University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #11	**TITLE: Study Closure**		**Page 1 of 5**
Approved By: ORI Director	Signature	Date	Date First Effective: 06-30-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 05-21-2023

OBJECTIVE

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

GENERAL DESCRIPTION

The principal investigator (PI) and/or the Institutional Review Board (IRB) may close approved protocols under certain circumstances. Generally, 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 data analysis and reporting are complete;
2. The PI never initiated the study;
3. Accrual for the study is finished, all data collection is complete and the only remaining activity is analysis of the data and:
    i. Data are de-identified; or
    ii. Data with identifiers for studies subject to the Revised Common Rule (approved on or after January 21, 2019) are encrypted; or
    iii. For FDA regulated studies, there are no outstanding data queries or other investigator/site responsibilities in the trial (confirm with external study sponsor);
4. The PI plans to leave the University and intends to continue the research activities at another institution;
5. The study has been open for a period of three (3) or more years and the PI has enrolled no subjects in the study, collected no data from records, and/or collected/received no specimens.

The PI submits a closure request to the Office of Research Integrity (ORI). The status of study activities dictates the process by which closure is completed:

1. Study Closure (executed by ORI staff as an administrative function) or
2. Final Review (executed by the IRB).

The PI cannot close an active IRB approval if:

1. Interaction or intervention with currently enrolled subjects is still occurring,
2. Data is being collected from currently enrolled subjects and/or samples.

Please note: If the PI is transferring from UK to another institution, the study should not be closed at UK until there is an active IRB approved protocol at the institution to which the PI is transferring.

The ORI 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 SOP.)

If a study has been open for a period of three (3) or more years and the PI has not enrolled subjects or acquired any specimens or recorded information for the study, the IRB may request the PI close the study, 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 three categories:

- Final review (FR);
- Study Closure due to
    - Non-response to requests for continuation or final review (See Continuation Review SOP);
    - Non-response to IRB requests for revisions (a vote of 2, 3, or 4);
- Study Closure due to study never being initiated (i.e., non-enrollment, no data collection from records, and/or no specimens having been obtained).

Regardless of the category for study closure, the expiration date for IRB approval falls on the date the protocol is closed.

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Study Personnel, Office of Research Integrity (ORI) Staff, IRB Chair, IRB Vice Chair, IRB Members

PROCEDURES

Submission Process

1. Approximately three (3) months prior to the IRB approval end date, the researcher is prompted by email to initiate either a Continuation Review (CR), Annual Administrative Review (AAR), or Study Closure/Final Review depending on the review type of the research (i.e., expedited or full) and the anticipated research end date previously provided by the PI.

2. If the study qualifies for closure, the PI submits either a Final Review (FR) or Study Closure request.

Final Review

1. The PI is required to submit a Final Review (FR) if the study qualifies for closure and any of the following apply:
   - The research is FDA regulated;
   - Subjects have been enrolled since the last CR/AAR [or initial review (IR) if the study has not yet undergone a CR/AAR];
   - There have been unanticipated problems, noncompliance concerns, subject concerns, and/or protocol violations not previously reported to the IRB;
   - There are other regulations impacting the research that require it;
   - A sponsor that requires it.

2. Regardless of initial protocol process type (full or expedited review), protocols undergo expedited review procedures for FR unless the IRB reviewer determines the circumstances surrounding the request for closure require full review. ORI staff screen the FR submission and an IRB Chair, Vice Chair, or designee conducts the review.

3. Review outcomes may include:
   - Request for revisions and/or additional information;
   - Full review at a convened meeting;
   - Request that the PI attend the convened IRB meeting at which the FR is scheduled for full review;
   - Closure;
   - Denial of the FR and submission of a continuation review (CR) is required.

4. Once the ORI or IRB issues approval for closure, the protocol status is set to inactive and approval is terminated.

Study Closure

1. The PI may submit a study closure request to the ORI during an approval period based on Study Closure eligibility. Upon receipt, ORI staff verify the conditions for Study Closure are met.

2. Sometimes it is unclear whether the PI has enrolled subjects or if other conditions for Study Closure are met. In such cases, ORI staff may return the Study Closure submission and request additional information. If the conditions for Study Closure are not met, the request is denied by the ORI and the PI is instructed by ORI staff to complete either an FR, CR, or AAR.

3. If the study is a reliance study in which UK reviews or UK cedes to another institution, ORI staff contact the Reliance Team to determine if the study should remain open until all reliance obligations are satisfied.

4. If the conditions for Administrative Study Closure are met, ORI staff process the request and prepare a Study Closure letter and send it to the PI.

Closure Due to Non-Response

1. If the PI fails to respond to the IRB's request for additional information/revisions at initial review within a specified period of time (e.g., approximately three (3) months) without providing communication outlining extenuating circumstances, the submission is administratively withdrawn. The PI must create a new submission to have the proposed study reviewed by the IRB again.

2. If the PI fails to submit a CR, AAR, or FR or fails to submit requested information related to one of those, ORI generates a notification letter stating that the protocol IRB approval is terminated and sends it to the PI. (See the Continuation and Annual Administrative Review SOP.)

3. Administrative closures for non-response are not reportable events, since the protocol approval is already expired, and there is no withdrawal of IRB approval.

Closure Due to Non-Enrollment

1. If the PI reports to the IRB at CR that they have never enrolled subjects into the study, has never collected any data from records, and/or has never received any biospecimens and the study has been open for a period of three (3) or more years, the IRB may request that the PI submit a study closure request.

2. If there are extenuating circumstances for keeping a study open, the PI submits a CR or AAR as applicable (see the Continuation and Annual Administrative Review SOP) with justification that the study be kept open. If the IRB agrees there are extenuating circumstances and the criteria for IRB approval for continuation are met, ORI staff generate a CR/AAR approval letter.

3. If the IRB determines the extenuating circumstances do not justify leaving the study open, ORI staff direct the PI to submit a study closure request.

Study Closure When PI is Leaving the Institution

1. When a PI leaves UK, they must:
    - Close his/her protocol(s) or

- Submit a modification request to transfer the protocol(s) to another PI who will then take responsibility for the research.

2. Appropriate changes must be made to consent/assent forms, advertisements, etc., and submitted to the IRB for review as part of the modification request if a PI transfers a protocol to another investigator. Additionally, the new PI must submit a completed Signature Assurance Statement.

3. If the PI fails to transfer the protocol to another PI, no study personnel have access to perform study closure, or extenuating circumstances warrant closure, ORI staff may administratively close the protocol before the end of the approval period in response to the request of or approval by the department chairperson or equivalent.

4. Administrative closures for failure to transfer are not reportable events, since the closure is in response to a request.

Reactivating IRB Approval

1. A PI may re-initiate research previously inactivated by the IRB by submitting a new IRB application for the project. The research in such cases is treated like a new initial review submission and managed accordingly by the ORI and IRB.

Document Retention and Destruction

1. The PI maintains signed documents, (e.g., signed consents/assents) and IRB records for at least six (6) 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 manner to prevent breaches of confidentiality.

2. For research 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 (6) 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.

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

REFERENCES

Not applicable