

IRB Procedures 10a: Modifications

Revision Date: April 16, 2008, revised November 11, 2009, revised January 27, 2011, revised February 9, 2015, revised October 15, 2015

I. Summary

The IRB policy is to make guidelines and procedures for investigators, IRB staff, and IRB members understandable and available to all involved in the process, including this information about procedures for submission, review and approval of modifications to previously approved studies or claims for exemptions.

II. Responsibilities

A. IRB Administration Responsibilities

1. The IRB Coordinator will receive the requested modification and review for completeness, including attachment of any pertinent documents. For VA studies, the IRB Coordinator will verify that the VA R&D has signed the modification request. If the modification request does not contain all necessary documents, the IRB Coordinator will reject the submission back to the submitter. If the information needed is minor (capable of being resolved with a brief communication), the IRB Coordinator may choose to hold the electronic submission, contact the study staff, and then process the electronic submission when necessary information is received. If the necessary information is not received within 3 business days, the electronic submission will then be rejected back to the submitter.
2. The IRB Coordinator will forward the modification to the Chair for his/her review.
3. Requested changes determined to be non-minor modifications will be prepared for IRB Committee review by providing all necessary documents to the IRB Chair for Primary Review, placing the study on the next available committee full agenda, and providing IRB members with all indicated documents prior to meeting.
4. Requested modifications determined to be minor modifications and approved by the Chair or his/her designee will be placed on the next available Expedited IRB agenda for IRB notification of approval.
5. The IRB Coordinator will assist in obtaining any additional information requested by the IRB Chair or IRB member.

6. Modifications that require changes to the ICD must include revised ICDs that are date-stamped and processed according to IRB policies and procedures.
7. Letters denoting the IRB determinations will be drafted using the appropriate template. All appropriate correspondence will be posted in the electronic system and the PI will be notified by email of the posting. For VA studies, the VA AO is additionally notified by email of the posting.

B. Principal Investigator Responsibilities

1. The investigator will complete the “Modification Request XForm or, for VA studies, the VA Modification Request XForm. Both forms include identification of the source of the initial modification request (sponsor or PI). For this section, reference to “Modification Request Form” applies to both VA and non-VA forms. If applicable, a copy of any pertinent correspondence from the sponsor must be attached to the “Modification Request XForm.” On the “Modification Request XForm,” the PI must also include a description of the nature of the modification, a rationale for the change, and itemized revisions resulting from this modification. All revisions must be incorporated in the corresponding documents. Revised documents must have a new version date. If the ICD is changed as a result of the modification, the following must be attached to the “Modification Request Form”:
 - a. one copy of the currently approved ICD
 - b. one copy of the revised ICD with changes highlighted or tracked
 - c. one copy of the revised ICD without highlighted changes (for approval date stamping)
2. The PI will be asked to make an initial determination of whether the modification changes the risks to participants, and if so, to provide, a detailed explanation.
3. The PI will indicate on the “Modification Request XForm” how new information will be communicated to currently enrolled participants.
4. If the application is rejected back to the submitter for incompleteness, the PI is responsible for re-submitting the modification request after the necessary documents are added. If an incomplete electronic submission is not rejected but is held pending information, the PI must respond within 3 business days or the electronic submission will then be rejected back to the submitter.
5. The PI will submit any changes to an exempt study to the IRB for approval prior to initiation of the change. If the modification will change the exempt status of a study, the PI will be informed in writing. The investigator may withdraw the modification request and continue the study as previously

determined to qualify under exemption guidelines or submit the study for appropriate review and approval through an expedited or full board review. The PI will not initiate any changes to exempt studies without appropriate approvals.

6. The PI will not implement the modification or revised documents prior to IRB approval with the following exception: if the modification must be implemented immediately to avoid an immediate hazard to the participant. In this case, the "Modification Request XForm" with all required documents, as well as an XForm 109 reporting implementation must be submitted to the IRB within 10 working days.
7. If requested, the PI (or other study investigator) will present a non-minor modification to the convened board for review.

C. IRB Committee Responsibilities

1. The IRB Chair will evaluate each modification and determine whether the requested modification is minor or non-minor in nature, and clearly indicate this decision on XForm 119 linked to the "Modification Request Form." The IRB Chair or his/her Designee may review and approve research modifications that meet the definition of a minor modification.
2. When a proposed modification represents a non-minor change, the convened IRB Committee (with appropriate quorum, including member whose concerns are primarily non-scientific) must review and approve changes before the change can be implemented. All IRB Committee members are responsible for reviewing the following:
 - a. Cover letter, if applicable
 - b. "Modification Request XForm"
 - c. All modified documents
 - d. Attachments to the "Modification Request XForm," including currently approved ICD and any revised ICD, narrative or other forms
 - e. Copy of approved narrative or narrative portion of new protocol submission xform
3. The IRB Chair or his/her Designee will serve as Primary Reviewer and are responsible for reviewing the following materials:
 - a. Cover letter, if applicable
 - b. "Modification Request XForm"
 - c. All modified documents
 - d. Attachments to the "Modification Request XForm," including currently approved ICD and any revised ICD, narrative or other forms

- e. Copy of approved narrative or narrative portion of new protocol submission xform
 - f. Copy of any revised protocol and/ or investigator brochure
4. The Primary Reviewer completes Non-Minor Modification Primary Reviewer Form (xForm 120) and presents his/her evaluation of the non-minor modification to the convened board for review.
5. The IRB Committee must determine if the modification provides new information regarding a change in the risk/benefit ratio that would possibly affect a participant's decision to continue with the research study. The IRB determines whether re-consenting of currently enrolled participants is necessary and whether participants who have completed research involvement must be provided any additional information.
6. Changes to exempt research may be approved by the Chair or his/her designee if such changes do not alter the review status. If the proposed modification would change exempt status, the PI will be notified that he may withdraw the modification and continue the study as originally processed, or submit the study for an expedited or full review.
7. If PI reports immediate implementation of a modification to avoid an immediate hazard to the participant, the IRB Chair reviews all submitted documentation to determine that the change was consistent with ensuring the participants continued welfare. The report of implementation will be processed per Policy 18, Reporting of Unanticipated Problems/Events. The modification will be processed per Policy 10 and Procedure 10a.

References:

IRB Modification Policy