



West Texas A&M University™

ACADEMIC RESEARCH ENVIRONMENTAL HEALTH AND SAFETY

STANDARD OPERATING PROCEDURES

SOP No. 15.99.05.W1.11AR Institutional Review Board for Human Subjects - Post Approval Monitoring (PAM) Procedure

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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](#)

Table of Contents

Introduction.....	2
1. Purpose.....	2
2. Scope.....	2
3. Institutional Audits and Compliance Reviews	2
4. Non-University Institutional Audits and Compliance Reviews	3
5. Reporting and Disposition.....	3
6. IRB Internal Compliance Reviews	3
7. IRB Internal Quality Improvement.....	3
8. Training	4
9. Record Retention.....	4

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

This procedure describes the policies and procedures relating to post approval monitoring (PAM) in the Institutional Review Board for Human Subjects (IRB). The post approval monitoring is intended to enhance human subject protection, the quality of research data and education of faculty, staff, and students involved in the conduct of human subjects research and the individuals involved in the ethics and compliance activities related to such research, including IRB members and staff.

2. Scope

This procedure applies to education and quality improvement activities initiated at the request of the Institutional Review Board (IRB), IRB Chair, or IRB Administrator, and as specified in this SOP.

3. Institutional Audits and Compliance Reviews

3.1. Directed (“for cause”) audits and periodic compliance reviews (“not for cause”) will be conducted to assess investigator compliance with federal, state, and local law and University policies; to identify areas for improvement; and to suggest recommendations based on existing policies and procedures. Directed audits of IRB-approved research studies are in response to identified concerns.

3.2. Periodic (“not for cause”) compliance reviews are conducted using a systematic method to review IRB-approved research on a regular basis. The results will be reported to the IRB Chair, IRB Committee, and the Institutional Official (IO).

Activities of auditors during directed audits and periodic compliance reviews may include:

- requesting progress reports from researchers;
- examining investigator-held research records;
- contacting research participants;
- observing research sites where research involving human research participants and/or the informed consent process is being conducted;
- auditing advertisements and other recruiting materials as deemed appropriate by the IRB;
- reviewing projects to verify from sources other than the researcher that no unapproved changes have occurred since the previous review;
- monitoring conflict of interest concerns to assure the consent documents include the appropriate information and disclosures;
- conducting other monitoring or auditing activities as deemed appropriate by the IRB.

4. Non-University Institutional Audits and Compliance Reviews

4.1 External directed (“for cause”) audits and compliance reviews may be conducted at non-University sites, where the University’s IRB serves as the “IRB of Record” to assess compliance with federal, state, and local law; participant safety; and IRB policies and procedures. These directed audits are implemented in response to identified concerns that require an IRB determination. These reviews may include items listed in Section 3 above.

5. Reporting and Disposition

5.1 The results are reported to the IRB Chair and the IO. Any noncompliance will be handled according to the Standard Operating Procedure 15.99.05.W1.05AR Potential Non-Compliance in the Course of Human Subjects.

If an audit or review finds that participants in a research project have been exposed to unexpected serious harm, such findings will be promptly reported to the IRB Chair and the IO for immediate action.

6. IRB Internal Compliance Reviews

6.1 Internal directed audits and random internal compliance reviews may be conducted. The results may impact current practices and may require additional educational activities, and will be reported to the IRB Chair and IO. The TAMU System Research Compliance Officer will:

- review the IRB minutes to determine that adequate documentation of the meeting discussion has occurred. This review will include assessing the documentation surrounding the discussion for protections of vulnerable populations as well as other risk/benefit ratio and consent issues that are included in the criteria for approval;
- assess the IRB minutes to assure that quorum was met and maintained;
- assess the current adverse event reporting process;
- assess that privacy provisions, as needed, have been adequately reviewed, discussed, and documented in the IRB minutes;
- evaluate the continuing review discussions to assure they are substantive and meaningful and that no lapse has occurred since the previous IRB review;
- observe IRB meetings or other related activities;
- review IRB files to assure retention of appropriate documentation and consistent organization of the IRB file according to current policies and procedures;
- review the IRB database to assure all fields are completed accurately;
- verification of IRB approvals for collaborating institutions or external performance sites, as necessary; and
- other monitoring or auditing activities deemed appropriate by the IRB.

7. IRB Internal Quality Improvement

7.1 The IRB Committee will review the results of internal compliance reviews with the IRB Chair. If any deficiencies are noted in the review, a corrective action plan will be developed by the IRB Committee and approved by the IO. The IRB Chair will have responsibility for implementing the corrective action plan, the results of which will be evaluated by the IO.

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](#)

Contact Office

WTAMU Environmental Health and Safety
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General Resources

[IRB – Standard Operating Procedures](#)

Topic-Specific Resources

The following WTAMU standard operating procedures provide further guidance

- SOP 15.99.05.W1.01AR Institutional Review Board for Human Subjects
- SOP 15.99.05.W1.08AR Institutional Review Board for Human Subjects – Initial Review of Research Procedure
- SOP 15.99.05.W1.09AR Institutional Review Board for Human Subjects – Continuing Review of Research Procedure
- SOP 15.99.05.W1.05AR Potential Non-Compliance in the Course of Human Subjects Research
- SOP 15.99.05.W1.11AR Institutional Review Board for Human Subjects – Post Approval Monitoring Procedure
- SOP 15.99.05.W1.10AR Institutional Review Board for Human Subjects – Amendment of Research Procedure