

Institutional Review Board  
Operating Paper

November 2020

## ***General Information***

The Vice Chancellor for Research of Southern Illinois University Carbondale, acting as the Institutional Official, gives the Southern Illinois University Carbondale Institutional Review Board (IRB) the authority to approve or disapprove of research proposals involving human subjects, and to require modifications of protocols in order gain approval, in an effort to protect the rights, dignity, and well-being of human research participants, and to assure compliance with all Federal and State regulations.

## ***Introduction***

This document, the Operating Paper of the Southern Illinois University Carbondale Institutional Review Board, describes and establishes the operations of the committee itself. Another set of documents describes the Policies and Procedures of the Southern Illinois University Carbondale IRB.

## ***Structure of the Board***

The responsibility for compliance with Federal, State, and Institutional regulations concerning activities involving human participants rests with the Vice Chancellor for Research of Southern Illinois University Carbondale, the Institutional Official. The Vice Chancellor for Research has delegated this authority to the IRB. The Board is comprised of a chair, a coordinator, and at least five diverse members with varying backgrounds, including scientific and non-scientific members as required by 45 CFR 46. .

## ***Job Descriptions***

### **Chair**

The Chair shall be responsible to the Vice Chancellor for Research for the general supervision of the activities of the IRB. The Chair provides leadership, and promotes an environment conducive to scholarly research and activities that protect human participants who take part in research. The duties of the Chair are as follows:

1. Preside at all meetings of the IRB.
2. Call special meetings of the IRB.
3. Conduct or direct reviews of all protocols submitted to the IRB proposing use of human participants in research.
4. Advise and counsel Principal Investigators.
5. Make decisions on emergency conditions as they relate to the IRB's protection of human participants in compliance with Federal regulations.
6. Keep the IRB informed of developing problems in the area of human research on any current or pending IRB protocol.
7. Perform functions delegated to an official of the IRB in accordance with institution, State and Federal regulations.

## **Coordinator**

1. Take and distribute minutes of IRB meetings that record the attendance and actions of the IRB, including deliberations and actions during meetings.
2. Develop and assists in the orientation and continuing education of faculty, staff and students with IRB procedures and policies.
3. Maintain accurate records of all protocols, including relevant discussions, correspondence, modifications and final actions.
4. Maintain and distribute forms and manuals including those posted on the university website.
5. The IRB Coordinator is an administrative position, not a voting member, and as such, does not count toward quorum.

## **Members**

The university will provide orientation and training opportunities at the local and/or national levels in IRB matters. The duties of the IRB members are as follows:

1. Attend all meetings.
2. Review materials before each meeting.
3. Review all introductory and regulatory documents relating to the use and protection of human participants.
4. Disqualify themselves from participating in voting on any activity in which he/she has a conflict of interest.
5. Contact the IRB Chair if unable to attend a meeting.
6. Willingly participate in subcommittee activities as time and interests allow.
7. Protect the confidentiality of the records and information provided to him/her.

## **Appointments**

1. Members of the IRB are appointed by the Vice Chancellor for Research guided by the recommendation of the IRB Chair and the Director of the Office of Research Compliance. Membership will comply with the requirements of 45 CFR 46.107.

2. All members serve a term of one year, which may be renewed from year to year. The Vice Chancellor for Research will select members from among various disciplines involved in research with human subjects, including faculty and staff.

3. A Chair shall be appointed by the Vice Chancellor for Research from among those IRB members who have served on the IRB for at least one year.

4. At least one, and preferably two, community members are appointed by the Vice Chancellor for Research to serve as voting members of the board. These members may not be affiliated with the Institution and are not part of the immediate family of someone who is.

5. One VCR appointee, the Director of Research Compliance, will serve as a voting member of the committee and will represent any concerns of the University with regards to the conductance human research.

## ***General Principles***

The IRB accepts as basic principles the ideology expressed in the Nuremberg Code (1947), the Declaration of Helsinki (revised 1975), and the Belmont Report (1979). The IRB operates according to the regulation Title 45 CFR Part 46, Protection of Human Subjects, administered by the Office of Human Research Protections.

## ***Meetings***

### **Meeting Schedule**

IRB meetings are scheduled monthly or as needed for protocols requiring full board review. Otherwise, the committee meets once at the beginning of the academic year, to review committee policies and training credentials of the committee members, and at the end of the academic year, to summarize activity for the year and plans going forward.

Board meeting dates and times will be posted on the IRB website at the beginning of the academic year, and updated as needed.

### **Attendance at IRB Meetings**

Because each member of the IRB serves a particular role, attendance at meetings is imperative. A member who misses three consecutive meetings without University approved leave of absence, or who misses half or more of the meetings in a year, forfeits his/her membership on the IRB.

### **Meeting Quorum**

An IRB meeting can conduct business only when a quorum exists. A quorum is defined as a majority of voting members.

### **Principal Investigator's Participation during IRB Meetings**

A Principal Investigator or Co-Investigator may request to attend or be invited by the IRB to attend an IRB meeting to provide information. The Principal Investigator or Co-Investigators will be asked to leave the meeting during the discussion and voting phase of the review and approval process. Such action will be noted in the minutes of the IRB meeting.

## ***Orientation and Training of New Members***

Each new member of the IRB will be provided orientation and training through the following procedures:

- 1) Completion of assigned readings and signature of member stating their familiarity with the Southern Illinois University Carbondale IRB:
  - a) *Standard Operating Procedures Manual*
  - b) *Principal Investigator's Manual*
2. Completion of Collaborative Institutional Training Initiative (CITI) online training found at: <https://about.citiprogram.org/en/homepage/>

## ***Continuous Improvement Plan***

In order to best provide protection of human participants and maintain compliance with all regulatory guidelines, the IRB will:

1. Update the IRB *Standard Operating Procedures Manual* annually, or as needed; distribute dated revisions to all committee members; and post the revised manual on the IRB website.
2. Annually, the Office of Research Compliance will select at least two protocols from the active files Category II and two from Category III to audit. The IRB Chair will direct this review. A written report of the summary of this audit will be presented to the IRB members, with recommendations listed, if any. The procedure of audit is described in the *Standard Operating Procedures Manual*.
4. Provide continuing education to IRB members and Principal Investigators via written and oral communications.