

## **SOP: 201 COMPOSITION OF IRB**

### **1. POLICY**

Each IRB shall be composed of members who are able to ascertain the acceptability of proposed research in terms of University commitments and regulations, applicable law, and standards of professional conduct and practice. Each IRB shall also be composed of members able to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

Each IRB shall consist of at least five regular, voting members. Qualified persons from multiple professions shall be considered for membership. IRB membership shall not consist entirely of members of one profession.

The University shall make every effort to have a diverse membership appointed to the IRB, within the scope of available expertise needed to conduct IRB functions.

#### **Specific Policies**

##### **1.1 Membership Selection Criteria**

- 1.1.1 The members of the IRB shall be sufficiently qualified, through experience and expertise, to review research proposals in terms of regulations, applicable law, standards of professional conduct and practice, and institutional commitments. The IRB shall include persons knowledgeable in these areas.

The membership shall be diverse, so selection shall include nondiscriminatory consideration of race, gender, cultural backgrounds, clinical experience, healthcare experience, and sensitivity to such issues as community attitudes to assess the research submitted for review.

There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be one member who has no affiliation with this institution, either self or family member. For research involving an FDA-regulated article, at least one member who is a licensed physician must be included in the quorum.

- 1.1.2 VA Research:

The HSC IRB has been designated as the IRB of record for the Oklahoma City Veterans Affairs Medical Center and the Muskogee Veterans Affairs Medical Center. The HSC IRB membership for IRBs 1, 2, 3, 4, and 5 shall include two or more VA employees as voting members.

The Norman Campus IRB shall not review VA research.

The VA members shall serve as full members of the IRB and review both VA and non-VA research matters presented to the IRB. At least one of the VA members of the IRB must have scientific expertise. At least one of the VA members of the IRB must be present during the review of VA research.

VA Research and Development administration officials including, but not limited to, the Associated Chief of Staff for Research and Development and the Administrative Officer for Research and Development, are prohibited from serving as voting members of the IRB.

## 1.2 Composition of the IRB

IRB members: The backgrounds of the IRB members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB. Regular members shall include:

- A. Nonaffiliated member(s): The nonaffiliated member(s), who can be either scientific or nonscientific reviewers, shall be knowledgeable about the local community and be willing to discuss issues and research from that perspective. The HRPP Director shall give consideration to recruiting individuals who speak for the communities from which the University will draw its research participants. The nonaffiliated member(s) shall not be vulnerable to intimidation by the professionals on the IRB, and their services shall be fully utilized by the IRB.
- B. Scientific members: Most IRBs include physicians and Ph.D. level physical, social, or biological scientists. Such members satisfy the requirement for at least one scientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as provided by 45 CFR 46.107(f) and 21 CFR 56.107(f). However, when research involving an FDA-regulated article is reviewed, at least one member who is a licensed physician must be included in the quorum; therefore, at least one (1) member of each IRB shall be a physician licensed in the State of Oklahoma.
- C. Nonscientific member: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, at least one nonscientific member whose education, work, or interests is not solely in medical or scientific areas shall be on each IRB.
- D. Representatives of special groups of subjects: When certain types of research are reviewed, the IRB may require members or consultants who are knowledgeable about the concerns of certain groups. For example, if an IRB reviews research involving prisoners, a member who can represent this group, either an ex-prisoner or an individual with specialized knowledge about this group, must be included on the IRB.
- E. IRB Chairs: The individual IRB Chairs shall be highly respected individuals, from within or outside the University, fully capable of managing the IRB and the matters brought before it with fairness and impartiality.
- F. Special Consultants: The IRB Chair may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. The IRB Chair invites consultants to either attend the IRB meeting or provide a written report so that IRB members are made aware of and provided with information concerning the consultants' review. These individuals shall not vote with the regular and alternate members of the IRB, and their presence or absence shall not be used in establishing a quorum for an IRB meeting. Consultants shall be used at the IRB Chair's discretion or if requested by the convened IRB. All consultants shall be asked to sign an IRB Guest Confidentiality Agreement. The consultant may be asked to participate via a teleconference or attend the IRB meeting to lend his/her expertise to the discussions. Consultants shall not vote.

Documentation of key information provided by consultants shall be summarized in the IRB minutes and, if available, the Consultant's written report shall be filed in the IRB file.

- G. Alternate members: The IRB roster shall identify the primary member(s) for whom each alternate member may substitute. To ensure an appropriate quorum is maintained, the alternate's qualifications shall be comparable to the primary member to be replaced. The IRB minutes shall document when an alternate member replaces a primary member. When an alternate substitutes for a primary member, the alternate member shall have received and reviewed the same material that the primary member received or would have received. If both the primary and alternate members attend the meeting, only one may vote.

### **1.3 Conflict of Interest**

See SOP 104B, Conflicts of Interest for IRB Members, for information regarding IRB member's participation in the IRB's review of any project in which the IRB member has a conflicting interest.

## **2. SCOPE**

These policies and procedures apply to the membership of the IRB.

## **3. RESPONSIBILITY**

The HRPP Directors and IRB Chairs are responsible for the composition of the IRB.

## **4. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.107

21 CFR 56.107

FDA Information Sheets, Guidance for IRBs and Clinical Investigators, Frequently Asked Questions, 1998 Update OHRP Guidance Document, IRB Guidebook

## **5. REFERENCES TO OTHER APPLICABLE SOPS**

SOP 104B, Conflict of Interest for Board Members.

## **6. ATTACHMENTS**

201-A IRB Roster Template

201-B HSC Campus IRB Membership Rosters

201-C Norman Campus IRB Membership Rosters

201-D HSC Campus IRB Meeting Schedules

201-E Norman Campus IRB Meeting Schedules

## 7. PROCESS OVERVIEW

- 7.1 The HRPP Director identifies IRB members with varied backgrounds and experiences to provide optimal review of research giving consideration to gender, race, ethnicity, community affiliation, and professional experience. The HRPP Director consults with IRB Chairs as needed for selection of IRB members.
- 7.2 The HRPP Director consults with the VA Medical Center Director as needed for selection of IRB member representation from the VA.
- 7.3 The HRPP Director considers a number of factors in developing IRB membership. These factors include the specialty of the IRB (i.e., Oncology, Pediatrics, and Behavioral), number of members required to fill the IRB and allow for a thorough review of all research, and consideration of the requirements of an IRB as described above in section 1.2.

**APPROVED BY:** \_\_\_\_\_ **DATE:** 09/01/2009

**NEXT ESTABLISHED REVIEW DATE:** May 2012