

## SOP: IRB MEMBERSHIP

### 1. PURPOSE

To outline the composition and responsibilities of the Governors State University (GSU or University) Institutional Review Board (IRB) and establish the processes for selecting, appointing, and evaluating the members of the IRB.

### 2. COMPOSITION, QUALIFICATIONS, DIVERSITY

#### 2.1. IRB Members

- 2.1.1. The IRB is delegated by the Provost and convened by that office.
- 2.1.2. The IRB shall consist of at least seven members, who are individuals with various experiences and skills in evaluating human research and its institutional, legal, scientific, and social implications.
- 2.1.3. There shall be at least five faculty members appointed by the Faculty Senate, one shall be from each of the four colleges and one shall be from the Library or Student Affairs.
- 2.1.4. The IRB shall have at least one alternate member appointed by the Provost who may vote in place of an absent voting member.
- 2.1.5. The members of the IRB shall be appointed for three-year renewable terms. The Chair of the IRB will be elected by IRB members every three years. Consecutive terms are allowable.
- 2.1.6. The IRB shall include at least one member whose primary concerns are in a scientific discipline (scientist), and at least one member whose primary concerns are in nonscientific areas (nonscientist). These shall be among the five recommended by the Faculty Senate.
- 2.1.7. Each IRB shall include at least one member who is not affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University. The Office of the Provost shall appoint this person upon recommendation from the IRB.
- 2.1.8. IRB membership shall be diversified with regard to race, gender, and cultural backgrounds. To ensure this diversity, the Office of the Provost shall provide additional members. The Office of the Provost shall appoint additional persons with expertise to review specific proposals as recommended by the IRB.
- 2.1.9. All persons as IRB members or researchers must be properly qualified (through education and experiences) and trained to conduct their duties. GSU requires that each member of the IRB have on file a current resume or curriculum vitae attesting to their personal education and experiences.

- 2.1.10. Each member of the IRB is required to maintain an active IRB Board Member Certification through the CITI Training Website. New appointees must have initial training completed by the first full-board meeting of the academic year.

### **3. SELECTION, APPOINTMENT, LENGTH OF SERVICE**

#### **3.1. IRB Members**

- 3.1.1. Candidates for IRB membership may be nominated by the IRB chair, the deans, IRB staff, faculty, or academic departments. They may also be self-nominated. Unaffiliated members are identified by interest and relevance, and are recommended for appointment by members of the IRB, IRB staff, deans, faculty, and academic departments.
- 3.1.2. The nominations for IRB membership are reviewed by the Director of the Office of Sponsored Programs and Research. Following that review, the Director of the Office of Sponsored Programs and Research will forward a list of candidates for IRB membership to the Provost for consideration. For the avoidance of doubt, the formal appointment of IRB members, except those appointed by the Faculty Senate, is made by the Provost.
- 3.1.3. The IRB member nomination packet must include a copy of the nominee's resume or curriculum vitae. An appointment is considered effective at the time and date when the appointment letter is signed by the Provost.
- 3.1.4. IRB members are appointed to membership slots of 3-year terms. Appointments are renewable by mutual agreement. Appointments end if they are not renewed after the 3-year appointment. Non-renewal does not preclude from future services on the IRB. Members may end their appointment before completion of the 3-year term by notifying in writing the IRB chair and the Director of the Office of Sponsored Programs and Research. The Director will notify the Provost.

#### **3.2. IRB Chair**

- 3.2.1. The IRB chair must be a member of the University faculty and have previously served as a member of the GSU IRB.
- 3.2.2. The IRB chair is nominated by and voted for by IRB members. The Director of the Office of Sponsored Programs and Research will review and forward the nominee to the Provost for consideration.
- 3.2.3. The Director of the Office of Sponsored Programs and Research may nominate the IRB chair if none was nominated by the IRB.
- 3.2.4. For the avoidance of doubt, the formal appointment of the IRB chair is made by the Provost. An appointment is considered effective at the time and date when the appointment letter is signed by the Provost. The IRB chair is appointed to membership slots of 3-year terms. Appointments are renewable by mutual agreement. Appointments end if they are not renewed after the 3-year appointment

#### **3.3. IRB Co-Chair**

- 3.3.1. The procedure for nominating and appointing the IRB co-chair is the same as the procedure described in 2.2.

## **4. RESPONSIBILITIES**

### **4.1. IRB Members**

In summary form, the duties and responsibilities of the IRB members are as follows:

- 4.1.1. Participate in IRB convened meetings. Federal regulations mandate at least two meetings per year, though they can be scheduled as frequently as once per month during the contract year.
- 4.1.2. Understand the principles of the Belmont Report and the federal regulations related to the protection of human research subjects.
- 4.1.3. Complete the required CITI training for IRB members every three years before voting on any research protocols.
- 4.1.4. Review and investigate concerns, and make protocol recommendations to the Institutional Official (Provost) and IRB Chair, and Director of the Office of Sponsored Programs and Research regarding any aspect of the institution's human participant's research program.
- 4.1.5. Review and approve exempt and expedited research protocols as well as protocols submitted for full board review to assure compliance with the *Protection of Human Subjects (45CFR46)* and order the suspension of any activity not in compliance.
- 4.1.6. Complete at least 8 hours of professional development designated for IRB members over the appointment period.
- 4.1.7. Recuse himself/herself from the review of and voting on any research protocol or issue in which he/she has a real or perceived conflict of interest.
- 4.1.8. Agree to the requirements of the IRB Member Confidentiality Agreement.

### **4.2. IRB Chair and Co-Chair**

- 4.2.1. Share the responsibilities of IRB members.
- 4.2.2. Determine the type of IRB review required (*exempt, expedited, full board*) based on official regulatory criteria. The chair may delegate this task to qualified IRB staff and IRB members.
- 4.2.3. Review *expedited* studies. The chair may delegate this task to another IRB member.
- 4.2.4. Convene and chair the meetings of the IRB.
- 4.2.5. Review amendments to expedited studies, except for changes in personnel, performance sites, and funding that do not affect the study's expedited status. The Chair may delegate this task to another IRB member.
- 4.2.6. Review reports of unanticipated problems.
- 4.2.7. Participate in investigations of non-compliance.
- 4.2.8. Make recommendations to the IRB about suspension or termination of research studies based on the results of investigation of noncompliance.
- 4.2.9. Serve as a resource for investigators and IRB members regarding issues and policies related to human subjects protection.
- 4.2.10. May recommend an IRB member who is not adequately fulfilling the responsibilities to the Provost for additional training or the termination of appointment.

### **4.3. Director of the Office of Sponsored Programs and Research**

- 4.3.1. Review and forward a list of candidates for IRB membership to the Provost for

- consideration of appointment.
- 4.3.2. Review and forward the nominee for the IRB chair to the Provost for consideration of appointment.
  - 4.3.3. Notify the Provost of termination of IRB member, IRB Chair, and Co-Chair appointments.
  - 4.3.4. May nominate the IRB chair if none was nominated by the IRB.
  - 4.3.5. May recommend an IRB member, IRB Chair, and Co-Chair who is not adequately fulfilling the responsibilities to the Provost for additional training or the termination of appointment.

## **5. IRB MEMBER CONFLICT OF INTEREST**

- 5.1. IRB member conflicts of interest are defined and handled as described in the SOP “IRB Member Conflict of Interest.”

## **REGULATIONS**

45 CRR 46.102  
45 CFR 46.107  
21 CFR 56.107

## **AUTHOR REFERENCE**

Northeastern Illinois University, IRB SOP “IRB Membership”  
Governors State University Policy 53

## **CONTACT INFORMATION**

Office of the Sponsored Programs and Research  
Governors State University  
1 University Parkway  
University Park, IL 60484  
708.235.2846

## **DISCLAIMER**

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as the Institutional Official calls for review. Requests for exception to any portion of this SOP must be presented in writing to the Institutional Official.

