### Suspension or Termination of Research
#### Policy and Procedure

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## I. Policy

A. The convened IRB or Institutional Official (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.

B. The IRB Chair or designated IRB 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.

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

2. The IRB Chair or designated IRB reviewer will 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.

C. The issue resulting in suspension (by the IO, IRB Chair or designated IRB reviewer) is:

1. Presented to the next scheduled meeting for consideration by the convened board.

2. 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 IRB reviewer may call a special meeting of the IRB to review the issue.

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

## II. Overview

A. The process of considering suspension or termination of research may be prompted for several reasons, for example:

1. During the IRB review of reports of noncompliance or unanticipated problems

2. During the IRB review of progress reports submitted for continuation review

3. Based on results of compliance reviews, audits, or other institutional processes
4. based on complaints from participants, family members, or others

B. The IRB Director (IRBD) and Associate Director (IRBAD) are designated IRB reviewers for this process. Given their positions in the IRB Office, these individuals are readily available to promptly review issues such as allegations of noncompliance, unanticipated problems, progress reports, compliance reviews and complaints that may indicate research is not conducted in accordance with IRB requirements or associated with unexpected serious harm to participant requiring consideration of suspension.

C. This procedure starts upon the Institutional Official, convened IRB, IRB Chair or designated IRB reviewer becoming aware of 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.

D. This procedure ends when the convened IRB, the Institutional Official, IRB Chair or designated IRB reviewer determines: 1) suspension is not an appropriate action, or 2) these officials suspend the research and the convened IRB or IO makes a final determination whether to continue or alter the suspension or terminate the research.

III. Procedure

A. Suspension of IRB Approval:

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

2. The convened IRB, IO, IRB Chair, or designated IRB reviewer, when making the determination of suspension, when a suspension involves the withdrawal of current subjects from a research protocol or interruption of research procedures, considers 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:

   a) transfer of subjects to another investigator that would allow continuation of research (i.e., assign a new PI),

   b) arrangement of clinical care outside the research,

   c) continuation of some research activities under the supervision of an independent monitor,

   d) permitting follow-up of subjects for safety reasons,

   e) requiring reporting of adverse events or outcomes to the IRB and the sponsor,

   f) re-consent participants.

3. If the Institutional Official, IRB designated reviewer, or IRB Chair suspends IRB approval,

   a) The IO, IRB designated reviewer or IRB Chair documents the reason for suspension and the PI is notified as described in Reporting Policy and Procedure.

   b) The OIRB staff adds the issue to the agenda of the next schedule meeting and the IRB discusses the suspension at a convened meeting.
c) IRB members attending the convened meeting are provided access to the protocol, consent, information relevant to the suspension, and who ordered the suspension.

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

a) An explanation of the extent of the suspension in terms of enrollment, recruitment, interventions, interactions, and data analysis;

b) 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;

c) 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;

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

5. The PI notifies enrolled subjects (active and 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.

B. Termination of IRB Approval

1. 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:

a) add, remove or limit the responsibilities of investigator(s),

b) arrangement of clinical care outside the research,

c) Add or modify the local safety monitoring plan (e.g., addition of an independent monitor, addition of safety monitoring procedures or data),

d) Re-consent participants,

e) requiring reporting of adverse events or outcomes to the IRB and the sponsor,

f) shortening the current approval period.

2. The convened IRB when making the determination of termination, when a termination involves the withdrawal of current subjects from a research protocol, 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, e.g.:

a) immediately provide the IRB of list of current and/or former participants,

b) possible transfer of subjects to another research study,

c) arrangement of clinical care outside the research,

d) permitting follow-up of subjects for safety reasons,
e) requiring reporting of adverse events or outcomes to the IRB and the sponsor.

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

a) An explanation of the extent of the termination in terms of enrollment, recruitment, interventions, interactions, and data analysis;

b) 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;

c) 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;

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

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

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

C. See the IRB Minutes Policy and Procedure for details concerning documenting suspensions and terminations.

D. After review, suspension or termination is reported in accordance with the Reporting Policy and Procedure. Also, the OIRB staff sends copies of the termination notification to other HSC administrative units in accordance with the Coordination with Other Committees or Offices Policy and Procedure (e.g., South Texas Veterans Health Care System, Institutional Biosafety Committee, Radiation Safety Committee, and the Office of Sponsored Projects).

E. Administrative Holds in VA Research

1. An administrative hold is a voluntary interruption of VA research enrollments and ongoing VA research activities by an appropriate VA facility official, researcher, or Sponsor (including the ORD when ORD is the sponsor).

2. The term “administrative hold” does not apply to interruptions of VA research related to concerns regarding the safety, rights, or welfare of human research participants, research investigators, research staff, or others.

3. An administrative hold must not be used to avoid reporting deficiencies or circumstances that otherwise require reporting by federal agencies.

IV. References

A. Definitions (see Glossary)

B. Regulatory (see Policy on Policies Policy and Procedure)