IRB Procedure 7a: IRB Exempt Review
Revision Date: October 6, 2008, revision November 11, 2009, revision July 17, 2010, revised January 27, 2011, revised February 9, 2015, revised October 15, 2015, December 1, 2020

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 exempt review as described in this document.

II. Procedure

1. Researchers that intend to engage in human subjects research are required to submit the research proposal to the ETSU IRB for prospective approval. Researchers must complete and submit the New Protocol Submission xform in IRBManager, and the researcher is to include all relevant study attachments for the IRB to review. If someone other than the Principal Investigator completes the xform, it will electronically route to the PI for completion of the attestation and signature.
2. Following submission of the New Protocol Submission xform by the researcher, the Principal Investigator's Faculty Advisor or Department Chair will be notified to complete their review stage electronically in IRBManager.
3. 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.
4. Once the New Protocol Submission xform is received by the IRB office in IRBManager, 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.
5. Simultaneously, the IRB Coordinators perform an administrative pre-review of the submission to ensure completeness and consistency among all submission materials. If any necessary documents are not present, proposed documents are incomplete or inconsistent, or the submission is not consistent with IRB policies and procedures, the IRB Coordinator will return the New Protocol Submission xform to the submitter to request missing items or completion of documents.

6. It is not uncommon for each New Protocol Submission xform to be returned to the submitter for at least one round of revisions. The goal is to help the researcher compile a complete submission in order to streamline IRB review. 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, Faculty Advisor) before returning to the IRB Office.
7. Once the submission is complete, the IRB Coordinator electronically routes the xform for any other required administrative approvals such as Vice Provost for Research approval for Biosafety. Then the xform returns to the IRB Coordinator for initial data entry and IRB Committee assignment. The IRB Coordinator makes the initial determination of whether the proposal is routed to the ETSU IRB or the ETSU/VA IRB Chair by evaluating the protocol. The IRB Coordinator documents this determination during the coordinator stage of the xform. During this stage, the IRB Coordinator also makes the initial determination as to whether the proposal will receive Exempt or non-Exempt review. The IRB Coordinator stage is completed to document information regarding conflict of interest, funding, training, and external site(s).
8. The xform electronically routes to the assigned IRB Chair, who determines whether the proposal was assigned to the appropriate committee. The IRB Chair may choose to refer the review to the other committee or Vice Chair, as deemed appropriate. The IRB Chair may request any additional information that is pertinent to the review, and the IRB Coordinator will assist with obtaining any such requested information from the researcher. The IRB Chair will evaluate each proposed study and determine whether the proposed study meets exempt status and document the determination(s) using the Chair Determinations xform. If the study requires Limited IRB Review, the IRB Chair completes the review and documents the outcome in the xform.
9. Any changes requested by the IRB Chair will be communicated in writing by the IRB Coordinator to the Principal Investigator.
10. If the study meets the exempt criteria and is approved by the IRB Chair, the IRB Coordinator ensures that the “New Exempt Submission” event is created in IRBManager containing all review materials. The IRB Coordinator updates the assigned IRB protocol number and confirms that all fields are appropriately updated in the study record. The IRB Coordinator changes the study site status in IRBManager to Approved and enters the date of the exempt determination as a new approval period and labels the type exempt, which does not receive an expiration date. If the study received Limited IRB Review, the IRB Coordinator ensures the field is marked affirmatively. The study automatically receives an administrative check-in date, which is noted in the letter. The IRB Coordinator enters exempt in the study fields last review and next review.
11. A letter, including a citation of the applicable category of exemption, will be prepared by the IRB Coordinator using the appropriate template. For non-

VA studies, 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 IRB Coordinator will post the exempt approval letter as an "Internal Only" attachment in IRBManager. When the VA R&D approval is verified, the IRB Coordinator will remove the "Internal only" status, so the letter is visible to study staff.

12. The researcher may initiate the study as soon as the IRB approval documentation is received and any other required institutional/study site approvals are obtained.
13. Studies determined to be exempt by the Chair will be placed on the next available IRB agenda for IRB acknowledgement of approval.

III. 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 exempt research. Only the ETSU IRB has the authority to determine that a study qualifies for IRB exempt status. Research that is determined to be exempt from IRB review is not exempt from protection of human subjects. The PI is responsible for complying with all applicable ethical principles, regulations, policies, and site-specific requirements during the conduct of the study. The PI is responsible for training research study staff and ensuring they complete all IRB required training, carrying out the study as approved by the IRB, obtaining IRB approval for any proposed changes, notifying the IRB of reportable events, and submitting the administrative check-in xform in a timely manner.

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

The IRB Chair is responsible for being familiar with the eligibility criteria for IRB exemption and completing review of assigned submissions in a timely manner. The IRB Chair is responsible for communicating with the researcher and IRB Coordinator, as necessary, to obtain information needed to complete the review. The IRB Chair is responsible for ensuring that all exempt submissions fulfill the ETSU IRB ethical standards. The IRB Chair is responsible for documenting the review determinations using the appropriate xforms.

Corresponding IRB Policy:
Policy 3: Roles and Responsibilities
Policy 7: IRB Exempt Review
Policy 10: Modification Review
Policy 11: Continuing Review