UT Southwestern Medical Center

Human Research Protection Program Departmental Policy and Procedure

9.4 Suspension or Termination of Research

Effective Date: August 31, 2026

I. Policy Statement

a. UT Southwestern Medical Center's IRB or Institutional Official (IO) retains the authority to suspend or terminate IRB approval of any research study, including research approved through the limited IRB review process.

b. The convened IRB or IO may suspend or terminate approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to participants.

c. The IRB Chair or designated reviewer may suspend approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to participants.

   i. The IRB Chair or designated reviewer may only suspend the research; authority to terminate the research is limited to the convened IRB or the Institutional Official.

   ii. The IRB Chair or designated reviewer may suspend approval of some or all of the research when the continuation of the research may adversely affect the rights and welfare of research subjects or when continuation may represent an immediate threat of harm to the subjects.

II. Scope

a. This policy and procedure applies to all human subject research.

b. Summary of Responsibilities

   i. The IO, convened IRB, IRB Chair, or designated reviewer are responsible for actions taken in this policy.

   ii. The Assistant Vice President for Human Research Administration

(AVPHRA) or IRB Director (IRBD) will be designated reviewer(s) for this process. Given the position in the HRPPD, these individuals are readily available to promptly review issues such as allegations of noncompliance, unanticipated problems, annual updates/continuing reviews, compliance reviews, and complaints that may indicate research is not conducted in accordance with IRB requirements or associated with unexpected serious harm to participants requiring consideration of suspension.

III. Procedures For Policy Implementation

a. This procedure starts with the IO, convened IRB, IRB Chair, or designated reviewer becoming aware of apparent serious or continuing noncompliance, or an issue has been associated with harm to the rights and welfare of human subjects in which suspension or termination may be appropriate or when continuation may represent an immediate threat of harm to the subjects. The process of considering suspension or termination of research may be prompted for several reasons, for example:

   i. During the review of reports of apparent serious or continuing noncompliance or unanticipated problems

   ii. During the review of annual updates or continuing reviews

   iii. Based upon results of compliance reviews, audits, or other institutional processes

   iv. Based upon complaints from participants, family members, or others

b. This procedure ends when:

   i. The convened IRB, the Institutional Official, or IRB Chair determines the suspension is not an appropriate action, or

   ii. The convened IRB or IO makes a final determination whether to continue the suspension, alter the suspension, or terminate the research.

c. Suspension of IRB Approval:

i. The IO, IRB Chair or designated reviewer will consider suspension as an action pending review of the issue by the convened IRB.

ii. For issues of a more serious nature, if there is insufficient time to have the next scheduled convened IRB review the situation, the IRB Chair or designated reviewer may call a special meeting of the IRB to review the issue.

iii. When making the determination of suspension, which may involve the withdrawal of current subjects from a research protocol or interruption of research procedures, the convened IRB, IO, IRB Chair, or designated reviewer will consider alternative actions to protect subjects from harm that could result from withdrawal of research procedures that could affect their health or well-being. For example:

1. Transfer of subjects to another investigator that would allow continuation of research (i.e., assign a new PI),
2. Arrangement of clinical care outside the research,
3. Continuation of some research activities under the supervision of an independent monitor,
4. Permitting follow-up of subjects for safety reasons,
5. Requiring reporting of adverse events or outcomes to the IRB and the sponsor,
6. Re-consent participants.

iv. If the IO, IRB designated reviewer, or IRB Chair suspends IRB approval:

1. The reason for suspension is documented and the PI is notified as described in 8.2 Reporting Policy and Procedure.
2. The HRPPD staff adds the issue to the agenda of the next scheduled IRB meeting and the convened IRB discusses the suspension.

3. IRB members attending the convened meeting are provided access to the protocol, consent, information relevant to the suspension, and who ordered the suspension.

v. When the HRPPD staff notifies the PI of the suspension, the correspondence may include, but is not limited to, the following:

1. An explanation of the extent of the suspension in terms of enrollment, recruitment, interventions, interactions, and data analysis;
2. The reasons for the suspension, an explanation of the reasons for the decision, and an offer to the investigator to respond to the convened IRB;
3. A request for a description of any procedures needed to protect the rights and welfare of current subjects if the suspension involves currently enrolled subjects;
4. A description of whether follow-up of subjects for safety reasons is permitted or required.

vi. The PI notifies enrolled subjects (active and/or former) of the suspended research protocol, and the PI considers the appropriate procedures for withdrawal of enrolled subjects, taking into account their rights and welfare.

d. Termination of IRB Approval

i. The convened IRB may consider alternatives to termination as an approach to protect currently enrolled participants who may be harmed if the research is terminated. The IRB may require modification of the study to allow continuation including the following changes:

1. Add, remove or limit the responsibilities of investigator(s),
2. Arrangement of clinical care outside the research,
3. Add or modify the local safety monitoring plan (e.g., addition of an

independent monitor, addition of safety monitoring procedures or data),

4. Re-consent participants,
5. Requiring reporting of adverse events or outcomes to the IRB and the sponsor,
6. Shortening the current approval period.

ii. When a termination involves the withdrawal of current subjects from a research protocol, the convened IRB considers alternatives to termination that will result in protection of subjects from harm that could result from withdrawal of research procedures that could affect their health or well-being. For example:

1. Immediately provide the IRB of list of current and/or former participants,
2. Possible transfer of subjects to another research study,
3. Arrangement of clinical care outside the research,
4. Permitting follow-up of subjects for safety reasons,
5. Requiring reporting of adverse events or outcomes to the IRB and the sponsor.

iii. HRPPD staff notifies the PI of the termination. The notification may include, but is not limited to, the following:

1. An explanation of the extent of the termination in terms of enrollment, recruitment, interventions, interactions, and data analysis;
2. The reasons for the termination, an explanation of the reasons for the decision, and an offer to the investigator to respond to the convened IRB;
3. A request for a description of any procedures that need to be followed

to protect the rights and welfare of current subjects if the termination involves currently enrolled subjects;

4. A description of whether follow-up of subjects for safety reasons is permitted or required;

5. An explanation that any request for the IRB to reconsider the termination should be made within 30 days from date of the notification.

iv. The PI notifies enrolled subjects of any termination of the research protocol and considers the appropriate procedures for withdrawal of enrolled subjects taking into account their rights and welfare.

e. Any suspension or termination of approval shall include a statement of the reason for the action.

f. See 8.1 IRB Minutes for details concerning documenting suspensions and terminations.

g. After review, suspension or termination is reported in accordance with the 8.2 Reporting Policy and Procedure. In addition, the HRPPD staff sends copies of the termination notification to other UT Southwestern administrative units in accordance with 1.5. Communication With Other Committees and Offices (e.g., Institutional Biosafety Committee, Subcommittee for Human Use Radiation, Sponsored Programs Administration).

IV. Definitions

See Glossary of Human Research Terms

V. References

a. 21 CFR 50: Protection Of Human Subjects

b. 45 CFR 46: Protection Of Human Subjects

c. 45 CFR 164: Security And Privacy (HIPAA Privacy Rule)

d. 21 CFR 56: Institutional Review Boards

VI. Revision and Review History

a. Revision Date: August 2026; Author: HRPP; Description: Clarified that suspension or termination can occur for research approved through a limited review.

b. Revision Date: June 2021; Author: HRPP; Description: Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.

c. Revision Date: November 2019; Author: HRPP; Description: Clarifications of noncompliance, clarify procedures for all studies (including sIRB studies)

d. Revision Date: August 2017; Author: HRPP; Description: New Policy Development

e. Revision Date: May 2012; Author: IRB Office; Description: IRB Written Procedures