Human Research Protection Program
Policies & Procedures

Closure, Suspension & Termination of Studies

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BACKGROUND

With IRB approval, a study may be closed to enrollment or terminated at the request of the Principal Investigator. Continuing OHSU IRB review and approval is required as long as study activity is ongoing, including intervention or interaction with subjects, continued use of a drug or device, data analysis, and/or publication. Only when ALL study activity has ceased should an investigator terminate a research study. The IRB has authority to suspend or terminate research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

SCOPE

This policy describes when and how a study may be closed, suspended, or terminated by the Principal Investigator (PI) or the IRB.

I. POLICY

A. PI Requests for Closure or Termination

1. The PI may request IRB approval for closure to enrollment.
   - **a.** The closure may be temporary if the study is ceasing enrollment for a period of time, but research activities are ongoing.
   - **b.** The closure may be permanent, when no additional subjects will be enrolled in the study, but research activities are ongoing.
2. A study may be terminated by the PI when no further contact with human subjects or their individually identifiable information is planned; no subjects are or will be treated or followed; all data are gathered and analyzed; and any final reports or publications are complete.
   - **a.** The completion or termination of a previously approved research protocol or project constitutes a change in activity that must be reported to the OHSU IRB.
   - **b.** Subsequent use of any data from a terminated project will require a new IRB submission.
   - **c.** Study termination is not a withdrawal. It does not refer to an investigator's or IRB's withdrawal of a submission from the IRB review process prior to IRB approval.
   - **d.** Investigators should not terminate research which is "closed to enrollment," as this means only that no additional subjects will be enrolled in the study.

B. IRB Authority. The OHSU IRB may terminate or suspend projects without PI approval in the following circumstances:

1. If it is determined that the investigator is no longer affiliated with OHSU.

2. In response to unanticipated problems involving risk to subjects or others, serious or continuing non-compliance, findings presented during an IRB review, or problems identified in an audit or monitoring process.
3. If the investigator has not responded to the IRB's requests for revisions and/or clarifications within a set timeframe. This is determined on a case-by-case basis, based upon the vulnerability of the subject population and the risk of the research.
4. If a study is not accruing participants.
5. When deciding if a study should be terminated, the board considers, among other things:
    a. The level of risk
    b. Possible benefit
    c. Funding Source
    d. Value of the knowledge to be gained
    e. Possibility of remedy for any unanticipated risk or incidence of noncompliance

C. **Reporting.** Termination or suspension of IRB approval due to noncompliance with IRB requirements or serious unexpected risks to subjects will be reported to institutional officials and to the appropriate regulatory authorities as indicated in the OHSU HRPP Policy on Institutional Reporting Requirements. Administrative termination of an expired study is not termination of approval of research per 45 CFR 46.113 and is not reportable.

II. PROCEDURES

A. When a Study may be Terminated by the Investigator

1. Reasons for study termination may include but are not limited to:
    a. Completion of research and data analysis;
    b. Inadequate enrollment;
    c. Loss of funding;
    d. PI transfer
2. Investigator-initiated protocols may be terminated when individually identifiable follow-up data are no longer being collected or analyzed and any final reports and publications are complete.
3. Multi-site studies may be terminated when the sponsor has completed all data queries on the OHSU study records, has "locked" the OHSU data and remaining data analysis will not be completed by OHSU.

B. Closing a Study to Enrollment

1. An investigator may request a temporary or permanent closure of a study to enrollment. The request to close to enrollment must be submitted via the eIRB and must indicate the reason for closure and any plan to re-open the study to enrollment.
2. The IRB may close enrollment of a study permanently or temporarily.
    a. The IRB will provide the PI with written documentation of the reason for closure.
    b. IRB closure to enrollment does not constitute suspension or termination of IRB approval and is not reportable to federal or institutional authorities.

C. Investigator Responsibilities for Termination or Closure to Enrollment

1. **Termination:** PIs should submit a modification with a request to terminate the study to the OHSU IRB within 90 days of completion or termination of all research activity. This must be submitted even if the current approval period has expired.
2. **Closure to Enrollment:** A modification request for closure (either temporary or permanent) should be submitted as soon as the desired closure is to go into effect.

When a closure is pending, the eIRB will have a red notice that indicates closure is pending.

3. Investigators need not wait for the end of the study approval period to submit a modification to terminate or close to enrollment.
4. The OHSU IRB will provide the PI with written notice through the eIRB system when the PI's request to terminate or close to enrollment is approved.
5. Investigators must store the research records for a minimum of three years after termination, in accordance with federal regulations, OHSU policy, and any additional requirements stipulated by research sponsors and/or investigators' professional associations.
6. Subsequent use of data from terminated research, whether by the original investigator or other investigators, may constitute human subjects research requiring IRB approval or an exemption from IRB review.
7. Investigators are expected to continue to honor confidentiality protections for data.
8. Commitments made, such as the communication of research results or compensation to subjects, should be honored even if the study is terminated. These can be done for a terminated study with permission of the IRB Chair.
9. When a principal investigator terminates employment or other association with OHSU, he or she is obligated to either:
   a. Submit a modification with request to terminate, or
   b. Transfer the study to another OHSU PI. (Note: change of key personnel in federally funded or FDA-regulated research requires prior approval of the funding agency and/or FDA.)
10. Data and/or specimens from a study that is being terminated may be transferred to a research repository upon termination.

11. **ORIO and IRB Responsibilities for Suspension or Termination**When the OHSU IRB suspends or terminates a study, the IRB will provide investigators with written notice detailing the reasons for the decision and the scope of the suspension, if applicable.
12. Any suspension or termination may be appealed per the Appeal of an IRB decision policy.
13. Studies suspended or terminated by the IRB are required to be reported to appropriate institutional officials and the department or agency head per federal regulations. (See OHSU HRPP Policy on Institutional Reporting Requirements.)
14. Administrative Termination
    a. The PI will be warned, via a written notification through the eIRB system, of the potential for administrative termination when a study expires and then at 10 and 30 days post-expiration. Administrative termination is not reportable to officials, since the study's approval has expired and the termination is simply to close the administrative file.
    b. If a PI fails to respond to IRB requests within the given timeframe, ORIO staff will provide written notification that the study will be terminated in the eIRB and an administrative fee will be assessed to the PI's department.

D. DEFINITIONS

Closed to Enrollment – this action is either permanent or temporary.

Temporary Closure to Enrollment – A study may be temporarily closed or closed to enrollment when there is a pause in the conduct of research or recruitment. This often happens when conducting an interim analysis.

Permanent Closure to Enrollment – A study is closed permanently when no further enrollment will occur and individually-identifiable follow-up data are no longer being collected on subjects.

Suspension – is an action taken by the IRB or other body with such authority in response to concerns regarding noncompliance with the IRB's requirements or serious unexpected risks to subjects. It is a temporary or permanent halt to some or all research procedures short of a termination until the IRB determines whether the research may recommence (with or without modifications to the research) or whether the research must be terminated.

Termination – Taking action to end a study with the guarantee that no further contact with human subjects or their individually identifiable information is planned; no subjects are or will be treated or followed; all data are gathered and analyzed; and any final reports or publications are complete. A study may be terminated when it no longer constitutes human subject research, such as de-identifying the data. The IRB may also terminate a study for cause, therefore halting further research.

E. AUTHORITY

45 CFR 46.115(b) and 21 CFR 56.115(b) (IRB Records) - The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

45 CFR 46.113 and 21 CFR 56.113 – Addresses suspension or termination of IRB approval of research due to noncompliance with IRB requirements or serious unexpected risk of harm to subjects.