**IRB Procedure 11a: Continuing Review**
**Revision Date: May 15, 2007; revised November 11,2009;**
**Revision July 17, 2010; revised March 1, 2011; revised**
**February 9, 2015; revised December 1, 2020**

## I. <u>Summary</u>

This IRB procedure is to make guidelines for investigators, IRB staff, and IRB members understandable and available to all involved in the Continuing Review process.

## II. <u>Procedure for Continuing Review</u>

1. In the initial approval letter, the researcher is informed of the study expiration date. Additionally, IRBManager generally sends automated reminder notices of the upcoming expiration date as a courtesy for researchers.
2. No less than 45 days prior to the study expiration date, the researcher will complete and submit the Continuing Review or Study Closure xform (previously xForm 107) in IRBManager. The submission should include the following:
    a. Any required attachments as identified on the xform
    b. Summary of project activities that have occurred since previous IRB review including brief summary descriptions of events/reports
    c. If still consenting, a copy of the current, IRB stamped, approved Informed Consent Document (ICD) and a clean, unstamped copy of the identical ICD to be stamped with the new approval date
    d. If the study was approved under the Old Common Rule and qualifies for transition to the New Common Rule, and if the participants are still being consented (either during enrollment or follow-up procedures), the PI must ensure that the Informed Consent Document contains all the required elements of consent under the New Common Rule, which are clearly listed on the Continuing Review xForm
    e. Copies of any other stamped documents that are still being used, such as recruitment flyers
3. If someone other than the Principal Investigator completes the xform, it will electronically route to the PI for completion of the attestation and signature.
4. 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 Continuing Review or Study Closure xform (previously xForm 107) to the submitter for revisions, as necessary, to ensure compliance with VA research requirements. For VA studies,

information about VA audits is provided on the xForm by the VA Research Compliance Officer.

5. Once the Continuing Review or Study Closure xform (previously xForm 107) is received by the IRB office in IRBManager, the IRB IRT verifies that all study staff have current 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.

6. The xform is then routed to the IRB Coordinator for administrative pre-review to ensure completeness and consistency among all submission materials. This includes confirming that questions regarding modifications and research reports (UPIRTSO's, audits, complaints, etc.) contain accurate information regarding any submissions since the last approval. 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 xform to the submitter to request missing items or completion of documents.

7. The researcher must promptly respond to requested pre-review information in order to ensure adequate time for IRB review and approval prior to study expiration. Upon re-submission, the xform goes through all prior stages (i.e., PI signature, VA R&D Office) before returning to the IRB Office.

8. If the study was approved under the Old Common Rule and qualifies for transition to the New Common Rule, the IRB Coordinator reviews the submission and confirms that the study is eligible. If the participants are still being consented, the IRB Coordinator will confirm that the Informed Consent Document has been updated as necessary to comply with New Common Rule requirements.

9. Once the submission is complete, the IRB Coordinator will attach any additional required documentation and electronically route the xform to the appropriate IRB Chair.

10. The IRB Chair reviews each study submitted for continuing review and selects the appropriate review process (review by convened board or expedited review) and documents the determination in the Chair Determinations Stage if the xform.
    a. For studies previously reviewed by the convened board:
        i. The IRB Chair determines if the study must undergo continuing review by the convened board or if the study is eligible to undergo expedited review.
        ii. The Chair completes the Chair Determinations Stage of the xForm and will be directed to assign either Primary or Expedited reviewer(s) with appropriate expertise depending on the level of review.
    b. For studies previously reviewed by the expedited process, generally the continuing review will be conducted via expedited review. The Chair completes the Chair Determinations Stage of the xForm and

may either serve as the sole reviewer or assign expedited reviewer(s) with appropriate expertise.

11. Once the Chair completes the xform, it moves on to the IRB Coordinator, who will forward it the selected reviewers (if reviewers other than the chair were selected).

12. For full board continuing review of research, the IRB Coordinator the IRB coordinator will ensure that the "Continuing Review" event is created in IRBManager containing all pertinent review documents and available for all IRB members to review prior to the convened IRB meeting. The IRB Coordinator will ensure that, upon request, 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 assigned reviewers. The IRB Committee will conduct its review in accordance with applicable IRB Policies and Procedures, and the IRB Coordinator will record the deliberations and voting actions in the IRB Minutes.

13. For expedited continuing review of research, the IRB coordinator will ensure that the "Continuing Review" event is created in IRBManager containing all pertinent review documents for the assigned expedited reviewers to review and will obtain additional information, upon request.

14. The assigned reviewer(s) document the review of approval criteria using the appropriate "Expedited Reviewer xForm" or "Full Board Reviewer xForm." Reviewers should follow prompts in the xform to ensure that they are reviewing the submission under the appropriate regulations (Old Common Rule or New Common Rule). For studies deemed eligible for transition, the reviewer consider whether transition is appropriate and will document the transition determination and date in the xform.

15. The IRB Coordinator is notified when the reviewers complete their review xform and reviews the determinations documented. If the IRB or reviewer(s) approves the study pending changes, 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 prior to the expiration date.

16. 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

17. Once the continuing review is approved by the IRB, the IRB Coordinator enters the date of the continuing review for a new approval period, labels the type as either Expiring or Non-expiring, and generates the approval period (i.e., 12 months), which automatically assigns either the date for continuing review or an administrative check-in date. The IRB Coordinator enters expedited or full board in the study fields last review and next review.

18. Except in cases of waiver, the IRB Coordinator applies an IRB-approval stamp to each approved Informed Consent Document (ICD) in

IRBManager. For non-VA studies, the IRB Coordinator attaches the stamped ICD to the "Continuing Review" 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.

19. 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 that the submission is approved. For VA studies, the IRB Coordinator attaches 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.

20. For expedited continuing review approvals, the IRB Coordinator places the items on the next IRB agenda for IRB acknowledgement.

## III.  <u>Procedure for Expired Studies</u>

1. If a response is not received by the deadline for continuing review submission, an automated warning email from the Vice Provost of Research is sent to the Principal Investigator and CC recipient.

2. If the PI does not submit a Continuing Review or Study Closure xForm, or if the review is not complete by the expiration date, the IRB Coordinator ensures that IRBManager has emailed the Expiration Letter on the day prior to expiration to the PI.  Expiration notifications are copied to the VA AO (if VA study), external sites ceding to the ETSU IRB, and others, as applicable.

3. The IRB Coordinator ensures that the study site status in IRBManager is changed to Expired and may send additional courtesy reminders of the study expiration to the researcher, department chair, and faculty advisor.

4. The Principal Investigator will cease all research activities as instructed in the Expiration Letter.  Upon receipt of the Expiration Letter, the PI will immediately notify the IRB Chair of any subjects currently active in the project who could be harmfully affected by halting the research.

5. The IRB Chair will review the response and list of participants submitted by the PI. The IRB Chair will consult with (for VA) either the Chief of Staff (COS), or in his/her absence, the ACOS/R, or (for ETSU) the Vice Provost for Research (VPR), to determine if the subject(s) may continue in the research.  If the ACOS/R or VPR is not a physician, they will designate a physician as a consultant.  If the study is an FDA regulated study, the COS, ACOS/R or VPR and IRB Chair will follow FDA requirements in 21 CFR 56.108(b)(2) and (3) in making their decision.

6. If follow-up of subjects for safety reasons is permitted/required by the IRB, the subjects will be so informed, and any adverse events/outcomes should be reported to the IRB and sponsor.

7. If the researcher submits the Continuing Review or Study Closure xForm, or it was in process at time of expiration, the IRB will review the submission as described above. However, all research activities must remain halted until continuing review approval is obtained.

8. If the study remains Expired for a period of 90 days without any response from the Principal Investigator, the IRB Coordinator will notify the IRB Director and Chair. The study may be administratively closed, and the PI will be notified of the study closure.

## IV.   <u>Responsibilities</u>

### A.  Principal Investigator

The Principal Investigator is ultimately responsible for the conduct and compliance of any research activities carried out under their direction. It is the responsibility of the PI to provide the IRB information needed in order to carry out continuing review and to respond promptly to requests for information during the continuing review process. It is the responsibility of the PI to provide sufficient documentation to the IRB to make the necessary regulatory and ethical determinations needed for continuing 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 ensuring that all research activities halt immediately if the IRB approval expires and for notifying all appropriate parties (i.e., study staff, lab coordinators, research subjects, project directors, sponsors/funders, etc.). Upon expiration, it is the responsibility of the PI to provide the IRB information about the study subjects who might be harmed if research halts and to obtain IRB concurrence to continue any scheduled research visits or follow-up before proceeding. The PI is responsible for submitting a study closure to the IRB when the research is completed.

### 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 approval documentation using the appropriate template and containing all pertinent review determination information. The IRB Coordinator is also responsible for generating and issuing IRB Expiration notification and ensuring notification of all pertinent parties (i.e., VA R&D, sponsor, ORSPA, faculty advisor,

IRB Director, VPR, external sites, etc.). 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 reviewers 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.

For studies that expire, the IRB Chair is responsible for communicating with the Principal Investigator to ascertain the status of the research. The IRB Chair is responsible for reviewing the response from the researcher, and in consultation with others as appropriate, determining if the research activities may continue in order to avoid harm to subjects. The IRB Chair is responsible for documenting all correspondence and determinations related to study expiration and providing the correspondence to the IRB Coordinator to be placed in the study record.


Corresponding IRB Policy:
Policy 2: IRBs
Policy 3: Roles and Responsibilities
Policy 4: IRB Roles and Responsibilities
Policy 8: Expedited Review
Policy 9: Full Board Review
Policy 11: Continuing Review