24.0 CLOSING a STUDY

24.1 OBJECTIVE

To describe the policies and procedures followed to close a study.

24.2 GENERAL DESCRIPTION

The principal investigator (PI) and/or the Institutional Review Board (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/clinical investigation 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.

The PI submits the request to close out IRB approval in writing to the Office of Regulatory Research Compliance (ORRC). When closing out a study, the PI completes a final review report unless: 1) he/she never initiated the study or; 2) the study received initial/continuation review (CR) within the last six months and the PI has enrolled no subjects in the last six months.

The PI cannot close out an active IRB approval if:

- He/she is still following subjects or
- 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 (See the Termination or Suspension of Research by the IRB SOPP).

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 (e.g., the study is about a rarely seen condition).

Procedures for closing a study fall into five categories:

- Final review (FR);
- Non-response from PI to IRB requests for revisions (a vote of 2, 3, or 4);
- Closure due to non-enrollment;
- Lapse of approval due to non-response to requests for continuation or final review (See Continuation Review SOPP);
- 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.

24.3 RESPONSIBILITY

Execution of SOPP: Principal Investigator (PI)/Study Personnel, ORRC Staff, IRB Chair, IRB Vice Chair, IRB Members.

24.4 PROCEDURES

24.4.1 Final Review

- When a study nears its projected end date, ORRC staff generates a request for final review through the ORRC computerized tracking system. The format of the final review is similar to that of the format for the CR (See Continuation Review SOPP). The PI completes and signs the final review report and returns it to the ORRC. The Final Review Report Form specifies additional materials to submit.
- 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. ORRC staff screen the final report and informed consent/assent forms, and an IRB Co-Chair or designee conducts the review.
- 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.

- Once the IRB issues approval for closure, ORRC staff code the protocol records as terminated in the ORRC database. ORRC staff remove the protocol files from the active files and store them alphabetically by PI last name and further label and organize them by the month and year of the last review event in the event viewer section of the ORRC database. ORRC staff store the protocol files for at least six years from closure date.

24.4.2 Closure Due to Non-Response

- 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), the ORRC computerized tracking system generates a letter, which ORRC staff send to the PI reminding him/her that the IRB has never approved the study and had requested revisions to the protocol.

- If the ORRC has not received a response, ORRC staff generates a new letter 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.

- If the PI fails to return the Continuation or Final Review Report Form or fails to submit requested information, ORRC staff sends him/her a notification letter ending IRB approval (See the Continuation Review SOPP).

24.4.3 Closure Due to Non-Enrollment

- If, during CR, the PI reports to the IRB that he/she has never enrolled subjects into the study and the study have been open for a period of three or more years, the IRB requests that the PI submit a withdrawal request memorandum. ORRC staff prepares a withdrawal notification letter and send it to the PI.

- 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 CR report form. If the IRB agrees that there are extenuating circumstances, ORRC staff send the PI a notification letter of continued IRB approval, conditional upon criteria for IRB approval being met (See the Continuation Review SOPP).

- If the IRB determines that the extenuating circumstances do not justify leaving the study open, ORRC staff process the materials submitted for closure. ORRC staff prepares a withdrawal notification letter and send it to the PI.

24.4.4 PI Initiated Withdrawal

- During an approval period, the PI may request study closure. Upon receipt of a written request, the ORRC determines, based on the date of the study's last

review and research activity to date, whether a final review report form should be completed. A PI may also indicate at the time of CR that a study should be closed.

- 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 unless the study received initial/CR within the last six months and the PI has enrolled no subjects since that review.

- If a study is open, subject accrual is finished, and collected all data, 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.

- If the PI has never enrolled subjects in a study, regardless of when the last review occurred, the PI may request closure in writing providing the following information:
  - Request for inactivation of IRB approval;
  - Confirmation that no subjects were ever enrolled.

- Sometimes it is unclear with the original closure request whether the PI has enrolled subjects. In such cases, ORRC staff may generate a Final Review Report Form and send it to the PI for completion in order to appropriately close the study.

- If the study has not received initial/CR within the last six months and the PI has enrolled subjects since the last review, ORRC staff generates a Final Review Report Form and send it to the PI for completion in order to appropriately close the study.

- The IRB Co-Chair, expedited reviewer, or other designated IRB member reviews and signs closure/withdrawal notices/final reviews. ORRC staff prepares a withdrawal notification letter and send it to the PI after processing the request.

- When a PI leaves HU, he/she should close out his/her protocol(s) or notify the ORRC 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.

- If applicable, when a PI transfers a protocol, the new PI submits appropriate changes to consent forms, advertisements, etc. to the IRB for review. Additionally, the new PI submits a completed Signature Assurance Sheet.

24.4.5 Reactivating IRB Approval

- 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, Vice Chair, IRB members, or ORRC staff.

24.4.6 Document Retention and Destruction

- The PI maintains signed documents, (e.g., signed consents/assents) and IRB records for at least six 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.

- For research that falls under the authority of FDA 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 six 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 six years after study closure.

- The PI ensures that retained records are accessible for inspection and/or copying by authorized representatives of institutional or regulatory agencies.