
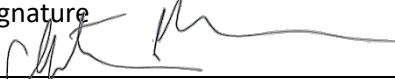


Standard Operating Procedures		
SOP #410.3 Revision 3	TITLE: Project Closure	Effective Date: 3/1/2019
Approved By: OIRB Director	Signature 	Date 3/1/2019
Approved By: IRB Chair	Signature 	Date 3/1/2019

PURPOSE

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

REVISIONS FROM PREVIOUS VERSION

Administrative corrections

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 the University 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 (see SOP 403 Suspension or Termination of Approved Research).

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 Continuation Review SOP);
- PI initiated withdrawal of a project from IRB review.

RESPONSIBILITIES

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

PROCEDURE

Final Review or PI Initiated Closure

1. The format of the review is similar to the format for continuing review (see SOP 305 Continuing Review). The PI completes and signs the Closure Application and submits it to the OIRB via IRBNet. The IRB Submission Checklist specifies additional materials to submit.
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, expedited or minimal risk), projects undergo administrative review procedures for final review, unless the OIRB 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.
5. Once the closure is reviewed, OIRB staff close the project 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).

Project Closure at time of Administrative Check-in

1. If it is determined that a minimal risk project is complete (i.e. data collection complete and no identifiers remain) at the time of administrative check-in, the project will be administratively closed by OIRB staff and a Closure Letter will be sent to the PI.

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 OIRB staff send an message to the PI reminding them that the package has been unlocked for revisions and that the review process cannot continue to review until the issues have been addressed.
2. If the OIRB does not received a response within 30 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 project 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, OIRB staff administratively close the project and send the PI a notification to cease all research activities (see SOP 408 Expiration of IRB Approval).

Project Transfer

1. When a PI leaves UNM, they must close out their project(s) or notify the OIRB in writing to transfer the project(s) to another PI who will take responsibility for the research. This transfer will require an Amendment Application signed by the previous and new PI 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 IRBNet.

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, expedited review, minimal risk, 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 project 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 project 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.

REFERENCES

- 1.21.2 NMAC, *et seq.*