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.
Based on United States Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(b)(4) and (5) require that institutions have written IRB procedures for which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

1. PURPOSE

1.1. This procedure describes the procedures relating to HHS regulation 45 CFR 46.103(b)(5) the procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous Institutional Review Board for Human Subjects (IRB) review. 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

2.1. This procedure applies to education and quality improvement activities initiated at the request of the Institutional Review Board (IRB), IRB Chair, or Institutional Official (IO), 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 that privacy provisions, as needed, have been adequately reviewed, discussed, and documented in the IRB minutes;
- verification of IRB approvals for collaborating institutions or external performance sites, as necessary; and
- other monitoring or auditing activities deemed appropriate by the IRB.

The TAMU System Research Compliance Officer will on a biennial process:

- 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;

The IO will:

- review the IRB minutes to determine that adequate documentation of the meeting discussion has occurred.
- approve the minutes attached to the Memorandum to IO. (Appendix A)

The IRB Committee will:

- evaluate the continuing review discussions to assure they are substantive and meaningful and that no lapse has occurred since the previous IRB review;
- submit minutes along with Memorandum to IO in a timely manner. (Appendix A)

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.

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**Related Statutes, Policies, or Requirements**

45 C.F.R., Part 46
21 C.F.R., Parts 50, 56, 312 and 812
Belmont Report
Texas Government Code, Chapter 552

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

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**Contact Office**
Office of Research
Institutional Review Board for Human Subjects
(806) 651-2270
Appendix A

Memorandum to IO

Memorandum to: Angela Spaulding, West Texas A&M University Research Compliance Officer
From: Institutional Review Board of Human Subjects (IRB), Committee Chair
Subject: Report of minutes
Date: [insert date]

This report summarizes the results of the IRB committee’s required review.

This report also meets the requirements of submission reports to the Institutional Official as a condition of this institution’s Review Board of Human Subjects. This form may also be used for any by the IRB committee for any requested inspections by the IO, and, as needed, to address any public and/or employees complaints.

Pre-evaluation Checklist:

_____ All committee members have been provided access to the approved WTAMU IRB proposals and supporting information for review well as the IRB Committee review checklist.

_____ All committee members have been notified of the full board review and a quorum was met.

_____ All committee members have been notified of the program review.

_____ No committee member wishing to participate in any part of this evaluation has been excluded.

Since the last review, the following changes have occurred in the institution’s program for human subjects.

I. Description of the Nature and Extent of the Institution’s Adherence to the HHS 49 CFR 46.103

Departures from the IRB Committee if appropriate. Select A or B:

[ ] A. There were no departures during this reporting period.

[ ] B. The following departures have been reviewed and approved by the IRB: [include reason for each departure]
II. Deficiencies in the Institution’s Review Board for Human Subjects Program

Human Subjects Program Review Date(s):
Select A or B:
[ ] A. There were no deficiencies in the program during this reporting period.
[ ] B. The following deficiencies have been identified: [describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of this Program Review form.]

III. Deficiencies in the Institution’s Human Subject’s proposal review

Audit Date(s):
Select A or B:
[ ] A. There were no deficiencies in the proposal reviews during this reporting period.
[ ] B. The following deficiencies have been identified: [describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of this Program Review form. The IRB committee has the authority to require Principal Investigators and research programs to meet the requirements outlined in the SOP No. 15.99.05.W1.11AR Institutional Review Board for Human Subjects – Post Approval Monitoring (PAM) procedure.]

IV. Minority Views

Select A or B:
[ ] A. No minority views were submitted or expressed.
[ ] B. The following minority views were expressed: [insert minority views here or attach]

V. Signatures [signatures of a majority of the IRB members]

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