accordance with the university Institutional Review Board policy (6.20).

### **2. Development of Standard Operating Procedures**

- a. The need for standard operating procedures may arise out of regulatory requirements, as well as from day-to-day business of the IRB and/or recommendations from IRB committee members.
- b. When the need for a standard operating procedure is identified, the IRB chairperson or the chairperson's designee will draft the text of a procedure for presentation to the IRB committee.
- c. Standard operating procedures will use a template to ensure uniform formatting.
- d. Efforts will be made to link the new standard operating procedure to relevant regulations and IRB procedures.

### **3. Deliberation and Approval of Standard Operating Procedures**

- a. All newly developed standard operating procedures will be scheduled as voting items when sufficiently developed to share with IRB members.

- b. New procedures will be presented to the IRB committee for discussion and possible revision.
- c. Revision of Draft Standard Operating Procedure
  - i. If IRB members request revisions to the draft standard operating procedure, efforts may be made within the IRB meeting to make minor changes to the initial draft.
  - ii. More substantive revisions will be made once the IRB meeting concludes. In situations where standard operating procedures require substantive revisions, the deliberation and approval process will restart at a subsequent IRB meeting.
- d. Approval of Standard Operating Procedure
  - i. Approval of standard operating procedures will follow the procedures for voting in an IRB meeting.
  - ii. To approve a new standard operating procedure, a majority of voting members present in the IRB meeting must vote for approval.

#### **4. Revision of Previously Approved Standard Operating Procedures**

- a. Previously approved standard operating procedures may be revised by the IRB committee.
- b. Any IRB member may propose the revision of an approved standard operating procedure, which may be done in an IRB meeting or through correspondence with the IRB chairperson.
- c. To initiate revision of a previously approved standard operating procedure, the IRB chairperson or the chairperson's designee will present the revision proposal to the IRB committee at an IRB meeting. This presentation will culminate in a vote to revise, which will follow procedures for voting in an IRB meeting.
- d. Revision of Standard Operating Procedure
  - i. To revise a standard operating procedure, a majority of voting members must approve the revision request. Previously approved standard operating procedures will not be revised without approval of the IRB committee.

- ii. If IRB members approve the request for revision, efforts may be made within the IRB meeting to make minor changes to the previously approved standard operating procedure. Minor revisions may be approved using the IRB's voting procedures.
- iii. More substantive revisions will be made once the IRB meeting concludes. In situations where previously standard operating procedures require substantive revisions, the deliberation and approval process will restart at a subsequent IRB meeting.