

IRB (Institutional Review Board) Member Responsibilities

Content Applies To

Mayo Clinic Human Research Protection Program

Purpose

The purpose of this document is to describe the responsibilities of IRB members and a suggested approach for conducting a thorough review of items, including new applications, modifications, continuing reviews, and reportable events.

Procedure

Responsibilities of IRB Members

Each IRB member's primary responsibility is the protection of the rights and welfare of the individual human beings who are serving as the subjects of research. In order to fulfill these responsibilities, IRB members are expected to be versed in regulations governing human subject protection, biomedical and behavioral research ethics, and Mayo Clinic IRB policies and procedures.

Assigned Reviewers

For each item to be considered by a convened IRB meeting, assigned reviewers are selected from the regular or alternate members of that specific IRB. Assigned reviewers may be designated as *primary* reviewers or *additional* reviewers.

The *primary* reviewer conducts a comprehensive review of all submitted materials for the assigned item, presents findings resulting from that review, provides an assessment of the criteria for approval, and recommends specific actions to the IRB. The primary reviewer leads the discussion of the assigned item.

One or more *additional* reviewers is assigned to new applications and to selected continuing reviews and modifications. Additional reviewers also conduct comprehensive reviews to supplement those provided by the primary reviewer, focusing on areas or issues not otherwise addressed. The additional reviewer may serve as the discussion leader in the unexpected absence of the primary reviewer.

All assigned reviewers are authorized and expected to contact investigators or other study personnel (if appropriate) to resolve questions or concerns whenever possible prior to the convened IRB meeting.

It is recommended that assigned reviewers use the IRB Reviewer Checklists and/or Reviewer Worksheets to assist in organizing and documenting reviews for presentation to committee members.

Assigned reviewers are expected to document reviews in the IRB electronic system at least 48 hours prior to the convened IRB meeting. This provides all members sufficient time to read the reviewer findings and recommendations, to be familiar with any issues, to contribute to the discussion, and to prepare to vote.

Pre-Meeting Distribution and Review of Documents in Advance of the Convened Meeting

Meeting agendas, including reviewer assignments and access to review materials, are distributed electronically to all members at least 1 week prior to the scheduled meeting date. See *Conduct of IRB Meetings* and *Management of IRB Member and Consultant Conflicts of Interest* for additional information. The IRB electronic system provides all IRB members (and alternates) access to the complete IRB record for each item under review, including the initial application, modifications, continuing reviews, reportable events, related reviewer notes, supporting materials, and the IRB minute history.

New Applications

Initial review materials available to the primary and additional assigned reviewers via the IRB electronic system include, when applicable, but are not limited to:

- IRB electronic application form
- Complete study protocol (DHHS-approved version when one exists)
- Proposed consent, assent, or HIPAA documents (DHHS-approved sample versions when available)
- Proposed consent or assent scripts
- Recruitment materials including any advertisements intended to be seen/heard by potential subjects
- Participant contact materials
- Any relevant grant application(s) and/or budget information
- Investigator's brochure, other study product information, or certificate of analysis
- Disclosures of Financial Interest and related letters of determination from the Conflict of Interest(COI) Review Board
- Certificate of Confidentiality
- Reviews by relevant Department/Division or Institutional committees (e.g. Pediatric and Adolescent Research Committee, Radiation Safety Committee, Biospecimen Subcommittee, OBGYN Research Committee, etc.)

Assigned reviewers perform a comprehensive review of each assigned item and make recommendations for consideration by the IRB. The reviewers assess whether:

- The ethical principles of research with human subjects are upheld
- All criteria at 45 CFR 46.111 (Criteria for Approval of Research) and 21 CFR 56.111 (as applicable) have been met
- The research includes enrollment of vulnerable subjects and if appropriate safeguards are in place
- The research involves use of an FDA-regulated product(s) and the regulatory status of the product(s)
- The consent process, as described by the investigator, is appropriate
- The consent document is understandable and contains all the required and additional elements as appropriate

- The study requires data and safety monitoring to ensure the safety of subjects
- The interval for continuing review of the research is appropriate.
- The research fulfills the criteria for referral for continuing review by expedited review procedures
- The research design and scientific merit are appropriate (often informed by departmental research scientific review recommendations)
- Conflict(s) of interest exist for any study team member(s) and, if present, there are adequate provisions to protect human subjects from any additional significant risk and to maintain the integrity of the research
- Ad hoc expertise (i.e. use of a consultant) is needed to assist in the review of issues which require expertise beyond or in addition to that available on the IRB (see *Use of Consultants by the IRB*)

As applicable to each new application under review:

- At least one member assesses whether the proposed research is consistent with any corresponding Department of Health and Human Services (HHS) funding application(s), and
- At least one member reviews the DHSS-approved sample consent document.

All members attending the convened IRB meeting have access to the same new application materials via the IRB electronic system. When a member is not an assigned reviewer, the member is to review, at a minimum, the following materials to prepare for active participation in the discussions and the vote:

- The full protocol, application, or a summary of sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111
- Proposed consent, assent, or HIPAA documents
- Proposed consent or assent scripts
- Any recruitment materials, including advertisements intended to be seen or heard by potential subjects

Modifications to Previously Approved Research

For convened IRB review of modifications to previously approved research:

- **All members** (including alternates in attendance) have access to and review the revised materials through the IRB electronic system.
- Assigned reviewers are selected from the regular or alternate members scheduled to attend the specific convened IRB meeting.
- Each assigned reviewer conducts a review of the request for modifications in accordance with the criteria for approval and assesses whether the proposed modifications are consistent with ensuring the continued protection of subjects. In addition, assigned reviewers consider whether:
 - Any new significant findings have arisen that may impact the subject's willingness to continue participation.
 - Any new information resulting from the modification or from other sources necessitates an adjustment to the IRB's prior determination(s), such as

inclusion of protected or vulnerable populations and findings regarding FDA-regulated products.

- The proposed modifications to the research require revision of the consent document(s), and if so, whether the revised consent documents are accurate and understandable to the subject population.
- The modifications warrant re-consenting of currently enrolled subjects or notification of subjects who have completed research interventions.
- Continuing review should occur more frequently than previously determined.
- Assigned reviewers present findings and recommendations during the convened IRB meeting.
- See Modifications to *Previously Approved or Exempt Research* for additional information.

Continuing Review

For continuing review of research by a convened IRB:

- **All members** (including alternates in attendance) have access to and review the:
 - Full protocol, application, or a protocol summary containing the relevant information necessary to determine whether the proposed research continues to fulfill the criteria for approval
 - Current consent document(s) (as applicable), and
 - A status report of the progress of the research (i.e. the investigator's continuing review application).
- Assigned reviewers are selected from the regular or alternate members scheduled to attend the specific convened IRB meeting.
- Each **assigned reviewer** conducts a comprehensive review of the ongoing research and status report, including the:
 - Full protocol,
 - Current consent document(s)(as applicable),
 - Modifications previously approved by the IRB and any occurring since the last IRB review, and
 - Progress and findings to date as reported in the investigator's continuing review application.
- At a minimum, assigned reviewers assess:
 - Whether the research continues to meet the criteria for approval,
 - If any new information resulting from the specific research under review or from other sources necessitates an adjustment to the IRB's earlier determination(s), and
 - The appropriate interval for continuing review.
- Assigned reviewers present findings and recommendations during the convened IRB meeting.

- See *Continuing Review of Research Projects* for additional information.
- NOTE: Revisions to research study protocol, consent form(s), or any other study materials proposed by the investigator at the time of continuing review, must be submitted as a separate request for modification via the IRB electronic system. The IRB will coordinate the review of the request for modification with the investigator's continuing review application, such that the items are considered by the same convened IRB during a single meeting.

Guidelines for Reviewer Presentations at Convened IRB Meetings

Oral presentations conducted by the primary reviewer should include:

- A succinct summary of the research study
- An overview of the population of subjects being studied, including protocol-specific findings pertaining to adequacy of protections for any vulnerable subjects
- As applicable, a description of the FDA-regulated product(s) under study and the regulatory status of the product(s), including recommendations for significant/non-significant risk device determinations
- A recommendation regarding whether or not the criteria for approval of research (45 CFR 46.111, and as applicable 21 CFR 56.111) are met
- Enough background to justify the performance of the research
- Information necessary for the members to make an informed decision on the approvability of the research
- A critique that includes pertinent deficiencies or criticisms of the application
- Comments regarding the consent process and the content of the consent document
- Points that should be changed by the investigator in sufficient detail so that other members and support staff understand what is needed in meeting minutes and notifications to the investigator
- A motion for a determination on the item. See the policy *IRB Determinations* for a description of the possible actions to be taken by vote.

Additional reviewers should focus on areas of disagreement with the previous reviewer(s) or on additional findings not previously covered.

Related Documents

[Conduct of Convened IRB Meetings](#)

[Management of IRB Member and Consultant Conflicts of Interest](#)

[Use of Consultants by the IRB](#)

[Modifications to Previously Approved or Exempt Research](#)

[Continuing Review of Research Projects](#)

[IRB Determinations](#)

Effective Date

March 23, 2016

Revision History

Date	Synopsis of Change
3/23/2016	Scheduled review – Removed language duplicated from “Purpose” under the “Procedure” section