



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 IRB Actions, Failure to Respond, Appeals

1.1 IRB Actions

In conducting its review of research, the IRB may take any of the following actions. With the exception of disapproval, the actions listed below may be used for either expedited or convened board review, **including limited IRB review**. Disapproval can only be decided at a convened IRB meeting. An expedited reviewer cannot disapprove a study.

Approval. The research, proposed modification to previously approved research, or another item is approved. The IRB has made all of the determinations required for approval (i.e., approval criteria and any applicable special determinations (e.g., waivers, alterations, vulnerable population determinations, etc.)). No further action is needed.

Approved with Conditions. The research, proposed modification to the previously approved research, or other item is approved but conditions must be satisfied before the approval becomes effective.

The IRB may approve research with conditions if, given scope and nature of the conditions, the IRB is able, based on the assumption that the conditions are satisfied, to make all of the determinations required for approval (i.e., approval criteria and any applicable special determinations (e.g., waivers, alterations, vulnerable population determinations, etc.)). Any time the IRB cannot make one or more of the determinations required for approval, the IRB may not approve the study with conditions.

The IRB may require the following as conditions of approval of research:

1. Confirmation of specific assumptions or understanding on the part of the IRB regarding how the research will be conducted (e.g., confirmation that research excludes children);
2. Submission of additional documentation (e.g., certificate of training);
3. Precise language changes to the study, consent, or other study documents; or
4. Substantive changes to the study, consent, or other study documents along with clearly stated parameters that the changes must satisfy.

When the IRB approves research with conditions, the conditions will be documented in the IRB minutes for research reviewed at a convened meeting or in the reviewer checklist for research reviewed under an expedited review procedure.

When the convened IRB approves research with conditions, the IRB will designate the final reviewer from among the IRB members to receive responsive materials from the investigator and to determine that the conditions have been satisfied. When an expedited reviewer approves research with conditions, the original expedited reviewer (and/or other qualified individual(s)) will receive the response materials.

After verification, the following will be documented in IRB records and written communication to the investigator:

1. The date when the IRB determined that the criteria for approval were satisfied (i.e., the "approval date");

2. The date when verification was made that all IRB conditions have been satisfied (i.e., the “effective date”), and;
3. For initial approval and continuing reviews, the date by which continuing review must occur (i.e., the “expiration date”)

The IRB will be informed of the outcome of this expedited review of the investigator’s response in the agenda of the next meeting.

Deferred. An IRB action taken when the convened IRB cannot fully evaluate the research under review and make the determinations required for approval without modifications to the protocol and/or informed consent document, or submission of clarifications or additional materials prior to reconsideration of the research. *Note: Convened IRB review of the investigator’s response(s) is required.*

Not Approved. An IRB action taken when the determinations required for approval of research cannot be made, even with substantive clarifications or modifications to the protocol and/or informed consent process/document. *Note: Research cannot be disapproved by expedited review.*

Tabled without Action. An IRB "action" that indicates that review was not initiated or was not completed, resulting in postponement of IRB review, usually due to loss of quorum or other administrative issue. Research tabled at a convened meeting will be reviewed at a future convened meeting.

1.2 Failure to Respond

Upon review of a research study, the IRB may require changes or request certain information from an investigator. Failure to respond to IRB required changes or requests for information within sixty (60) days (or less if the IRB determines that the information must be submitted earlier to ensure protection of the research subjects) may result in suspension or termination of IRB approval for the study. For studies that have not yet been approved, the study submission may be administratively withdrawn. At its discretion, the IRB may grant an extension beyond sixty (60) days if the investigator contacts the IRB office prior to the deadline and presents sufficient cause for delay.

1.3 Reporting IRB Actions

All IRB actions are communicated to the investigator, and/or the designated contact person for the research study, via the publication of a letter in IRBNet within ten (10) working days, whenever possible, of the review. When applicable, a stamped copy of the approved consent form, parental permission form, and/or assent form will also be published. For IRB actions of approved with conditions, disapproval, or tabled, the notification will include a listing of the conditions or requirements that must be satisfied or responded to.

The IRB reports its findings and actions to the organization in the form of its minutes, which are accessible to, and regularly reviewed by, the MaineHealth IO.

1.4 Appeal of IRB Decisions

When the IRB suspends, terminates, or disapproves research, the IRB letter communicating the decision will include the basis for the action and will offer the investigator the opportunity to respond in person or in writing. Additionally, whenever an investigator disagrees with an IRB requirement or decision, or believes that providing the IRB with additional information may result in a different outcome, they may request that the IRB reconsider its decision by submitting a memo and other supportive materials via IRBNet. The investigator may be invited to attend the IRB meeting to discuss the request and provide information, but will be asked to leave prior to the IRB's final deliberations and vote.