

Roles, Qualifications, and Evaluation of Institutional Review Board (IRB) Members Procedure

Scope

Applies to personnel in the Office of Human Research Protection Program when selecting and evaluating IRB members.

Purpose

To describe the role and qualifications of Mayo Clinic IRB members, and to set forth expectations and evaluation program for IRB members.

Equipment/Supplies

N/A

Procedure

The Mayo Clinic IRB committees are made up of scientific, non-scientific, and non-affiliated (community) members. Each IRB has two members designated as chairpersons.

Roles of IRB Members

- **Scientific Members:** Scientific members are expected to review assigned applications, 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.
- **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 if research project adequately protects the rights and welfare of subjects.
- **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.
- **Chairpersons:** In addition to 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.

Qualifications and Responsibilities of IRB Members

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 staff of the Mayo Clinic. The chairperson must have previously served on the Mayo Clinic IRB as a committee member.

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 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 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.
- Adhere to and administer determinations by the IRB

All chairpersons must have the approval of the chair of the academic division within Mayo Clinic to which she/he is appointed.

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., B.S.N., etc.). 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. 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 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
- 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
- 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,
- Keep abreast of regulations and policies governing IRB review and the conduct of human subjects research
- Participate in IRB educational activities

Scientific members employed by Mayo Clinic must have the approval of the chair of the academic division within Mayo Clinic to which she/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 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 not limited to, IRB staff members, research coordinators, lawyers, clergy, ethicists, teachers, engineers, accountants, 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.
- 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 the research is explained in order to comprehend the risk, benefit, and distributable justice (Belmont Principles).

Non-Affiliated (Community) Committee Member

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 Mayo Clinic and does not have an immediate family member who is a current or former employee or student of Mayo Clinic. Non-Affiliated members are asked annually to self-identify as having primary concerns in either scientific areas or primary concerns in nonscientific areas.

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 at least three years
- The minimum attendance requirement is for at least 75% 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 IRB Associate Specialist or [Research Service Center](#) 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 IRB Associate Specialist of the specific alternate identified. The IRB Associate Specialist 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 IRB Associate Specialist queries designated alternates in an effort to identify an available substitute.
 - Upon confirmation with the alternate, the IRB Associate Specialist 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

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

- In the third quarter of each calendar year, the Medical Director of the Mayo Clinic Office of Human Research Protection and 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.

Recruitment 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.

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.
- On a quarterly basis, the IRB Medical Director receives a Mayo Clinic IRB Board and Member Report summarizing the average scheduled meeting time used for each of the convened IRBs, 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 IRB Medical Director disseminates the report to the Chairpersons.

*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 rather are influenced by the broader business needs.

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

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.

Troubleshooting

N/A

Procedural Notes

N/A

Related Documents

N/A

Definitions

N/A

References

N/A

Owner

[Michelle K. Daiss](#), on behalf of Office for Human Research Protection

Contact

[Tamyra L. Armbrust, CIP, CCRP](#)

Revision History

Date	Synopsis of Change
08/31/2022	Scheduled review. Updated expected attendance percentage. Added Member Scorecard as a component of IRB member evaluation (excluding IRB staff). Owner updated. Added IRB staff and research coordinators as examples of non-scientists. Removed recognition from non-affiliated section header.
12/11/2020	Transferred to current template. Updated owner and minor edits. Revised language for consistency. Administrative Assistant changed to Associate Specialist.
09/12/2017	Scheduled review no changes
05/17/2010	Approval for need to establish document: OHRP