

<b>Oklahoma State University Institutional Review Board Standard Operating Procedures</b>		
<b>Composition of the IRB</b>	SOP #	OR 201
	Effective Date	1/1/2012
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## **1. POLICY**

The Institutional Review Board (IRB) at Oklahoma State University (OSU) will consist of a minimum of five primary voting members sufficiently qualified through experience to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The University will make every effort to have a diverse IRB through consideration of profession/discipline, race, ethnicity, cultural background, and gender.

### **Specific Procedures**

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

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

1.1.2 IRB membership will be diverse. Thus, membership recruitment will consider race, ethnicity, gender, cultural background, research experience, and academic discipline/profession, as well as sensitivity to community attitudes and issues. IRB membership will not consist entirely of men or entirely of women, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession. Every attempt will be made to recruit non-affiliated members, such as clergy, attorneys, and licensed physicians from the local community.

1.1.3 There will be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

1.1.4 There will be at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with OSU.

#### **1.2 Composition of the Board**

##### **1.2.1 Primary members**

The backgrounds of the primary members of the IRB will be varied in order to promote complete and adequate review of the types of research activities commonly conducted by agents of the University. Primary members must include:

- A. Scientific members: The IRB will include at least one member whose primary concerns are in scientific areas. A physical or biological scientist or physician who is, or has been, actively engaged in research or practice in the physical, educational, social, behavioral, or biological sciences and disciplines satisfies this membership requirement.

- B. Nonscientific member: The IRB will include at least one member whose primary concerns are in nonscientific areas. Nonscientific members are individuals whose background, training, and occupation predisposes them to view research from a vantage point that is external to any biomedical or behavioral scientific discipline. These members have little or no scientific or medical training and do not currently hold positions that involve scientific research or clinical practice (e.g., administrative positions).
- C. Nonaffiliated member(s): The IRB will include at least one member who is not otherwise affiliated with OSU and who is not part of the immediate family of a person affiliated with OSU. As a result, an individual could not be considered for IRB membership as a nonaffiliated member if he/she is a retiree of the university or has a spouse, parent, child, or sibling currently affiliated with OSU. However, a graduate of OSU from at least one year prior or someone whose family member attended OSU in the past could be considered. The nonaffiliated member(s), who can also serve as either a scientific or nonscientific member, must be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration will be given to recruiting individuals who speak for the communities from which OSU Investigators draw research subjects. The nonaffiliated member(s) will not be vulnerable to intimidation by other IRB members, and their services will be fully utilized by the IRB.
- D. Vulnerable Populations: When the IRB reviews research involving a vulnerable population, including categories of subjects vulnerable to coercion or undue influence, the review process will include one or more individuals who are knowledgeable about and experienced in working with these subjects. If the IRB regularly reviews such research (e.g., research involving prisoners), consideration will be given to including one or more individuals knowledgeable about and experienced in working with these subjects on the IRB.
- E. Special Consultants: The IRB chair, or designee, 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. These individuals will not vote with the primary and alternate members of the IRB and their presence or absence will not be used in establishing a quorum for a convened IRB meeting. Consultants will be used at the chair's or designee's discretion, or when requested by a board member.
- F. Chair/Vice chair: The individuals appointed as the IRB chair and vice chair will be highly respected individuals, who are members of the OSU faculty. These individuals will be capable of chairing convened meetings of the IRB and facilitating matters brought before it with fairness and impartiality.
- G. The IRB manager will be a primary voting member of the IRB, which will allow for effective management of the day-to-day activities of the IRB and the efficient review of certain IRB applications. The IRB coordinator will be an alternate member of the IRB. The IRB manager and coordinator will make determinations about which human subjects research proposals submitted to the IRB qualify for exempt status.

### 1.2.2 Alternate members

Alternate members are qualified voting members of the IRB who serve as designated alternates to primary members. Alternate members possess similar qualifications to those of primary members but they are not expected to attend every IRB meeting. An alternate member may be designated for more than one primary member. The chair, or designee, may ask an alternate member to attend an IRB meeting in order to draw on his/her expertise in an area that may be

relevant to that meeting's deliberations and/or to establish a quorum. An alternate member's presence at an IRB meeting in the place of an absent primary member may be used in establishing a quorum. Alternate members are encouraged to attend meetings and to participate in discussion as long as they reviewed all applicable meeting materials in advance. However, they will only vote when they are officially substituting for their designated primary member. An alternate member's absence is not used in establishing a quorum for a meeting. Alternate members may be asked to review applications qualifying for expedited review and to serve as primary reviewers for research proposals slated for review at convened meetings of the IRB.

### **1.3 IRB Roster/OHRP IRB Registration**

1.3.1 The IRB administrative staff will maintain an IRB Roster. IRB members and alternates will be queried occasionally regarding their areas of expertise. The IRB Roster, as presented in the IRB registration, will contain the following information:

- Name of IRB Member
- Earned Degrees
- Scientific Status (scientist/nonscientist)
- Expertise
- Representative Capacity (e.g., children, prisoners)
- Affiliation Status
- Office Held, where applicable
- Membership Status
- List of members for whom an alternate may substitute

1.3.2 The IRB manager will ensure that the IRB roster and the Office for Human Research Protections (OHRP) IRB registration are updated in a timely manner when membership changes are made.

## **2. SCOPE**

This policy and procedure applies to the membership of the IRB.

## **3. RESPONSIBILITY**

The IRB manager will maintain the IRB Roster and OHRP IRB Registration.

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

45 CFR 46.103(b)(3)

45 CFR 46.107

45 CFR 46.115(a)(5)

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

This SOP affects all other SOPs.

## 6. IMPLEMENTATION OF PROCEDURES

Who	Task	Tool
IRB Manager IRB Chair Institutional Official Assistant V.P. - URC	Ensure the overall diversity of the IRB membership through non-discriminatory selection methods.	
IRB Manager IRB Coordinator	Maintain a roster of all primary and alternate IRB members.	IRB Roster
	Maintain a file on all members to include their curriculum Vitae or résumé, letters of appointment, and other documentation of professional ability.	
	Maintain a roster of available consultants who are eligible and qualified to attend meetings as invited consultants.	