FRANKLIN UNIVERSITY

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.
- Participant 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 participants in the study or collected no data from records.

When closing out a study, the PI completes a Closure submission in Cayuse IRB.

The PI cannot close out an active IRB approval if:

1. He/she is still following participants, 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 participants 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

Closure Submission

1. When a study ends, the PI completes a Closure submission in Cayuse. The Closure submission specifies additional information and materials to submit.

2. Review outcomes may include:

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- Request revisions and/or additional information; or
- Immediate closure.

3. All doctoral candidates must close their studies with the IRB prior to graduation, regardless of initial review determination (exempt or non-exempt).

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. The notice informs the PI that the IRB will administratively close the protocol and require a new protocol submission if the PI wants consideration for IRB approval again.

2. If the PI fails to submit requested information, IRB staff administratively withdraw the protocol.

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 participants 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 submission. 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 closure submission 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 is no longer enrolling subjects; and
- Confirmation that data analysis is complete.

The PI completes a Closure submission in Cayuse.

3. If a study is open, participant accrual is finished and data collection is complete, data analysis is the only activity remaining, data are de-identified, and there are no participant 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 participant identifying codes or links to the de-identified data.

4. IRB staff review the Closure submission and officially close the study.

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.

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.