THE OHIO STATE UNIVERSITY

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 allows 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 following: confirmation of specific understandings by the IRB about how the research will be conducted, submission of additional documentation, precise language changes to the protocol and/or informed consent document(s), and/or substantive changes to documents with specific parameters the changes must satisfy. *Note: Verification that the investigator's response(s) satisfies the conditions for approval set by the IRB may be performed by the IRB Chair and/or other designated individual(s). Also: contingent approval, approval with conditions.*

Deferred: An IRB action taken when the convened IRB cannot fully evaluate the research under review and make the determinations required for approval without modifications to the protocol and/or informed consent document, or submission of clarifications or additional materials prior to reconsideration of the research. *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 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 can be performed (following notification from the IRB), consistent with federal regulations, state and local laws, and university policy. The approval date is the date that the research is approved by convened or expedited review, or if modifications are required (to secure approval), the date that the modifications/conditions are met by the investigator. *See also Approval Period.*

Approval Period: For initial review, the interval that begins on the day research is approved by convened or expedited review, or if modifications are required (to secure approval), the date that the modifications/conditions are met by the investigator. For continuing review, the interval that begins on the day research is re-approved (by convened or expedited review) or modifications are required. If the modifications are not met prior to the continuing review expiration date, the interval will begin on the date that the modifications/conditions are met by the investigator. *Note: An approval period for initial or continuing review may not be longer than one year.*

Expiration Date: The date that the IRB's approval of research has lapsed and research can no longer be performed. *Note: 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 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 HRPP policy [Review of Research by the Convened IRB]. Review of research by the expedited procedure is performed according to HRPP policy [Expedited Review Procedures].

5. IRB Approval Period

A. The IRBs may approve research for a period of up to one year. The initial and continuing review approval periods for a study reviewed by either convened or expedited review are determined as described below.

B. For initial review, the date that research is approved, or if modifications are required (to secure approval), the date that the modifications/conditions are met by the investigator is the "start date" for the approval period.

- For example, if modifications were required for a study reviewed by the convened IRB on May 1, 2016, and the required modifications/conditions were met by the investigator on May 15, 2016, the maximum approval period begins May 15, 2016, and ends May 14, 2017.

- In the example above, the first date that the research can be performed (assuming that notification from the IRB is received) is May 15, 2016.

C. For continuing review, the date that research is re-approved or modifications are required is the "start date" for the approval period. Note: When modifications are required, the approval period begins on the date that modifications are required by the IRB (e.g., date of the convened meeting), **NOT** the date that the modifications/conditions were met by the investigator, which is different from the initial review "start date."

- For example, if modifications were required for a study reviewed by expedited procedures on May 1, 2016, and the required modifications/conditions were met by the investigator on May 15, 2016, the maximum approval period begins May 1, 2016, and ends April 30, 2017.

D. 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, 2016, with a continuing review frequency of one year is June 1, 2017.
- In the example above, the last date that the research can be performed (unless the study is re-approved) is May 31, 2017.

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 a university 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 IRBs require modifications to research, investigators' responses will be reviewed to verify that the conditions for approval have been satisfied. Depending on the nature of the modifications, this subsequent review/verification may be performed by the IRB Chair, one or more IRB members or a consultant with specific expertise, and/or qualified ORRP staff (who may or may not be IRB members). Questions about whether the conditions for approval have been satisfied will be forwarded to the IRB Chairs or Vice-Chairs. When the conditions for approval are not met, investigators will be notified; and the submission will be referred to the convened IRBs for review (i.e., research cannot be disapproved except by convened review). For specific details regarding the administrative review/verification of investigators' responses to modifications, see Attachment 1.

B. When research is deferred by convened review, only the convened IRB may reconsider the clarifications and/or modifications made to the submission. 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 IRBs unless the research meets the criteria for expedited review, as described in HRPP policy [Expedited Review Procedures].

D. Investigator appeals of IRB decisions are reviewed by the IRBs as described in HRPP policy [Review of Research by the Convened IRB].

E. For IRB actions that require a response(s) from an investigator before the research can proceed, reminder notices are sent weekly from the Buck-IRB system until a response is received. If the response is not received within 90 days, the principal investigator will be notified that the submission has been administratively withdrawn.

8. Communication of IRB Actions

A. After the IRB Chairs (or designees) approve the minutes of the convened IRB meetings, ORRP staff prepare notification letters to inform investigators of IRB actions. Note: Approval letters can be sent prior to completion of the meeting minutes.

B. Notification letters sent from Buck-IRB include (minimally) the following information:

- Date of 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 required, or other conditions that must be satisfied by the investigator, if any, for IRB approval

- For initial review, any conditions under which the research may be initiated
- For continuing review and amendments, any conditions that must be satisfied before an investigator can continue research activities
- 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 Buckeye Box IRB distribution website.

9. Applicable Regulations/Guidance

21 CFR 56.109, 21 CFR 56.111, 45 CFR 46.108, 45 CFR 46.109, 45 CFR 46.111, FDA Information Sheets: Frequently Asked Questions: "IRB Procedures" and "IRB Records," OHRP "Guidance on IRB Approval of Research with Conditions" (11/10/10), OHRP "Guidance on Written IRB Procedures" (01/15/07)

10. History

Issued: 05/19/2008
Revised: 06/06/2008, 04/28/2009, 03/1/2012, 05/09/2012, 06/14/2016

Attachment 1.

Administrative Review/Verification of Investigators' Responses to Modifications

An IRB may specify conditions under which research can be approved (i.e., "modifications required") that, when satisfied, would permit the IRB to make the required determinations. The IRB may require any of the following as conditions for approval of research:

- Confirmation of specific understandings by the IRB regarding how the research will be conducted (e.g., the research will not include children)
- Submission of additional documentation (e.g., letters of support)
- Precise language changes to the protocol and/or informed consent document(s)
- Substantive changes to documents along with specific parameters the changes must satisfy.

When the IRBs require modifications to research, investigators' responses will be reviewed to verify that the conditions for approval have been satisfied. Depending on the nature of the modifications, this review/verification may be performed by the IRB Chair, one or more IRB members or a consultant with specific expertise, and/or qualified ORRP staff (who may or may not be IRB members).

Conditions that involve the application of specific scientific, scholarly, medical, or other professional or technical expertise (beyond knowledge of applicable human subjects protection requirements) should be reviewed by the IRB Chair or IRB member(s) or consultant with appropriate experience/training. In general, review of substantive changes to the protocol or informed consent documents, even with specific parameters that the changes must satisfy, should also be performed by the IRB or other designated individuals with the requisite knowledge.

Examples of investigators' responses to "modifications required" by the IRB that may be administratively reviewed/verified by qualified ORRP staff include the following:

1. Submissions of additional documentation, including letters of support, Individual Investigator Agreements, Certificates of Confidentiality, etc.
2. Corrections of grammatical and/or typographical errors in study documents, such as recruitment materials, consent forms, questionnaires, etc.
3. Verbatim changes (additions or deletions) to study documents or other submission materials, including the protocol, consent form, study instruments, IRB application, appendices, etc.
4. Revisions to consent documents to include template language (e.g., institutional contact information).
5. Changes in formatting, font size, etc. in consent forms, advertisements, or other recruitment materials or documents that will be seen by research participants.
6. Changes in method and/or timing of incentives to include pro-rated payments that are not contingent upon completion of the entire study.
7. Copies of translations of approved documents for previously approved participant groups.