

SOP: 202
MANAGEMENT OF IRB

1. POLICY

The HRPP Director shall manage the membership of the IRB(s) and oversight of member appointments, IRB membership rosters, IRB related activities, IRB communications, and other IRB administrative details.

The Senior Vice President and Provost, in consultation with the HRPP Director, shall appoint IRB Chairs, IRB Vice Chairs, and IRB members. Members shall be solicited from the University of Oklahoma and surrounding communities by the HRPP Director.

Specific Policies

1.1 Duty to the University of Oklahoma

The IRBs are appointed as Institutional Committees. As such, IRB members serve the University as a whole, rather than a particular department. Members shall not allow their own interests or that of their departments to supersede their duty to protect the rights and welfare of research participants.

1.2 Term of Duty

IRB members, including IRB Chairs and Vice Chairs, shall commit to a four-year renewable term to fulfill certain duties. These duties shall be described prior to appointment, and each IRB member is expected to fully understand the duties of IRB members prior to accepting such an appointment.

1.3 Appointments

The Senior Vice President and Provost of each campus has the authority to appoint IRB Chairs, IRB Vice Chairs, and IRB Members for his respective campus. The HRPP Director shall solicit the University and surrounding communities for selection of potential IRB Chairs, IRB Vice Chairs, and IRB members. (See SOP 201, Composition of IRB, for membership selection criteria.) In consultation with the HRPP Director, the Senior Vice President and Provost of each campus shall appoint IRB Chairs, IRB Vice Chairs, and IRB members to serve on the IRB.

1.3.1 Appointments of IRB Chair and IRB Vice Chair

IRB Chairs shall be appointed by the Senior Vice President and Provost of each campus. The IRB Chair shall have served as a member of the IRB and understand all functions, policies, and procedures of the IRB.

IRB Vice-Chairs shall be appointed by the Senior Vice President and Provost of each campus. The IRB Vice-Chair shall have served as a member of the IRB and understand all functions, policies, and procedures of the IRB.

1.3.2 Appointment of VA Members

VA members appointed to the IRB shall be approved by the VA Medical Center Director at least every three years.

1.3.3 Appointment of Unaffiliated Members

On selection of unaffiliated IRB members for appointment to the IRB, the HRPP Director shall determine whether any of their immediate family members are affiliated with the University. If so, they are changed to affiliated members.

The HRPP Director polls each unaffiliated IRB member annually to determine whether any of their immediate family members are affiliated with the University. If so, they are changed to an affiliated member.

IRB members who are affiliated with the VA or whose immediate family members are affiliated with the VA shall be considered affiliated with the University.

1.3.4 Appointment of Alternate Members

The HRPP Director shall solicit current IRB members, the University, and surrounding communities for selection of potential alternate members. In consultation with the HRPP Director, the Senior Vice President and Provost of each campus shall appoint alternate members to serve on the IRB.

1.4 IRB Membership

1.4.1 Roster

The IRB membership rosters shall be maintained by the HRPP Director or designee, who shall report to the OHRP when the IRB membership is revised.

Rosters of IRB members shall identify the members by name, earned degrees, representative capacity, scientific/nonscientific status, affiliation status (whether the member or an immediate family member of the member is affiliated with the University), employment or other relationship between each IRB member and the University (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant), and indications of experience sufficient to describe each member's chief anticipated contribution to the IRB deliberations. The rosters shall be maintained in the IRB office.

Alternate members shall be included on the IRB membership rosters. In addition to the above information, the rosters shall indicate the member for whom the alternate substitutes.

Current and obsolete membership rosters shall remain in the IRB Office.

1.4.2 Curricula Vitae or Resumes

Curricula Vitae or resumes shall be maintained with the IRB office for each current member of the IRB.

1.4.3 Periodic Review of IRB Membership

The HRPP Director or designee shall conduct a periodic review of the IRB membership and the composition of the IRB in order to maintain a diverse spectrum of qualified individuals. The HRPP Director or designee shall conduct the periodic review at least annually and adjust the IRB membership and composition of the IRB to meet the regulatory and organizational requirements of the IRB.

1.4.4 Periodic Review of IRB Members

The performance of the IRB Chairs, Vice Chairs, and IRB Members shall be evaluated on an annual basis. The periodic evaluation is conducted to assess performance, taking into consideration completion of education requirements, attendance, preparedness, knowledge and abilities in applying the ethical principles and regulations governing human research, and knowledge of IRB policies and procedures.

1.4.5 Resignations and Removals

An IRB member may resign but shall first give a one-month notice to the HRPP Director. An IRB member may be removed with or without cause by the Senior Vice President and Provost after consultation with the HRPP Director and Director of Compliance and with input from the IRB Chair and Vice Chair, if applicable.

1.5 Compensation

Norman Campus: Service on the IRB by the University faculty, staff, or students shall be considered a component of the individual's job responsibilities as established by their supervisors. IRB members who are not affiliated with the University shall receive reimbursement for parking and miscellaneous expenses upon request.

HSC Campus: Service on the IRB by the University faculty, staff, or students shall be considered a component of the individual's job responsibilities as established by their supervisors. IRB members who are not affiliated with the University shall receive reimbursement for travel expenses for each meeting attended.

1.6 Coverage

IRB members and alternate IRB members acting within the course and scope of their duties are self-insured according to the Oklahoma Governmental Tort Claims Act.

1.7 Periodic Evaluation of IRBs

The HRPP Director, in consultation with the Director of Compliance, shall evaluate each IRB annually to assess whether an additional IRB should be created to handle an increase in volume.

2. SCOPE

These policies and procedures apply to management of the IRB.

3. RESPONSIBILITY

The Senior Vice President and Provosts of each campus are responsible for ensuring the IRB has adequate resources to identify and recruit qualified potential members.

The HRPP Director is responsible for management of the IRB and IRB membership.

The HRPP Director is responsible for selection and recruitment of new IRB members.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.107

38 CFR 16.107

45 CFR 46.107

5. REFERENCES TO OTHER APPLICABLE SOPS

None

6. ATTACHMENTS

- 201-A, IRB Roster Template
- 201-B, HSC Campus IRB Membership Rosters
- 201-C, Norman Campus IRB Membership Rosters
- 202-A, HSC New Member Information Packet Checklist
- 202-A-1, Norman Campus New Member Information Packet Checklist
- 202-B, HSC Campus New Member Welcome Letter
- 202-B-1, Norman Campus New Member Welcome Letter
- 202-C, HSC Campus New Member Appointment Letter
- 202-C-1, Norman Campus New Member Appointment Letter
- 202-D, IRB Member Confidentiality Agreement
- 202-E, IRB Guest Confidentiality Agreement
- 202-F, Letter from Joseph Harroz, Jr., Vice President and General Counsel regarding Indemnification and Personal Liability
- 202-G, IRB Board Member Evaluation Form
- 202-G-A, IRB Chair / Vice Chair Evaluation Form

7. PROCESS OVERVIEW

7.1 Terms

IRB members, including the IRB Chairs and Vice Chairs, serve on the IRB for four-year renewable terms. Shorter terms and reappointments are made by mutual agreement between the HRPP Director and the IRB Chair, IRB Vice Chair, or IRB member.

7.2 Appointments

- 7.2.1 The HRPP Director discusses with IRB candidates the general responsibilities and time commitment involved with IRB membership and confirms the candidates' interest in serving on the IRB.
- 7.2.2 The HRPP Director requests the candidate's Curriculum vitae (CV) or resume and presents it to the IRB Chair for discussion and review. The HRPP Director provides a schedule of IRB meeting dates to the candidate for consideration, and the HRPP Director invites the candidate to attend and observe an IRB meeting. The IRB Administrator prepares an IRB Guest Confidentiality Agreement for the candidate to sign at the IRB meeting.
- 7.2.3 The HRPP Director notifies the IRB Education Coordinator of the candidate. The IRB Education Coordinator schedules a New Member Orientation with the candidate and prepares a New Member Information Packet and Checklist.
- 7.2.4 After the candidate attends an IRB meeting as a guest, the HRPP Director and IRB Education Coordinator conduct the New Member Orientation.

- 7.2.5 If the candidate agrees to serve and the IRB Chair concurs with the recommendation of the HRPP Director, the Senior Vice President and Provost will send an appointment letter to the IRB Member. A copy of the appointment letter and CV or resume of the of the IRB member are maintained on file in the IRB.
- 7.2.6 The HRPP Director or designee notifies the new member of the next scheduled IRB meeting, sends a packet of agenda materials, and informs the member that he/she will not be assigned specific protocols for review until his/her second meeting.

7.3 Rosters

The HRPP Director or designee updates the IRB roster on the IRB website and submits an electronic roster update to the OHRP.

7.4 Resignations

When IRB members resign from the IRB prior to the conclusion of their term, the HRPP fills vacancies as soon as possible via the appointment process outlined in Section 1.3 above.

7.5 Compensation

- 7.5.1 On the HSC Campus, the IRB Administrative staff prepares an Agreement for non-affiliated IRB members for reimbursement of travel expenses. The IRB Administrative staff prepares an invoice for each meeting attended by the non-affiliated member. Attendance is monitored by the meeting sign-in-sheet.
- 7.5.2 On the Norman Campus, the HRPP Director prepares reimbursements for non-affiliated members upon request.

7.6 Periodic Evaluation of IRBs

The periodic evaluation of IRBs conducted by the HRPP Director takes into consideration the volume of items for review, complexity and types of human research reviewed, time IRB members devote to the activity, quality of the review, and whether the entire review process is accomplished in a timely manner. This analysis is used to assess whether an additional IRB should be created to handle an increase in volume. The results of the evaluation are presented to the IRB Executive Committee by the HRPP Director for consideration.

7.7 Periodic Review of IRB Members

IRB Chairs and Vice Chairs shall evaluate the IRB members from their respective boards. IRB members shall evaluate the IRB Chair and Vice Chair from their respective Board. The evaluations will be conducted using the IRB Chair/Vice Chair Evaluation Form and the IRB Board Member Evaluation Form.

The HRPP Director or designee shall review the evaluations and provide a summary of results to the individual IRB Chair, Vice Chair, and IRB Member evaluated. Based upon the results of the evaluations, the HRPP Director may take no additional actions or consult with the Director of Compliance concerning the performance of an IRB Chair or Vice Chair; consult with the IRB Chair or Vice Chair concerning the performance of an IRB member; meet with the IRB Chair, Vice Chair, or IRB member concerning

responsibilities and expectations; provide additional training to improve performance; or remove the IRB Chair, Vice Chair or IRB member from the IRB.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012