Study Closure

I. Purpose

To describe the policies and procedures to close a project with the WCM Institutional Review Board (IRB).

II. Revisions from Previous Version

None.

III. Definitions

None.

IV. Policy

The Principal Investigator (PI) and/or the IRB may close approved protocols under certain circumstances. The PI is responsible for promptly closing out an IRB approved project if any of the following conditions exist:

1. All research/clinical investigation activities including analysis of identifiable data are complete;
2. The PI never initiated the research;
3. Participant enrollment and data collection is complete and the only remaining activity is analysis of the data, the data are de-identified, and there are no identifying links or codes to the de-identified data;
4. The PI plans to leave WCM and/or intends to continue the research activities at another institution.

The PI cannot close out an active IRB approval if:

1. They are still following participants or collecting identifiable data.
2. They are analyzing identifiable data (including data with codes or links to identifiers).

The IRB may notify a PI that IRB approval has expired or that the IRB has not granted IRB approval due to non-response from the PI to IRB requests. The IRB may also suspend or terminate IRB approval.

Procedures for closing a project fall into four categories:

- Final review;
- Non-response from PI to IRB requests for revisions;
- Expiration of approval due to non-response to requests for continuation or final review (see Continuing Review SOP);
- PI initiated withdrawal of a project from IRB review.

V. Procedure

Final Review or PI Initiated Closure

1. The format of the review is similar to the format for continuing review (see the Continuing Review SOP). The PI completes the Closure Application and submits it and additional materials to the IRB via WRG-HS.
2. The PI must provide confirmation that:
   - Participant enrollment is complete;
   - Data collection is complete;
   - Only data analysis, as approved in the protocol, of already collected data remains, if applicable;
   - Data are de-identified (e.g. link to participant identifiers has been destroyed; audio recording transcribed with pseudonyms then destroyed, etc.); and
   - There are no participant identifying codes or links to the de-identified data, unless previously approved by the IRB.
3. Regardless of initial review type (full or expedited), projects undergo administrative review procedures for final
review, unless the IRB staff determines the circumstances surrounding the request for closure require IRB member review.

4. Review outcomes may include:
   • Request revisions and/or additional information;
   • Full review at a convened meeting;
   • Closure.

4. Once the closure is reviewed, IRB staff close the project in the database, send the PI a closure letter. Electronic files are stored for at least three years from closure date, or as appropriate.

Withdrawal or Closure Due to Non-Response
1. If, at initial review, the PI fails to respond to the IRB’s request for additional information/modifications within a specified period, the IRB staff send a message to the PI reminding them that the submission is waiting for revisions and that the review process cannot continue to review until the issues have been addressed.
2. If the IRB does not receive a response within 90 days of the original request, the project will be withdrawn from IRB review and the PI will be notified that the IRB requires a new submission if the PI wants the project considered for IRB approval.
3. If the PI fails to submit the Continuing Review or Closure Application or fails to submit requested information by the end of the approval period, IRB staff administratively close the project and send the PI a notification to cease all research activities.

Project Transfer
1. When a PI leaves WCM, they must close out their project(s) or notify the IRB in writing to transfer the project(s) to another PI who will take responsibility for the research. This transfer will require an Amendment application and IRB review and approval.
2. If applicable, when a PI transfers a project, appropriate changes to protocol, consent forms, project team list, advertisements, etc. must be submitted to the IRB for review. Additionally, the new PI submits a current Curriculum Vitae via WRG-HS.

Reactivating IRB Approval
1. A PI may reactivate a project within 6 months of closure (administrative or otherwise) by following the procedures for initial full review, initial expedited review, or continuing review.

Document Retention and Destruction
1. The PI maintains signed documents, (e.g., signed consents/assents) and IRB records for at least three years after closure, and should take measures to prevent accidental or premature destruction of these documents. Researchers must store records consistent with the plan approved by the IRB in a secured fashion to prevent breaches of confidentiality.
2. For research that falls under the authority of FDA, HIPAA or other regulatory agency, the PI retains signed documents and IRB records for the period specified in the applicable regulations if the requirements are longer than three years after closure. For multi-site projects, the PI consults the sponsor regarding retention requirements, but must maintain records for a minimum of three years after closure.
3. The PI ensures that retained records are accessible for inspection and/or copying by authorized representatives of institutional or regulatory agencies.

VI. References

1.21.2 NMAC, et seq.