THE OHIO STATE UNIVERSITY



# REVIEW OF RESEARCH BY THE CONVENED IRB

**LANGUAGE IN GRAY BOXES IS ONLY APPLICABLE TO STUDIES APPROVED ON/AFTER JANUARY 21, 2019**

## 1. Overview

All research involving human subjects reviewed by the convened IRB must be evaluated for issues in proposed study design and conduct that may affect the rights and welfare of human subjects, consistent with federal regulations, state and local laws, professional standards, and university policy.

The purpose of this policy is to describe the procedures used by the Office of Responsible Research Practices and the convened IRBs when processing and reviewing submissions for initial and continuing review and for amendments to previously approved research to ensure the protection of research participants. Convened review of reportable events is described separately in HRPP policy [Event Reporting – Unanticipated Problems Involving Risks to Subjects or Others, Adverse Events, and Other Problems].

## 2. Definitions

**Appeal:** Request for reconsideration of an IRB determination in research involving human subjects, including (but not limited to) decisions regarding approval status, conditions for approval, or noncompliance. *Note: An appeal is reviewed by the convened IRB responsible for the determination being appealed; for a decision made by expedited review, the corresponding convened IRB may review the appeal. Also: request for reconsideration.*

## 3. General Information on Convened Review

**A.** The IRB must provide substantive and meaningful review of research on a continuing basis, at the interval (at least once a year) established by the IRB at the prior review. IRB review must be performed by the convened IRB unless the research meets the criteria for expedited review, as described in HRPP policy [Expedited and Administrative Review Procedures].

**B.** To be approved, research that is reviewed by the convened IRBs must satisfy all of the following regulatory requirements:

- Risks to participants are minimized (but not necessarily eliminated) by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk. Whenever appropriate, risks to participants are minimized by using procedures already being performed for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits (if any), and the importance of the knowledge that may reasonably be expected to result from the research. Note: *The IRB will consider risks and benefits that may result from the research, not risks and benefits of treatments or other activities the subject would undergo even if he or she were not participating in the research*.

- Selection of participants is equitable, taking into account the purposes of the research and the setting in which the research will be conducted. (For more information on equitable selection and recruitment, see HRPP policy [Recruiting Methods, Recruitment Materials, and Participant Compensation]).
- Informed consent is sought, obtained, and appropriately documented for each prospective participant or the participant's legally authorized representative as required by the regulations (unless the appropriate waivers have been requested and approved by the Board). (For more information, see HRPP policies [Informed Consent Process and Elements of Informed Consent] and [Documentation of the Informed Consent Process]).
- If the research involves greater than minimal risk, the data and safety monitoring plan and/or data and safety monitoring board (where appropriate) makes adequate provision for monitoring the data collected to ensure the safety of participants.
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data in accordance with HRPP policy [Privacy and Confidentiality].
- When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

**C.** When research involves the use of articles regulated by the Food and Drug Administration (e.g., drugs, devices, and biologics) or is otherwise regulated by the FDA, the convened IRB will also consider:

- Marketing status of the drug or device (e.g., investigational, investigational use of an FDA-approved product, or FDA-approved product used for an approved indication)
- For drugs, the appropriateness of the dose, formulation, and route of administration
- For devices, the recommended risk status of the device (i.e., significant or non-significant)
- For investigational agents, safety and efficacy data supporting the proposed phase of testing
- For investigational agents, a description of the plan for assuring appropriate accountability, storage, access, and control of the investigational agent(s)

For more information, see HRRP policies [Research Involving Investigational Drugs] and [Research Involving Medical Devices].

## 4. Convened Review Procedures

**A.** Once the Buck-IRB application has been submitted and determined to be complete in accordance with HRPP policy [Submission and Pre-Review], ORRP staff will determine the appropriate Board for review and assign appropriate reviewer(s) as described in HRPP policy [Board Assignment and Reviewer Assignment for Convened Review].

**B.** ORRP staff will prepare and distribute IRB materials as described below to IRB members in advance of the meeting in order to provide sufficient time for review, generally at least seven days before convened meetings. In extenuating circumstances (e.g., IRB approval would lapse without review), when sufficient space exists on a meeting agenda for a late submission, materials may be forwarded to IRB members past this deadline.

### 4.1 Initial Review

**A.** All IRB members are responsible for reviewing the submitted materials in enough depth to be familiar with and prepared to discuss the information at the convened meeting. All IRB members will receive and review the following materials:

- Buck-IRB initial review application
- Consent form(s), assent form(s) and permission form(s), and verbal script(s), including translated documents, as applicable
- Recruitment materials, as applicable, including advertisements intended to be seen or heard by potential participants
- Study instruments such as questionnaires, surveys, etc.

In addition to the materials above, the primary reviewers are also responsible for providing an in-depth review of the following:

- Complete research protocol
- Investigator's brochure, as applicable
- Questionnaires, when longer or more detailed than those normally reviewed by all IRB members
- Relevant grant application or funding proposal, as applicable
- All other information provided by the investigator

If the research is a DHHS-supported multi-center clinical trial, the primary reviewers also receive a copy of:

- DHHS-approved sample informed consent document (when one exists)
- Complete DHHS-approved protocol (when one exists)

**B.** Any IRB member can access the complete IRB file for review upon request to ORRP staff, prior to or during the convened meeting.

**C.** The primary reviewers are responsible for presenting findings regarding the submission and leading the discussion at convened IRB meetings. Additionally, all IRB members are responsible for the following:

- Declaration of any conflicting interests in accordance with HRPP policy [IRB Member and Consultant Conflict of Interest]
- Consideration of the need for any additional expertise
- Communication with investigators, as applicable

**D.** Reviewers will document their review and assessment of the research by completing an *IRB Reviewer Sheet* and submitting it via the IRB distribution website or in person to an ORRP staff member at the conclusion of the convened IRB meeting.

### 4.2 Continuing Review

**A.** Investigators and the IRBs should "plan ahead" to meet applicable continuing review requirements, allowing adequate time before the expiration date for review of the research and for resolution of any modifications that may be required prior to its re-approval.

**B.** Research approved under the pre-2018 Common Rule, must undergo continuing review as long as the protocol remains active and involves human subjects.

**C.** Research approved under the Final Rule, must undergo continuing review if one or more of the following is true:

- FDA-regulated
- Greater than minimal risk
- Remains active and involves human subjects interventions

**D.** Under certain conditions, continuing review of research previously approved by the convened IRB may receive expedited or administrative review in accordance with HRPP policy [Expedited and Administrative Review Procedures].

**E.** All IRB members are responsible for reviewing the submitted materials in enough depth to be familiar with and prepared to discuss the information at the convened meeting. All IRB members will receive and review the following materials:

- Buck-IRB continuing review application, including:
  - Protocol summary
  - Status report on the progress of the research
- Current informed consent document
- Recruitment materials (if still in use), including advertisements intended to be seen or heard by potential participants
- Study instruments (if still in use) such as questionnaires, surveys, etc.
- Relevant multi-center trial reports
- Data and safety monitoring reports (as applicable)
- Any interim findings
- Any other relevant information or recent literature, especially information about risks associated with the research
- Summary of participant benefits
- Current risk-benefit assessment based upon study results

In addition to the materials above, the primary reviewers are also responsible for providing an in-depth review of the following:

- Complete research protocol (including any amendments previously approved)
- Investigator's brochure, as applicable

- Questionnaires, when longer or more detailed than those normally reviewed by all IRB members
- Relevant grant application or funding proposal, as applicable
- All other information provided by the investigator

If the research is a DHHS-supported multi-center clinical trial, the primary reviewers also receive a copy of the following:

- DHHS-approved sample informed consent document (when one exists)
- Complete DHHS-approved protocol (when one exists)

**F.** Any IRB member can access the complete IRB file for review upon request to ORRP staff, prior to or during the convened meeting.

**G.** The primary reviewers are responsible for presenting findings regarding the submission and leading the discussion at convened IRB meetings. Additionally, all IRB members are responsible for the following:

- Declaration of any conflicting interests in accordance with HRPP policy [IRB Member and Consultant Conflict of Interest]
- Consideration of the need for any additional expertise
- Communication with investigators, as applicable

**H.** As with initial review, the IRBs must determine that the regulatory criteria for approval are met. Additionally, during continuing review the IRBs must also find the following:

- The informed consent document is accurate and complete.
- No material changes have occurred since the previous IRB review.
- Significant new findings that may relate to a participant's willingness to continue taking part in the research are provided.

**I.** The IRBs will consider obtaining verification from sources other than the investigator(s) that no material changes have occurred since previous IRB review in the following situations:

- Numerous protocol deviations or violations reported
- Inconsistent information/documentation submitted for continuing review
- Previous investigator noncompliance involving changes without IRB approval
- Complaint from research personnel or participant(s)

**J.** Reviewers will document their review and assessment of the research by completing an *IRB Reviewer Sheet* and submitting it via secure website or in person to an ORRP staff member at the conclusion of the convened IRB meeting.

**K.** If an investigator fails to provide continuing review information to the IRB, or the IRB has not reviewed and approved a protocol by the expiration date:

- The investigator is notified immediately of the study expiration, and research activities must stop, including recruitment, enrollment, interventions, interactions, and data analysis.

- For current participants, investigators who believe it is in the best interest of individual subjects to continue participating in the research interventions or interactions must contact the IRB chair. The chair will determine whether there is an overriding safety concern or ethical issue involved that justifies individual subjects' continued participation in the research.
- The IRB will determine whether the lapse in approval should be evaluated as noncompliance in accordance with HRPP policy [Noncompliance].

### 4.3 Review of Amendments

**A.** Changes to IRB-approved research may not be initiated without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to participants. Minor changes to previously approved research can be reviewed by expedited procedures as described in HRPP policy [Expedited and Administrative Review Procedures]. Changes meeting the definition of "minor changes" are described (with specific examples provided) in HRPP policy [Expedited and Administrative Review Procedures].

**B.** Amendments that do not meet the criteria for expedited review must be reviewed by the convened IRB. All IRB members will be provided all modified documents (and any other information supplied by the investigator) and are responsible for reviewing the submitted materials in enough depth to be familiar with and prepared to discuss the information at the convened meeting.

**C.** Any IRB member can access the complete protocol file for review purposes upon request to ORRP staff, prior to or during the convened IRB meeting.

**D.** The primary reviewer(s) are responsible for presenting findings regarding the submission and leading the discussion at convened IRB meetings. Additionally, all IRB members are responsible for the following:

- Declaration of any conflicting interests in accordance with HRPP policy [IRB Member and Consultant Conflict of Interest]
- Consideration of the need for any additional expertise
- Communication with investigators, as applicable

**E.** As with initial and continuing review, for a proposed amendment the IRBs must determine that the regulatory criteria for approval are met (when the modification affects one or more criteria for approval). Additionally, the IRBs must also find that significant new findings that may relate to a participant's willingness to continue taking part in the research are provided.

**F.** Reviewers will document their review and assessment of the amendment by completing an *IRB Reviewer Sheet* and submitting it via secure website or in person to an ORRP staff member at the conclusion of the convened IRB meeting.

**G.** Changes to approved research initiated without IRB approval that are made to eliminate apparent immediate hazards to subjects may represent unanticipated problems involving risks to subjects or others and should be promptly reported as described by HRPP policy [Event Reporting – Unanticipated Problems Involving

Risks to Subjects or Others, Adverse Events, and Other Problems]. Such changes will be reviewed by the convened IRB to determine whether the change is consistent with ensuring the continued welfare of participants.

**H.** Completion and/or closure of a study also represent changes to research. A *Final Study Report* is submitted to notify the IRB that a study is completed or is being closed. Notification of study completion/closure may be submitted at any time during the review period. A *Final Study Report* form should not be submitted until all research activities involving human subjects, including collection and/or analysis of private, identifiable (or coded) data and/or biospecimens have ended.

Note: For further information regarding data retention following study completion, see the university's Research Data policy and HRPP policies [IRB Recordkeeping] and [Research Involving Data and/or Biospecimens].

## 5. IRB Determinations and Post-Review Procedures

**A.** The range of possible actions that the convened IRBs may take following review of research is described in HRPP policy [IRB Actions and Communications]. To approve research, the IRBs must determine that the research meets the regulatory criteria for approval.

**B.** Determination of the approval period for research approved by the convened IRBs is made as described in HRPP policy [IRB Actions and Communications].

**C.** IRB actions and findings will be reported to the principal investigator and institutional officials as described in HRPP policy [IRB Actions and Communications].

**D.** Research that has been approved by the IRBs may be subject to further review and approval (or disapproval) by officials of the institution (e.g., institutional official, deans, college research officers, etc.). However, no one may approve human subjects research (i.e., and authorize it to proceed) that has not been approved by the IRB.

## 6. Investigator Appeals/Requests for Reconsideration

**A.** Investigators may appeal an IRB decision by submitting a request addressed to the appropriate IRB chair to IRBinfo@osu.edu, including a statement of the reason(s) for the appeal and any materials supporting the request. Supporting materials may include (but are not limited to) letters of support, current literature, and/or other information relating to the state of the art/science in the research discipline.

**B.** Requests for reconsideration will be reviewed by the convened IRB responsible for the determination being appealed. Decisions made by expedited review can be reconsidered by expedited review, but rejection of an appeal can be made only by the corresponding convened IRB. Investigators will be notified of and may attend the IRB meeting at which this review will occur.

**C.** Appeals must be made within 30 days of investigator notification of the IRB decision in question. The IRB will review the request within 30 days of receipt of the investigator's written materials. Investigators and institutional officials will be notified of the IRB's

decision regarding the appeal within 14 days of convened review as described in HRPP policy [IRB Actions and Communications].

**D.** Institutional officials may not overrule IRB decisions regarding appeals in research activities involving human subjects.

**7. Applicable Regulations/Guidance**

21 CFR 50.25, 21 CFR 56.108, 21 CFR 56.111, pre-2018 and Final Rule (45 CFR 46.103, 45 CFR 46.111, 45 CFR 46.116), FDA Information Sheets: Frequently Asked Questions, OHRP "Guidance on Continuing Review" (11/10/10), OHRP "Institutional Review Board Written Procedures: Guidance for Institutions and IRBs" (05/18), The Ohio State University "Research Data Policy" (03/24/17)

**8. History**

Issued: 05/19/2008
Revised: 04/28/2009, 06/07/2009, 01/06/2011, 05/04/2012, 06/20/2016, 12/17/2018
Edited: 01/14/2022, 04/20/2022