HUMAN RESEARCH PROTECTION PROGRAM DEPARTMENTAL POLICY AND PROCEDURE

1.4 STUDY CLOSURE AND INACTIVATION

RESPONSIBLE OFFICE: Human Research Protection Program Department (HRPPD) **EFFECTIVE DATE: June 7, 2021**

I. POLICY STATEMENT

A. All studies that were previously approved by the UT Southwestern IRB or an external IRB should be inactivated upon completion of the study. Inactivation is appropriate when enrollment is closed, data is no longer being collected, and analysis is complete or involves only de-identified data.

   a. Note that if the study is federally funded, the study team must confirm that approval to inactivate the study from the funding entity has been received. If UTSW or an affiliate is acting as the lead site on a multi-center trial with active sites, study activities at all sites must be complete to inactivate the study.

B. The Principal Investigator (PI), the Institutional Review Board (IRB) or the Human Research Protection Program Department (HRPPD) may initiate inactivation of active approved studies in certain circumstances.

C. Voluntary study inactivation may be initiated by the PI when human subjects' research activities are complete. Alternatively, the HRPPD may administratively inactivate studies due to non-response of a PI after study expiration or the annual update due date has passed. Finally, the IRB may terminate IRB approval. See 9.4 SUSPENSION OR TERMINATION OF RESEARCH.

II. SCOPE

A. This policy and procedures applies to all non-exempt human subjects' research.

III. PROCEDURES FOR POLICY IMPLEMENTATION

A. PI Initiated Notice of Study Closure for all research reviewed by UTSW IRB or any external IRB

   a. The Notice of Study Closure should be completed and submitted via the eIRB system when all of the following apply:

      i. All subject recruitment and enrollment is complete (i.e., no new subject recruitment or enrollment are ongoing),

      ii. All subject specimens, records, data have been obtained (i.e., no further collection of data/information from or about living individuals will be obtained),

      iii. No further contact with subjects is necessary (i.e., all interactions or interventions are complete and no further contact with enrolled subjects is necessary),

      iv. Analysis of subjects' identifiable data is no longer necessary (i.e., subjects' records will no longer be required or all data/specimens have been de-identified). This includes review of source documents by study sponsors, and

      v. If the study is industry-sponsored, the sponsor or sponsor's representative has agreed the study may be closed at this site.

b. The format of the Notice of Study Closure is similar to that of the Continuing Review with respect to reviewing the status of participants since the last IRB approval (see 2.2. CONTINUING REVIEW OF RESEARCH).

c. All requests to inactivate (notice of study closure in eIRB) receive an administrative pre-review by the designated HRPPD staff.

d. The final report is reviewed via administrative HRPPD staff review.

e. Administrative HRPPD inactivation– Administrative review allows the HRPPD to quickly inactivate research that is not likely to have significant issues related to the rights, welfare or safety of the participants.

1. Criteria used to determine that a final report is acceptable

    a. Criteria 1: the proposed research is eligible for inactivation

    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 9.3 NONCOMPLIANCE REVIEW

    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

2. 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 HRPPD staff will consult with management and resolve prior to closure.

    a. Notice of study closures 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).

3. Outcomes: the HRPPD 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. Acceptance of the Notice of Study Closure in eIRB.

f. The record is stored according to institutional policy on 8.3 RECORDKEEPING.

B. Administrative Closure Due to Non-Response may be completed for studies reviewed by the UTSW IRB as follows:

1. If the study has not expired

   a) If the PI fails to respond to the HRPPDs request for submission of a Continuing Review or additional information/revisions to a submitted Continuing Review within a specified period of time (e.g., approximately one month), the HRPPD staff remind the PI of the incomplete status of the submission and request an immediate response.

   b) HRPPD continues to contact the PI by telephone and email. If the PI fails to respond to additional information/revisions to a submitted Continuing Review approved with stipulations within 30 days, HRPPD staff may refer the study to HRPPD leadership who may consider administratively closing the study.

   c) When the study expiration is within 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 Continuing Review (CR) or Notice of Study Closure (NSC) or fails to submit required additional information/clarifications to an already submitted CR/NSC, the HRPPD 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 2.2. CONTINUING REVIEW OF RESEARCH).

   b) If the PI fails to respond to the notice of expiration within one month, the IRB will administratively close the study and the HRPPD 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 2.2. CONTINUING REVIEW OF RESEARCH). Future research may require a new protocol submission if the PI still desires consideration for IRB approval.

C. Inactivation Due to Inactivity/Non-Enrollment

1. If, during Continuation Review for a study open for a period of three or more years, the PI reports that very few or no subjects have been enrolled or that the study has failed to report progression of the study to enroll subjects or analyze collected data, the IRB may consider inactivating the study, request addition information to justify continuation, or request that the PI submit a Notice of Study Closure.

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. If the IRB agrees that there are extenuating circumstances, the HRPPD staff sends the PI a notification letter of continued IRB approval. (See 2.2. CONTINUING REVIEW OF RESEARCH)

3. If the IRB determines that the extenuating circumstances do not justify leaving the study open, the HRPPD staff process the materials submitted for closure (for safety exceptions where subjects are enrolled, see 2.2. CONTINUING REVIEW OF RESEARCH). The HRPPD staff prepares an inactivation notification and sends it to the PI.

D. Change in PI in lieu of Inactivation

1. When a PI leaves the institution, the protocol should be inactivated. The current PI may request a modification to assign a new PI (via separate modification to the HRPPD) 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 modification request to the IRB.

E. Reactivating IRB Approval

1. A PI may request the IRB consider re-initiating research previously inactivated by the HRPPD or IRB following the procedures for 2.1. INITIAL REVIEW OF RESEARCH (i.e., submit the study for a new initial review of research).

IV. DEFINITIONS

SEE GLOSSARY OF HUMAN RESEARCH TERMS

V. REFERENCES

Resource
21 CFR 50 – PROTECTION OF HUMAN SUBJECTS
45 CFR 46 – PROTECTION OF HUMAN SUBJECTS
45 CFR 164 – SECURITY AND PRIVACY (HIPAA PRIVACY RULE)
21 CFR 56 – INSTITUTIONAL REVIEW BOARDS

VI. REVISION AND REVIEW HISTORY

Revision Date	Author	Description
June 2021	HRPP	Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.
August 2017	HRPP	New Policy Development
March 2012	IRB Office	IRB Written Procedures