IRB Policy 26: Suspension and Termination
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I. Definitions:

A. Suspension: is the temporary closing of a human research project. The suspension may be partial in that certain activities may continue while others may stop or it may be complete in that no activity related to the human research may proceed. The IRB will make this determination. For VA studies,
suspension refers to a temporary interruption in selected research activities (e.g., new enrollments or specific interventions) due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, regardless of whether the action to suspend was taken by an investigator, facility official, research review committee, or external entity. Suspension does not refer to interruptions for other reasons, including the expiration of project approval periods.

B. Termination: is the ending of all activities related to a human research project at ETSU or the VA except for the continuation of follow-up activities necessary to protect participant safety. For VA studies, termination refers to a permanent halt in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.
Termination refers to a permanent halt in all research activities due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, or about the welfare of laboratory animals, regardless of whether the action to terminate was taken by an investigator, facility official, research review committee, or external entity. Termination does not refer to interruptions for other reasons, including the expiration of project approval periods.

C. For VA studies, Administrative hold is a voluntary interruption of research enrollments and ongoing research activities by an appropriate VA facility official, investigator, or Sponsor (including the ORD when ORD is the sponsor). The term “administrative hold” does not apply to interruptions of VA research related to concerns regarding the safety, rights, or welfare of human research subjects, research investigators, research staff, or others. An administrative hold must not be used to avoid reporting deficiencies or circumstances that otherwise require reporting by federal agencies.

II. Summary Policy

It is the policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/ Veterans Institutional Review Board (ETSU/VA IRB) that human subjects are protected through the suspension or termination of approval for research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to participants.

Any suspension or termination of approval shall include a statement of the reasons for the IRB's action, and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head. (45 CFR 46.113, 21 CFR 56.113)

A. Authority

The chair of the IRB may act alone to suspend previously approved human research if the purported serious or continuing noncompliance with the requirements or determinations of the IRB, or any incident that has been associated with unexpected serious harm to subjects appears to pose imminent threat to subject safety. Authority to suspend or terminate IRB or EC approval is retained, regardless of whether research was approved by the convened IRB, or through the expedited procedure, or through limited IRB review or is exempt. The IRB or EC retains the ability to suspend or terminate research even when continuing IRB or EC review is not required. The Vice Provost for Research has the authority to suspend an investigator's or key personnel's privileges to conduct human subject research in the instance of serious and continuing non-compliance.

IRB staff will place on the agenda of the next convened IRB meeting suspensions taken by the IRB Chair. The IRB will confirm or reverse the decision of the chair to suspend or terminate previously approved human research.

Before ordering a suspension or termination of research, the convened IRB, IRB chair must consider the effect of the suspension or termination on the rights and welfare of current participants, and consider whether any additional actions should be taken to protect their interests, such as:

a. Requiring follow-up by the current investigator;
b. Transferring responsibility for the protocol to another principal investigator;
c. Arranging for follow-up with another physician; or
d. Arranging for the participant to stay on the study at another institution.

If a termination or suspension involves the withdrawal of current participants from

the research the investigator and key personnel must:

a. Respond immediately to any requests from the IRB for additional information regarding the suspension or termination;
b. Notify subjects that their enrollment in the study has been terminated and inform the subjects why their enrollment has been terminated. The reasons given will be those reasons determined to be appropriate by the IRB. The notice given may be oral but will also be in writing and copied to the IRB;
c. Inform the subjects of any actions the investigator and key personnel will take to ensure the subjects rights and welfare; and
d. When follow-up of subjects for safety reasons is permitted or required, indicate that subjects will be so informed and that any unanticipated problems involving risks to participants or others will be reported to the IRB and others as required by the protocol and the University's policies and procedures

When study approval is suspended or terminated, the IRB or the person ordering the suspension or termination has any adverse events or outcomes reported to the IRB.

The HRPP Director will inform the Vice Provost for Research (VPR), the Principal Investigator, and key personnel of the suspensions or terminations executed by the IRB chair as they occur, and by the convened IRB immediately after the meeting in which they occur.

The HRPP Director will notify the PI when a human research protocol on which he/she is the PI has been suspended or terminated. If the HRPP Director cannot contact the investigator, the HRPP Director will inform the department chair, who will be responsible for taking further action to notify the PI, key personnel and participants

III. Sanctions and Disciplinary Actions

Failure to abide by the ETSU/VA IRB Guidelines and federal regulations may result in the following sanctions, among others:

1. **Suspension or termination of IRB approval** of specific research protocols or of all research involving human subjects in which the investigator participates. The IRB also has the authority to suspend or terminate approval of research that has been associated with unexpected serious harm to subjects. The IRB shall report any suspension or termination of IRB approval to the investigator, appropriate institution representatives, and the OHRP and the FDA, as appropriate. This report will include a statement of the reason(s) for the IRB's actions.

2. **Institutional or individual action by the FDA or OHRP.** The FDA, DHHS and OHRP may (a) withhold approval of all new ETSU/VA studies by the IRB; (b) direct that no new subjects be added to any ongoing studies; (c) terminate all ongoing studies, except when doing so would endanger the subjects; and/or (d) notify relevant state, federal and other interested parties of the violations.

3. **Individual disciplinary action** of the investigator or other personnel involved in a study, up to and including dismissal, pursuant to University and Veterans Affairs policies and procedures. Failure to secure necessary ETSU/VA IRB approval before commencing human subject research will be reported to the Associate Vice President for Research, East Tennessee State University, and to the Associate Chief of Staff for Research, James H. Quillen Veterans Affairs Medical Center, for disciplinary action. Refer also to the ETSU Policies on Scientific Misconduct.

4. **Suspension or termination of project support by the Department of Health and Human Services.**

5. **Indemnification**: Investigators should also be aware that, in general, East Tennessee State University and the James H. Quillen Veterans Affairs Medical Center indemnifies them from liability for adverse events that may occur in ETSU/VA studies approved by the ETSU/VA IRB. Failure to follow approved procedures may compromise this indemnification and make the investigator personally liable in such cases. (If a Principal Investigator conducts an activity involving human subjects, but does not obtain the approval of the ETSU or ETSU/VA IRB, that investigator is not in compliance with federal regulations. Consequently, neither ETSU nor the James H. Quillen Veterans Affairs Medical Center is obligated to defend or indemnify the principal investigator if legal action were instituted by the subject.

IV. REPORT OF FINDINGS

Follow the ETSU Reporting Policy 34 for reporting suspensions and terminations of previously approved human research or an investigator's or key personnel's privilege to conduct human subject research.

References:
FDA continuing review guidance

45 CFR 46.103(b)
45 CFR 46. 113
OHRP Compliance Activities: Common Findings and Guidance
21 CFR 56. 108
21 CFR 56.113