West Texas A&M University™

ACADEMIC RESEARCH ENVIRONMENTAL HEALTH AND SAFETY

STANDARD OPERATING PROCEDURES

SOP No. 15.99.05.W1.12AR Institutional Review Board for Human Subjects - Suspension or Termination of Research

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Environmental Health and Safety at WTAMU is composed of two distinct but integrated environmental safety departments that report to the Vice President of Research and Compliance. Academic and Research Environmental Health and Safety (AR-EHS) is responsible for research and academic related compliance, which includes laboratory and academic research and the associated compliance committees. Fire and Life Safety (FLS-EHS) is responsible for fire related compliance and conducts fire and life safety inspections of campus buildings and assists with the testing all fire detection and suppression systems. General Safety (GHS-EHS) promotes safe work and health practices, to all faculty, staff, students, and visitors. Examples of General Health and Safety components include: office safety, proper lifting techniques, trip, and fall prevention.

Supplements TAMUS Regulation 15.99.05

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INTRODUCTION

West Texas A&M University (hereafter referred to as "the University") recognizes the need for investigations in which human beings may serve as research subjects. The University is also cognizant of its responsibility for ensuring that the privacy, safety, health, and welfare of such subjects are adequately protected. The University has thus established an Institutional Review Board (hereafter referred to as "IRB") to review and approve the

adequacy of human subject protection. The University has assured federal regulatory agencies that the institution will review and approve all research involving human subjects, regardless of funding source, before it is initiated.

1. PURPOSE STATEMENT

1.1 The purpose of this document is to explain the process to be used by the Institutional Review Board (IRB) for suspension or termination of research.

2. SCOPE

2.1 This procedure applies to all faculty, staff and students, affiliated researchers or other affiliated individuals who are involved in human subjects research being conducted under the auspices of the University regardless of the location of the research and regardless of the source of funding or whether the research is funded or unfunded.

3. DEFINITIONS

3.1 Suspension: temporary withdrawal of IRB approval of some or all of a protocol. It occurs when the Chair of the IRB or the convened IRB places a temporary hold on the previously approved research, such that no research activities can be conducted, including recruitment/enrollment of new participants, further research interventions (unless necessary for the safety and well-being of the enrolled participants), follow-up (unless it is in the best interests of the participants and approved by the IRB), analysis of data, publications, and presentations. Suspended research is still subject to Continuing Review.

3.2 Termination: permanent withdrawal of IRB approval of a previously approved protocol. It occurs when the convened IRB votes to withdraw approval or stop all research activities permanently. However, future follow-up may be conducted with the approval of the IRB to monitor the well-being of and any potential risks to participants, but no research data may be collected from the follow-up. Terminated research is no longer subject to Continuing Review. Resumption of a terminated protocol requires the submission of a new protocol application for review and approval by the IRB.

4. AUTHORITY TO SUSPEND OR TERMINATE HUMAN SUBJECTS RESEARCH

4.1 The University's Institutional Official (IO), the IRB Chair and/ or the IRB have authority to immediately suspend approval of research that is not being conducted in accordance with Federal Regulations, or in the case of serious adverse events or unanticipated problems, research noncompliance or protocol violations. This authority is derived from federal law. Specific details may be found in 45 CFR 46.109, 45 CFR 46.112 and 45 CFR 46.113.

4.2 Research not in compliance as defined in WTAMU SOP 15.99.05.W1.05AR Potential Non-Compliance in the Course of Human Subjects Research can be suspended by any of the aforementioned persons upon first discovery of possible harm to the safety, rights or welfare of human subjects, research staff or others.

5. PROCESS OF SUSPENSION OR TERMINATION

5.1 In the case of immediate suspension by the IRB Chair, the IRB Chair will instruct HSPP staff to issue a suspension notice pending further investigation. Upon being instructed to issue a suspension notice, HSPP staff will draft and finalize a formal letter to the Investigator outlining the reason(s) for the suspension and either proposing a corrective plan to be implemented within a certain timeframe or requesting a corrective plan and a completion timeline from the Investigator. The letter will also inform the Investigator that further information may be provided after discussion of suspension by the convened IRB.

5.2 Whenever the IRB Chair instructs HSPP staff to issue a suspension notice for a protocol, HSPP staff will place the suspension as a discussion item on the agenda for the next available convened IRB meeting and proceed in administering the matter in accordance with processes established in WTAMU SOP 15.99.05.W1.05AR Potential Non- Compliance in the Course of Human Subjects Research.

5.3 All suspensions will be reviewed at the next convened IRB meeting to determine the best course of future action. In cases requiring immediate review by the convened IRB, an emergency meeting will be called within 72 hours of the suspension. Termination of approval shall be decided by a majority vote at the first available meeting of the convened IRB.

5.4 HSPP staff will monitor the Investigator's implementation of the IRB approved corrective action plan. If the plan is implemented within the requisite timeframe, the convened IRB or the IRB Chair may withdraw the suspension notice and research may resume. If, however, the suspension has not been complied with in the prescribed timeframe, the IRB Chair or HSPP may place the suspension on the agenda of the next available meeting of the convened IRB in order to proceed with termination of IRB approval.

5.5 At any time before, during or after the issuance of a suspension notice, the IRB Chair may instruct HSPP staff to conduct an audit. The report on the results of the audit will be provided to the IRB Chair, the IRB, the HSPP Manager, and Associate Vice President for Research. Where an audit report has been generated, it will be reviewed and considered by the IRB in the suspension and/ or termination decision making process.

5.6 While the IRB Chair may suspend a study, pending IRB review, only the convened IRB may vote to terminate a study. The convened IRB may vote to terminate IRB approval of a research protocol when:

a) The IRB determines at any time that termination is in the best interests of the safety and welfare of the research participants;
b) The IRB determines that serious or continuing noncompliance has occurred; and/ or

c) A corrective plan approved by the IRB has not been implemented in a complete and satisfactory manner as determined by the IRB.

6. REPORTING SUSPENSIONS OR TERMINATIONS

6.1 The IRB Chair, through HSPP staff, will send a written statement of the reasons for suspension or termination to the Investigator, appropriate institutional officials and the department or agency head/Institutional Official of the Investigator.

6.2 All protocols suspended or terminated by the IRB must be reported to the Office for Human Research Protections (OHRP). Any other affiliated agency that governs the research must also be contacted. If the research is United States Food and Drug Administration (FDA) regulated, the FDA must be contacted, as appropriate, with a report. The Institutional Official is responsible for all required reporting of suspension or termination by the IRB to the appropriate federal agencies. This reporting will generally be coordinated through the HSPP. Reporting will be done within the required time frame of each appropriate agency, or, if there is not a stated required time frame, within two (2) weeks of final determination.

6.3 The IRB must determine whether it is appropriate to inform the research participants of the suspension or termination. Participants will be encouraged to submit reports of any adverse events. Actions must be taken to protect the rights and welfare of participants already enrolled, such as providing medical care outside of the research study, transfer participants to another Investigator or continue research under independent monitoring, and so forth.

6.4 When following Department of Defense (DoD) regulations:

The following shall be promptly (no longer than within 30 days) reported to the DoD human research protection officer:

- When significant changes to the research protocol are approved by the IRB.
  - The results of the IRB continuing review
  - Change of reviewing IRB
- When the organization is notified by any Federal department, agency or national organization that any part of the HRPP is under investigation for cause involving a DoD-supported research protocol.

7. RESUMING HUMAN SUBJECTS RESEARCH AFTER SUSPENSION OR TERMINATION

7.1 If the Investigator wishes to resume a research protocol that has been terminated, she/he must submit an entirely new protocol application for IRB review and approval.

7.2 If the IRB determines, at a convened meeting, that it is appropriate to lift a suspension, the documented determination will be subject to further review and approval by the Institutional Official(s) in accordance with 45 CFR 46.112. The IRB's determination to lift a suspension will include a written statement of the reasons for lifting the suspension. On approval by the

Institutional Official(s), the IRB's determination will be sent to the Investigator, the HSPP Manager, the Associate Vice President for Research, the sponsored research administration office, and the Office of General Counsel by the IRB Chair through HSPP staff.

8. TRAINING

West Texas A&M University Environmental Health and Safety will follow the Texas A&M University System Policy 33.05.02 Required Employee Training. Staff and faculty whose required training is delinquent more than 90 days will have their access to the Internet terminated until all trainings are completed. Only Blackboard and Single Sign-on will be accessible. Internet access will be restored once training has been completed. Student workers whose required training is delinquent more than 90 days will need to be terminated by their manager through Student Employment.

9. RECORD RETENTION

No official state records may be destroyed without permission from the Texas State Library as outlined in Texas Government Code, Section 441.187 and 13 Texas Administrative Code, Title 13, Part 1, Chapter 6, Subchapter A, Rule 6.7. The Texas State Library certifies Agency retention schedules as a means of granting permission to destroy official state records.

West Texas A&M University Records Retention Schedule is certified by the Texas State Library and Archives Commission. West Texas A&M University Environmental Health and Safety will follow Texas A & M University Records Retention Schedule as stated in the Standard Operating Procedure 61.99.01.W0.01 Records Management. All official state records (paper, microform, electronic, or any other media) must be retained for the minimum period designated.

Related Statutes, Policies, or Requirements

42 U.S.C. §1230d, *et seq.*
45 C.F.R., Part 46
21 C.F.R., Parts 50, 56, 312 and 812
Belmont Report

56 Fed. Reg. 28012, 28022, June 18, 1991, as amended at 70 Fed. Reg. 36328, June 23, 2005

Texas Government Code, Chapter 552

System Regulation 15.99.01 – *Use of Human Participants in Research*

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