

## IRB ACTIONS AND COMMUNICATIONS

### 1. Overview

When reviewing research, the convened IRB is responsible for determining the approval status and appropriate approval period (up to one year) of a study under review, and must notify the investigator and institutional officials of its decisions.

This policy describes actions that the convened IRBs may take during review of research and communication of these actions, as well as the process for review of investigator responses to IRB determinations.

### 2. Definitions

**Approved:** An IRB action taken when the required determinations are made that allow research involving human subjects to proceed consistent with federal regulations, state and local laws, and University policy.

**Modifications Required:** An IRB action that specifies conditions under which research can be approved, pending the completion of minor, non-substantive (i.e., not directly relevant to the determinations required for approval by the IRB) clarifications or modifications to the protocol and/or informed consent process/document. *Note: Review of the investigator's response(s) may be performed by expedited review. Also: contingent approval.*

**Deferred:** An IRB action that specifies conditions under which research can be reconsidered for approval, pending substantive (i.e., directly relevant to the determinations required for approval by the IRB) clarifications or modifications to the protocol and/or informed consent process/document, without which, the IRB could not fully evaluate the research under review. *Note: Convened IRB review of the investigator's response(s) is required.*

**Disapproved:** 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:** An IRB "action" that indicates that review was not initiated or was not completed, resulting in postponement of convened 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.

**Approval Date:** The first date that research could be performed (following notification from the IRB). For research reviewed by the convened IRB, the approval date is the date that the research was approved at a convened meeting, or if modifications were required (to secure approval), the date that modifications were met by the investigator. For research reviewed

using expedited procedures, the approval date is the date that the research was approved by expedited review, or if modifications were required, the date that modifications were met by the investigator. *See also Approval Period.*

**Approval Period:** For research reviewed by the convened IRB, the interval that begins on the day that the research was approved or modifications were required (to secure approval) at a convened meeting; an approval period may not be longer than one year. *Note: For research reviewed by the expedited procedure, the approval period may be up to one year from the date that the research was approved or modifications were required by expedited review.*

**Expiration Date:** The date that the IRB's approval of research has lapsed and research can no longer be performed; an expiration date may not be longer than one year from the date the approval period begins.

### 3. Actions of the IRB

A. When reviewing research the convened IRBs will take one of the following actions:

- Approved
- Modifications Required
- Deferred
- Disapproved
- Tabled

B. These actions are applicable when the convened IRBs conduct initial review, continuing review, or review of amendments to previously approved research. Actions that can be taken when reviewing research by expedited procedures are described in OSU HRPP policy [[Expedited Review Procedures](#)].

### 4. IRB Review

Initial and continuing review of research and review of amendments to previously approved research by the convened IRBs are conducted as described in OSU HRPP policy [[Review of Research by the Convened IRB](#)]. Review of research by the expedited procedure is performed according to OSU HRPP policy [[Expedited Review Procedures](#)].

### 5. IRB Approval Period

A. The IRBs may approve research for a period of up to one year. The approval period for a study reviewed by the convened IRB is determined as described below.

B. For research reviewed by the convened IRBs, the date that the research was approved or modifications required at a convened meeting is the “start date” for the approval period.

Note: When modifications are required by the convened IRBs, the approval period begins

on the original meeting date that modifications were required, **NOT** the date that modifications were met.

- For example, if modifications were required for a study reviewed by the convened IRB on May 1, 2008, and the required modifications were met by the investigator on May 15, 2008, the maximum approval period is from May 1, 2008, to April 30, 2009.
- In the example above, the first date that the research could be performed (assuming that notification from the IRB is received) is May 15, 2008.

C. The expiration date is the first date following the approval period, on which the IRB's approval of research has lapsed and research can no longer be performed.

- For example, the expiration date for research that was approved on June 1, 2008, with a continuing review frequency of one year is June 1, 2009.

## 6. Frequency of IRB Review

A. The IRBs will require continuing review at intervals appropriate to the degree of risk, but not less than once per year. The criteria used to consider whether more frequent review is required includes, but is not limited to, the following:

- High-risk research where there is concern about serious adverse events
- Research where the potential risks in humans are unknown and may have the potential to be serious (e.g., phase I drug study)
- Protocols with complex regulatory compliance requirements, such as research involving an investigator-held IND or IDE
- Research being conducted in international or other off-site location(s) when an OSU IRB is serving as the IRB of record
- Research in which an investigator has a potential conflict of interest that warrants more frequent reporting and review
- Investigator/protocol has had compliance problems in the recent past
- Other issue warranting more frequent review at the discretion of the IRB.

B. Depending on the research, the following types of interval frequencies may be considered:

- Specified time period (such as annual, semi-annual, or quarterly review)
- Requirement to report back to the IRB after a specified number of participants have been enrolled or undergone study interventions
- Other point in the research meriting reporting and review (e.g., completion of phase I of a multi-phase study).

## 7. Review of Investigator Responses

- A. When the convened IRBs require modifications to research, review of the investigators' responses to modifications without subsequent review by the convened IRB represents review by the expedited procedure. When the conditions for approval are not met, the IRB Chairs, Vice Chairs, or designated expedited reviewers will refer the submission to the convened IRBs for review (i.e., research cannot be disapproved by expedited review).
- B. When research is deferred by the convened review, only the convened IRB may reconsider the substantive (i.e., directly relevant to the determinations required for approval by the IRB) clarifications or modifications made to the research. Whenever possible, the original IRB reviewer(s) will be reassigned review of the research.
- C. When research is disapproved, an investigator will submit a new, revised application to request approval. Review of such applications will be by the convened IRB unless the research meets criteria for expedited review, as described in OSU HRPP policy [[Expedited Review Procedures](#)].
- D. Investigator appeals of IRB decisions are reviewed by the convened IRBs as described in OSU HRPP policy [[Review of Research by the Convened IRB](#)].
- E. For IRB actions that require a response(s) from an investigator before the research is approved if a response is not received within 30 days, a reminder notice is sent. A follow-up reminder is sent at 60 and 90 days. If a response is not received within 90 days, the principal investigator will be notified that the submission will be withdrawn.

## 8. Communication of IRB Actions

- A. Once the IRB Chairs (or designees) approve the minutes from the convened IRB meetings, including determinations made by the Boards, the IRB Protocol Analysts prepare notification letters on behalf of the IRBs to inform investigators of the outcome of IRB review. Note: Approval letters can be sent prior to completion of the meeting minutes.
- B. Notification letters include (minimally) the following information:
  - Date of the review
  - Type of submission reviewed (e.g., initial review, continuing review, or review of amendments to previously approved research)
  - IRB action
  - Approval and expiration date (when applicable)
  - Any associated approvals requiring specific regulatory findings (e.g., waiver of the requirement for obtaining informed consent)
  - Modifications or additional clarifications, if any, required for IRB approval

- For research that is deferred, a statement of the reasons for deferral and a description of how the investigator can respond
- For research that is disapproved, a statement of the reasons for disapproval and a description of how the investigator can respond.

C. IRB members and institutional officials are notified of the IRBs' actions and findings via summary documentation that is posted on the secure IRB Members' web page.

## **9. Applicable Regulations/Guidance**

21 CFR 56.111, 45 CFR 46.111, FDA Information Sheets: Frequently Asked Questions: "IRB Procedures" and "IRB Records", OHRP "Guidance on Written IRB Procedures" (01/15/07)