



CONDUCT OF A CONVENED MEETING OF THE DUHS INSTITUTIONAL REVIEW BOARD

7/7/2021

This document serves as guidance for the conduct of convened meetings of the Duke University Health System Institutional Review Board (DUHS IRB).

A. Definitions

Amendments: Also refers to business items. Amendments are processed according to the "Amendments Policy".

Deferral: A submission presented for re-review after responding to deficiencies from a previous review, which were unable to be approved using the expedited procedure.

Discussion Items: An item considered by the IRB that is not a new study, renewal, amendment, deferral or safety event. Examples include modifications requiring full board review, reports to IRB of emergency use of a test article, or audit reports for noncompliance assessment.

New Studies: Research studies submitted to the IRB for initial review.

Primary Reviewer: The IRB member who is responsible for the in-depth review and presentation of a protocol at an IRB meeting.

Renewal: Research studies previously approved by the IRB and submitted for continuing review, as required by 45 CFR 46.109 and 21CFR 56.109.

Safety Event: Adverse event reports, reports of unanticipated problems or other problems, protocol deviations, and some sponsor correspondence. Safety events are processed according to the applicable policy, either "Problems or Events That Require Prompt Reporting to the IRB" or "Non-compliance with the Requirements of the Human Research Protection Program."

B. Preparation for Meeting

A Meeting Team in the IRB will consist of one Chair, one Vice Chair, one Writer and one Board Specialist. Meetings will be held on consecutive Wednesdays and Thursdays from 1 pm until approximately 4 pm, or longer as required. Rapid response and noncompliance boards may meet at different days/times, as needed. For the purposes of this document, two IRB meetings held on a consecutive Wednesday and Thursday will be referred to as "IRBs A/B". At least two weeks prior to the IRB Meeting, Board Specialists will identify approximately 20 to 25 items per meeting from iRIS. These items will be assigned to the agendas.

- Agenda items will consist of new studies, continuing reviews (renewals), amendments, and safety events. These will be assigned to IRBs A/B in equivalent proportions based on: (i) the subject matter of the study; and (ii) the expertise represented on each IRB. Agendas may also include deferrals and discussion items.
- Approximately ten days prior to the meetings of IRBs A/B, the Chair or his/her designee

will assign Primary Reviewers for all items assigned to each of the agendas. Primary Reviewer assignments will be made on the basis of the Chair's review of the relevant study protocol and the Chair's knowledge of the Primary Reviewer's research training and his/her experience as an IRB member. After Primary Reviewer assignments have been completed by the Chair, the Board Specialists will assign the Primary Reviewer items via iRIS.

- At least 7 days prior to the IRB Meeting, the Board Specialist will email the agenda to the IRB members scheduled to attend the meeting. The agenda lists the items to be reviewed, the primary reviewer, and the items for which members will provide expertise.
- All members have access to the complete IRB protocol file for all agenda items through the meeting workspace in iRIS. Members also have access, through iRIS, to all reported safety events (including events requiring prompt reporting to the IRB), amendments, specialty committee reviews, and previously-requested modifications
- Primary Reviewers may complete their Primary Reviewer Form in iRIS, and upload revised documents to the Review Board Internal Documents space in iRIS beginning on the date of electronic assignment. Primary reviewers are asked to complete checklists and revise documents no later than 9 AM of the day of the meeting.

C. Initiation and Logistics of Meeting

The following IRB office personnel must be present before an IRB meeting is called to order: Chair or Vice Chair, 1 Writer, 1 Board Specialist. A Vice-Chair may perform all the functions of the Chair described in this document. The meeting will be called to order when the Chair has confirmed with the Board Specialist that a Quorum has been achieved and a non-scientist is present.

- **Voting Log and Quorum:** The Board Specialist will record the votes and monitor quorum throughout the meeting. See the IRB policy titled: "IRB Membership, Voting, and Quorum" for a description of the Board Specialists' responsibilities regarding monitoring quorum and voting. At any time during the meeting, the Board Specialist(s) will inform the Chair to halt the meeting when Quorum is lost, or if there is no Non-Scientist present. The Chair will not resume the meeting until the Board Specialist has confirmed that Quorum has again been achieved or the Non-Scientist is present. No discussion will occur on any agenda items until Quorum has been re-established.
- **Minutes:** The Writer will record the minutes. See the IRB policy titled "The Preparation, Recording and Finalization of Meeting Minutes" for a description of the Writer's responsibilities during the meeting.
- **Visitors/Observers:** The Chair will introduce visitors and new members to the Board. The Board Specialist(s) will obtain the signature of each visitor on a Confidentiality Agreement. All visitors (not including IRB Members or IRB Staff Members) will sign a Confidentiality Agreement prior to the start of the meeting. A new Confidentiality Agreement will be signed by each visitor at each meeting, regardless of the number of times an individual visitor has attended in the past. The Board Specialist will also check to see if the visitor is on one of the studies on the agenda or has a conflict with any of the studies. If so, the visitor will be recused during the presentation and vote for the study.
- **Attendance Log:** The Board Specialist will circulate a log for attending members to indicate their intent to attend the next meeting. For remote meetings, attendance can be confirmed via email.

- **Educational Presentation:** For regularly scheduled IRB meetings, an educational presentation may be made before protocol review begins. The Chair will introduce the presenter, who will make a 5-10 minute presentation to the members on educational issues of interest. Presentations are typically given monthly, with all boards receiving the same educational presentation that month. At the discretion of the IRB Executive director, some months may not include an educational presentation, or members may be provided an educational handout without a formal presentation.
- **Vote to Accept Minutes:** The Chair will call for a vote to accept any minutes from previous IRB meetings. Minutes to be accepted will be uploaded to the agenda in iRIS. The Board Specialist(s) will record the vote count.
- **Conflict of Interest:** The Chair will remind members of the importance of declaring a conflict, as described in the Conflict of Interest Policy Statement. At the beginning of each convened meeting, the Chair or Vice Chair will query the members as to any known conflicts they might have with all agenda items for that day. The COI query by the Chair will be recorded in the meeting minutes, along with any member's conflict declaration and recusal. Any IRB member absent from the meeting because of a conflict of interest will be noted in the minutes and not be counted toward quorum for any vote taken in his/her absence.

D. Primary Reviewer Responsibilities

The Primary Reviewer will review all documents associated with his/her assigned protocol and will confirm consistency between the consent form(s), full protocol, and protocol application regarding the described study activities, anticipated risks, potential benefits, and compensation, if any. For initial review of research, the Primary Reviewer will be provided with, and will review, the DHHS-approved sample consent document and the complete DHHS-approved protocol (when these documents exist), in the case of DHHS-supported research.

- **Primary Reviewer Checklist:** Prior to the IRB meeting, the Primary Reviewer will complete the appropriate Primary Reviewer Checklist within iRIS for his/her assigned protocol. In using the required form, the Primary Reviewer will include in his/her review an evaluation of the appropriateness of all components of the study necessary to determine that the regulatory criteria for approval of the study are met.

Prior to the scheduled IRB Meeting, the Primary Reviewer will complete his/her Primary Reviewer Checklist and upload any marked-up study documents into iRIS. Any relevant written correspondence with the study team should also be uploaded to the Review Board Internal Documents area within iRIS.

- **Contact with Study Team:** Prior to the IRB meeting, the Primary Reviewer should contact the PI or study coordinator to ask any questions or obtain any needed clarifications, and may propose changes to various elements of the study packet.

E. Protocol Review and Meeting Order

The order of items for review will proceed at the Chair's discretion, but will usually follow the format of the meeting agenda, which typically lists, in order, New Studies, Renewals, Amendments, and Safety Events.

- **Primary Reviewer Presentation:** The Primary Reviewer will approximate the presentation methods described in Attachment 1. The Primary Reviewer will present his/her comments as reflected on the Primary Reviewer Checklists within iRIS, including his/her notations for whether the regulatory criteria for approval will be or have been met,

and have the convened IRB consider any areas where the regulatory criteria for approval will not be or have not been met.

- **Questions and Comments:** Once the Primary Reviewer's presentation is complete, the Chair will solicit questions/comments and general discussion from the Board Members and expertise. At this time, the Chair will ask any questions he/she may have and make comments on the review. The Board Members, in their discussion of the protocol, will consider the criteria for IRB approval as set forth in the federal regulations at 45 CFR 46.111, .116 and .117, and (as applicable) 21 CFR 56.111, including additional regulatory criteria for approval in 21 CFR 50.20, .25 and .27 and must decide as a committee whether the regulatory criteria for approval have been met.
- **Invitations to Investigators:** The Chair may invite the PI to speak to the Board Members in person or by phone or virtually if, in the Chair's judgment, this is necessary to facilitate the discussion. The Chair may also invite one or more expert consultants to attend the meeting and contribute according to the Policy titled "DUHS IRB Use of Consultants".
- **Motions:** At the end of discussion, the Chair will summarize comments and re-state the motion made by the Primary Reviewer. The Chair will confirm the period of time for approval (one year or less, as specified by the motion), the pediatric risk level, if applicable, and any other conditions of approval, such as use of a Legal Representative in the consent process. He/she will then request the vote. The Board Specialist will record the vote as per the Policy titled IRB Membership, Voting and Quorum. The IRB has a range of possible actions it may take. The investigator is notified via iRIS of the action by the IRB. Actions include the following:

Approve

The approval refers to the entire submission, including the supporting documents associated with the submission. The duration of approval for new studies and continuing reviews (renewals) must be specified at the time of the convened IRB's vote.

Modifications Required

A modification is specific if the investigator is able to make the modification by simple concurrence. Examples of such a modification are statements like "Get CT scans with contrast every 3 months instead of every 6 months", specific wording changes to the consent form when the wording changes are provided by the IRB to the investigator, completion of ethics education requirements, adding a pediatrician specialist as a co-investigator for a study involving adolescents, and declaring which of two options, either of which is approved by the convened board, the investigator wishes to choose. The modifications cannot include any requests for additional information directly relevant to the criteria for approval.

See the policy on "Modifications Processing Procedures" for a description of how modifications are reviewed and approved.

See the policy on "Modifications Processing Procedures" for a description of how modifications for a protocol may be deferred when the IRB is unable to determine if the criteria for approval have been met or if the IRB proposes revisions that cannot be addressed by simple concurrence. The investigator is asked to submit a response and revised documents to the IRB within 90 days of the review date. Unless there are extenuating circumstances at the end of that 90-day period, if the investigator has not submitted a response, the protocol may be scheduled for review and consideration for disapproval at the

next available convened meeting of the IRB. When the investigator responds to the IRB's request for modifications, the investigator's response, including revised documents, are reviewed by the IRB chair or may be scheduled for review at the next available convened meeting of the IRB.

Disapproval

Disapproval means that the study as designed is inherently flawed, and the IRB can envision no straightforward modification or additional information that would likely result in an approval. The investigator is notified via iRIS of this action by the IRB.

Deferral

If the convened IRB is unable to document that the criteria in 45 CFR 46.111 or its corresponding criteria under the FDA regulations have been satisfied, then a motion for deferral may be made. A deferred study will be returned to the study team with a detailed explanation of the reason(s) for the deferral and corrections/additional information necessary for the convened IRB's further consideration.

F. Conclusion of Meeting

After the vote on the last agenda item has been recorded, the Chair will adjourn the meeting.

- **Finalize Voting Log:** The Board Specialist will finalize the Voting Log. The Writer will save the electronically recorded minutes to the IRB shared drive (S:).
- **Unaffiliated Members:** At any time before or after the meeting, the Board Specialist(s) will present an invoice to each Unaffiliated Member to sign. After the meeting, the Board Specialist will forward each signed invoice to the delegated IRB Staff for processing and forwarding to DUHS Accounting for check issuance. Within 5 business days following an IRB Meeting, the Writer will complete the modification requests from the meeting.
- Following an IRB Meeting, the following items are entered into the IRB Meeting Notebooks stored in the IRB small conference room:
 - DUHS IRB Attendance Form
 - IRB Meeting Agenda
 - Confidentiality Agreement(s) if any
 - IRB Schema
 - Any relevant meeting correspondence
- **Final Minutes** See the IRB policy titled "The Preparation, Recording and Finalization of Meeting Minutes" for a description of the Post-Meeting Finalization of Minutes.

G. Appeals

The decision of the IRB to disapprove human research cannot be overruled by any other institutional body or individual(s); however, an investigator may appeal the decision of the IRB in writing directly to the IRB, or to the Institutional Official (IO) or other senior university official. The IO will review the appeal, if possible, with the Chair and/or Vice-Chair who presided over/attended the IRB meeting where the disapproval of the research occurred. The presiding Chair/Vice-Chair will schedule the appeal for review at the next available convened meeting of that board. At that time, the investigator may request to attend the meeting during the presentation of the study, or they may be asked by the IRB or the IO to attend to answer questions. The investigator will not be permitted to remain in attendance during the IRB's deliberation and vote on the study.

If the IO's assessment of the IRB's review leads the IO to conclude that the IRB has not

complied with federal regulations and/or its policies and procedures, and therefore the IRB must be reviewed for noncompliance, the IO will work with the IRB Executive Director to ensure that the protocol receives a complete re-review by a different convened IRB. At that time, the range of possible IRB actions described above will apply.

Previous Version Date(s): 8/13/2008, 12/4/2008, 1/13/2009, 6/12/2011, 3/3/2016

ATTACHMENT 1

RECOMMENDED SEQUENCE FOR PRESENTATION OF PRIMARY REVIEW

Initial Review

- Primary Objective
- Description of Subject Population
- Study Activities
 - Screening
 - Mode of drug/device administration and schedule
 - IND/IDE issues
 - Safety Monitoring
 - Data Analysis
 - Data disclosed outside of DUHS
- Consent form
- Method of Ascertainment/Recruitment
- Advertisement
- Risks/Benefits and Alternatives to Participation (*for Peds, state: category, risks, benefits, ways risks are minimized, and relation of risk/benefit to alternatives and number of parent signatures required*)
- Concerns
- Recommended conditions of approval: (*use of legal representative, non-significant risk device, submission of interim reports*)
- Recommended interval of IRB review (*1 year, 9 months, etc.*)
- Recommended vote

Continuing Review

- PI name and department
- Duke's role, if multicenter
- Primary Objective
- Brief Description of Study Activities
- Brief description of Subject Population and Method of Ascertainment/Recruitment
- Risks/Benefits Assessment (*for Pediatric studies, discuss: category, risks, benefits, minimization of risks, and relation of risk/benefit to alternatives*)
- Consent form
- Data/specimen storage
- Data and safety monitoring reports
- Study progress since last review (enrollment, safety events, changes to the study)
- Concerns
- Recommended conditions of approval
- Recommended interval of IRB review (*1 year, 9 months, etc.*)
- Recommended vote

Amendment Review

- Primary Objective
- Description of Subject Population
- Brief Description of Study Activities prior to the amendment
- Summary of the amendment
- Effect of amendment on risks/benefits
- Changes to Study Documents from the amendment
 - Protocol/summary
 - Consent form
 - Other
- Concerns
- Recommended conditions of approval
- Recommended vote