



Human Research Protection Program / Institutional Review Board
Standard Operating Procedure
2018 Common Rule

**For Studies Initially Approved on
or After January 21, 2019**

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1 MaineHealth Institutional Review Board

MaineHealth has established one Institutional Review Board (IRB) to ensure the protection of human subjects in research conducted its auspices.

1.1 IRB Authority

The IRB derives its authority from MaineHealth policy, as cited in Section 1.2. Under the federal regulations, IRBs have the authority:

1. To approve, require modifications to secure approval, or disapprove human subjects research activities including exempt research activities under 45 CFR 46.104 for which limited IRB review is a condition of exemption;
2. To require that informed consent is obtained and documented in accordance with regulatory and policy requirements unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the IRB. The IRB may require that information, in addition to that specifically mentioned in the regulations, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects;
3. Regarding Continuing Review:
 - For research subject to the 2018 Common Rule: To conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk of the research, but not less than once per year, except as described in Section 12.5;
 - When research is subject to other regulations (e.g., pre-2018 Common Rule, FDA) or requirements (e.g., grant or contract terms), the IRB will conduct continuing review of research at intervals appropriate to the degree of risk of the research, but not less than once per year
4. To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants;
5. To observe, or have a third party observe, the consent process; and
6. To observe, or have a third party observe, the conduct of the research.

The IRB functions independently. Attempts to coerce or otherwise unduly influence the actions of the IRB are forbidden by policy, and are to be reported as described in Section 10.6. Likewise, the IRB must remain free from the influence of financial and other organizational interests. No individual with responsibility for the business and financial interests of the organization, for example, the director of grants and contracting, the vice president for research, or deans of research who are responsible for raising funds or garnering support for research may serve on the IRB

Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of MaineHealth. However, those officials may NOT approve research if it has not been approved or has been disapproved by the IRB. Reviewing officials may strengthen requirements and/or conditions, or add other modifications before approval, or may require approval by an additional committee, office, or person. Previously approved research proposals and/or consent forms must be re-approved by the IRB before initiating any changes or modifications that result from such additional organizational reviews.

1.2 Roles and Responsibilities

1.2.1 Chair of the IRB

The IO, in consultation with the ORC Director and the IRB Manager appoints a Chair and Vice Chair of the IRB. Any change in appointment, including reappointment or removal, requires written notification.

The IRB Chair should be a highly-respected individual, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the research community falls primarily on the shoulders of the Chair. The IRB must be perceived to be fair, impartial, and immune to pressure by administration, the investigators whose research plans are brought before it, and other committees and departments.

The IRB Chair is responsible for conducting IRB meetings and expedited reviews and may serve as signatory for correspondence generated by the IRB.

The IRB Chair is authorized to take immediate action to suspend a study or studies if subjects may be at risk of harm, when serious noncompliance may have occurred, or for any other reason where such action would be deemed appropriate. Such action requires subsequent notice to and review by the convened IRB.

The IRB Chair may designate other experienced IRB members to perform duties such as expedited reviews and other IRB functions.

The IRB Chair advises the IO, the ORC Director, and the IRB Manager about IRB member performance.

The performance of the IRB Chair will be reviewed on an annual basis by the ORC Director in consultation with the IO, IRB Manager, and ORC Staff. Feedback from this evaluation will be provided to the Chair. If the Chair is not acting in accordance with the IRB's mission, following policies and procedures, has an undue number of absences, or is not fulfilling the responsibilities of the Chair, s/he may be removed.

1.2.2 Vice Chair of the IRB

The Vice Chair serves as the Chair of the IRB in the absence of the Chair and has the same qualifications, authority, and duties as the Chair.

The performance of the IRB Vice Chair will be reviewed on an annual basis by the ORC Director in consultation with the IO, IRB Manager, and ORC Staff. Feedback from this evaluation will be provided to the Vice Chair. If the Vice Chair is not acting in accordance with the IRB's mission, following policies and procedures, has an undue number of absences, or is otherwise not fulfilling their responsibilities, s/he may be removed.

1.2.3 IRB Members

The role of an IRB member is to ensure that human research activities comply with federal regulations, state and local laws, and organizational policies and procedures, by:

- Completing member education and training, both initial and on-going (See Section 3.1)
- Maintaining the confidentiality of IRB deliberations and research reviewed by the IRB
- Conducting and documenting reviews in a timely fashion

- Attending IRB meetings as scheduled
- Recusing self from reviewing or voting on research when s/he has a conflict of interest (See Section 25.2)
- Participating in subcommittees of the IRB if requested and available
- Conducting themselves in a professional and collegial manner

Members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, they should inform the IRB Manager and/or the ORC Staff. If a member's availability changes and they are no longer able to regularly attend IRB meetings or will be absent for an extended period of time, they should inform the IRB Manager. The Manager will assess the situation, including the availability of the alternate when applicable, and make recommendations to the ORC Director and the IRB Chair to ensure that the IRB is able to meet quorum requirements and has the necessary expertise to review the research which regularly comes before it.

The performance of IRB members will be reviewed on an annual basis by the ORC Director, the IRB Manager, the ORC Staff, and the IRB Chair. Feedback from this evaluation will be provided to IRB members. Members who are not acting in accordance with the IRB's mission, not following policies and procedures, have an undue number of absences, or are otherwise not fulfilling the responsibilities of membership, may be removed by the IO or his/her designee.

1.2.4 Alternate members

The appointment and function of alternate members is the same as that for primary IRB members. An alternate's expertise and perspective should be comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting, in part or in full, or when the regular member has a conflict of interest in regard to a protocol under review. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member would have received.

The IRB roster identifies the primary member(s) or class of members (e.g., physician scientist) for whom each alternate member may substitute. When both the regular member and the alternate is in attendance at an IRB meeting, only one may be counted towards quorum and vote. The IRB minutes will document when an alternate member replaces a primary member.

Experienced alternate members may be designated by the Chair to conduct expedited reviews.

1.2.5 Subcommittees of the IRB

The IRB Chair, in consultation with the ORC Director and the IRB Manager, may appoint one or more other IRB members to a subcommittee of the IRB to review issues and to make recommendations to the IRB (e.g., to supplement the IRB's review of research proposals or to review of reports of potential unanticipated problems or noncompliance). The size and composition of the subcommittee shall depend on the scope of duties delegated by the IRB Chair. Any such subcommittee cannot approve research or issue determinations that require review by the convened IRB.

1.3 Composition of the IRB Membership

The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of the research that comes before it and must possess the professional competence necessary to review specific research activities. The structure and composition of the MaineHealth IRB is based upon regulatory requirements and the characteristics of the research it reviews. A member of the IRB may fill multiple membership position requirements (e.g., nonscientific and unaffiliated).

- The IRB will have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the organization. The IRB shall not consist entirely of members of one profession
- The IRB will be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects
- In addition to possessing the professional competence necessary to review specific research activities, the IRB will be able to ascertain the acceptability of proposed research in terms of organizational commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas
- The IRB will include members who are knowledgeable about and experienced working with **subjects vulnerable to coercion or undue influence** (e.g., children, prisoners, **individuals with impaired decision-making capacity**, or economically or educationally disadvantaged persons) that are regularly included in the research under its review
- Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the organization's consideration of qualified persons of both sexes, so long as no selection is made to the IRB solely on the basis of gender
- The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas
- The IRB includes at least one member who 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
- The IRB includes at least one member who represents the general perspective of participants

At the discretion of the IO and ORC Director, IRB staff may be appointed as IRB members or alternates.

Individuals from the MaineHealth Grants and Contracts Office, the Development Office, or the Intellectual Property Officer may not serve as members of the IRB or carry out day-to-day operations of the IRB. Individuals from these offices may provide information to the IRB and attend IRB meetings when invited as guests.

On an annual basis, the IRB Chair, the IRB Manager, and the ORC Director review the membership and composition of the IRB to determine if it continues to meet regulatory and organizational requirements.

1.3.1 Appointment of Members to the IRB

When the need for a new IRB member or alternate is identified, the ORC Director, the IRB Manager, and ORC Staff work together with the IRB Chair to obtain qualified candidates. Attendings and Staff of MaineHealth and others may forward recommendations to the Institutional Official, ORC Director, or to the ORC.

The final decision in selecting a new member is made by the IO, in consultation with the ORC Director, the IRB Manager, and the IRB Chair.

Initial appointments are made for a one-year term. Subsequent appointments are made for a renewable three-year period of service. Any change in appointment, including reappointment or removal before the end of a member's term, requires written notification. Members may resign by written notification to the ORC Director, IRB Manager, and/or the IO.

The ORC Director will ensure that changes in IRB membership are reported via the federal IRB registration in accordance with the instructions provided on [OHRP's website](#).

1.4 Liability Coverage for IRB Members

All IRB members have liability insurance coverage as part of their IRB membership in their capacity as agents of the Maine Medical Center.

1.5 Use of Consultants

When necessary, the ORC Director or IRB Manager may solicit individuals from within or outside the organization with the expertise to assist in the review of research or issues which require expertise beyond or in addition to that available on the IRB. The IRB Office will ensure that all relevant materials are provided to the consulting reviewer prior to the convened meeting or expedited review.

The ORC Director or IRB Manager reviews the COI policy for IRB members with consultants and consultants must confirm that they do not have a conflict of interest prior to review. Individuals who have a conflicting interest or whose spouse or immediate family members have a conflicting interest will not be invited to provide consultation.

The consultant's findings will be presented to the IRB for consideration either in person or in writing. If in attendance at an IRB meeting, consultants may provide information and assist in the IRB's deliberations, but may not participate in the vote.

Written statements from consultants will be kept in the IRB records. Information provided by consultants at IRB meetings will be documented in the minutes.

Ad hoc or informal consultations requested by individual members (rather than the convened board) will be managed in a manner that protects the investigator's confidentiality and that complies with the IRB COI policy.

1.6 Reporting and Investigation of Allegations of Undue Influence

If an IRB Chair, member, or staff person feels that the IRB has been unduly influenced by any party, they shall make a confidential report to the ORC Director or IO. The IO will ensure that a thorough investigation is

conducted and, if the allegation is determined valid, that corrective action is taken to prevent additional occurrences. In the event that the allegation is regarding the IO, the matter will be referred to the Chief Academic Officer for investigation and any necessary action.

Undue influence means attempting to interfere with the normal functioning and decision-making of the IRB, or to attempt to influence an IRB member or staff member or any other member of the research team, outside of the established processes or normal and accepted methods in order to obtain a particular result, decision, or action by the IRB or one of its members or staff.