

	Institutional Review Board	
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Responsibility: OIRB		Page 1 of 5

Study Inactivation  
Policy and Procedure

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- I. Policy: The [Principal Investigator](#) (PI) and/or the Institutional Review Board (IRB) may decide to inactivate an active approved study in certain circumstances.
  - A. Study Inactivations fall into three categories:
    1. PI initiated inactivation (Final review) - Circumstances when a PI is responsible for promptly inactivating an IRB-approved study include:
      - a) The study was approved by the IRB but was never initiated.
      - b) All human research activities are complete and no further data collection or research procedures are planned.
        - (1) For a multi-center study where the HSC is the Study Operations Center or the HSC investigator is the Lead Investigator, the study must also be inactivated at all participating sites.
        - (2) For research externally supported, the project funding must be closed.
        - (3) All subjects have been enrolled; all data collection is complete and the only remaining activity at the local study site(s) under HSC IRB jurisdiction is analysis of the data or specimens. In this situation, the study may be inactivated only if:
          - (a) The identifiable data (and original data set) and key to any codes are permanently stored (archived) in a secure location, and
          - (b) A copy of the original data set (called a secondary data set) or specimens actively being analyzed are permanently de-identified (and there are no identifying links or codes to the de-identified data).
      - c) The PI plans to leave the University and there are no plans to continue the research at the HSC. If a Clinical Trial record exists in ClinicalTrials.gov, the PI remains responsible for updating and maintaining the record and reporting results, and updating contact information.
      - d) The PI has a premature closure of the study. If the premature closure is associated with a possible UPIRSO the UPIRSO and UADE Policy will be followed.

2. IRB Initiated Inactivation due to Non-response - Circumstances when the IRB may inactivate an IRB approved study include:
  - a) Non-response from the PI
    - (1) Non-response to IRB requests, e.g., for revisions to the study to secure re-approval. Note: IRB may choose to require a Department Head initiated "Change in PI" in lieu of Inactivation when IRB approval is not yet expired
    - (2) No response from the PI to OIRB requests for submission of a progress report for continuing review, leading to expiration of IRB approval (aka Lapse of Approval)
  - b) 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 may consider inactivating the study unless there are extenuating circumstances for keeping the project open (e.g., the study is about a rarely seen condition).
3. The IRB may terminate IRB approval. See the [Suspensions or Terminations of Research Policy and Procedure](#).

## II. Procedures:

### A. Final Review (PI request for inactivation)

1. When the PI determines that the IRB approval to conduct research should be inactivated (using the criteria listed above), he/she submits either:
  - a) A Final Report. The PI must complete a Final Report unless he/she never initiated the study (See option under 3.a)(1)(a) below); or
  - b) In limited situations, a memo requesting inactivation. The IRBD or IRBAD must approve a PI's request to submit a memo in lieu of the final report. OIRB staff will confirm the IRBD or IRBAD approval before processing the memo.
2. All requests to inactivate (Final Report) receive an administrative pre-review by the designated OIRB staff.
3. Depending on the status of research activities since the previous IRB review (e.g., Continuation Review) the final report is either reviewed via administrative OIRB review or expedited review.
  - a) Administrative OIRB inactivation– Administrative review allows the IRB to quickly inactivate research that is not likely to have significant issues related to the rights, welfare or safety of the participants.
    - (1) Criteria: If the PI does not report any new risks, information or other problems that may adversely affect subject rights, safety or welfare, the study may be eligible for administrative OIRB inactivation.
      - (a) If there is any new information associated with an unanticipated problem or other problems that may adversely affect subject rights, safety or welfare since the last IRB review, the OIRB staff will consult with OIRB management or forward the report for expedited review.
    - (2) Outcomes: If the report is eligible for administrative closure, the OIRB staff complete the review of the report. Review outcomes for administrative review of a final report may include:

- (a) Request revisions and/or additional information;
    - (b) Review by the expedited reviewer;
    - (c) Acceptance of the Final Report and administrative OIRB inactivation of study.
  - b) Expedited review – final reports not eligible for administrative OIRB inactivation are reviewed by the designated IRB reviewer.
    - (1) Criteria: Any reports not administratively inactivated by the OIRB staff will be reviewed by the expedited reviewer. The expedited review serves two main purposes:
      - (a) review the status of participants since the last IRB review, and
      - (b) inactivate the study.
    - (2) Review outcomes may include:
      - (a) Request revisions and/or additional information;
      - (b) Forward for full review at a convened meeting of the IRB;
      - (c) Request that the PI attend the convened IRB meeting in person or by telephone at which the inactivation request is scheduled for full review;
      - (d) Acceptance of the Final Report and inactivation of study.
4. The format of the Final Review is similar to that of the Progress Report with respect to reviewing the status of participants since the last IRB approval (see [Continuation Review Policy and Procedure](#)). The [Final Report](#) form specifies additional information (attachments) that should be included in the report.
5. Final reports that are reviewed by expedited review may be referred to the convened IRB if the reviewer determines the circumstances surrounding the request for closure or information provided in the final report indicate that review by the convened IRB is warranted (e.g., previously unreported UPIRSOs, new reports of serious or continuing non-compliance).
6. Criteria used to determine that a final report is acceptable
  - a) Criteria 1: the proposed research is eligible for inactivation (listed [A 1 a](#) above)
  - b) Criteria 2: if the report is received after the current approval period has expired, no research occurred during the lapse period (confirmation from the PI is needed if research occurred during the lapse). See [Noncompliance Policy and Procedure](#)
  - c) Criteria 3: there are no unresolved issues related to UPIRSOs, reports of noncompliance or other issues related to rights, welfare or safety of participants
  - d) Criteria 4: no new information needs to be communicated to participants
7. Once the reviewer has reviewed the final report and determined it is eligible for inactivation, the inactivation request is accepted and the study is officially inactivated.

8. Once the final report has been accepted, the OIRB staff code the protocol records as "inactivated" in the OIRB database. The OIRB staff removes the protocol files from the active files and store them according to institutional policy on [Recordkeeping Policy and Procedure](#).

B. Inactivation Due to Non-Response

1. If the study has not expired
  - a) If the PI fails to respond to the OIRB's request for submission of a progress report or additional information/revisions to a submitted progress report within a specified period of time (e.g., approximately one month), the OIRB staff remind the PI of the incomplete status of the submission and request an immediate response.
  - b) OIRB continues to contact the PI by telephone and email. When the study expiration is less than 14 days, the PI's Department Chair may also be contacted requesting immediate submission of the progress report or inactivation report.
2. If the study has reached the expiration date
  - a) If the PI fails to submit a Progress Report or Final Report or fails to submit required additional information/clarifications to an already submitted Progress/Final Report, the OIRB staff notifies the PI of the expired status of IRB approval and that all research activity must cease. (For safety exceptions where subjects are enrolled, see the [Continuation Review Policy and Procedure](#)).
  - b) If the PI fails to respond to the notice of expiration within one month, the IRB will inactivate the study and the OIRB staff notify the PI that the IRB has inactivated the study and all research activity must cease (for safety exceptions where subjects are enrolled, see the [Continuation Review Policy and Procedure](#)). Future research requires a new protocol submission if the PI still desires consideration for IRB approval.

C. Inactivation Due to Non-Enrollment

1. If, during Continuation Review, the PI reports that no subjects have been enrolled and the study has been open for a period of three or more years, the IRB may consider inactivating the study, request addition information to justify continuation, or request that the PI submit a Final Report.
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 Continuation Review Report form. If the IRB agrees that there are extenuating circumstances, the OIRB staff sends the PI a notification letter of continued IRB approval. (See the [Continuation Review Policy and Procedure](#))
3. If the IRB determines that the extenuating circumstances do not justify leaving the study open, the OIRB staff process the materials submitted for closure. The OIRB staff prepares an inactivation notification letter and sends it to the PI.

D. Change in PI in lieu of Inactivation

1. When a PI leaves the HSC, the protocol should be inactivated. The current PI may request a modification to assign a new PI (with the progress report or via separate amendment to the OIRB) as an alternative to inactivating the study.
2. If applicable, when a PI transfers a protocol, the new PI submits appropriate changes to consent forms, advertisements, etc. as part of the amendment request to the IRB. Additionally, the new PI submits a completed Form A, Signature Assurance Sheet.

#### E. Reactivating IRB Approval

1. A PI may request the IRB consider re-initiating research previously inactivated by the OIRB or IRB following the procedures for [Initial Review of Research Policy and Procedure](#) (i.e., submit the study for a new initial review of research).
2. A PI may request the IRB consider re-initiating research previously voluntarily inactivated by the PI if no research activity has occurred after the inactivation date and the research activities are limited to minimal risk procedures (i.e., collecting private identifiable data). The research activities may not include more than minimal risk research procedures such as administering medication, performing invasive procedures, etc.
  - a) The PI must provide a Request for Re-Activation form describing the circumstances for the request, delineate all research activities planned, and confirm that no research has occurred since the inactivation date.
  - b) The IRB will review the documents and decide on a case by case basis whether the study can be re-initiated. The request is reviewed using the [Continuation Review Policy and Procedure](#).

#### III. References

- A. Definitions (see [Glossary](#))
- B. Regulatory (see [Policy on Policies Policy and Procedure](#))