

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>			
<b>Revision #9</b>	<b>TITLE: Membership of IRB</b>		<b>Page: 1 of 4</b>
Approved By: ORI Director	Signature	Date	Date First Effective: 05-10-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 02-15-19

### **OBJECTIVE**

To define policies and procedures for appointing Institutional Review Board (IRB) members

### **GENERAL DESCRIPTION**

Each IRB at the University of Kentucky (UK) has a minimum of five voting members sufficiently qualified through experience and expertise to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The membership includes regular members who have designated alternates with qualifications comparable to the regular member. Additionally, in accord with OHRP policy, a regular member of any of the UK IRBs may serve as an alternate for any comparably qualified member on any other UK IRB. Consultants and *ex officio* members provide guidance and input regarding IRB operations and protocol review.

IRB membership complies with federal requirements outlined in [45 CFR 46.107](#), [46.108\(a\)\(2\)](#) and [21 CFR 56.107](#) to ensure appropriate diversity of the members through consideration of multiple professions/disciplines, ethnicities and cultural backgrounds, gender, and sensitivity to such issues as community attitudes and representation of the general perspectives of human subjects. In addition, the IRB includes members who can determine the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. If the IRB regularly reviews research involving a vulnerable category of subjects, the IRB membership includes individuals who are knowledgeable about and experienced in working with those subjects.

Each IRB includes at least one member with each of the following primary affiliations: nonscientific, scientific, and nonaffiliated (i.e., not affiliated with UK and not part of the immediate family of a person affiliated with UK), and (on IRB committees that review FDA regulated studies) a physician.

In addition, the IRB invites individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

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## **RESPONSIBILITY**

Execution of SOP: Office of Research Integrity (ORI) Staff, ORI Director, Vice President for Research (VPR), IRB, IRB Chairs

## **PROCEDURES**

### *Appointment Procedures/Terms of Membership*

1. The VPR appoints members to standing University research committees and, as authorized by the Provost and President, appoints Chairs, Vice Chairs, and members to the IRB. Approximately once a year upon request, the ORI submits recommendations for membership to the VPR. The ORI designated staff is responsible for soliciting recommendations from a variety of sources for either non-tenure track faculty/staff or individuals in a tenured position (preferable), preparing the recommendations for submission to the VPR, and ensuring that the membership meets federal requirements. Other UK administrative units may also submit nominations for membership on the IRB.
2. The ORI designated staff provides IRB Chairs and the ORI Director with a copy of the recommendations sent to the VPR.
3. Appointments for IRB Chairs, Vice Chairs, and IRB members (including alternates) are for staggered three-year terms beginning the fall of each academic year. UK has no limit on the number of terms IRB Chairs, Vice Chairs, members, and alternates may serve on the IRB. The VPR automatically reappoints *ex officio* members each year. See the Quality Improvement Program Administrative Assessment Review SOP for procedures for periodically evaluating the performance of IRB Chairs, Vice Chairs, and members.
4. Individuals under consideration for appointment as an IRB Chair must meet the following requirements: completion of human research protections training; experience as a voting IRB member (or comparable experience); display of adequate knowledge of ethical principles, professional standards, federal regulations, and other applicable law through IRB meeting attendance and participation; and demonstration of professional competence necessary to review specific research activities.
5. IRB Chairs, Vice Chairs, members, and alternates are responsible for providing the ORI with curriculum vitae to document each member's expertise, degrees, and/or license number. The ORI maintains vitae for each member throughout his/her term on the IRB and periodically requests updates, as appropriate.

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6. Individuals under consideration for appointment as voting IRB members must not have competing business interests or hold research business positions at the University of Kentucky. In addition, individuals who are responsible for business development do not carry out day-to-day operations of the review process.
7. Alternate IRB members replace regular IRB members who are unable to attend convened meetings of the IRB. Alternate members have qualifications comparable to the applicable regular members and may be an alternate for more than one IRB member. Designated ORI staff maintain a list of alternate members on the official IRB membership list. Terms of appointment, length of service, and duties are identical to those for regular IRB members. Regular members on any IRB can serve as alternate members for comparably qualified members on any other IRB.
8. Alternates attending a meeting or conducting protocol review have all the authority of regular IRB members and receive the same training and protocol review application materials as the regular members. If the regular member and the alternate member substituting for that meeting attend the same convened meeting, only one individual may vote.
9. *Ex officio* members are non-voting members who serve as liaisons to ensure coordination among other research administrative units. Examples include but are not limited to the Investigational Drug Service (IDS) representative, ORI Director, Radiation Safety Officer (RSO), Legal Counsel, and Institutional Biosafety Officer.
10. ORI staff recruit ad hoc and cultural consultants 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. Ad hoc or cultural consultants may provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the review. These ad hoc and cultural consultants do not vote with the IRB and do not count toward a quorum at a convened meeting. See the Initial Full Review SOP for procedures for contacting consultants.
11. When the IRB reviews research that involves prisoners, a majority of the IRB (exclusive of the prisoner representative) must not have any association with the prison involved, apart from their relationship on the IRB.
12. For IRB review of research on prisoners, at least one voting member at the IRB meeting must be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity.
13. For IRB review of research supported by the National Institute on Disability and Rehabilitation Research, the IRB membership includes at least one person primarily

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concerned with the welfare of children with disabilities or individuals with mental disabilities when the study purposefully requires their inclusion as research participants.

#### *Filling Appointments Due to Resignations During the Year*

1. Designated ORI staff solicit recommendations from a variety of sources, recruit potential members, and make recommendations for replacement of members who resign during the year. The VPR makes all final appointments as authorized by the Provost and President.

#### *OHRP/FDA IRB Registration/IRB Membership Roster*

1. The ORI designated staff member completes the OHRP/FDA IRB registration forms in accordance with OHRP and FDA registration requirements and updates the registration in a timely manner.
2. The ORI designated staff member maintains a list of all IRB members and denotes in which scientific capacity each member serves.
3. ORI staff use the membership list to determine who may attend IRB meetings and count toward the quorum. It includes a list of regular members and designated alternates and indicates the scientific status and area(s) of expertise of all members.
4. To meet OHRP/FDA registration requirements and in order to hold convened meetings, the scientist and nonscientist member designations are as follows:
  - Nonscientist: members who have had little or no scientific or medical training or who do not currently hold positions which involve scientific research or clinical practice (e.g., administrative positions).
  - Scientist: members who are physicians or who hold Ph.D., Pharm.D., or other advanced degrees who are actively engaged in research in the physical, educational, social, behavioral, or biological sciences and disciplines and/or hold regular faculty appointments.

#### **REFERENCES**

[21 CFR 56.107](#)

[21 CFR 56.115\(a\)\(5\)](#) & [56.106](#)

[45 CFR 46.103\(b\)\(3\)](#) & [115\(a\)\(5\)](#)

[45 CFR 46.107](#)

[45 CFR 46.108\(a\)\(2\)](#)

[45 CFR 46 Subpart E](#)

[U.S. Department of Health and Human Services \(HHS\) Registration of an IRB](#) (Notes)