



CONDUCT OF A CONVENED MEETING OF THE DUHS INSTITUTIONAL REVIEW BOARD

8/13/08

This document is meant to serve as guidance for the conduct of convened meetings of the Duke University Health System (DUHS) Institutional Review Board.

Definitions

- “Business items” means amendments, modifications, adverse event reports, reports of unanticipated problems or other problems, sponsor correspondence, and any other study documentation determined by the IRB office to require review by a convened IRB. Amendments will be processed according to the “Amendments Policy”. Adverse event reports, sponsor correspondence, reports of unanticipated problems and any other problems or events requiring prompt reporting to the IRB will be processed according to the policy titled “Problems or Events That Require Prompt Reporting to the IRB”. Other reports, sponsor correspondence related to investigator compliance with protocol requirements or study documentation requiring convened board review that is not a modification to previously approved research will be processed according to the policy and procedure applicable to that item, such as the policy titled “Non-compliance with the Requirements of the Human Research Protection Program”.
- “New studies” means research studies submitted to the IRB for initial review.
- “Renewals” will mean research studies previously approved by the IRB and submitted for continuing review, as required by 45 CFR 46.109(e) and 21CFR 56.109(f).

Preparation for Meeting

- A Meeting Team in the IRB will consist of one Chair, one Vice Chair, one Writer and two Board Specialists. Each Meeting Team will be responsible for two consecutive IRB meetings each month. Meetings will be held on consecutive Wednesdays and Thursdays from 1 pm until approximately 4 pm. 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 forty items from the e-IRB. These items will be assigned to the agendas for IRBs A/B, with approximately 20 to 25 items assigned to each meeting’s agenda.
- Agenda items will consist of three types: new studies, continuing reviews (renewals) and business items and 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.
- 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. A “Primary Reviewer” is the IRB member who is responsible for the in-depth review and presentation of a protocol at an IRB meeting. 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. The Board Specialists will prepare a Primary Reviewer Assignment List to assist the Chair in

protocol assignments. After Primary Reviewer assignments have been completed, the Board Specialists will assemble/copy/forward meeting packets.

- At least 7 days prior to the IRB Meeting, Meeting Packets will be sent electronically or hand-delivered to on-campus IRB members, and sent electronically or via Federal Express to IRB members who are located off-campus.
- A Primary Reviewer's Meeting Packet for either new studies or renewals will consist of the following documents for each assigned protocol:
 - Submission Form
 - Progress Report (renewals only)
 - Protocol Summary
 - Consent document(s)
 - Advertisement(s) (if applicable)
 - Other recruitment material (if applicable)
 - Waiver Requests (if applicable)
 - Notice of Review Preparatory to Research (if applicable)
 - List of problems or events requiring prompt reporting to the IRB occurring in previous year (renewals only)
 - Investigator's assessment of whether the frequency of expected adverse events was higher than expected (renewals only)
 - Full Protocol
 - Pediatric Risk Assessment Form (if applicable)
 - Investigator's Brochure(s) (if applicable)
 - Copy of the entire grant, if research is federally funded, or if the funding agency applies federal standards
 - DHHS-approved sample consent document (when one exists)
 - Complete DHHS-approved protocol (when one exists)
 - Any protocol modifications previously approved by the IRB
 - All modified documents
 - Any other relevant Study Documentation
- An attending IRB member's Meeting Packet for either new studies or renewals will consist of the following study documents for all protocols to be reviewed at the convened IRB for which he/she is **not** a Primary Reviewer:
 - Submission Form
 - Progress Report and Continuing Review Summary (renewals only)
 - Protocol Summary
 - Consent document(s)
 - Any newly proposed consent document(s)
 - Waiver Request(s) (if applicable)
 - Notice of Review Preparatory to Research (if applicable)
 - Advertisement(s) (if applicable)
 - Other recruitment material (if applicable)
 - Pediatric Risk Assessment Form (if applicable)
 - Selected portions of the grant, if research is grant-funded
 - All modified documents
 - Any other relevant Study Documentation
- The Primary Reviewer's Meeting Packet for business items (modifications/amendments) will consist of the following documents for each assigned protocol:
 - Submission Form (if applicable)
 - Most Recent Continuing Review Submission Form
 - Protocol Summary
 - Full Protocol

Most Recent Approved Consent Form(s)
Other Study Documents affected by revision (all modified documents)

- The attending IRB member's Meeting Packet for business items (modifications/amendments) will consist of the following documents for each protocol:
 - Submission Form (if applicable)
 - Most Recent Continuing Review Submission Form
 - Protocol Summary
 - Most Recent Approved Consent Form(s)
 - Other Study Documents affected by revision (all modified documents)
- Beginning on the date of delivery until one hour prior to the start of the meeting, Primary Reviewers will complete the Primary Reviewer Form for a New Study, Renewal or Business Item, as appropriate, and will upload documents to the e-IRB system, or e-mail or FAX reviews and revised study documents to the Board Specialists and/or Writer. The Board Specialists will make copies of all revised documents (if still on paper) to distribute to IRB members at the start of the meeting.
- The Board Specialists will assemble one packet of all revised paper documents for all agenda items for each attending member. These packets will be placed at each member's seat prior to the start of the meeting. For studies that are electronic, all revised documents appear in the e-IRB system.

Initiation of Meeting/IRB Staff Responsibilities

- 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.
- See the IRB policy titled: "IRB Membership, Voting, and Quorum" for a description of the Board Specialists' responsibilities regarding monitoring quorum and voting.
- One Board Specialist will process modifications as determined by the convened IRB and recorded by the Primary Reviewer and Writer.
- See the IRB policy titled "The Preparation, Recording and Finalization of Meeting Minutes" for a description of the Writer's responsibilities during the meeting.
- At any time during the meeting, the Board Specialist(s) will inform the Chair to halt the meeting when Quorum is lost or if, as per 45 CFR 46.108(b), there is no Non-Scientist in the room. 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.
- To begin the meeting, the Chair will confirm with the Board Specialist(s) that a Quorum has been achieved. The Chair will then call the meeting to order and call the members' attention to the packets in their seats. Each packet is prefaced with the most current meeting agenda. 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. The Board Specialist will circulate a "Will you be at the next meeting?" log to the attending members to complete during the course of the meeting.

- An educational presentation will 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.
- The Chair will then announce the intent to review and vote to accept any minutes from previous IRB meetings that are contained in the packets. The Chair will ask for any questions/comments on the minutes, and call for a vote. The Board Specialist(s) will record the vote count.
- The Chair will then announce the intent to note the list of studies that were approved via expedited review since the last IRB meeting, and the list of studies closed since the last IRB meeting. Members will be provided the opportunity to ask questions regarding the expedited review report(s) or report(s) of closed studies.
- 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 room 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.

Primary Review

- The order of items for review will proceed at the Chair's discretion, but will usually follow the format: New Studies, First Year Renewals, Subsequent Year Renewals, and finally Business Items (BIs).
- The Primary Reviewer will review all documents associated with his/her assigned protocol. The Primary Reviewer will confirm consistency between the consent form(s), full protocol, and protocol summary regarding the described study activities, anticipated risks, potential benefits, and compensation, if any.
- In the case of a new study that is federally funded, or whose funding source applies federal standards, the Primary Reviewer will closely examine the study protocol and the associated grant to determine if concordance exists between the two documents.
- Prior to the IRB meeting, the Primary Reviewer will complete the appropriate Primary Reviewer Form (Checklist) for his/her assigned protocol. The Primary Reviewer Forms for New Studies, for Renewals, and for Business Items/Amendments are all available as part of the eIRB. 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 IRB meeting, the Primary Reviewer will contact the PI or study coordinator via e-mail, telephone or fax to ask any questions or obtain any needed clarifications, and may propose changes to various elements of the study packet.
- At least 1 business day prior to the scheduled IRB Meeting, the Primary Reviewer will upload into the eIRB or forward any revised Consent forms or other study documents that he/she has received from the PI or study coordinator to one of the Board

Specialists or the Writer assigned to the scheduled IRB Meeting. The Primary Reviewer will also upload or forward an electronic version of his/her completed Primary Reviewer Checklist to the Writer.

- On the day of the IRB Meeting, the Primary Reviewer will bring to the meeting the entire packet of all protocols to be presented, including hard copy versions of his/her Primary Reviewer Forms and any marked-up study documents if not already uploaded to the eIRB.
- During the IRB meeting, 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 REVIEW CHECKLIST FOR NEW PROTOCOLS, or the PRIMARY REVIEW CHECKLIST FOR CONTINUING REVIEW (RENEWAL) PROTOCOLS, 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.
- During the IRB's discussion regarding the protocol, the Primary Reviewer will, at the direction of the IRB Chairperson, make notes directly on the Primary Reviewer Form, either the written or electronic version. At the conclusion of the IRB's vote on the protocol, the Primary Reviewer will deliver any marked-up documents to the Board Specialists for further processing.
- Once the Primary Reviewer's presentation is complete, the Chair will solicit questions/comments and general discussion from the Board Members. 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.
- If a question arises that requires a reply from the Principal Investigator (PI), the Primary Reviewer or other Board member will leave the room to contact the PI. At the Chair's discretion, the meeting may pause until the Primary Reviewer's, or other member's, return, or move to the next agenda item. At the end of the next vote following the relevant Reviewer's return, the Chair will return to the unfinished agenda item and obtain the Primary Reviewer's, or other member's, report of his/her conversation with the PI. Discussion on this agenda item will continue as described below.
- The Chair may invite the PI to speak to the Board Members in person 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".
- At the end of discussion, the Chair will summarize comments and re-state the motion made by the Primary Reviewer. The IRB has a range of possible actions it may take:
 - Approve, including the period of approval. The investigator is notified via the eIRB of this action by the IRB. The approval refers to the entire submission, including the supporting documents associated with the submission.
 - Specific modifications required

- The modifications cannot include any requests for additional information directly relevant to the criteria for approval.
 - 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 IRB also determines the period of approval should the minor modifications be made.
 - The investigator is notified via the eIRB of the action voted on by the IRB and, point-by-point, the required modifications to the research proposal. The investigator is asked to submit a point-by-point response as well as revised documents to the IRB within 90 days of the review date. Unless there are extenuating circumstances as determined by the IRB, at the end of that 90-day period, if the investigator has not submitted a response, the protocol is 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 minor modifications, IRB Chair/Vice-Chair and the Board Specialist review the response, including the revised documents, to determine if the investigator responded by simple concurrence. The reviewer indicates whether the modifications required by the IRB have been made and whether the protocol can now be approved. If the modifications have not been made as required, and the investigator is unable or unwilling to make the required modifications, the protocol with the investigator’s response is scheduled for review at the next available convened IRB meeting, where it is considered for disapproval.
- Defer for more information
 - When the IRB votes to defer pending receipt of additional information, the investigator is notified via the eIRB of the action approved by the IRB. Questions and concerns that need to be addressed as well as point-by-point modifications required to the research proposal are described. The investigator is asked to submit a point-by-point response and revised documents to the IRB within 90 days of the review date. Unless there are extenuating circumstances as determined by the IRB, at the end of that 90-day period, if the investigator has not submitted a response, the protocol is 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 scheduled for review at the next available convened meeting of the IRB.

- Disapproval
 - When the IRB disapproves the research, the investigator is notified in writing of the basis for the 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 the eIRB of this action by the IRB.
- 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.

Conclusion of Meeting

- After the vote on the last agenda item has been recorded, the Chair will adjourn the meeting.
- The Board Specialist will finalize the Voting Log, and complete the Wrap-Up Report. The Medical Writer will save the electronically recorded minutes to the IRB shared drive (J:).
- At any time before or after the meeting, the Board Specialist(s) will present an invoice to each Community Member to sign. After the meeting, the Board Specialist will forward each signed invoice to the IRB Staff Specialist for processing and forwarding to DUHS Accounting for check issuance. Community Members are defined as those IRB members who do not have an affiliation with the institution either through their own associations or those of their immediate family. They may be either scientists or non-scientists.
- Within 1-3 business days following an IRB Meeting, the Medical Writer will complete the modification requests from the meeting.
- Within 1-3 business days following an IRB Meeting, the following items are entered into the IRB Meeting Notebooks stored in the IRB Workroom:
 - DUHS IRB Attendance and Voting Log
 - IRB Meeting Agenda
 - IRB Meeting Wrap-Up Report
 - Reviewer Assignments for Meeting
 - Confidentiality Agreement(s) if any
 - "Will you attend..." Log
 - Voting/Attendance for Meeting Roster
 - DUHS IRB Invoice for Community Member
 - Expedited Study Report presented and approved
 - Any relevant meeting correspondence
- See the IRB policy titled "The Preparation, Recording and Finalization of Meeting Minutes" for a description of the Post-Meeting Finalization of Minutes.

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 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.

ATTACHMENT 1

SEQUENCE FOR PRESENTATION OF PRIMARY REVIEW Recommended Duration: ≈5-10 minutes

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)
- 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

- 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
 - AEs since previous IRB review
 - Accrual summary
 - Preliminary data analysis *(if available)*
- Consent form
- Method of Ascertainment/Recruitment
- Advertisement *(if changed since previous review)*
- Risks/Benefits and Alternatives to Participation
(for Pediatric studies, discuss: category, risks, benefits, minimization of risks, and relation of risk/benefit to alternatives)
- Concerns
- Recommended conditions of approval *(use of legal representative, non-significant risk device declaration, submission of interim reports to the IRB, etc.)*
- Recommended interval of IRB review *(1 year, 9 months, etc.)*
- Recommended vote

Business Item Review

- Primary Objective
- Description of Subject Population
- Study Activities
 - Screening
 - Mode of drug/device administration and schedule
- Summary of Business item
- Effect of business item on risks/benefits
- Changes to Study Documents caused by business item
 - Protocol/summary
 - Consent form
 - Other
- Concerns
- Recommended conditions of approval
- Recommended vote