

MEMBERSHIP OF IRB

The Franklin University IRB 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. 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, 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 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.

The IRB includes at least one member with each of the following primary affiliations: non-scientific, scientific, and non-affiliated (i.e., not affiliated with Franklin University and not part of the immediate family of a person affiliated with Franklin University). The scientist and non-scientist member designations are as follows:

- The individual should self-identify as a scientist or a non-scientist.
- Scientist – Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral, biomedical, natural, and physical research discipline should be considered a scientist.
- Non-scientist – Members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical, behavioral, natural, and physical scientific discipline should be considered a non-scientist.

Each Franklin University educational unit, including Urbana University, should be represented in the IRB membership.

In addition, the IRB invites 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.

PROCEDURES

Appointment Procedures/Terms of Membership

1. Members are recruited to serve on the IRB. At any given time, each educational unit will have a qualified faculty or staff member sitting on the Franklin University IRB. Approximately once a year, IRB staff are responsible for soliciting recommendations from a variety of sources for IRB membership. IRB staff review credentials and ensure individuals meet federal and institutional requirements before forwarding names and accompanying information to the IRB Chair.

2. The IRB Chair reviews credentials and approaches individuals to discuss their interest in membership and availability to serve on the IRB.

3. The IRB Chair confirms a potential appointment with the individual's supervisor.
4. The IRB elects members and will vote on candidates who have been approved by the IRB Chair and his/her supervisor.
5. Procedures for electing alternates are the same as those for electing IRB members.
6. Appointments for IRB members are for staggered three-year terms beginning in the fall of each academic year. There is no limit to the total number of years a member may serve on the Franklin University IRB, though individuals are limited to two consecutive terms unless waived by the IRB Chair. There is no term limit for alternates.
7. The IRB Chair, members, and alternates are responsible for providing the IRB Office with curriculum vitae to document each member's expertise, degrees, and/or license number. The office maintains vitae in the files for each member throughout his/her term on the IRB and periodically requests updates, as appropriate.
8. Each year, the IRB Chair, members, and alternates must complete and return a signed Member Confidentiality Agreement and Conflict of Interest Statement to the IRB Office.
9. 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 alternate for more than one IRB member. Terms of appointment and duties are identical to those of regular IRB members.
10. 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.
11. Ex officio members are non-voting members who serve as liaisons to ensure coordination among other research administrative units.
12. IRB staff may 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.

Appointment Procedures for IRB Chair

1. Chairs are recruited to serve on the IRB. The IRB Manager is responsible for soliciting recommendations from a variety of sources for IRB Chair. IRB staff review credentials and ensure individuals meet federal and institutional requirements before forwarding names and accompanying information to the current IRB Chair.
2. The IRB Chair approaches a potential replacement to discuss their interest in the position and availability to serve as IRB Chair.
3. The IRB Chair confirms a potential appointment with the individual's supervisor.

4. The IRB elects Chairs and will vote on candidates who have been approved by the IRB Chair and his/her supervisor.
5. Appointments for IRB Chair are for two-year terms beginning the fall of each academic year.
6. There is no term limit for IRB Chairs.
7. An individual under consideration for IRB Chair may or may not be an existing member of the IRB, but must meet the following requirements: completion of human research protections training; display of adequate knowledge of ethical principles, professional standards, federal regulations, and other applicable law; and demonstration of professional competence necessary to review specific research activities.

Filling Appointments Due to Resignations During the Year

1. Alternates replace IRB members who resign during the year and become full voting members.
2. IRB staff solicit recommendations from a variety of sources, recruit potential members, and make recommendations for replacement of alternates who become full voting members.

OHRP IRB Registration/IRB Chair

1. IRB staff complete the OHRP IRB registration forms in accordance with OHRP registration requirements and update the registration in a timely manner when the IRB Chair changes.
2. IRB staff maintain membership records.