

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 participants. The membership includes regular members and 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 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 participants. 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 participants, the IRB membership includes individuals who are knowledgeable about and experienced in working with those participants.

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 should aim for representation on the IRB, though there are practical reasons why this may not always be possible.

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, the IRB will aim to have a qualified faculty or staff member from each educational unit sitting on the Franklin University IRB. In consultation with the IRB Manager and/or the IRB Chair, the Institutional Official (IO), as authorized by the President, appoints Chairs and members to the IRB. 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 and/or IO.

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2. The IO, IRB Chair, and/ or IRB Manager reviews credentials and approaches individuals to discuss their interest in membership and availability to serve on the IRB.
3. The IO, IRB Chair, and/ or IRB Manager confirms a potential appointment with the individual's supervisor.
4. Appointments for IRB Chairs and IRB members (including alternates) are for staggered three-year terms beginning in January of the calendar year. There is no limit to the total number of terms an IRB Chair, member, or alternate may serve on the Franklin University IRB.
5. The IRB Chair, IRB members, and alternates are responsible for providing the IRB Office with curriculum vitae or resume to document each member's expertise, degrees, and/or license number. The office maintains vitae and resumes in the files for each member throughout his/her term on the IRB and periodically requests updates, as appropriate.
6. 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.
7. The IRB Chair, IRB members, and alternates are responsible for completing the Collaborative Institutional Training Initiative (CITI) training every three years. The IRB Chair must complete and pass the IRB Members and IRB Chair courses and ensure his or her training is current. IRB members and alternates must complete and pass the IRB Members course and ensure their training is current.
8. 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.
9. 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.
10. Ex officio members are non-voting members who serve as liaisons to ensure coordination among other research administrative units.
11. 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.

Filling Appointments Due to Resignations or Term Expirations

1. IRB staff solicit recommendations from a variety of sources, recruit potential members, and make recommendations for replacement of members who resign or whose terms have expired. The IO makes all final appointments, as authorized by the President.

OHRP IRB Registration/IRB Membership Roster

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