

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

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 continuing review.

II. Responsibilities

A. IRB Administration Responsibilities

1. The IRB Coordinator will ensure that IRBManager sends an email to the Principal Investigator (PI) requesting submission of a completed xform 107. The template email will clearly state the protocol number, Study title, the date of expiration of approval, and the deadline for submission of the completed xform 107.
2. The email will be sent approximately 4 weeks prior to the submission deadline, which will be approximately 8 weeks prior to the project expiration. If a response is not received by the deadline, a Warning email is emailed to the PI and Cc recipient.
3. The xform 107, when received, will be checked by the IRB Coordinator for completeness. The IRB Coordinator will ensure that the VA continuing reviews have been signed by the VA R&D office.
4. If the xform 107 is not complete, i.e., unanswered questions or lack of required attachments, the IRB Coordinator will reject the xform back to the PI.
5. The IRB Coordinator is responsible for ensuring that a copy of any IRB audits that have occurred in the period since the last review is posted in IRBManager. Information about VA audits is provided on the xform 107 by the VA Research Compliance Officer.
6. The IRB coordinator will attach any required documentation, (see continuing review policy) and forward to the IRB Chair. The IRB Chair reviews each study submitted for continuation review and selects the

appropriate review process (review by convened board or expedited review).

For studies previously reviewed by the convened board:

- The IRB Chair determines if the study must undergo continuation review by the convened board or if the study is eligible to undergo expedited review. If the study must undergo continuation review by the convened board, the Chair completes Chair Determinations Stage, Section “Full Continuation Reviews” and “Reviewers” section of the Xform 107 to document reviewer assignments.
- If the study is eligible for expedited review, the Chair completes Chair Determinations Stage, Section “Full Potentially Eligible for Expedited” of the xform 107 and “Reviewers” section of the xform 107 to document reviewer assignments.

For studies previously reviewed by the expedited process:

- The Chair determines if the study continues to be eligible for expedited review, and documents this decision on Chair Determinations Stage, “Expedited Continuation Review” section of the xform 107. The Chair then completes “Reviewer” section of the xform 107 to document reviewer assignments.
 - If the study must undergo continuation review by the convened board, the Chair documents this decision on the Chair Determinations Stage, “Expedited Continuation Review” section of the xform 107. The Chair then completes “Reviewers” section of the xform 107 to document reviewer assignments.
7. The IRB Coordinator posts a copy of the complete packet to the primary reviewers for full continuation review; or to the Expedited Reviewer(s) for expedited continuing review.
 8. For full continuing review of research (research that does not qualify for expedited review), the IRB coordinator will ensure that the following documents are available in IRBManager for all IRB members to review:
 - a. Project Narrative, which serves as protocol summary, or narrative section of new protocol submission
 - b. Continuing Review /Study Closure application (xform 107), which serves as status report, and any attachments (complete documents as received from investigator)
 - c. copy of the current approved informed consent document
 - d. copy of any newly proposed consent document

- e. summary history of modifications submitted to IRB and list of interim adverse events (if applicable)
- f. copy of any IRB (and if appropriate, VA) audits that have occurred in the period since the last review
- g. For VA studies, Form 10-3203 for studies that are obtaining picture or video information from subjects (not required if the information is embedded in the 10-1086)

For full continuing review of research (research that does not qualify for expedited review), the IRB coordinator will ensure that the following documents are available in IRBManager for primary reviewers to review:

- a. Project Narrative, which serves as protocol summary, or the narrative section of the new protocol submission
 - b. Continuing Review /Study Closure application (xform 107), which serves as status report, and any attachments (complete documents as received from investigator)
 - c. copy of the current approved informed consent document
 - d. copy of any newly proposed consent document
 - e. copy of current HIPAA Authorization document
 - f. summary history of modifications submitted to IRB and list of interim adverse events (if applicable)
 - g. copy of any IRB (and if appropriate, VA) audits that have occurred in the period since the last review
 - h. copy of complete protocol, including any protocol modifications previously approved by the IRB
 - i. For VA studies, Form 10-3203 for studies that are obtaining picture or video information from subjects not required if the information is embedded in the 10-1086)
9. 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 individual reviewers.
10. For continuing review by the expedited procedure, the IRB Coordinator will ensure that the following documents are available in IRBManager for the IRB Chair or designated IRB member(s) (Expedited Reviewers) to review:
- a. Project Narrative, which serves as protocol summary, or the narrative portion of the new protocol submission xform
 - b. Continuing Review /Study Closure application (xform 107), which serves as status report, and any attachments (complete documents as received from investigator)
 - c. copy of the current approved informed consent document

- d. copy of any newly proposed consent document
 - e. copy of current HIPAA Authorization document
 - f. summary history of modifications submitted to IRB and list of interim adverse events (if applicable)
 - g. copy of any IRB (and if appropriate, VA) audits that have occurred in the period since the last review
 - h. copy of complete protocol, including any protocol modifications previously approved by the IRB
 - i. For VA studies, Form 10-3203 for studies that are obtaining picture or video information from subjects not required if the information is embedded in the 10-1086)
11. When continuing review requirements are not met by the Investigator, the IRB Coordinator emails (or 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) and to MSHA (if MSHA study). IRB Coordinator makes the appropriate entries on the next full or expedited agenda.
12. The IRB Coordinator will draft letters requesting reviewer revisions and final approval letters using the appropriate template. Appropriate letters will be posted in IRBManager.
13. The IRB Coordinator will complete appropriate database entries in IRBManager, including placing full continuation reviews and notification of expedited continuing reviews on the next available IRB agenda.

B. Principal Investigator Responsibilities

1. Submission of complete, accurate Continuing Review xform 107. It is the investigator's responsibility to initiate an appropriate response, allowing sufficient time for the review and re-approval process to be completed before the current approval expires. Prior to the identified submission deadline, the PI will submit the following in response to the Request Letter for Continuing Review Application:
- a. completed Continuing Review/Study Closure Application (xForm 107) The investigator's electronic signature on xForm 107 indicates his/her assurance that the information presented for continuing review is complete and accurate.
 - b. Any required attachments as identified on the xform 107, including but not limited to applicable brief descriptions of summary events/reports

- c. A copy of the current, IRB stamped, approved informed consent (this will provide a verification that the investigator is using the current approved version)
- d. a clean, unstamped copy of the identical informed consent to be stamped with the new continuing review approval dates. However, if a modification that changes the ICD is being submitted at the time of continuing review, the investigator must submit the revised ICDs as indicated in the modification policy.

VA submissions are processed by the VA prior to IRB review.

2. The Investigator ensures that the Continuing Review/Study Closure Application (xForm 107) is complete, answering all items as noted below and attaching necessary summary descriptive information:

- Project status, IND information, population involved, enrollment update, including total number of consented participants, including screen failures/withdrawals, total multi-center enrollment if applicable, number of subjects consented by local PI since previous IRB review, number of male/female subjects, and number of participant withdrawals, any recruitment problems
- Summary of project activities that have occurred since previous IRB review, including
 - 1) Adverse events summary
 - 2) Any Data and Safety Monitoring Reports
 - 3) Any unanticipated problems involving risks to participants or others
 - 4) Any protocol changes (amendments or modifications)
 - 5) Any audits
 - 6) Any change in risk/benefit ratio
 - 7) Any complaints received from participants
 - 8) Any participant withdrawals and reasons for withdrawals
 - 9) Any interim findings
 - 10) Any progress reports
 - 11) Any multi-center reports, if applicable
 - 12) Any recent relevant literature
 - 13) Any protocol violations or deviations
 - 14) Any other relevant information, especially information about risk associated with the research

3. Study Expiration: If study approval expires, the Investigator will cease all research activities as instructed in the Expiration Letter. Upon receipt of the Expiration Letter, the investigator will immediately notify the IRB Chair

of any subjects currently active in the project who could be harmfully affected by expiration of the research. 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.

C. IRB Committee Responsibilities

1. If an IRB member has a conflict of interest, he/she will not participate in the continuing review of the protocol, except to provide information requested by the IRB. If an assigned reviewer has a conflict on interest, he/she is required to identify that conflict and notify the IRB office for reviewer re-assignment. The IRB Committee will conduct its review in accordance with applicable IRB Policies and Procedures. Refer to IRB Continuing Review Policy.
2. All continuing 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 11, Section IIIA. The reviewer documents the review of approval criteria and appropriate interval determination criteria and the need for any source verification using the appropriate “Continuing Expedited Reviewers Xform” or “Continuing Full Reviewer Xform”. In addition, the reviewer documents the review of the informed consent process using the xform section 128. The reviewer who serves as an advocate for a vulnerable population documents the review of required determinations using the appropriate xform sections (130-138).
3. If study approval expires, the IRB Chair will review the 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.

References:

IRB Continuing Review Policy