



## MODIFICATIONS PROCESSING PROCEDURE

7/15/2008

This document outlines the DUHS IRB procedure for preparing and processing the modifications (“mods”) necessary before a protocol can receive final approval. Modifications may range from changing minor typographical errors in a consent form to making a substantive change in the study protocol. Whether small or large, all mods must get communicated by IRB staff to the research team (Principal Investigator/Study Coordinator), acted upon and completed by the research team, returned to the IRB office, and then reviewed by IRB staff as a precursor to final approval.

### Processing Modifications for New Protocols with Full Board Review

i.) When a protocol goes through full board review, the board will often determine that there are “modifications required.” The IRB also determines the period of approval, should the modifications be accepted by simple concurrence. After the IRB meetings, a Writer will complete the Modifications in the e-IRB for either protocols (new submissions, first year renewals, and renewals) or amendments (business items) by including comments from the Primary Reviewer’s checklist, the Chair’s notes, and the draft minutes, the sum of which reflects the actions of the convened board. In addition, the Writer will review the consent form to confirm that all changes required by the convened board are noted in order to ensure consistency with Duke policy and the federal regulations. The Writer lists all deficiencies and the revisions to be made in the Modifications Section in the e-IRB. If the Writer finds and makes corrections to the consent form *post-meeting*, these corrections can only be administrative or involve the use of standard IRB language as directed by the convened board. Post-meeting changes (administrative in nature) must meet the IRB definition of “minor” as defined in the amendments policy titled “Amendments to Previously Approved Research”. The Writer tags these revisions, to make them readily distinguishable from changes made in the convened meeting by the Board, for the Chair/Vice Chair’s review in step (ii) below. The Writer also specifies any other modifications required, such as credentialing, alterations to the study summary or advertisement changes. The Writer then completes the “Approval with Modifications Letter” and forwards it to the Chair or the Chair’s designee for review.

ii.) The Chair, or Chair’s designee, reviews, modifies (if necessary) and, if modified, obtains investigator agreement, then signs off on the modifications in the e-IRB. The sign-off consists of reviewing the modifications listed, approving them and electronically signing and dating the letter. The Chair or Chair’s designee then forwards this letter electronically to the PI and study staff.

iii.) When the IRB has voted to require minor modifications to secure approval, its use of the term “minor” indicates that the investigator can make the modifications by simple concurrence. Examples of such a minor modification are specific wording changes to the consent form, 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 Mods request asks the PI to submit a point-by-point response as well as revised documents to the IRB within 90 days of the review date. When extensive revisions are required, the modifications are requested from the PI with submission of the tracked version of the changes.

If the PI has not submitted a response at the end of that 90-day period, the protocol is scheduled for review and consideration for disapproval at the next available convened meeting of the IRB unless there are extenuating circumstances.

iv.) Completed modifications that are submitted by Investigators to the IRB office are directed to the appropriate Board Specialist through the e-IRB for review. The Board Specialist will review and determine if the modifications are complete. If complete, the Date Completed category is dated in the e-IRB under each Modification request.

Once all modification requests have been reviewed and dated, the Board Specialist will prepare the IRB Notification of Approval in the e-IRB. The Board Specialist forwards the approval letter to the IRB Chair or designee. The Chair or designee reviews all documentation, requests changes as needed, and if no changes are needed, provides his/her electronic signature.

If the modifications have not been made as required, and the PI is unable or unwilling to make the required modifications, the protocol with the PI’s response is scheduled for review at the next available convened IRB meeting, where it is considered for disapproval.

### **Processing Mods for Protocols Undergoing Expedited Review**

i.) For new expeditable reviews, (1) modifications to the consent form and/or protocol are made by the Writer, (2) the Writer then sends the expedited protocol to the expedited pool for distribution to a Chair/Vice Chair, and then (3) a Chair or Vice Chair may alter those or make further modifications. In the e-IRB, the mods are marked as edits pertaining to the consent form, protocol, study summary, or other document. When needed, IRB staff may require that standard language from the IRB website be added.

ii.) The new expedited study is forwarded in the e-IRB to the Board Specialist by the Chair. The Board Specialist will double-check any other mods required (for example, approval from ancillary committees, or to ensure that ethics education is current) and

then forward the noted modifications to the PI. After the PI sends the completed mods back to the IRB, the returned edited information is checked by the Board Specialist. Once all modification requests have been reviewed and dated, the Board Specialist will prepare the IRB Notification of Approval in the e-IRB. The Board Specialist forwards the approval letter to the IRB Chair or designee. The Chair or designee reviews all documentation, requests changes as needed, and if no changes are needed, provides his/her electronic signature.

iii.) When extensive revisions are required, the modifications are requested from the PI with submission of the tracked version of the changes.

iv.) Issues requiring clarification are addressed with the PI within the e-IRB by the Board Specialist, Chair/Vice Chair or both. The ensuing correspondence becomes a part of the protocol file.

### **Processing Mods for First Year Renewals and Continuing Renewals**

If first year renewals and continuing renewals receiving full board review require modifications, then the mods process is the same as that for new studies receiving full board review. Processing mods for first year renewals and continuing renewals that receive expedited review follows the same procedure as that used for new expedited studies.

### **Processing Mods for Amendments**

Modification processing for amendments follows the same series of steps described above, depending on whether the review occurs via a convened IRB or using the expedited procedure.