IRB Determinations Procedure

Scope
Mayo Clinic Human Research Protection Program
Research for which the Mayo Clinic is the IRB of Record

Purpose
This document describes the determinations which are used by the Mayo Clinic 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 Mayo Clinic 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 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 will 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 will include a copy of any revised documents 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 research may continue as previously approved.
o The investigator will continue to conduct the research activities as previously approved by the IRB.

o 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.

o The investigator will include a copy of any revised documents including protocol and consent form with their deferral response.

o The investigator will not implement proposed modifications until he/she receives written notification of approval from the IRB.

o The date of approval is the date on which the IRB reaches an approval determination.

- Deferred Continuing Review:
  o The investigator will complete the defined 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*.
  o The investigator will include a copy of any revised documents including protocol and consent form with their deferral response.
  o The investigator will not continue the research activities beyond the expiration date unless or until they have received the written notification of approval from the IRB.
  o 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 document(s), or other relevant documents in order to assess the risk/benefit ratio of the research.

When a convened 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:
  o The application may be reconsidered as a new submission after substantial changes have been made to the proposed study.

- Disapproved Modification(s):
  o The change cannot be implemented, and the research may continue as previously approved.

The investigator will 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 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.

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 system via electronic mail 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**

Tammy Neseth on behalf of the Office for Human Research Protection

**Contact**

Michelle Daiss, Angie Patterson

**Revision History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Synopsis of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 21 2019</td>
<td>Expanded determinations to include exempt, not research and not human subjects research. Updated owner and contact.</td>
</tr>
<tr>
<td>May 23, 2018</td>
<td>Updated per AAHRPP recommendation that we state the Institutional Official has access to Investigator notifications and the complete IRB record.</td>
</tr>
<tr>
<td>February 27, 2018</td>
<td>Scheduled review. Revised appeal process per Dr. Wright.</td>
</tr>
<tr>
<td>4/1/2016</td>
<td>Added appeals process per Administrative Executive Committee and minor editorial changes</td>
</tr>
<tr>
<td>2/24/2016</td>
<td>Scheduled review, no changes</td>
</tr>
</tbody>
</table>