Issuing Department: Human Subjects Protection Program
Policy Number: 2011-009.5
Policy Title: Institutional Review Board (IRB) – Review by Convened Board

Purpose

The purpose of this policy is to describe when and how the IRB members conduct reviews (initial, continuing, and modifications) in preparation for and at a convened meeting.

Definitions

See policy 2011-007.0 for definition of:

Risk, Minimal	Test Article

Policy

Proposed research that does not qualify for either exempt status or expedited review will be sent to the convened board for review. If the board determines that the study is minimal risk and continuing review is a requirement, continuing review may be done through expedited review providing that 1) there have been no changes or developments that indicate an increase in risks to subjects, 2) prisoners are not involved as subjects (excluding studies for which activity is limited to chart reviews) and 3) the study does not involve the use of an investigational test article.

A primary reviewer system will be used for all types of reviews conducted by the board. The reviewer form used by the primary reviewers to conduct reviews of studies incorporates the regulatory criteria for approval and specific points for consideration under each criterion. This is an unofficial document that guides the review process. Determinations made at a convened meeting will be documented in the meeting minutes and supersede the comments of the individual reviewer on the reviewer form.

For initial review of studies subject to FDA oversight one reviewer will be an M.D. (for drug or device studies) or a Pharm.D. (drug studies).

For initial submissions, continuing submissions and submissions of requests for modifications, all members of the IRB are provided with and review sufficient information about the proposed research (or change in the proposed research) to determine that the research fulfills the regulatory criteria for approval. At least one member will be provided with and review the Investigators Brochure, when one exists. For initial submission at least one member is provided and reviews the DHHS approved sample consent (when one exists); the complete DHHS-approved protocol (when one exists) and any relevant grant application.

For continuing review submissions, all members are provided with the submission materials for review prior to the convened meeting. Any member of the IRB (or consultant) may request to see additional information, including the IRB file and previous minutes related to the study. When modifications are requested as part of a continuing review submission, all members have access to previously approved documents and the newly proposed documents in order to compare versions and review changes, such as the current consent document and any newly proposed consent document.

When there are contingencies that must be addressed before final approval can be granted, the Regulatory Specialist (RS)* may review the responses and grant the final approval. This does not preclude the RS from assigning the review to the Chair or other experienced IRB member.

*The RS does not have to be a member of the IRB in order to review such responses. Experienced staff of the HSPP/IRB may also conduct the review of response material and issue the approval if the RS is unavailable.

Procedure

Screening

A designated RS will screen the submission for completeness and, during this screening process, may request through communications in the electronic system that the PI provide additional documents or clarifications.

Once all requested additional information is received, the submission will be eligible for review and approval and the RS will place the submission on the agenda for the next regularly scheduled IRB meeting.

Assigning Reviewers

At least two primary reviewers are assigned to each submission. The RS may make the preliminary assignments but the Chair will make the final determination of assignments. The RS / Chair will ensure one scientific and one experienced member is assigned to each study, ensuring that at least one of the primary reviewers has the appropriate scholarly and scientific expertise.

Primary Reviewers

Members will have at least 5 days for review of the material prior to the meeting date. The assigned reviewers will be notified of assignments by e-mail notifications generated from the electronic submission system.

A primary reviewer system will be used for initial and continuing review and review of modifications. The two primary reviewers will receive and review all material requested on the initial/continuing application checklist, or the instructions for requesting a modification, as applicable to the study, including the complete protocol and any protocol modifications previously approved by the IRB. Reviewers may elect to contact the Principal Investigator (PI), either directly or through the IRB office, to seek clarification or additional information prior to the convened meeting.

All other IRB members will have access to the same documentation as the primary reviewers, and at a minimum will be expected to review the relevant IRB form (e.g. application, request for modification, addendum to application for continuation), the consent form and other relevant material (e.g. recruitment material, survey tools etc.) such that they can participate fully in the discussion, deliberation and voting.

At the convened meeting the primary reviewers will present a summary of the study, noting any concerns with specific items in the submission. Discussion and voting will follow. A majority vote of the members present will decide the motion.

If one or both of the primary reviewers are absent the review will be deferred unless the Chair or another member or consultant has also conducted an in-depth review of the study and has the appropriate expertise, or the absent reviewers have provided a detailed written summary of the review such that the Chair determines there is sufficient information available to conduct the review.

The RS will document the determinations of the convened board in the minutes. The RS will send the minutes of the meeting to the membership for review and comment. The RS may also send the minutes to other parties with a legitimate interest as needed / requested (e.g. Research Compliance).

Communications

Decisions of the convened IRB will be communicated to the PI in writing through the electronic submission system. This correspondence, and related documents, will be sent to the PI by the RS after the minutes of the meeting have been provided to the IRB panel and the members have had 48 hours to respond with any comments/corrections. Official communication from the RS to the PI is to be sent within approximately 10 working days after the meeting date.

- For submissions that have been approved as submitted the RS will send to the PI the standard approval letter accompanied by other study related documents.
- For submissions that are approved contingent upon minor modification or confirmation of IRB assumptions, the standard approved contingent letter, along with a list of contingencies, will be prepared and sent by the RS. The IRB Chair, or RS, will review* responsive material. If issues have not been satisfactorily addressed the communication cycle will repeat. If the Chair or RS and the investigator disagree on the adequacy of a response, the material will be placed on the agenda for the next convened meeting for which the submission deadline has not passed. Once the Chair or RS determines that all contingences are addressed, the RS will then send to the investigator the standard approval letter, accompanied by other study related documents.
- If there is a contingent issue that the PI must address to secure continuing approval, the RS may inform the PI informally via phone or e-mail the day after the meeting to allow sufficient response time to prevent a lapse in the continuing approval of a study. The PI will be informed that the official communication will be forthcoming after the minutes have been reviewed by the membership.
- For studies that are deferred the standard deferral letter, with a listing of contingencies, will be prepared and sent by the RS. This letter will explain the reason for the deferral. Responses to deferred protocols will be reviewed at subsequent meetings following the same procedures for the type of review. For example, if a study is deferred on initial review, the response will be handled as an initial review being reviewed by the convened board. When possible the same primary reviewers will be assigned.
- For studies that are disapproved a letter will be prepared by the RS and signed by the Chair. The letter will describe the reasons for the disapproval and how the investigator may respond. Refer to the section regarding Investigator Appeals for more details.

***While the RS or Chair are the default reviewers, response material may be reviewed by any member of the IRB or experienced staff of the IRB/HSPP.**

Related Policies

2011-007.0 – Definitions Applied to Policies
2011-009.4 – Institutional Review Board - Convened Meeting Operations
2011-009.7 – Institutional Review Board – Assignment of Status Codes
2011-009.8 – Institutional Review Board – Appeals Process
2011-009.10 – Institutional Review Board – More Frequent Review

Basis

45 CFR 46
21 CFR 56
OHRP - Guidance on IRB Approval of Research with Conditions (11/10/2010)

Document Attributes

Effective Date: 11/20/23

Replaced Version: 2/5/2018

Reviewed and Approved By:

Richard H. Simon *11/01/23*

Richard H. Simon, MD **Date**
Director Human Subjects Protection Program