TEXAS A&M UNIVERSITY
SAN ANTONIO

Institutional Review Board (IRB) STANDARD OPERATING PROCEDURE (SOP)

SOP #: 10	**Version:** 2.0	**Effective Date:** June 4, 2024
Title: Managing IRB Noncompliance		
Approved by: Dr. Vijay Golla, PhD Vice Provost for Research and Health Sciences		**Date:** June 4, 2024

1. Purpose

1.1 This SOP covers the process to ensure ethical research and safety of human subjects. The IRB must review and address all complaints of ethical concern. Procedures are established to ensure concerns are communicated to the IRB by investigators. The form for reporting concerns can be found here. The IRB chair or designee must review each concern in a timely and systematic manner and when necessary, take prompt action and corrective actions.

2. Scope

2.1 Federal requirements, system and university guidelines and policies are formed in line with 45 CFR 46.103 and enforced for the ultimate purpose of human subjects' protection.

3. Responsibilities

3.1 All investigators are strongly encouraged to self-report or report any adverse events within 24 hours using the Adverse Events Form.

Other options available to report an adverse event or ethical concern at A&M-SA:

- Director of Research Compliance (DRC) at 210-784-1223
- Research Compliance Administrator (RCA) at 210-784-2317
- IRB Chair at 210-784-2281
- Institutional Official (IO) at 210-784-1215
- Campus Coordinator at 210-784-2003

In addition to the A&M-SA personnel, a risk, fraud, and misconduct hotline utilized by the Texas A&M University System, may also be used when reporting concerns (click here).

3.2 If the complaint is received verbally, the DRC/RCA/IRB Chair/IO will document the report with details such as date and location of the event, names of the personnel involved and depending on the incident will forward it to appropriate personnel. For example, if the incident involves safety, campus police and other responsible personnel will be notified.

3.3 Texas A&M University System Rule is to prohibit unlawful retaliation against employees as a consequence of good faith actions in the reporting of, or the participation in an investigation pertaining to, allegations of wrongdoing. A&M-SA will treat ethical concerns submitted in the same manner.

4. Procedure

4.1. Complaints will be reviewed by the IRB Chair or designee to form a subcommittee to screen the initial complaint. A determination will be made whether:

- Immediate action needs to be taken to ensure human subjects' safety.
- If the non-compliance is serious and/or continuing, then the findings are sent to the IRB convened meeting.
- If there is no serious or continuing noncompliance, generate correspondence with a determination of Noncompliance that is Neither Serious nor Continuing.
- If the complaint has no basis, a correspondence with a determination of Allegation of Noncompliance with no Basis in Fact.

4.2. To investigate complaints of noncompliance, the IRB Chair or designee may request as needed:

- Additional information from the PI.
- Consultation with General Counsel in correspondence with the IO.

4.2.1. An Investigative Sub-committee, which may include outside expertise.

The investigative Sub-committee will be tasked with information gathering, drafting a report of the investigation, and determining a completion date. The assigned completion date will depend on the IRB's determination of whether immediate remedial action may be required. The nature of the investigation will vary depending on the circumstances, but often involves:

• Interviewing complainants (if known), potential witnesses, any persons against whom allegations were directed, and relevant administrators.
• Interviews may be done in-person, via live-streaming platforms (Zoom, Microsoft Teams, etc.), phone or by email.
• More than one member of the Investigative Sub-committee shall be present during the interview.
• Reviewing any pertinent records.
• Identify relevant rules and regulations.
• As part of the investigation, additional allegations found may be investigated and could result in an additional investigation or maybe included in the original investigation.
• As part of the investigation, the Investigative Sub-committee may sequester evidence if it is appropriate and needed to conduct the investigation. If evidence is to be sequestered, interested parties will be notified and provided

with copies of the evidence and the Investigative Sub-committee will take possession of the originals until the investigation is completed, at which time the original documents will be returned.

The report presented to the IRB should review the allegation(s) and may include:

- Who was involved.
- What happened.
- Where the alleged noncompliance occurred.
- When the alleged noncompliance occurred.
- The root cause of the alleged noncompliance.
- The results of interview(s).
- The condition of the laboratory.
- The results of records and other document reviews.

The report reviewed should also contain:

- Any supporting documentation such as correspondence, reports, and records.
- Requirements of the funding agencies, institutional policies, and procedures.
- Recommended corrective actions, if appropriate, ensure the non-compliance issue will not occur in the future.

4.3. The investigator will be given the opportunity to respond to the allegations of suspected noncompliance.

4.4. Upon completion of the initial investigation of the allegation, the IRB Chair or designee will prepare a written report describing the allegation and the outcome of the review.

4.4.1. This report will be submitted to the IO as Reportable New Information and a copy will be provided to the investigator.

4.4.2. If the allegation involves the IRB or any other component of the institution, the IRB staff will forward the report to the IRB Chair and IO.

4.5. When required, a Corrective Action Plan (CAP) will accompany the report submitted to the IRB.

4.5.1. The CAP will outline what steps the investigator has taken or will take to resolve the noncompliance and sufficient detail to ensure adequate measures or training is taken to prevent future violations and to prevent such noncompliance from occurring in any current or future research that may be conducted by the research team.

4.5.2. When appropriate, or upon request by an investigator, the IRB Chair or designee may assist in the development of the CAP to accompany the investigator's response.

4.5.3. The report of the investigator may request additional input from the IRB Chair.

4.6. If the noncompliance cannot be resolved as described above or an appropriate CAP that is acceptable to the IRB cannot be developed, the IRB has the authority to impose corrective actions, take additional measures to protect human subjects or to refer the noncompliance to the Institutional Official (IO) with recommendations.

4.7. Noncompliance that is determined not to be Serious or Continuing.

4.7.2 Educating the respondent and the PI, if appropriate, as well as the department.

4.7.3 Requiring investigators to complete training courses/seminars.

4.7.4 Requiring the respondent or PI, if appropriate, to create a plan of action to remedy the noncompliance.

4.7.5 Modifying current subjects of the noncompliance (required when such information may relate to subject' willingness to continue to take part in the study).

4.7.6 Requiring current subjects to re-consent to participate in the study.

4.7.7 Sending a letter of reprimand to the respondent and the PI, if appropriate, (Copied to their respective department chair, dean, college and/or center director, faculty advisor (student research), research compliance administrator and IO).

4.7 Noncompliance that is determined to be Serious or Continuing:

4.7.1 A meeting of the IRB shall be convened to review:

- A copy of the approved IRB protocol.
- The minutes of the relevant IRB meeting, if the protocol warranted a full IRB review.
- A copy of the Inquiry Committee Final Report; and
- Any other relevant materials.

4.7.2 The IRB shall determine what actions to take to protect the rights and welfare of the subjects. These actions may include, but are not limited to:

- Obtaining more information pending a final decision.
- Requesting the PI provide a CAP.
- Educating the respondent and the PI, if applicable, and/or all research staff.
- Requiring investigators to complete training courses/seminars.
- Suspending or terminating the study.
- Suspending all protocols of the respondent or the principal investigator (temporary or permanently).
- Conducting random audits of the studies conducted by the respondent or the principal investigator and/or all research staff.
- Modifying the research protocol.
- Confiscating all data collected during the period of noncompliance.
- Notifying current subjects of the noncompliance (required when such information may relate to subjects' willingness to continue to take part in the study).
- Requiring current subjects to re-consent to participate in the study.
- Modifying the IRB's Continuing Review schedule for the study.
- Monitoring of the research or the consent process.
- Recommending as relates to the respondent of the PI, if applicable, suspension or revoking the privilege to conduct human subjects research as a PI or Co-PI or serve as a faculty advisor of student research at A&M-SA.

5. Noncompliance with IRB Policies, Procedures, or Decisions

Noncompliance occurs when procedures or policies approved by the IRB are not being adhered to. When the investigation results in a determination of noncompliance, the IRB's first step will be to notify the PI that the research must be brought into compliance.

If allegations of noncompliance are verified, the IRB will review corrective actions put in place by the PI to ensure the safety of all individuals. A clearly minor and unintentional misinterpretation of an IRB policy that has created no additional risk for an individual is an example of where a verified allegation of noncompliance might lead to an explanation, not a corrective action.

Noncompliance

Compliant		Noncompliant	
Non-serious Halted	Non-serious continuing	Serious Halted	Serious continuing

6. Consequences of Noncompliance

Subsequent actions of the IRB will include:

- Notifying funding agencies.
- Implementing measures to prevent recurrence.
- Notifying the PI's academic supervisor.
- Notifying the Vice Provost for Research and Health Sciences.
- Notifying funding or regulatory agencies, as required.
- Notifying the complainant, any persons against whom allegations were directed, and pertinent program officials (appropriate supervisory and management staff, the public affairs office, A&M-SA attorneys, A&M-SA Office of Research Compliance, etc.).
- Suspending privileges on a case-by-case basis resulting in a PAM (post approval monitoring).

7. Definitions and References

7.1 Definitions

Noncompliance: Conducting research in a manner that is not in compliance with federal regulations, laws, required guidelines, A&M-SA IRB policies and procedures, university rule, or the decisions of the A&M-SA IRB to the policies and procedures page on the website.

- Non-serious noncompliance: An isolated incident that is not serious or continuing in nature. Includes unintentional mistakes, oversights, or misunderstandings resulting in inadvertent errors, inattention to detail, or inadequate training and supervision of research staff.
- Serious noncompliance: An intentional violation of IRB or university policy or willful noncompliance with applicable federal regulations, laws, and/or guidelines.

- Continuing noncompliance: A pattern of repeated actions or omissions taken by investigator or research personnel that indicates a lack of ability or willingness to comply with federal regulations, laws, guidelines, A&M-SA policy, A&M-SA IRB policy and procedures, or the determinations of IRB.

7.2 References

- Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance
- Texas A&M University System Rule 08.01.01.M1 Civil Rights Compliance

8. Revision History

8.1 February 22, 2021, May 8, 2024