



Roles, Qualifications and Evaluation of IRB Members

Content Applies To

Mayo Clinic Human Research Protection Program

Purpose

The purpose of this procedure is to describe the role of IRB members, the qualifications of IRB members, the expectations of IRB members and the evaluation program for IRB members.

Roles of IRB Members

Scientific Members: Scientific members are expected to review assigned studies, as well as contribute to the evaluation of a research project on its 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.

Nonscientific Members: Nonscientific members are expected to provide input on areas germane to his/her knowledge, expertise and experience, professional and otherwise. Nonscientific members advise the IRB if additional expertise in a nonscientific area is required to assess if research project adequately protects the rights and welfare of subjects.

Non-Affiliated (Community) Members: Non-affiliated members are expected to provide input regarding his/her 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.

Chairpersons: In addition to scientific member responsibilities listed above, the Chairpersons review all studies presented to the IRB committee 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 or may delegate to the Vice Chairperson to assist or act on behalf of the Chairperson in particular IRB matters and at IRB meetings.

Qualifications and Responsibilities of IRB Members

Chairperson

The chair must hold a terminal degree (M.D., D.O., D.D.S., or Ph.D.) and be a member of the staff of the Mayo Clinic. The chairperson must have previous service on the Mayo Clinic IRB as a committee member and/or committee vice chairperson.

Responsibilities:

- Chair the meetings to which they are assigned

- Substitute as chair on other IRB committees
- Serve as an alternate IRB member as needed
- Serve as Designated Expedited Reviewer
- Participate in the on-call schedule for emergency consultation with investigators
- Advise investigators on and acknowledging the appropriateness of emergency use of investigational drugs and devices in accordance with federal regulations
- Participate on 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
- Adhere to and administer determinations by the IRB

Vice Chairperson

The vice-chairperson must hold a terminal degree (M.D., D.O., D.D.S, or Ph.D.) and be a member of the staff of the Mayo Clinic. The vice chairperson must have experience as an IRB member.

Responsibilities:

- Serve as vice-chair to the IRB to which they are assigned
- Substitute as chair of the IRB to which the individual is assigned and to other convened IRBs
- Serve as an alternate IRB member as needed
- Serve as Designated Expedited Reviewer
- Participate in the on-call schedule for emergency consultation with investigators
- Advise investigators on and acknowledging the appropriateness of emergency use of investigational drugs and devices in accordance with federal regulations
- Participate in the IRB Executive Committee meetings
- Keep abreast of regulations and policies governing IRB review and the conduct of human subjects research
- Adhere to and administer determinations by the IRB
- Facilitate and participate in IRB educational activities

Scientific Committee Member

The IRB Scientific Member must hold a scientific degree (e.g., M.D., D.O., D.D.S., Ph.D., Pharm.D. or Bachelor of Science in Nursing) and be a Mayo Clinic employee. 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 a behavior or biomedical research discipline. Registered nurses, nurse practitioners,

pharmacists, therapists, radiologists and other biomedical health professionals would be regarded to have primary concerns in the scientific area.

Responsibilities:

- Participate as a reviewer on applications to which the individual is assigned
- Review and participate in a discussion of all applications and agenda items for each convened IRB meeting
- Serve as an alternate IRB member as needed
- Inform the IRB Administrative Assistant, a minimum of fourteen days in advance of the meeting, barring emergencies, of unavailability to attend a scheduled meeting
- Provide a written review summary to the Committee Chair prior to the meeting, if assigned as a primary reviewer and unable to attend the meeting due to an emergency
- Keep abreast of regulations and policies governing IRB review and the conduct of human subjects research
- Participate in IRB educational activities

All chairpersons, vice chairpersons, and scientific members employed by Mayo Clinic must have the approval of the chair of the academic division within Mayo Clinic to which s/he is appointed.

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 in email and the internet. Examples of non-scientific or non-medical occupations may include, but not limited to, lawyers, clergy, ethicists, teachers, engineers, accountants, musicians, or business majors.

Responsibilities:

- Participate as a reviewer on applications to which the individual is assigned
- Review and participate in a discussion of all applications and agenda items for each meeting
- Serve as an alternate IRB member as needed. Inform the IRB Administrative Assistant, a minimum of fourteen days in advance of the meeting and barring emergencies, of unavailability to attend a scheduled meeting
- 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

- Represent nonscientific interests such as: how well is the research explained in order to comprehend the risk, benefit, and distributable justice (Belmont Principles).

Non-Affiliated (Community) Committee Member

The Non-Affiliated Committee Member is experienced with 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 in email, and have access to high-speed internet. The Non-Affiliated Member is not a current or former employee or student of Mayo Clinic and does not have an immediate family member who is a current or former employee or student of Mayo Clinic.

Responsibilities:

- Participate as a reviewer on applications to which the individual is assigned
- 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

Attendance Expectations and Length of Service for All Members

- The anticipated length of service for members is three years
- The minimum attendance requirement is for at least 70% of the meetings to which the member is scheduled
- When acting as primary IRB reviewer, attempt to resolve questions or concerns prior to the meeting, which may necessitate contacting researchers
- Pursue current knowledge of human subjects regulations
- Provide written review in emergent situations in which attendance cannot be realized

Recruitment of IRB Committee Members (except non-affiliated community members)

- In June and July of each calendar year, the Medical Director of the Mayo Clinic Office of Human Research Protection/IRB contacts selected chairpersons of academic departments and physicians 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, in particular, to ensure representation from those specialties that have a high volume of human studies research. 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 Medical Director and/or the Administrator of the Mayo Clinic Office of Human Research Protections/IRB makes the final determination of whether nominated IRB members' primary concerns fall into scientific or non-scientific areas.

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 Medical Director.
- Chairpersons should 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 on-going committee membership. The Chairperson shall discuss the evaluation with IRB members and provide documentation of the evaluation to the IRB Medical Director and IRB Administrator. Areas for improvement that are identified for an IRB member are forwarded to the IRB Administrator and Medical Director for review.
- The IRB Medical Director shall 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 Chairperson to meet the expectation for on-going Chairperson role and committee membership. The IRB Medical Director shall discuss the evaluation with IRB Chairpersons and provide documentation of the evaluation to the IRB Administrator. Areas for improvement that are identified for an IRB Chairperson are forwarded to the IRB Administrator for review.
- IRB staff who may also serve as convened IRB members undergo periodic performance evaluations as a component of Mayo Clinic's Human Resource performance management program. IRB operations 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.
- On a periodic basis, a survey is distributed to all members and results are used to improve processes surrounding orientation, training, and education.

Recruitment and Recognition of Non-Affiliated (Community) Members

- Individuals not affiliated with Mayo Clinic are recruited to serve as members on convened IRBs.
- Non-Affiliated members participate in the IRB orientation, education and training program.
- Events are conducted throughout the year to recognize the non-affiliated members' service on the IRB.

Alternate Members

- 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 designates the member role for which each member may substitute.

Effective Date

March 22, 2014