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 or designee, in consultation with the HRPP Director, shall appoint IRB Chairs, Vice-Chairs, and IRB members. The HRPP Director shall solicit members from the University of Oklahoma and surrounding communities.

Specific Policies

1.1 Duty to the University of Oklahoma

The IRBs are appointed as University committees. As such, IRB members serve the University as a whole, rather than a particular department. Members shall not allow their own interests or those of their departments to supersede their duty to protect the rights and welfare of human 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 or designee of each campus has the authority to appoint IRB Chairs, Vice-Chairs, and IRB Members for the respective campus. The HRPP Director shall solicit the University and surrounding communities for selection of potential IRB Chairs, 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 or designee of each campus shall appoint IRB Chairs, Vice-Chairs, and IRB members to serve on the IRB.

1.3.1 Appointments of IRB Chair and Vice-Chair

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

The Senior Vice President and Provost or designee of each campus shall appoint IRB Vice-Chairs. 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

The VA Medical Center Director shall approve VA members appointed to the IRB 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 his or her immediate family members are affiliated with the University. If so, that member is 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 or designee 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 by 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.

The IRB Office shall maintain current and obsolete membership rosters.

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 University 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 or designee, after consultation with the NC HRPP Director and Director of Compliance for the NC, and the HSC HRPP Director and HSC VPR for HSC, and with input from the IRB Chair and Vice-Chair, if applicable.

1.5 Compensation
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.

1.6 Coverage
IRB members and alternate IRB members acting within the course and scope of their duties are covered by the Oklahoma Governmental Tort Claims Act.

1.7 Periodic Evaluation of IRBs
The NC HRPP Director, in consultation with the Director of Compliance, and the HSC HRPP Director in consultation with the HSC VPR, shall evaluate each IRB annually to assess whether an additional IRB should be created to handle an increase in volume and to ensure compliance with policies and other applicable requirements and regulations.

2. SCOPE
This SOP applies to management of the IRB.

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

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

3.3 The HRPP Director is responsible for recommendation and recruitment of new IRB members and the Senior Vice President and Provost makes the final decision.

4. APPLICABLE REGULATIONS AND GUIDELINES
21 CFR 56.107
38 CFR 16.107
5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 201: Composition of IRB

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 Anil Gollahalli 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, 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 each 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.

7.2.3 The HRPP Director notifies the HRPP Education Coordinator of the candidate. The HRPP Education Coordinator schedules a New Member Orientation with the candidate and prepares a New Member Information Packet and Checklist. An
IRB Guest Confidentiality Agreement is prepared for the candidate to sign prior to the IRB meeting.

7.2.4 The HRPP Director or designee and HRPP 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 or designee will send an appointment letter to the IRB Member. Copies of the appointment letter and curriculum vitae or resume of the IRB member are maintained in the IRB office.

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 new member that he/she will not be assigned specific research 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 Reimbursement

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 travel expense 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 and to ensure compliance with policies and other applicable requirements and regulations. The HRPP Director presents the results of the evaluation to the IRB Executive Committee 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 elect to take no additional actions or to consult with the Director of Compliance for the NC or the HSC VPR for HSC 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: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016