

Institutional Review Board (IRB) Determinations Procedure - Arizona, Florida, Rochester

Scope

Applies to personnel in Mayo Clinic Human Research Protection Program when making determinations about research for which the Mayo Clinic IRB is the IRB of Record.

Purpose

To define the possible determinations resulting from IRB review of proposed research activities and the appropriate investigator responses. To describe how the IRB notifies investigators and the institution in writing of its determinations.

Equipment/Supplies

N/A

Procedure

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](#) and/or [32 CFR 219.111](#), when applicable.
 - The date of approval is the date on which the IRB reaches an approval determination.
 - The investigator shall not begin research activities until he/she has received the written notification of IRB approval.

Deferred

- To secure approval, the convened IRB requires modifications in the research or other action(s) to be taken by the Investigator.
- The convened 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 complete the defined 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 must include a copy of all revised documents with their deferral response.

- The investigator cannot 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 modifications cannot be implemented, and the research may continue as previously approved.
 - The investigator will continue to conduct the research activities as previously approved by the IRB.
 - The investigator will complete the defined 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 cannot 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 complete the defined actions, make the requested changes and/or justify why the recommended changes are not needed 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 cannot continue the research activities beyond the expiration date unless or 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

- A convened 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 and/or 32 CFR 219.111](#), when applicable and/or that the IRB requires substantial revisions to the application, informed consent documents, or other relevant documents in order to assess the risk/benefit ratio of the research
- When a convened IRB disapproves a research activity, it must 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 proposed study.
- Disapproved Modification(s):
 - The change cannot be implemented, and the research may continue as previously approved.
- The investigator shall not conduct any research activities that have been disapproved in writing by the convened IRB.

Tabled

A convened IRB may table an item 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 Chair

The investigator shall 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.

Exempt

The IRB has determined the human subject research activities meet the criteria for exemption under 45 CFR 46.104. Exempt human subject research activities do not require ongoing review by the IRB unless a change in the research is planned.

Not Research

The IRB has determined the proposed activities do not meet the definition of research under 45 CFR 46.102(i).

Not Human Subjects Research

The IRB has determined the proposed research activities do not involve human subjects as defined in 45 CFR 46.102(e)(1).

Notifications

- The Mayo Clinic IRB notifies investigators in writing of its determinations. IRB notifications are generated by authorized IRB personnel and are issued through the electronic IRB (IRBe) system via email to the investigator and other study personnel designated by the investigator to receive the notifications.
- 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 that deferred the item.
- When the IRB disapproves an initial application or modification, a statement of the reasons for the disapproval is provided and the investigator may request to respond in writing or in person to the IRB that disapproved the item.
- Investigators requesting appeal of deferral or disapproval by the IRB should provide written justification for the request to the IRB Medical Director. This request will be assigned to a convened IRB for review. It may or may not be the same convened IRB that made the initial determination once the IRB Medical

Director determines that the appeal is appropriate for convened IRB consideration. The convened IRB may choose to review the appeal or recommend reassignment to a different convened IRB for review.

- 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](#).

Troubleshooting

N/A

Procedural Notes

N/A

Related Documents

[Exempt Human Subjects Research](#)

[Expired IRB Approval](#)

[Reporting to the Institutional Official and Regulatory Agencies](#)

Definitions

N/A

References

[45 CFR 46.111](#) Criteria for IRB Approval of Research

[21 CFR 56.111](#) Criteria for IRB Approval of Research

[32 CFR 219.111](#) Criteria for IRB Approval of Research

Owner

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Contact

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Revision History

Date	Synopsis of Change
04/21/2022	Scheduled review. Updated owner and contact.
01/21/2019	Expanded determinations to include exempt, not research and not human subjects research. Updated owner and contact.
05/23/2018	Updated per AAHRPP recommendation that we state the Institutional Official has access to Investigator notifications and the complete IRB record.
02/27/2018	Scheduled review. Revised appeal process per Dr. Wright.
04/01/2016	Added appeals process per Administrative Executive Committee and minor editorial changes

02/24/2016

Scheduled review, no changes