IRB Determinations

Content Applies To

Mayo Clinic Human Research Protection Program

Purpose

This document describes the determinations which are used by the IRB to indicate the results of their review, and includes the appropriate investigator response/s upon receipt of the written notification from the IRB. This document also describes how the IRB notifies investigators and the institution in writing of its determinations.

Determinations

The IRB will render decisions on research activities and may make one of the following determinations:

Approved

The research activity, as submitted, meets the criteria for approval as defined in 45 CFR 46.111 (and 21 CFR 56.111, if applicable).

- The date of approval is the date on which the IRB reaches an approval determination.
- The investigator will not begin research activities until he/she has received the written IRB notification of approval.

Deferred

To secure approval, the IRB requires modifications in the research or other action(s) to be taken by the Investigator.

The IRB will include in its written notification of deferral, a statement of the reasons for its decision and give the Investigator an opportunity to respond. **Investigator deferral responses require review by the convened IRB.**

- Deferred New Application: The application may be revised and resubmitted for reconsideration by the IRB **or** the Investigator may provide justification to the IRB why the actions or changes are unnecessary.
    - The investigator will take the actions, make the requested changes, and/or justify in the deferral response why the actions or changes are unnecessary before the IRB will reconsider the application.
    - The investigator will include a copy of any revised documents including protocol and consent form with their deferral response.
    - The investigator will not begin the research activities until he/she receives written notification of approval from the IRB.
    - The date of approval is the date on which the IRB reaches an approval determination.
- Deferred Modification(s): The modification(s) cannot be implemented and the IRB expects the research will continue as previously approved.

    - The investigator will continue to conduct the research activities as previously approved by the IRB.
    - The investigator will take the actions, make the requested changes and/or justify in the deferral response why the actions and/or changes are unnecessary before the IRB will reconsider the application.
    - The investigator will include a copy of any revised documents including protocol and consent form with their deferral response.
    - The investigator will not implement proposed modifications until he/she receives written notification of approval from the IRB.
    - The date of approval is the date on which the IRB reaches an approval determination.
- Deferred Continuing Review:
    - The investigator will take the actions, make the requested changes and/or justify why the changes are unnecessary before the IRB will reconsider the application.
        - If the Continuing Review has not been approved by the expiration date, IRB approval will expire and the Investigator must proceed in accordance with IRB procedure *Expired IRB Approval*.
    - The investigator will include a copy of any revised documents including protocol and consent form with their deferral response.
    - The investigator will not continue the research activities beyond the expiration date until they have received the written notification of approval from the IRB.
    - The date of approval is the date on which the IRB reaches an approval determination.

Disapproved

The IRB has determined that the research activity, as submitted, does not meet the criteria for approval as defined in 45 CFR 46.111 (and 21 CFR 56.111, if applicable) and/or that the IRB requires substantial revisions to the application, informed consent document(s), or other relevant documents in order to assess the subject's risk/benefit ratio.

If the IRB disapproves a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing, at the discretion of the IRB.

- Disapproved New Application:
    - The application may be reconsidered as a new submission after substantial changes have been made to the study.
- Disapproved Modification(s):
    - The change cannot be implemented, and the IRB expects the research will continue as previously approved.

The investigator will not conduct any research activities that have been disapproved in writing by the IRB.

Tabled

An application may be tabled for the following reasons:

- Lack of meeting time to conduct thorough review of the item
- Loss of quorum
- Insufficient information to make a determination
- Other reasons as determined by the Chairperson
- The application will be placed on a future IRB agenda

The investigator will not initiate any new research activities or implement proposed changes to previously approved research until the application has subsequently been reviewed by the IRB and they have received written notification of IRB approval.

Notifications

The IRB notifies investigators in writing of its determinations, including decisions to approve, disapprove, or defer an item under review. When the IRB defers an item under review, the investigator is notified of the required investigator actions and mechanism for requesting further consideration by the IRB. If the IRB disapproves an application, a statement of the reasons for the disapproval is provided and the investigator may request to respond in writing or in person.

IRB notifications are generated by authorized IRB personnel and are issued through the electronic IRB system via electronic mail to the investigator and other study personnel designated by the investigator to receive the notifications.

Individual IRB notifications and the complete IRB record are available to the Institutional Official. The IRB procedure for reporting problems or events to the Institutional Official is described in *Reporting to the Institutional Official and Regulatory Agencies*.

Related Document

Expired IRB Approval

Reporting to the Institutional Official and Regulatory Agencies

References

45 CFR 46.111 *Criteria for IRB Approval of Research*

21 CFR 56.111 *Criteria for IRB Approval of Research*