

# IRB Composition, Member Appointment, Terms of Service & Member Evaluation

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## Policy Statement

Appointment of members to the IRB is conducted in accordance with federal regulations [45 CFR 46.107 and 21 CFR 56.107] and must meet the following criteria:

- The IRB has at least five members with varying backgrounds to promote a complete and adequate review of research commonly conducted by the organization;
- The IRB is not comprised of either all male or all female members;
- The IRB is not comprised of members who represent only a single profession;
- At least one member has primary concerns in a scientific area;
- At least one member has primary concerns in a nonscientific area;
- At least one member is not otherwise affiliated with the organization and who is not part of the immediate family of a person who is affiliated with the organization; and
- At least one member represents the perspective of research participants,

While also ensuring the committee:

- Is sufficiently qualified through experience and/or expertise (i.e., preferably composed of members with experience conducting independent research beyond the dissertation or terminal degree project) to safeguard the rights and welfare of human research subjects;
- Possesses the professional competence necessary to review research activity; and
- Is able to ascertain the acceptability of proposed research in terms of institutional commitments and policy, federal regulations, and standards of professional conduct and practice.

## Purpose

This policy aims to describe the role and qualifications of the University of the Incarnate Word (UIW) IRB members and to set forth expectations and evaluation of IRB members.

## Description and Procedures

### A. Committee Composition

The UIW IRB committee is composed of scientific, non-scientific, and non-affiliated (community) voting members. The IRB may establish up to two (2) members designated as chairpersons. The Dean of Research & Graduate Studies serves as an ex officio (non-voting) member.

1.

- a. **Scientific Members:** Scientific members are expected to review assigned applications and contribute to the evaluation of research projects on their scientific merits and standards of practice. These members are able to advise the IRB if additional expertise in a scientific area is required to assess if a research project adequately protects the rights and welfare of subjects.
- b. **Non-Scientific Members:** Non-scientific members are expected to provide input on matters germane to their individual knowledge, expertise, and experience, professional and otherwise. Nonscientific members advise the IRB if additional expertise in a nonscientific area is required to assess whether the research project protects human subjects' rights and welfare adequately.
- c. **Non-Affiliated (Community) Members:** Non-affiliated members are expected to provide input regarding their individual knowledge about the local community and be willing to discuss issues and research from that perspective. A non-affiliated member is also a scientific or nonscientific member and would be expected to provide input on areas germane to his/her knowledge, expertise, and experience, professional and otherwise.
- d. **Chairpersons:** In addition to scientific or non-scientific member responsibilities listed above, the Chairpersons review all applications presented to the convened IRB and communicate with other reviewers as needed so that important IRB issues or concerns are resolved or identified prior to the convened IRB meeting and are empowered to administer convened IRB decisions. Chairpersons also direct the proceedings and discussion of convened IRB meetings.

## 2. *Qualification and Responsibilities of IRB Members*

The commitment of IRB Members to research subjects, regulatory requirements, and the University is carried out through the following functional responsibilities:

- a. **Scientific Committee Member:** IRB Scientific Members must hold a scientific degree (e.g., M.D., D.O., D.D.S., Ph.D., Pharm.D., B.S.N., etc.) and demonstrate active engagement in research and scholarship in the fields of application submissions. Active engagement is defined as a scholarly publication, presentation, and relevant grant award. Scientific members must have professional training and experience in an occupation that would incline them to view scientific activities from the standpoint of someone within an appropriate discipline (e.g., behavior or biomedical research). All IRB members are asked annually to self-identify as having primary concerns in either scientific areas or primary concerns in nonscientific areas. Registered nurses, nurse practitioners, pharmacists, therapists, radiologists, and other biomedical health professionals would be regarded as having primary concerns in the scientific area.
  1. Responsibilities
    - Participate as a reviewer on applications to which the individual is assigned ensuring:
      1. risks to subjects are minimized through sound research design and study hypothesis,
      2. risks to subjects are reasonable in relation to anticipated benefits,
      3. selection of subjects is equitable,
      4. informed consent is obtained (or waived, as appropriate) and documented effectively,
      5. the protocol includes data and safety monitoring (if needed),
      6. subject's privacy and confidentiality are protected, and

7. additional safeguards are incorporated for vulnerable subjects;
- If assigned as a primary reviewer and unable to attend the meeting due to an emergency, provide a written review summary to the Committee Chair before the meeting;
  - Review and participate in a discussion of all applications and agenda items for each convened IRB meeting;
  - When acting as the primary IRB reviewer, attempt to resolve questions or concerns before the meeting, which may necessitate contacting researchers;
  - Serve as an alternate IRB member as needed;
  - Keep abreast of regulations and policies governing IRB review and the conduct of human subjects research;
  - Advise the IRB when additional, external expertise is required to adequately review the protection of the rights, safety, and welfare of subjects or to comment on the acceptability of practices outside the IRB Members' fields;
  - Participate in IRB educational activities;
  - Maintain current IRB Member CITI training;
  - Adhere to the IRB Member Confidentiality Policy; and
  - Adhere to the IRB Member Conflict of Interest Policy.

Scientific members must have the approval of the Dean of Research & Graduate Studies.

- b. **Non-Scientific Committee Member:** The IRB Non-Scientific Member must have experience with complex information processing and interpersonal communication. In addition, the non-scientific member must be comfortable with the electronic environment and able to navigate email and the internet. All IRB members are asked annually to self-identify as having primary concerns in either scientific areas or primary concerns in nonscientific areas. Examples of non-scientific occupations may include but are not limited to, IRB staff members, research coordinators, lawyers, clergy, ethicists, teachers, engineers, accountants, or business majors.

- i. Responsibilities

- Participate as a reviewer on applications to which the individual is assigned ensuring:
  1. risks to subjects are minimized through sound research design and study hypothesis,
  2. risks to subjects are reasonable in relation to anticipated benefits,
  3. selection of subjects is equitable,
  4. informed consent is obtained (or waived, as appropriate) and documented effectively,
  5. the protocol includes data and safety monitoring (if needed),
  6. subject's privacy and confidentiality are protected, and
  7. additional safeguards are incorporated for vulnerable subjects;
- Review and participate in a discussion of all applications and agenda items for each meeting;
- Serve as an alternate IRB member as needed;
- Keep abreast of regulations and policies governing IRB review of research and the conduct of human subjects research;
- Participate in IRB educational activities;
- Contribute expertise with regulations, policies, and the conduct of human subjects research; and

- Represent nonscientific interests such as how well the research is explained to comprehend the risk, benefit, and distributable justice (Belmont Principles);
- Maintain current IRB Member CITI training;
- Adhere to the IRB Member Confidentiality Policy; and
- Adhere to the IRB Member Conflict of Interest Policy.

Non-Scientific members must have the approval of the Dean of Research & Graduate Studies.

- c. **Non-Affiliated (Community) Members:** The Non-Affiliated Committee Member must be experienced in complex information processing, interpersonal communication, and is sensitive to unique community populations and cultures. In addition, the non-affiliated member must be comfortable with the electronic environment, able to navigate email, and have access to high-speed internet. The Non-Affiliated Member is not a current or former employee or student of UIW and does not have an immediate family member who is a current or former employee or student of UIW. Non-Affiliated members are asked annually to self-identify as having primary concerns in either scientific areas or primary concerns in nonscientific areas.

i. Responsibilities

- Participate as a reviewer on applications to which the individual is assigned ensuring:
  1. risks to subjects are minimized through sound research design and study hypothesis,
  2. risks to subjects are reasonable in relation to anticipated benefits,
  3. selection of subjects is equitable,
  4. informed consent is obtained (or waived, as appropriate) and documented effectively,
  5. the protocol includes data and safety monitoring (if needed),
  6. subject's privacy and confidentiality are protected, and
  7. additional safeguards are incorporated for vulnerable subjects;
- Review and participate in a discussion of all applications and agenda items for each meeting;
- Serve as an alternate IRB member as needed;
- Keep abreast of regulations and policies governing IRB review of research and the conduct of human subjects research;
- Maintain current IRB Member CITI training;
- Adhere to the IRB Member Confidentiality Policy; and
- Adhere to the IRB Member Conflict of Interest Policy.

All non-affiliated (community) members must have the approval of the Dean of Research & Graduate Studies.

- d. **Chairpersons:** The chairperson must hold a terminal degree (for example M.D., D.O., D.D.S., Ph.D., Ed.D., DNP, etc.) and be a member of the faculty of the UIW. The chairperson must have previously served on the UIW IRB as a committee member. The chairpersons must have experience in Biomedical/Clinical research or Social/Behavioral research that is representative of the research conducted at UIW.

i. Responsibilities

- Chair the meetings to which they are assigned;
- Substitute as chair for other IRB meetings as needed;

- Serve as an alternate IRB member as needed;
- Serve as Designated Expedited Reviewer;
- Participate in the on-call schedule for an emergency consultation with investigators;
- Advise investigators on and acknowledge the appropriateness of emergency use of investigational drugs and devices in accordance with federal regulations;
- Participate in IRB Executive Committee meetings;
- Facilitate and participate in IRB educational activities;
- Keep abreast of regulations and policies governing IRB review of research and the conduct of human subjects research;
- Evaluate IRB member's thoroughness of review and level of engagement and attendance at convened IRB meetings; and
- Adhere to and administer determinations by the IRB;

All chairpersons must have the approval of the Dean of Research & Graduate Studies.

### 3. Alternate Members

Alternate members are appointed to serve as a substitute for a regular IRB member and/or to ensure that the IRB has the appropriate expertise to review research (e.g., prisoner representative, pharmacy representative, etc.).

- Each IRB member serves as an alternate for others within the same IRB member role (scientific, non-scientific, or non-affiliated). Qualifications, responsibilities, and recruitment processes do not differ from the member's primary role.
- The IRB roster indicates which regular member for which the alternate can substitute.
- The alternate must have the same qualifications, meet the same criteria for their role (scientific, non-scientific, or non-affiliated), and observe the same responsibilities as the person they are replacing.
- When an alternate member substitutes for a regular IRB member, the alternate receives and reviews the same materials as the regular IRB members.
- When an alternate member substitutes for a regular member, the alternate counts towards quorum and may vote during the appointed time.
- The IRB minutes will document when an alternate member substitutes for a regular member.

If both a regular IRB member and his or her alternate(s) attend the same IRB meeting, the regular member is acting as the official voting member of the IRB for review of research protocols, unless the minutes clearly indicate otherwise. A designated alternate IRB member for a regular IRB member may substitute for the regular IRB member for an entire meeting or at any time during a meeting.

### 4. Consultants

If the board does not have the appropriate expertise to review a research study, a consultant may be used to assist in the IRB review. Consultants may be used for exempt, expedited, and convened studies.

- The IRB Director or designee will determine if a consultant is needed. In addition, any member of the IRB may request the use of a consultant during the review process.
- The IRB Director or designee will contact the consultant to determine if he/she is able to act as a consultant to the IRB.

- The consultant will be asked to provide a written review. If determined to be necessary, the consultant will be asked to attend the meeting.
- If the consultant attends the meeting, the consultant does not count towards quorum and cannot vote.
- The use of consultants will be documented in the meeting minutes.

## B. Appointment of Members

### 1. *UIW-Affiliated Members*

In the third quarter of each calendar year, the Human Research Protection Program (HRPP) Compliance Coordinator contacts selected chairpersons of academic departments throughout the institution to seek recommendations for convened IRB members to replace members whose term ends at the new calendar year. There is an attempt to approach departments and divisions to achieve broad participation throughout the institution and ensure representation from those specialties with a high volume of human studies research. The IRB may communicate particular areas of expertise to be filled to ensure the board includes sufficient representation of backgrounds and experience. The IRB also welcomes requests to join the IRB from members of the academic staff, and these requests are submitted to the individuals' academic chairs for consideration for recommendation to the IRB. Unscheduled vacancies on the committees that occur during the course of the year are filled in a similar fashion.

The IRB Chair(s) and Dean of Research & Graduate Studies are responsible for selecting members to serve on the IRB. The Dean of Research & Graduate Studies (HRPP/IRB) with the advice of the Chairpersons and Compliance Coordinator, makes the final determination of whether nominated IRB members' primary concerns fall into scientific or non-scientific areas.

The HRPP will appoint IRB members. IRB members receive an appointment letter after their appointment is confirmed. The letter states the term of service. IRB members serve 3-year renewable terms. There are no term limits.

Members may resign at any time by submitting a letter of resignation to the IRB Chair(s) and Dean of Research & Graduate Studies. The IRB Chair may remove members from the committee if the member is not able to complete his/her responsibilities as an IRB member.

### 2. *Non-Affiliated (Community) Members*

Individuals not affiliated with UIW are recruited to serve as members on convened IRBs. The HRPP will appoint Non-Affiliated IRB member(s). Non-Affiliated IRB member(s) receive an appointment letter after their appointment is confirmed. The letter states the term of service. The member(s) serve 3-year renewable terms. There are no term limits.

Member(s) may resign at any time by submitting a letter of resignation to the IRB Chair(s) and Dean of Research & Graduate. The IRB Chair may remove members from the committee if the member is not able to complete his/her responsibilities as an IRB member.

Non-Affiliated members participate in the IRB orientation, education, and training.

The roster of members is communicated online.

## C. Terms of Service

IRB Members are appointed for three-year terms and serve from Fall to Summer. IRB Members are expected to continue their service throughout the summer. IRB Member service will break for UIW holidays, including Christmas break.

The minimum attendance requirement is at least 85% of the meetings scheduled for the member's assigned IRB (prorated for members who share a member position on their assigned IRB).

Individuals are to notify the HRPP of unavailability for a previously confirmed assignment, i.e., convened meeting attendance and for chairpersons, on-call, and expedited review rotations.

- If notification occurs **30 days or less prior to the assignment date**, the individual is responsible for identifying an available alternate for the assignment and must notify the HRPP Compliance Coordinator of the specific alternate identified. The HRPP Compliance Coordinator will contact the identified alternate to confirm the assignment.
- If notification occurs **more than 30 days prior to the assignment date OR the absence is due to a medical/other emergency**, the HRPP queries designated alternates in an effort to identify an available substitute.
- Upon confirmation with the alternate, the HRPP updates related IRB schedules and notifies affected IRB Operations personnel.

When possible, if attendance cannot be realized/resolved due to an emergency arising after the meeting agenda is distributed, the member will record the assigned written reviews.

#### D. Evaluation of Convened IRB Members

IRB member self-assessment is used to provide members the opportunity to reflect on the IRB experience and identify potential learning needs. An IRB Member Self-Assessment survey and an IRB Chair Self-Assessment survey are used to facilitate the annual assessment process between the IRB members and Chairpersons and between the Chairpersons and the Dean of Research & Graduate Studies.

##### 1. IRB Members

On a quarterly basis, the Dean for Research & Graduate Studies receives a Board and Member Report summarizing the average scheduled meeting time used for the convened IRB, and the following for individual convened IRB members (excluding IRB staff\*): number and percentage of scheduled meetings attended, total items assigned for review, and percentage of assigned reviews recorded less than 48 hours before the scheduled meeting. The Dean for Research & Graduate Studies disseminates the report to the Chairpersons.

Chairpersons should periodically, at a minimum annually, evaluate each member's review of research and record of attendance for consideration of coaching or assessment regarding the ability of the member to meet the expectation for ongoing committee membership. The Chairpersons shall discuss the evaluation with IRB members and provide documentation of the evaluation to the Dean for Research & Graduate Studies. Areas for improvement that are identified for an IRB member are forwarded to the Dean for Research & Graduate Studies.

##### 2. Chairperson(s)

The Dean for Research & Graduate Studies shall periodically, at a minimum annually, evaluate each IRB Chairperson's ability to lead meetings, review of research, and record of attendance for consideration of coaching and assessment regarding the ability of the Chairpersons to meet the expectation for ongoing Chairperson role and committee membership. The Dean for Research & Graduate Studies shall discuss the evaluation with IRB Chairpersons and provide documentation of the evaluation to the IRB Administrator.

##### 3. HRPP Staff

IRB staff who may also serve as convened IRB members undergo periodic performance evaluations as a component of UIW's Human Resources. Performance management program. IRB staff supervisors solicit input from IRB colleagues and Chairpersons during the evaluation process. In addition, IRB staff serving as convened IRB members are evaluated annually using the *IRB Member Self-Assessment survey* and the process described above.

- IRB staff serve as convened IRB members as a component of their primary employment assignment and convened IRB participation is assigned by an IRB supervisor as part of departmental scheduling activities. Therefore, attendance frequency, review timeliness, etc. are not a reflection of the individual but rather are influenced by the broader business needs.

Periodically, a survey is distributed to all members, and results are used to improve orientation, training, and education processes.

Effective Date

August 24, 2020

Revision History

Revised June 22, 2023