IRB Procedures 9a: Full review procedures
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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 submitting research for initial full review.

II. Responsibilities

A. IRB Administration Responsibilities

1. The IRB Coordinator will review the new protocol submission xform and attachments for completeness and inform the PI of any needed documents (IRB Pre-Review Stage for non-VA submissions). Once the IRB Pre-Review stage is complete, the IRB Coordinator forwards the new protocol submission xform for required signatures. IRB coordinator then completes the IRB Initial Review and IRB Coordinator Stage, which includes a submission checklist. IRB coordinator checks the question regarding external sites to identify whether the PI has provided complete information for each external site. IRB Coordinator contacts PI and/or site if additional information is needed. If documents are not received at time of review, the approval letter will indicate approval pending receipt of necessary documents. 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 Sponsored Programs. The IRB Coordinator provides the contract consistency checklist to the expedited reviewer(s) when complete. For VA studies, the IRB Coordinator verifies that the VA new protocol submission xform was submitted and that the VA signatories have indicated that the submission meets VA requirements.

2. The IRB Coordinator makes the initial determination of whether the proposal is routed to the ETSU IRB or the ETSU/VA IRB by evaluating the protocol by the criteria outlined in IRB Policy II. The IRB Coordinator documents this determination on the IRB Initial Review Stage. The IRB Coordinator forwards the proposal to the relevant IRB Chair who makes the final determination of board assignment. IRB

coordinator checks the question regarding external sites to identify whether the PI has provided complete information for each external site. IRB Coordinator contacts PI and/or site if additional information is needed. If documents are not received at time of review, the approval letter will indicate approval pending receipt of necessary documents. 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 Sponsored Programs. The IRB Coordinator provides the contract consistency checklist to the IRB Chair when complete.

3. Appropriate materials (as follows) will be forwarded to the Primary Reviewers. The IRB Coordinator obtains the names of the selected Primary Reviewers from the xform 115 completed by the IRB Chair.

4. The IRB Coordinator forwards a letter of invitation to the PI notifying him of the scheduled presentation date, time, and location. The study will be added to the agenda for the next meeting.

5. The following materials are provided to the Primary Scientific Reviewer approximately 10 days prior to meeting:

- ✓ completed new protocol submission xform (VA or non-VA), which includes narrative section, with required signatory attestations full protocol
- ✓ proposed informed consent document
- ✓ any relevant grant application
- ✓ investigator's brochure, if there is one
- ✓ any recruitment materials, including any advertisements intended to be seen or heard by potential participants
- ✓ for HHS supported multicenter clinical trials, a copy of the HHS approved sample informed consent document*
- ✓ for HHS supported multicenter clinical trials, a copy of the complete HHS approved protocol
- ✓ Investigator CV
- ✓ any advertisements, questionnaires, surveys, testing forms and/or introduction letters associated with the study and intended for participant use or view
- ✓ any consultant's report (if , otherwise posted prior to IRB meeting)
- ✓ for studies that have an associated contract, verification from Sponsored Programs of the consistency for provisions of medical care or other care and services for research-related injury between the consent document and the contract

6. The following materials are provided to the Primary ICD Reviewer approximately 10 days prior to meeting:

- ✓ completed new protocol submission xform (VA or non-VA), which includes narrative section, with required signatory attestations
- ✓ full protocol
- ✓ proposed informed consent document
- ✓ any relevant grant application
- ✓ any recruitment materials, including any advertisements intended to be seen or heard by potential participants
- ✓ for HHS supported multicenter clinical trials, a copy of the HHS approved sample informed consent document*
- ✓ for HHS supported multicenter clinical trials, a copy of the complete HHS approved protocol
- ✓ Investigator CV
- ✓ any advertisements, questionnaires, surveys, testing forms and/or introduction letters associated with the study and intended for participant use or view
- ✓ any consultant's report (if available; otherwise posted prior to IRB meeting)
- ✓ for studies that have an associated contract, verification from Sponsored Programs of the consistency for provisions of medical care or other care and services for research-related injury between the consent document and the contract

7. If the IRB Chair determines that an external consultant is necessary, the Chair or Director contacts the designated consultant to determine his/her availability and lack of conflict of interest, and to ensure consultant agrees to confidentiality per policies. The IRB Coordinator forwards a Conflict of Interest Form for Consultants in addition to a copy of the IRB Conflict of Interest Policy to the consultant. Upon receipt of the signed Conflict of Interest Form for Consultants indicating no conflict, the IRB coordinator forwards the packet as detailed above to the consultant. If the conflict of interest form indicates any conflict, the IRB Coordinator immediately notifies the Director, and the consultant is disqualified and the proposal is not forwarded to him/her for review. Another consultant will then be identified by the Chair. The consultant will be asked to provide a written report within 3 days. The IRB Coordinator posts the consultant's written report in IRBManager prior to the board meeting per Policy 4, Section III. If the consultant is attending the IRB meeting, the IRB Coordinator notifies consultant in writing of the meeting date, time, and location.

8. Approximately ten days prior to the meeting, the IRB Coordinator provides complete proposal information as documented below in IRBManager, IRB members are responsible for reviewing:

- ✓ completed new protocol submission xform (VA or non-VA), which includes narrative section, which serves a protocol summary and includes sufficient details to make required determinations, with required signatory attestations and proposed informed consent document
- ✓ any recruitment materials, including any advertisements intended to be seen or heard by potential participants
- ✓ Investigator CV (if new investigator)
- ✓ any advertisements, questionnaires, surveys, testing forms and/or introduction letters associated with the study and intended for participant use or view
- ✓ any consultant's report

9. The IRB Coordinator is responsible for ensuring that any IRB member has access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting and that any IRB member has access to additional information provided to individual reviewers.

10. The IRB staff is responsible for recording all votes. The IRB Coordinator is responsible for ensuring that the minutes record those IRB members who are in attendance at the meeting but are absent from the room at the time of vote. The recording of votes will denote the number of votes for, opposed, and abstained.

11. If the IRB determines an approval of the proposal, the IRB coordinator prepares the appropriate approval letters. For non-VA studies, the IRB Coordinator will post the full approval letter on the "New Protocol Submission" event. For VA studies, the IRB Coordinator will post the approval letter as an INTERNAL ONLY attachment on the "New Protocol Submission" event in IRBManager. When the VA R&D approval letter is verified by the IRB, the IRB Coordinator will remove the "Internal only" status so that the letter is visible to study staff. For both VA and non-VA, the IRB Coordinator changes the status in IRBManager to "approved" and enters the date of the initial full approval as a new approval period, enters the length of approval, and selects "calculate". The IRB Coordinator enters "full" in the fields "last review" and "next review".

12. If the IRB determines an approval pending modification status for an initial full submission, the IRB Coordinator will draft a letter requesting changes identified by the IRB and reviewers. The Approval Pending Modification letter is forwarded to the PI in a timely manner.

13. When the PI responds with requested changes that required his/her concurrence, the IRB Coordinator will review those changes for completeness and obtain the Chair's or his/her Designee's expedited

approval of those changes. The Chair's expedited approval of research contingent upon specific minor conditions will be placed on the agenda and documented in the minutes of the first IRB meeting after the date of the approval. If the changes require full board review (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 and action.

Once final approval is obtained, for non-VA studies, the IRB Coordinator will post the initial approval letter on the "New Protocol Submission" event. For VA studies, the IRB Coordinator will post the approval letter as an INTERNAL ONLY attachment on the "New Protocol Submission" event in IRBManager. When the VA R&D approval letter is received by the IRB, the IRB Coordinator will remove the "Internal only" status so that the letter is visible to study staff. For both VA and non-VA, the IRB Coordinator changes the status in IRBManager to "approved" and enters the date of the initial full approval as a new approval period, enters the length of approval, and selects "calculate". The IRB Coordinator enters "full" in the fields "last review" and "next review".

14. Upon study approval (except in cases of waiver), the IRB Coordinator is responsible for posting an approved copy of the Informed Consent document to the investigator for non-VA studies.
    Each page of the Consent will bear an IRB stamp of approval and expiration date over the initials of either the IRB Chair, Vice Chair, Director or IRB Coordinator.

    For non-VA studies, the IRB Coordinator will post the stamped approved consent document as an attachment on the "New Protocol Submission" event and on the protocol page (Attachment Section). For VA studies, the IRB Coordinator will post the informed consent document as an INTERNAL ONLY attachment on the "New Protocol Submission" event and on the protocol page (Attachment Section) in IRBManager. When the VA R&D approval letter is received by the IRB, the IRB Coordinator will remove the "Internal only" status so that the informed consent document is visible to study staff.
    In addition, for both VA and non-VA, the IRB Coordinator enters the version date and the date of approval of the informed consent document in the appropriate protocol field in IRBManager.

15. If the IRB determines a deferral or disapproval of the proposal, the IRB Coordinator will prepare a letter informing the PI of the committee's decision, question, and concerns, and the reason(s) for the action.

16. For a deferral, if the investigator responds with revisions, the IRB Coordinator places the proposal on the agenda for the following meeting for full IRB review. The coordinator provides the IRB with the documents outlined above for initial submission as well as a copy of the IRB deferral letter to the PI and the PI's response, including any revised documents. The project is given full IRB review again, and the IRB Coordinator once again communicates the outcome of the IRB's deliberations to the PI in writing.
17. The IRB Coordinator is responsible for filing any paper documentation, and appropriate data entry in IRBManager

B. Principal Investigator Responsibilities

1. The PI is responsible for submitting a complete new protocol submission xform for initial full review, as applicable, no less than 2 weeks prior to any convened meeting date. The submission deadlines and meeting dates are posted on the IRB web site, www.etsu.edu/irb
2. Applications must be submitted electronically on the New Protocol Submission xform. The PI is responsible for submitting a completed New Protocol Submission xform, which contains a narrative section. In addition, the PI is responsible for attaching:

- ✓ proposed informed consent document
- ✓ any recruitment materials, including any advertisements intended to be seen or heard by potential participants
- ✓ any questionnaires, surveys, testing forms and/or introduction letters associated with the study and intended for participant use or view
- ✓ Investigator CV
- ✓ full protocol
- ✓ any relevant grant application (Investigators who are seeking funding, whether federal or otherwise, must submit a copy of the funding packet for review)
- ✓ investigator's brochure, if there is one (investigational drugs only per 21 CFR 312)
- ✓ for HHS supported multicenter clinical trials, a copy of the HHS approved sample informed consent document*
- ✓ for HHS supported multicenter clinical trials, a copy of the complete HHS approved protocol
- ✓ for studies that have an associated contract, 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 (one copy only)

3. If the protocol involves use of an investigational drug, it is the responsibility of the sponsor [21 CFR 50.3(22)(e)] and/or Principal Investigator to apply to, and receive approval from FDA for the

investigational use of a new drug. Protocols submitted to the IRB indicating IND use **MUST** be submitted with an appropriate IND number (indicating FDA approval). Under no circumstances will an investigational drug protocol be accepted for review prior to its having received an IND number. For Investigational Devices (IDE),refer to Device policy.

4. During the convened IRB meeting, the investigator will present an overview of the goals, design, study procedures, and safety features of the protocol. Particular attention will be paid to the risk/benefit ratio and to the adequacy of the informed consent.

5. If an approval pending modifications is received by the PI, the investigator is required to concur and provide written revisions of the documents. The PI does not initiate the study until final written approval is received.

6. If a deferral action is made by the IRB, which is action taken when substantial modification is required or if sufficient information is not available to judge the application adequately, the investigator is informed of the reason(s) for the action. In order to receive approval, the PI must re-submit the study with appropriate changes for Full Review.

C. IRB Committee Responsibilities

1. The IRB Chair evaluates the proposal and determines whether the IRB Coordinator's choice of board assignment is appropriate. The IRB Chair ensures that the proposal is assigned to the appropriate board with relevant expertise and documents this determination on xform 115. The Chair will assign primary scientific reviewer(s) that have the scientific or scholarly expertise to understand the research. In studies that involve vulnerable populations, the IRB Chair will assign a primary reviewer that serves as an advocate for that population.

2. If the IRB Chairman is a co-investigator, he/she may chair the meeting and participate in the explanation of the study. At the time that the IRB begins deliberation, the Chair will turn the meeting over to the Vice-Chair, leave the room, and not participate in the deliberation and vote. The minutes will reflect this activity.

3. The IRB Committee will conduct its review in accordance with applicable IRB Policies and Procedures. Refer to IRB Full Review Policy.

4. All initial full review determinations are completed using the criteria found in 45 CFR 46.111 for approval of research. In addition, the review interval is determined after consideration of the criteria identified in IRB Policy 9, Section J. The Primary Reviewer documents the review of approval criteria and appropriate interval determination criteria using the **"**xform 111." In addition, the Primary ICD Reviewer documents the review of the informed consent process using xForm section 128. The Primary Reviewer who serves as an advocate for a vulnerable population documents the review of required determinations using the appropriate xform sections130-138.

References:
IRB Full Review Policy