

IRB Procedure 10a: Modification Review

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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. Per IRB Policy 10, all changes to previously approved research (except to eliminate immediate hazards to subjects or others) must receive prior IRB approval; this includes but it not limited to changes in research study staff, designating a new Principal Investigator or Faculty Advisor, adding a new research site, changing the enrollment numbers, revising previously approved study documents, or notifying the IRB of new study funding. Modifications must be submitted for review and approval for Exempt, Expedited, and Full Board research.

II. Procedure for Minor Modifications

1. If a researcher wants to make a change to previously approved research, the researcher will complete the Modification Request xForm and attach any proposed new or revised documents for IRB review. If applicable, a copy of any pertinent correspondence from the sponsor must be included with the submission. The researcher must also include a description of the nature of the modification, rationale for the change, and itemized revisions resulting from the modification. All revisions should be incorporated in the corresponding study documents using tracked changes to assist the IRB reviewer. Revised documents should have a new version date in the footer for document version control. The xform asks the researcher to make an initial determination of whether the modification changes the risks to participants, and if so, to provide a detailed explanation. Additionally, the xform asks for a description of how new information will be communicated to currently enrolled participants, if applicable.
2. If the xform is completed by someone other than the Principal Investigator, it will electronically route to the PI for attestation and signature. For VA studies, the VA Research & Development Office completes electronic administrative review prior to formal submission to the ETSU IRB. The VA R&D Office may return the New Protocol Submission xform to the submitter for revisions, as necessary, to ensure compliance with VA research requirements.
3. Once the Modification Request xform is submitted via IRBManager to the IRB Office, if it involves a change in study staff, the IRB IRT verifies that

- all study staff have completed the required education and training (i.e., CITI Human Subjects, GCP, HIPAA). If training cannot be verified for all study staff, the IRB IRT notifies both the PI and the individual missing training of the deficiency.
4. The IRB Coordinator completes the preliminary review to ensure completeness and consistency. If the xform does not contain sufficient detail regarding the proposed changes, including all necessary documents, the IRB Coordinator will return the submission back to the submitter to request additional information.
 5. If the xform is returned to the submitter for revisions, the researcher is responsible for re-submitting the modification request after the necessary documents are added. The researcher may take as much time as needed to respond to requested pre-review information. Upon re-submission, the xform goes through all prior stages (i.e., PI signature, VA R&D Office) before returning to the IRB Office.
 6. Once the submission is complete, if the modification is administrative in nature (i.e., adding study staff), the IRB Coordinator will administratively review and approve the submission by completing the xform stages. Otherwise, the IRB Coordinator will electronically route the xform to the appropriate IRB Chair for review. The IRB Coordinator will assist in obtaining any additional information requested by the IRB Chair
 7. The IRB Chair will evaluate each modification and determine whether the requested modification is minor or non-minor in nature and document the determination by completing the Chair Review stage of the Modification Request xForm. If determined to be a minor modification, the IRB Chair may approve the modification by completing the xform.
 8. For exempt study modifications, if the modification will change the exempt status of a study, the Principal Investigator will be informed in writing. The investigator may withdraw the modification request and continue the study as previously approved for exempt status or submit the study for appropriate review and approval through an expedited or full board review.

III. Procedure for Non-Minor Modifications

1. If the IRB Chair determines that the proposed change is non-minor, or refers the submission to the full board at their discretion, the Chair completes the Chair Review stage and assigns appropriate reviewers to complete the full board modification review. The Chair may serve as one of the Primary Reviewers.
2. The IRB Coordinator prepares the modification submission for full board review by placing the submission on the next available meeting agenda and notifying the assigned reviewers of the due date. The IRB Coordinator will also notify the researcher in writing of the assigned IRB meeting review date.

3. The IRB Coordinator ensures that the assigned reviewers and committee members are provided a copy of the completed Modification Request xForm, all modification attachments, and the previously approved study materials for review prior to the convened IRB meeting. The IRB Coordinator will assist in obtaining any additional information requested by the IRB Chair or IRB members.
4. The IRB may request that the Principal Investigator (or other study investigator) attend the convened IRB meeting to present an overview of the proposed modification and address potential committee concerns. The IRB Coordinator would prepare a written invitation to the PI upon request.
5. The assigned reviewers complete the Non-Minor Modification IRB Reviewer xForm approximately three days prior to the meeting and presents his/her evaluation of the non-minor modification to the convened board for review.
6. A majority of the quorum of the convened IRB is needed to approve the proposed modification, or the IRB may approve the proposal with requested changes. The review recommendation, deliberation, and voting actions of the convened IRB will be documented and recorded in the IRB Minutes by the IRB Coordinator.

IV. Procedure for Approval Notification

1. The IRB Coordinator ensures that a new "Modification" event is created in IRBManager containing the xform, all attached materials, and pertinent correspondence.
2. Once the Chair or IRB has reviewed the submission, the IRB Coordinator ensures that the appropriate xforms were completed to document the review determination(s) and ensures that all fields are appropriately updated in the study record.
3. If the modification included a new or revised Informed Consent Document (ICD), the ICD is stamped with the IRB approval (and expiration, as applicable) date and attached to the study record.
4. If the modification was approved with requested changes, the IRB Coordinator notifies the researcher in writing of the requested changes. Upon receipt of the requested changes from the researcher, the IRB Coordinator routes the requested changes to the IRB Chair for final approval.
5. A modification approval letter is prepared by the IRB Coordinator using the appropriate template and incorporating all pertinent review determination information. The letter is saved as an attachment in the study record and the Principal Investigator is notified via IRBManager of the submission approval. For VA studies, the VA AO is additionally notified by email of the approval.
6. Minor Modifications approved by the IRB Chair will be placed on the agenda of the next available meeting for IRB acknowledgement.

V. Responsibilities

A. Principal Investigator

The Principal Investigator is ultimately responsible for the conduct and compliance of any research activities carried out under their direction. The PI must ensure that prior IRB approval is obtained in writing before initiating any changes to previously approved research. As changes are approved by the IRB, the PI is responsible for communicating the changes to research study staff and ensuring that the study is carried out as approved by the IRB. If changes are implemented without IRB approval, it must be reported to the IRB in accordance with applicable policies and procedures.

B. IRB Coordinator

The IRB Coordinator is responsible for assisting researchers with preparing a complete protocol submission and promptly responding to research inquiries. The IRB Coordinator is responsible for ensuring a complete submission prior to assigning it for IRB review and may request revisions or information, as necessary, to facilitate IRB review. The IRB Coordinator will record all correspondence with the researcher in the study record. The IRB Coordinator is responsible for generating and issuing IRB approval documentation using the appropriate template and containing all pertinent review determination information. The IRB Coordinator is responsible for accurate and complete data entry for each study record in IRBManager and will complete periodic quality assurance checks to ensure that IRB records are complete.

C. IRB Chair and Committee

The IRB Chair and committee are responsible for ensuring proposed research complies with regulatory and institutional criteria and completing review of assigned submissions in a timely manner. The IRB Chair is responsible for assigning reviewers with the appropriate expertise. The IRB Chair and reviewers are responsible for communicating with the researcher and IRB Coordinator, as necessary, to obtain information needed to complete the review. The IRB Chair and reviewers are responsible for documenting the review determinations using the appropriate xforms.

The IRB Committee is responsible for determining 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 is responsible for determining whether re-consenting of currently enrolled participants is necessary and whether participants who have completed research involvement must be provided any additional information.

Corresponding IRB Policy:

Policy 3: Roles and Responsibilities
Policy 10: Modification Review