

 **West Texas A&M University**<sup>TM</sup>  
**ACADEMIC RESEARCH ENVIRONMENTAL HEALTH AND SAFETY**  
**STANDARD OPERATING PROCEDURES**

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**SOP No. 15.99.05.W1.05AR Potential Non-Compliance in the Course of Human Subjects Research**

Approved: March 21, 2013

Last Revised: February 27, 2019

Next Scheduled Review: February 27, 2023

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.

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**1. Purpose**

This procedure describes the process and reporting requirements and obligations in the case of reports of potential non-compliance in the course of human subjects research.

**2. Scope**

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 West Texas A&M 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

**Noncompliance** is a failure (intentional or unintentional) to comply with applicable federal regulations, state or local law, the requirements or determinations of the IRB (including failure to follow approved protocol), System policies or regulations, university rules or procedures in the conduct of human subjects research. Noncompliance can result from action or omission.

Noncompliance may be non-serious (minor) or serious, and may also be continuing (see below).

**Non-serious or minor noncompliance** is noncompliance that does not increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the human subjects protection program. Examples of minor noncompliance may include, but are not limited to: lapses in continuing IRB approval, failure to obtain exempt determination before exempt research involving human subjects is conducted, minor changes in or deviations from an approved protocol, or administrative errors.

**Serious noncompliance** is noncompliance that a reasonable investigator should have foreseen would increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the human subjects protection program. Examples of serious noncompliance may include, but are not limited to: conducting or continuing non-exempt human subjects research without IRB approval; lack of legally effective informed consent from research participants; failure to report or review serious adverse events, unanticipated problems, or substantive changes in research; or inappropriate oversight of the research to insure the safety of human subjects and the integrity of the research/data.

**Continuing noncompliance** is noncompliance (serious or non-serious) that is a pattern of repeated actions or omissions taken by an investigator that indicates a deficiency in the ability or willingness of an investigator to comply with human subjects protection requirements that may affect research participants or the validity of the research and suggest the potential for future noncompliance without intervention. Examples of continuing noncompliance may include, but are not limited to: repeated failures to provide or review progress reports resulting in lapses of IRB approval, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

**A report of potential noncompliance** is an unconfirmed written report of noncompliance. Actions taken to avoid the occurrence of adverse events or unanticipated problems, if deviating from approved Protocol, must also be reported in accordance with this procedure.

### 4. General Procedure

Anyone may report potential noncompliance involving human subjects research verbally or in writing to the Institutional Review Board Chair or the Research Compliance Officer. Reports of potential noncompliance should contain sufficient information to determine whether the report is sufficiently credible and specific so that potential evidence of noncompliance may be identified and acted upon. If the IRB Chair, in consultation with the Research Compliance Officer, determines that the report of potential noncompliance is unjustified (i.e. no basis in fact) or that the complaint is a minor administrative issue that is able to be resolved by the IRB Chair and does not represent noncompliance, no further action is taken.

The IRB Chair will process all reports of potential non-compliance and findings of noncompliance, whether these reports arise internally (e.g., from WTAMU faculty, staff, the IRB, or investigator self-reports) or from outside the University (e.g., research participants or regulators).

Reports of potential noncompliance will remain confidential to the extent permitted by Texas law, consistent with the need to conduct an adequate investigation.

Actions undertaken in response to a report of potential noncompliance or a finding of noncompliance will be completed in a timely manner, based on the circumstances or seriousness of the potential noncompliance.

If the report of potential noncompliance involves an Investigator of another university, the appropriate institutional official from that university will be notified either verbally or in writing by the IRB Chair or Chief Research Officer. The communication will be documented and added to the IRB files of the associated case.

## **5. Initial Inquiry**

The IRB Chair will notify the IRB Committee on all reports of potential noncompliance or findings or noncompliance – unless as exempted in section 4.1 of this document. The Research Compliance Officer – along with the IRB Chair - will consult, as necessary, with the Office of General Counsel, on reports of potential noncompliance or findings of noncompliance.

Any individual with a potential conflict of interest may not participate in any investigations related to IRB noncompliance. If the IRB Chair has a conflict of interest and must be recused, the IRB Committee will assign a chair from the current IRB committee membership.

The Investigator(s), as applicable, shall be informed of a report of potential noncompliance and/or contacted for a response during the initial inquiry, unless the available information and the nature of the potential noncompliance dictate otherwise.

In the initial inquiry, the IRB Chair will gather information related to the report of potential noncompliance and forward the information to the IRB Committee for review and determination.

Possible outcomes of the initial inquiry include:

- Dismissal of the allegation
- Referral to other appropriate University process
- No further action required
- Corrective action(s) required (i.e., for minor violations)
- Review by convened IRB

When further investigation or convened IRB review is not warranted, the Investigator(s) and Research Compliance Officer will be notified in writing within 14 business days by the IRB Chair of the outcome of the initial inquiry - and within 30 business days to OHRP, FDA (as applicable for FDA-regulated research), any other sponsoring federal department or agency, and others (e.g., Office of Sponsored Research, Academic and Research Environmental Health and Safety) as necessary. The determination will be documented in a report reviewed and approved by the IRB.

University Administration, including the Investigator(s)' Dean, and/or the Department Head (or equivalent) may also be informed of the outcome of the inquiry, at the discretion of the IRB Chair or Research Compliance Officer.

Initial inquiries should be completed within 30 business days of receipt of the report of potential noncompliance or the finding of noncompliance, depending on the nature of the potential noncompliance.

## 6. Investigation: Convened IRB

Unless the initial inquiry has resolved the noncompliance question, reports of potential noncompliance are forwarded to a convened IRB for review and action.

Any individual with a potential conflict of interest may not participate in the investigation. If the IRB Chair has a conflict of interest and must be recused, the IRB Committee will assign a chair from the current IRB committee membership.

At least one IRB member should possess related expertise appropriate for review of the report of potential noncompliance; additional IRB members or external consultants may also be included as determined necessary by the IRB Chair.

The IRB Committee will be assisted by the Research Compliance Officer and, as necessary, advised by TAMU System Office of General Counsel.

The IRB Committee will meet as necessary to ensure timely review of the reports of potential noncompliance.

The IRB Chair will lead and/or facilitate the discussion. All available materials collected and/or associated with the noncompliance investigation will be distributed to all scheduled attendees in advance of the meeting.

The Investigator(s) may respond in person to the IRB at the convened meeting during which the noncompliance review will take place. The IRB Chair will be responsible for providing the Investigator(s) with reasonable notice of the meeting including notice that the Investigator(s) may address the IRB about the matter under review at the meeting.

A personal advisor or legal counsel may accompany the Investigator(s), but the advisor or legal counsel may not participate in the discussion.

The IRB will make final determinations in closed session by majority vote of a quorum of the members at the convened meeting.

The convened IRB should, as appropriate:

- Clearly describe the noncompliance, if any
- Determine whether the noncompliance is serious and/or continuing
- Consider the cause of the noncompliance
- Assess the adequacy of corrective actions for future compliance
- Consider the allowability of data use
- Determine if any harm to human subjects has occurred

The Investigator(s) and Research Compliance Officer - and within 30 business days to OHRP, FDA (as applicable for FDA-regulated research), any other sponsoring federal department or agency, and others (e.g., Office of Sponsored Research, Academic and Research Environmental Health and Safety) as necessary - will be informed in writing of the outcome and report (described below) of potential noncompliance and investigation by IRB Chair.

The Investigator(s), other members of the research staff, and/or others may be interviewed and/or an audit completed of the Investigator(s)' research conducted during the investigation, as necessary. The IRB Committee will consider materials and recommendations from the initial inquiry, the Investigator's

response, and other information relevant to the investigation (e.g., interviews, audit reports, literature searches, etc.).

A summary report that includes the report of potential noncompliance, information considered by the IRB Committee, and its conclusions will be prepared by the IRB Chair.

Possible outcomes of the investigation include:

- Dismissal of the report of potential noncompliance.
- Referral to other appropriate University process
- No further action required
- Corrective action(s) required

The Investigator(s) will be given an opportunity to respond to the IRB Committee's findings in writing within 14 business days of receipt of the report.

University Administrators', including but not limited to the Investigator(s)' Dean, and/or the Department Head (or equivalent) may also be informed, at the discretion of the Chair of the IRB and Research Compliance Officer.

Investigations should be completed as expedited as possible, depending on the nature of the potential noncompliance and the complexity of the investigation.

## **7. Corrective Actions**

Corrective action(s) will be based on the nature of the noncompliance, degree to which research participants were placed at risk, occurrence of previous noncompliance, etc. The range of possible corrective actions that the IRB Chair and IRB Committee may consider includes, but is not limited to:

- Modification(s) of the research or consent form
- Notification of current and/or past research participants
- Re-consent of current research participants (when such information may relate to their willingness to continue in the research)
- Monitoring of the research (including audits) or consent process
- Education or mentoring for the Investigator(s)
- Additional reporting (e.g., more frequent continuing review)
- Additional resources to support the investigator's research activities
- Limitations (e.g., restriction to co-investigator status) on research activities or use of research data
- Suspension of IRB approval for one or more of the Investigator(s)' studies
- Termination of IRB approval for one or more of the Investigator(s)' studies.
- Submission of a new research consent form for consideration by IRB Committee
- Notification of the Investigator(s) department and college administration. College or departments may seek corrective actions appropriate to TAMUS policies and University procedures.

If the Investigator(s) do not comply with the required corrective action(s) within the time specified in the corrective action plan, additional action may be required, including reporting of the lack of compliance to the appropriate university supervisor for further action in accordance with the WTAMU faculty handbook and/or TAMUS policies and University procedures for personnel responsibilities and obligations.

## **8. Appeals**

The convened IRB will review an Investigator's request for reconsideration or appeal of a determination of noncompliance and/or corrective actions as warranted by the presentation of new information or unusual circumstances.

All investigator petitions must be made within 30 business days of his/her receipt of notification of the IRB's findings.

The IRB will review an Investigator's request or appeal within 30 business days, and the Investigator will be notified in writing of the IRB's decision within 14 business days of the review.

## **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.

## **10. 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.

## **11. References and Related Materials**

Code of Federal Regulations: Title 45: Part 46 Protection of Human Subjects

Code of Federal Regulations: Title 21: Part 50 Protection of Human Subjects

Code of Federal Regulations: Title 21: Part 56 Institutional Review Boards Guidance on Reporting [Incidents to OHRP](#)

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### **Contact Office**

WTAMU Environmental Health and Safety  
(806) 651-2270

## Appendix A

### Office for Human Research Protections (OHRP)

#### Guidance on Reporting Incidents to OHRP

Date: May 27, 2005

#### Scope:

This document provides guidance about procedures institutions may use to file incident reports with OHRP. Incident reports include reports of unanticipated problems involving risks to subjects or others; serious or continuing noncompliance with Department of Health and Human Services (HHS) regulations at 45 CFR part 46 or the requirements or determinations of the institutional review board (IRB); and suspension or termination of IRB approval. In particular, OHRP offers guidance on the following topics:

- I. Applicability of incident reporting requirements;
- II. Information to be included in incident reports;
- III. Time frame for reporting incidents;
- IV. OHRP focus on corrective actions when reviewing incident reports;
- V. OHRP's response to incident reports; and
- VI. Additional guidance.

**Target Audience:** IRBs, institutional officials, and institutions that may be responsible for review, oversight, or conduct of human subjects research covered by an OHRP-approved assurance.

#### Regulatory Background:

HHS regulations at 45 CFR 46.103(a) and (b)(5) require that institutions have written procedures to ensure that the following incidents related to research conducted under an OHRP-approved assurance are promptly reported to OHRP:

- a. **Any unanticipated problems involving risks to subjects or others;**
- b. **Any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and**
- c. **Any suspension or termination of IRB approval.**

#### Guidance:

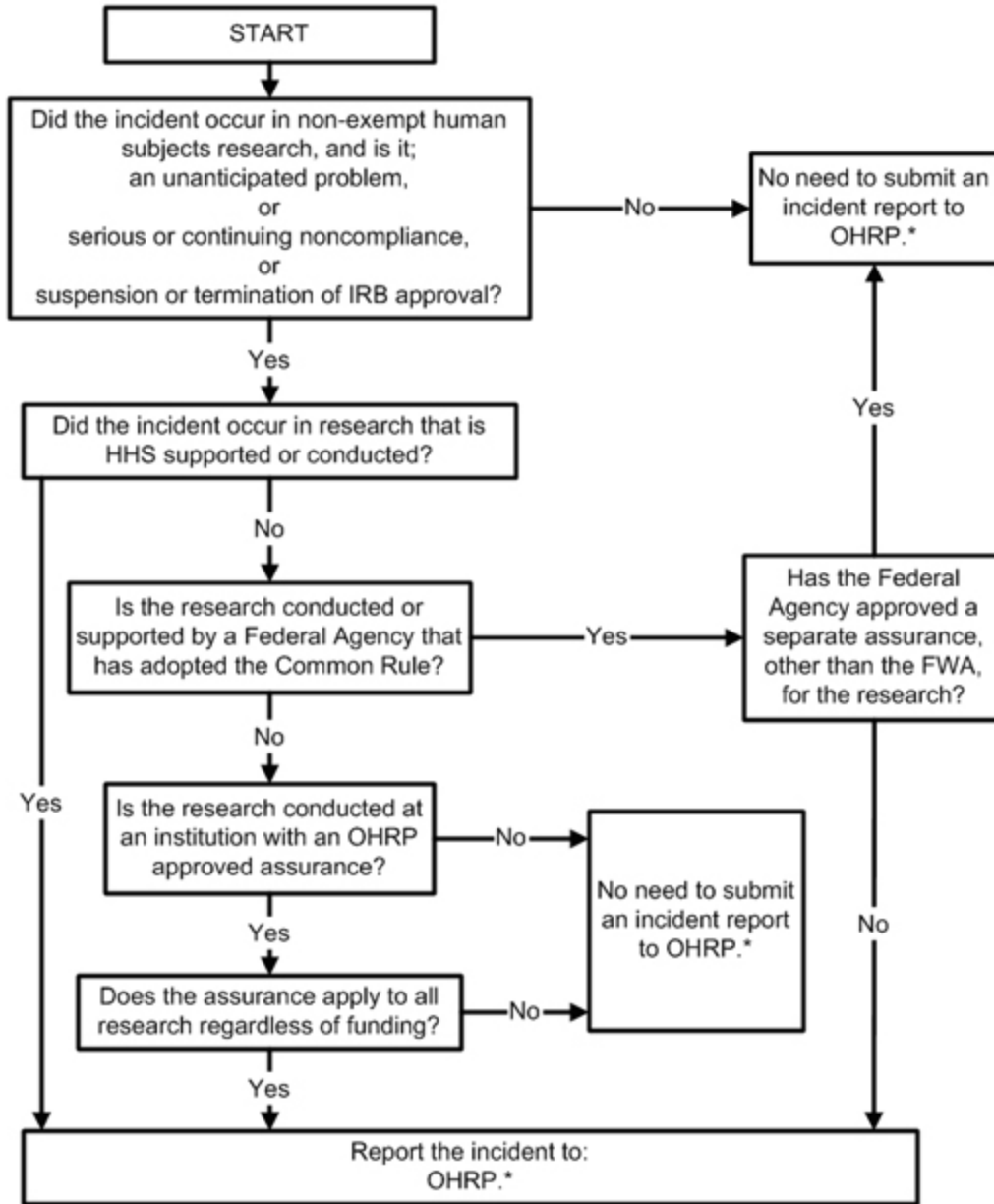
- I. Applicability of incident reporting requirements

In general, these reporting requirements apply to all nonexempt human subjects research that is:

- a. conducted or supported by HHS;
- b. conducted or supported by any non-HHS federal department or agency that has adopted the Common Rule and is covered by a Federalwide Assurance (FWA) determined to be appropriate for such research; or
- c. covered by an FWA, regardless of funding source.

Federal departments or agencies other than HHS that have adopted the Common Rule may determine that the FWA is not appropriate for certain research that they conduct or support. OHRP notes that these incident reporting requirements are **not** applicable to such research. In such cases, the institution should contact the non-HHS department or agency that supports the research about reporting requirements. See decision chart below:

## What Incidents Should be Reported to OHRP?



\* Other reporting requirements may apply, whether or not a report to OHRP is required.

[Data/text from the decision chart above can be found on page 12.](#)

### II. Information to be included in incident reports

To fulfill the regulatory requirements for reporting incidents, OHRP would consider it acceptable for an institution to comply with written procedures specifying that the following information be included in an incident report submitted to OHRP:

#### A. For unanticipated problems involving risks to subjects or others:

- Name of the institution (e.g., university, hospital, foundation, school, etc) conducting the research;
- Title of the research project and/or grant proposal in which the problem occurred;



- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the problem; and
- Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.).

**B. For serious or continuing noncompliance:**

- Name of the institution (e.g., university, hospital, foundation, school, etc) conducting the research;
- Title of the research project and/or grant proposal in which the noncompliance occurred;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the noncompliance; and
- Actions the institution is taking or plans to take to address the noncompliance (e.g., educate the investigator, educate all research staff, suspend the protocol, suspend the investigator, conduct random audits of the investigator or all investigators, etc.).

**C. For suspension or termination:**

- Name of the institution (e.g., university, hospital, foundation, school, etc) conducting the research;
- Title of the research project and/or grant proposal that was suspended or terminated;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB that was suspended or terminated and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the reason for the suspension or termination; and
- The actions the institution is taking or plans to take to address the suspension or termination (e.g., investigate alleged noncompliance, educate the investigator, educate all research staff, require monitoring of the investigator or the research project, etc.)

III. Time frame for reporting incidents

The regulations at 45 CFR 46.103(a) and (b)(5) do not specify a time frame for reporting, except "promptly." For a more serious incident, this may mean reporting to OHRP within days. For a less serious incident, a few weeks may be sufficient. It may be appropriate to send an initial report, and indicate that a follow-up or final report will follow by the earlier of:

- a specific date; or
- when an investigation has been completed or a corrective action plan has been implemented.

IV. OHRP focus on corrective actions when reviewing incident reports

When reviewing a report of an unanticipated problem, OHRP assesses most closely the adequacy of the actions taken by the institution to address the problem. Likewise, when reviewing reports of non-compliance or suspension or termination of IRB approval, OHRP assesses most closely the adequacy of

the corrective actions taken by the institution. In particular, OHRP assesses whether or not the corrective actions will help ensure that the incident will not happen again, either with the investigator or protocol in question, or with any other investigator or protocol. Therefore, OHRP recommends that, when appropriate, corrective actions be applied institution-wide.

#### V. OHRP response to incident reports

After receiving and evaluating an incident report from an institution, OHRP will respond in writing and state that the report was adequate or request additional information. For questions on reporting, please contact the Director of the Division of Compliance Oversight, 301-496-7005 or 866- 447-4777.

#### VI. Additional guidance

Please see [OHRP guidance](#) on continuing review regarding the distinction between suspension and expiration of IRB approval.

## What Incidents Should be reported to OHRP

Start here

- Did the incident occur in non-exempt human subjects research; and is it; an unanticipated problem, or serious or continuing non-compliance, or suspension or termination of IRB approval?
  - Yes - Did the incident occur in research that is HHS supported or conducted?
    - Yes - Report the incident to OHRP\*
    - No - Is the research conducted or supported by a Federal Agency that has adopted the Common Rule?
      - Yes - Has the Federal Agency approved a separate assurance, other than the FWA, for the research?
        - Yes - No need to submit an incident report to OHRP\*
        - No - Report the incident to OHRP\*
      - No - Is the research conducted at an institution with an OHRP approved assurance?
        - Yes - Does the assurance apply to all research regardless of funding?
          - Yes – Report the incident to OHRP\*
          - No – No need to submit an incident report to OHRP\*
        - No – No need to submit an incident report to OHRP\*
    - No - No need to submit an incident report to OHRP\*

\*Other reporting requirements may apply, whether or not a report to OHRP is required.