PURPOSE
To describe the policies and procedures followed to close a study with the Institutional Review Board (IRB).

REVISIONS FROM PREVIOUS VERSION
Five year retention requirement for state research records; add reference

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 study if any of the following conditions exist:

1. All research/clinical investigation activities including analysis of identifiable data and reporting are complete;
2. The PI never initiated the study;
3. Subject accrual is finished, all 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 the University and intends to continue the research activities at another institution.

The PI submits the request to close out IRB approval by submitting a Closure Application via IRBNet. The PI cannot close out an active IRB approval if:

1. He/she is still following subjects or;
2. He/she is 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 inactivated IRB approval due to non-response from the PI to IRB requests. The IRB may suspend or terminate IRB approval. (See SOP 403 Suspension or Termination of Approved Research.)

Procedures for closing a study fall into four categories:

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

RESPONSIBILITIES
Execution of SOP: Researchers, IRB Chair, IRB, OIRB, Institutional Official (IO).

PROCEDURE
Final Study Review or PI Initiated Closure

1. The format of the review is similar to that of the format for the continuing review. (See Sop 305 Continuing Review.) The PI completes and signs the Closure Application and submits it to the OIRB. The IRB Submission Checklist specifies additional materials to submit.

2. The PI must provide confirmation that:
   • Subjects 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 subject identifiers has been destroyed; audio recording transcribed with pseudonyms then destroyed, etc.); and
   • There are no subject identifying codes or links to the de-identified data.

3. Regardless of initial review type (full or expedited), protocols undergo administrative review procedures for final review, unless the IRB reviewer determines the circumstances surrounding the request for closure require expedited or full review.

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

4. Once the IRB approves the study for closure, OIRB staff close the protocol in the database, send the PI a closure letter, move the electronic project files to the “CLOSED” folder on the network, and store them by IRB#, PI name and year of closure. Electronic files are stored for at least three years from closure date, or as appropriate. (See SOP 105 IRB Records Management and Retention).

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 of time (~30 days), the OIRB staff send an email to the PI reminding him/her that the IRB has never approved the study and had requested modifications.

2. If the OIRB has not received a response within 45 days of the original request, the submission will be withdrawn and the PI will be notified that the IRB requires a new protocol submission if the PI wants consideration for IRB approval again.
3. If the PI fails to return the Continuing or Closure Application or fails to submit requested information by the end of the approval period, OIRB staff administratively close the study and send the PI a notification to cease all research activities. (See SOP 408 Lapse of IRB Approval SOP.)

**Study Transfer**

1. When a PI leaves UNM, he/she must close out his/her protocol(s) or notify the OIRB in writing to transfer the protocol(s) to another PI who will take responsibility for the research. This transfer will require an amendment request signed by the previous and new PI and IRB review and approval.
2. If applicable, when a PI transfers a protocol, 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 IRBNet.

**Reactivating IRB Approval**

1. A PI may reactivate research administratively closed by the IRB by following the procedures for initial full review, expedited initial review, or continuing review, as described in the SOP 408 Lapse of IRB Approval.

**Document Retention and Destruction**

1. The PI maintains signed documents, (e.g., signed consents/assents) and IRB records for at least five years after study 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 study closure. For multi-site studies, the PI consults the study sponsor regarding retention requirements, but must maintain records for a minimum of five years after study closure.
3. The PI ensures that retained records are accessible for inspection and/or copying by authorized representatives of institutional or regulatory agencies.

**REFERENCES**

N.M. Code R. § 1.20.3.339