IRB Procedure 9a: Full Board 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 initial full board review.

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. For studies that have an associated contract, the IRB Coordinator forwards a copy of the contract or, at minimum, a copy of any contract pages referencing provisions for medical care or other care and services for research-related injury and any information regarding the consent process to the Office of Research and Sponsored Programs Administration. ORSPA completes the contract review checklist to ensure consistency between the consent and contract. For studies that have an associated grant, the IRB Coordinator provides a copy of the grant and New Protocol Submission xform to the Vice Provost for Research for congruency review. Results of the review are placed in the study record.
7. 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.
8. Once the submission is complete, the xform electronically routes to any other signatories for 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).
9. 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 to determine whether the proposed study requires full board review. The Chair documents the appropriate review level and assigns primary reviewers with the appropriate expertise using the Chair Determinations xform.
10. If the IRB Chair determines that the study requires Full Board review, the IRB Coordinator ensures that the “New Protocol 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.
11. The IRB Coordinator assigns the submission for the next available IRB meeting. The IRB Coordinator obtains the names of the selected Primary

Reviewers from the Chair Determinations xform completed by the IRB Chair and notifies the assigned reviewers of the review assignment and due date, which is typically three business days prior to the meeting. The IRB Coordinator ensures that the reviewers and committee members have access to all pertinent review documentation prior to the meeting.

12. The IRB Coordinator sends an electronic invitation to the Principal Investigator to attend the convened IRB meeting to present an overview of the proposed research and address any committee concerns.
13. The IRB reviewers and members review all proposals prior to the convened meeting and make request additional information from the researcher prior to the meeting. The IRB Coordinator ensures that all IRB members have access to all new or revised study materials provided by the researchers.
14. The assigned reviewers complete the Full Board Reviewer xForm and present their review recommendations to the convened board for consideration and voting. The review recommendation, deliberation, and voting actions of the convened IRB will be documented and recorded in the IRB Minutes by the IRB Coordinator.
15. If the IRB determines a deferral or disapproval of the proposal, the IRB Coordinator, in consultation with the IRB Director and Chair, will prepare a letter informing the Principal Investigator of the committee's decision and the reason(s) for the action.
16. For a deferral, the investigator may respond with revisions, and the IRB Coordinator assigns the revised proposal to the next available agenda for full board review following the same procedures noted above.
17. If the IRB approves the study pending determinative changes, the IRB Coordinator changes the study site status in IRBManager to Approval Pending. The IRB Coordinator prepares the Approval Pending Letter using the appropriate template and creates an "IRB Requested Changes" event in IRBManager. The letter is shared with the PI via the Requested Changes xform, and the PI must respond to the request by completing the xform.
18. When the PI submits the Requested Changes xform, the IRB Coordinator reviews the xform for completeness, and assigns it to the IRB Chair, or designee, for final IRB approval. The approval of the IRB Requested Changes will be placed on the next agenda for IRB acknowledgement. If the changes require full board review (i.e., additional changes made by PI, or board requested review, etc.), the IRB coordinator will add the requested changes to the next agenda for IRB review.
19. Once the study is approved by the IRB, the IRB Coordinator changes the study site status in IRBManager to Approved, creates a new approval period by entering the date of the convened IRB approval decision as the approval date, labels the type as either Expiring or Non-expiring, and generates the approval period (i.e., 12 months), which automatically assigns either the expiration date for continuing review or an

administrative check-in date. The IRB Coordinator enters Full Board in the study fields last review and next review.

20. For studies that include an Informed Consent Document (ICD), the IRB Coordinator stamps the approved ICD(s) with the IRB approval (and expiration, as applicable) date and attaches a copy to the study record in IRBManager. For non-VA studies, the IRB Coordinator attaches the stamped ICD to the "New Protocol Submission" event and on the protocol page (Attachment Section). For VA studies, the IRB Coordinator attaches the stamped ICD as an "Internal Only" attachment. When VA R&D approval is verified by the IRB, the IRB Coordinator will remove the "Internal only" status, so the approved ICD is available to study staff.
21. A letter, including a citation of the applicable regulatory determinations, 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 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.
22. 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.

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 the research. It is the responsibility of the PI to provide sufficient documentation to the IRB for the committee to make the necessary regulatory and ethical determinations needed for IRB approval. 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 completing other submission requirements in a timely manner.

If the protocol involves use of an investigational drug or device, it is the responsibility of the sponsor and Principal Investigator to apply to, and receive approval from FDA as required by their regulations. It the responsibility of the PI to ensure compliance with regulatory and institutional requirements for storage, labeling, and control of investigational drugs, biologics, or devices.

If the IRB requests information or changes, the PI is responsible for providing the requested information in a timely manner in order to facilitate IRB review and approval. The PI is responsible for ensuring that the research is not initiated until final written approval is obtained.

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 providing the submission materials to the IRB members prior to the convened meeting, and during the convened meeting, the IRB Coordinator is responsible for ensuring quorum is maintained and recording attendance, discussion, and voting actions. The IRB Coordinator is responsible for generating and issuing IRB determination 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, and the IRB members are responsible for actively participating in the convened IRB discussion.

Corresponding IRB Policy:
Policy 2: IRBs
Policy 3: Roles and Responsibilities
Policy 4: IRB Roles and Responsibilities
Policy 9: Full Board Review
Policy 11: Continuing Review
Policy 19: Devices
Policy 31: Storage of Investigational Agents
Policy 33: IND