

## **STUDY CLOSURE**

The 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:

- All research activities including data analysis and reporting are complete.
- The PI never initiated the study.
- 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.
- The PI plans to leave the University and intends to continue the research activities at another institution.
- The study has been open for a period of three or more years and the PI has enrolled no subjects in the study or collected no data from records.

When closing out a study, the PI completes a Final Report form and submits it to the IRB Office.

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 or active IRB status 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.

If a study has been open for a period of three or more years and the PI has not enrolled subjects in the study, the IRB requires study closure unless there are extenuating circumstances for keeping the project open.

Procedures for closing a study fall into five categories:

- Final review;
- Non-response from PI to IRB requests for revisions;
- Closure due to non-enrollment;
- Lapse of approval due to non-response to requests for continuing or final review;
- PI initiated withdrawal.

Regardless of the category for study closure, the expiration date for IRB approval falls on the first day after the approval period end date.

## **PROCEDURES**

### ***Final Report***

1. When a study nears its projected end date, IRB staff generate a request for final review. The PI completes and signs the final report and returns it to the IRB Office. The Final Report form specifies additional materials to submit.

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

3. Review outcomes may include:

- Request revisions and/or additional information;
- Full review at a convened meeting;
- Request that the PI attend the convened IRB meeting at which the protocol is scheduled for full review;
- Closure at the end of the current approval period.

4. Once the IRB issues approval for closure, IRB staff code the protocol records as terminated in the IRB database. IRB staff store the protocol files for at least three years from closure date.

#### ***Closure Due to Non-Response***

1. If, at initial review, the PI fails to respond to the IRB's request for additional information/ revisions within a specified period of time (e.g., approximately three months), IRB staff send a letter to the PI reminding him/her that the IRB has never approved the study and had requested revisions to the protocol.

2. If the IRB Office has not received a response, a new letter is sent approximately four weeks after generation of the original letter informing the PI 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 Review or Final Report form or fails to submit requested information, IRB staff send him/her a notification letter ending IRB approval.

#### ***Closure Due to Non-Enrollment***

1. If, at continuing review or annual check-in, the PI reports to the IRB that he/she has never enrolled subjects into the study and the study has been open for a period of two or more years, the IRB requests that the PI close the study.

2. If there are extenuating circumstances for keeping a study open, the PI files a response to the IRB to justify that the study be kept open along with the continuing review report or annual check-in form. If the IRB agrees that there are extenuating circumstances, IRB staff send the PI a notification letter of continued IRB approval, conditional upon criteria for IRB approval being met.

3. If the IRB determines that the extenuating circumstances do not justify leaving the study open, IRB staff process the materials submitted for closure.

#### ***PI Initiated Withdrawal***

1. During an approval period, the PI may request study closure. Upon receipt of a written request, the IRB Office determines, based on the date of the study's last review and research activity to date, whether a final report form should be completed. A PI may also indicate at the time of continuing review or annual check-in that a study should be closed.

2. If all research activities are complete, the PI may request closure in writing providing the following information:

- Request for inactivation of IRB approval;
- Confirmation that the PI has enrolled no subjects since the last review; and
- Confirmation that data analysis is complete.

The PI completes a Final Report form.

3. If a study is open, subject accrual is finished and data collection is complete, data analysis is the only activity remaining, data are de-identified, and there are no subject identifying codes or links to the de-identified data, the PI may request closure in writing providing the following information:

- Request for inactivation of IRB approval;
- Confirmation that all subjects have been enrolled;
- Data collection is complete;
- Confirmation that only data analysis, as approved in the protocol, of already collected data remains;
- Data are de-identified (an explanation of what this means); and
- There are no subject identifying codes or links to the de-identified data.

4. An IRB member reviews final study reports and officially closes the study. IRB staff inform the PI processing the request.

5. When a PI leaves Franklin University, he/she should close out his/her protocol(s) or notify the IRB Office in writing to transfer the protocol(s) to another PI who will take responsibility for the research. This transfer may require a modification request and/or further IRB review and approval.

6. If applicable, when a PI transfers a protocol, the new PI submits appropriate changes to consent forms, advertisements, etc. to the IRB for review.

### ***Reactivating IRB Approval***

1. A PI may re-initiate research previously inactivated by the IRB by following the procedures for initial full review, expedited initial review, or continuing review, as determined by the IRB Chair, IRB members, or IRB staff.

### ***Document Retention and Destruction***

1. The PI maintains signed documents, (e.g., signed consents/assents) and IRB records for at least three years after study closure, taking measures to prevent accidental or premature destruction of these documents. Investigators 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 a 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 three 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.