

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
<b>SOP #1-2 Revision #4</b>	<b>TITLE: Membership of IRB</b>		<b>Page: 1 of 5</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: 08-21-09

## **OBJECTIVE**

To define policies and procedures for appointing Institutional Review Board (IRB) members and for maintaining the Office for Human Research Protections (OHRP)/Food and Drug Administration (FDA) roster

## **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 and *ex officio* non-voting members.

IRB membership complies with federal requirements outlined in 45 CFR 46.107, 21 CFR 56.107, and 38 CFR 16.107 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. 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 or the Veterans Affairs Medical Center [VAMC]) and not part of the immediate family of a person affiliated with UK or the VAMC), and a physician (on IRB committees that review FDA regulated studies). Each Medical IRB includes two representatives from the VAMC, one of whom must be a scientific member.

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, ORI Associate Director, Vice President for Research (VPR), IRB, IRB Chairs, VAMC Director, VAMC Research and Development Committee, VAMC Associate Chief of Staff for Research and Development, VAMC Research and Development Officer

## **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 Associate Director or designee is responsible for soliciting recommendations from a variety of sources, 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 Associate Director provides IRB Chairs and the ORI Director with a copy of the recommendations sent to the VPR.
3. The ORI Associate Director and the VAMC Associate Chief of Staff for Research and Development or designee coordinate VAMC member appointments. The VAMC Research and Development Committee nominates candidates to represent the VAMC. VA Research and Development administration officials may not serve as voting IRB members. The VAMC Director and the VPR, as authorized by the Provost and President, appoint these members to the IRB.
4. 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.
5. Individuals under consideration for appointment as an IRB Chair must meet the following requirements: completion of human research protections training; recent experience as a voting IRB member (or comparable experience) for at least one year prior to nomination as IRB Chair; display of adequate knowledge of ethical principles, professional standards, federal regulations, and other applicable law, through IRB meeting attendance and

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participation; and demonstration of professional competence necessary to review specific research activities.

6. 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 in the files for each member throughout his/her term on the IRB and periodically requests updates, as appropriate.
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 member and may be alternates for more than one IRB member. The ORI Associate Director or designee maintains lists of alternate members on the official membership list approved by OHRP. The OHRP list specifies which members the alternate is qualified to replace. Terms of appointment, length of service, and duties are identical to those for regular IRB members.
8. Alternates attending a meeting or conducting a 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 his/her alternate 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: Investigational Drug Service representative, ORI Director, Radiation Safety Officer, 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. These ad hoc and cultural consultants do not vote with the IRB and do not count toward a quorum at a convened meeting. 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. 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 have no 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.

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13. When the IRB reviews VAMC research that involves mentally disabled persons or persons with impaired consent capacity, there is at least one IRB member who is an expert in the area of the research involved in the review.

*Filling Appointments Due to Resignations During the Year*

1. The ORI Associate Director or designee solicits recommendations from a variety of sources, recruits potential members, and makes recommendations for replacement of members who resign during the year. ORI staff send a copy of the recommendations to the ORI Director and the IRB Chairs. The VPR makes all final appointments, as authorized by the Provost and President.

*OHRP/FDA IRB Registration/IRB Membership Roster*

1. The ORI Associate Director or his/her designee completes the OHRP/FDA IRB registration forms in accordance with OHRP and FDA registration requirements and updates the registration in a timely manner when the IRB membership changes. The OHRP registration form serves as the IRB roster and denotes in which scientific capacity each member serves.
2. The ORI Associate Director or designee provides the Health Science Specialist in the Office of Research Oversight in the Department of Veteran Affairs and the Associate Chief of Staff for Research at the VAMC a copy of the OHRP/FDA registration report as soon as he/she submits it to OHRP.
3. The ORI Associate Director or designee provides ORI staff and the ORI Director a copy of the registration report as soon as he/she submits it to OHRP.
4. The ORI Associate Director or his/her designee maintains membership records. ORI staff use the OHRP/FDA membership list as the official membership list to determine who may attend IRB meetings and count toward the quorum. It includes a list of regular members and their designated alternates and indicates the scientific status of all members.
5. To meet OHRP/FDA registration requirements and in order to hold convened meetings, the scientist and nonscientist member designations are as follows:
  - Nonscientific: 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).
  - Scientific: 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.

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## **REFERENCES**

21 CFR 56.107  
21 CFR 56.115(a)(5) & 56.106  
38 CFR 16.103(b)(3) & 115(a)(5)  
38 CFR 16.107  
45 CFR 46.103(b)(3) & 115(a)(5)  
45 CFR 46.107  
45 CFR 46 Subpart E