DUKE UNIVERSITY HEALTH SYSTEM
Human Research Protection Program

MODIFICATIONS PROCESSING PROCEDURE

11/20/2023

This document outlines the DUHS IRB procedure for preparing and processing the modifications ("mods" or stipulations) necessary before a protocol, amendment or renewal 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 be communicated by IRB staff to the research team (Principal Investigator/Regulatory Coordinator/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 Submissions, Amendments, Renewals and Safety Events with Full Board Review

i.) When a new submission, renewal, amendment, or safety event goes through full board review, the board will often determine that there are "modifications required." After IRB meetings, an IRB writer will prepare modifications in iRIS by including comments from the Primary Reviewer, the Chair's notes, and the minutes taken during the meeting, the sum of which reflects the actions of the convened board. In addition, the Writer will review the study documents to confirm that all changes required by the convened board are noted in order to ensure consistency with Duke policies and federal regulations. The Writer lists all modifications and the revisions to be made in the Modifications Section in iRIS. 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 notifies the Chair/Vice Chair of any changes prior to sending out the modification. The Writer also specifies any other modifications required, such as credentialing. The Writer then prepares the Modifications Letter and forwards it to the Chair/Vice Chair for review.

ii.) The Chair/Vice Chair reviews, modifies (if necessary), and then signs off on the modifications letter in iRIS. Sign off consists of reviewing the modifications listed and approving them. The IRB Specialist forwards the signed 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 or adding

a Pediatrician specialist as a co-investigator for a study involving adolescents. The Mods request asks the PI to submit revised documents to the IRB. The mods letter states that studies are not activated until all IRB questions/concerns have been adequately answered and all revised material has been received and approved by the IRB as indicated by the "Approval Letter" sent separately.

iv.) Completed modifications that are submitted by Investigators or study staff to the IRB office are directed to the appropriate Board Specialist through iRIS for review. The Board Specialist will review and determine if the modifications are complete. If complete, the "Accepted" category with date is noted in iRIS under each Modification request.

Once all modification requests have been reviewed and accepted, the Board Specialist will prepare the IRB Notification of Approval in iRIS. 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, approves the Notification of Study Approval letter. The Board Specialist then forwards the approval letter to the study staff.

If the modifications (other than minor changes that can be accepted by simple concurrence) 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 may be considered for disapproval.

Processing Modifications for Protocols Undergoing Expedited Review
IRB Chairs, the Executive Director, and specially trained IRB personnel may conduct expedited reviews.

i.) For new submissions, amendments, and renewals the Board Specialist can request pre-review changes in iRIS when doing a pre-review screening. Pre-review changes are requested as modifications. When the study team returns modification requests, the Board Specialist indicates "Accepted" or "Not Met" whichever is applicable. With accepted modifications, the Board Specialist moves the submission to "Pending Expedited Review"; If not met, modifications are returned to study team with further instructions.

ii.) The Chair or designee may concur with the Board Specialist and/or request further modifications. In iRIS, the mods are marked as edits pertaining to the submission form, consent form, protocol, study application, recruitment material, or other documents.

iii.) When revisions are required, the modifications are requested from the PI and study staff with submission of the tracked version of the changes. These are displayed in iRIS with changes tracked.

iv.) Issues requiring clarification are addressed with the PI and study staff within iRIS by the Board Specialist, Reviewer or both. The ensuing correspondence becomes a part of the protocol file.

v.) After all modifications are complete, the Chair or designee indicates “Review Complete” in iRIS. Board Specialist prepares the IRB Notification of Approval in iRIS and indicates “Approved” on the submission outcome. The Board Specialist then forwards the approval letter to the study staff.

Previous Version Date(s): 7/15/2008, 6/2/2011, 3/1/2016, 4/14/2021