TEXAS A&M UNIVERSITY-SAN ANTONIO
IRB STANDARD OPERATING PROCEDURE

SOP #: 4	Version: 1.0
Title: Managing IRB Non-Compliance	
Authorized: Dr. Vijay Golla, Vice Provost for Research and Graduate Studies	
Signature: February 22, 2021	

1. **Purpose**

   This SOP establishes the process to manage any allegations of suspected or actual non-compliance reported to the Texas A&M University-San Antonio IRB to ensure the protection of human subjects in research.

2. **Scope**

   This SOP applies to faculty, staff, students, and affiliated investigators or other affiliated individuals who are involved in human subjects research being conducted under the purview of Texas A&M University-San Antonio regardless of location of the research, funding source or whether the research is funded or unfunded.

3. **Responsibilities**

   3.1. Complaints may be received by any IRB Office staff member. The IO will be immediately informed of any non-compliance complaints received.

   3.2. The Office of Research and Graduate Studies Compliance staff carries out the activities related to handling complaints and/or allegations or non-compliance.

   3.3. The Office of Research and Graduate Studies Compliance staff reports the post-approval monitoring activities to the IRB Chair.

4. **Procedure**

   4.1. Non-compliance will be reviewed by the IRB Chair or designee to see:

      4.1.1. If immediate action needs to be taken to ensure subject safety.

      4.1.2. If the allegation has no basis in fact, generate correspondence with a determination of Allegation of Non-Compliance with no Basis in Fact.

      4.1.3. If the non-compliance is serious and/or continuing, then send findings to a meeting of the convened IRB and applicable parts of this SOP will apply.

      4.1.4. If there is no serious or continuing noncompliance, generate correspondence with a determination of Noncompliance that is Neither Serious nor Continuing.

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

      4.2.1. Additional information from the PI.

4.2.2. Consultation with General Counsel in correspondence with the IO.

4.2.3. An investigative sub-committee; which may include outside expertise.

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 into 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 will accompany the report submitted to the IRB.

4.5.1. The corrective plan will outline what steps the investigator has taken or will take to resolve the non-compliance 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 corrective action plan 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 non-compliance cannot be resolved as described above or an appropriate corrective action plan 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. Non-Compliance that is determined not to be Serious or Continuing

4.7.1. Sending a letter of reprimand to the respondent and the PI, if appropriate,

(Copied to their respective department chair, dean, institute and/or center director, faculty advisor (student research), research compliance administrator and IO);

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

4.7.3 Requiring researchers to complete training courses/seminars;

4.7.4 Requiring that the respondent or the PI, if appropriate, create a plan of action to remedy the non-compliance;

4.7.5 Modifying current subjects of the non-compliance (required when such information may relate to subject' willingness to continue to take part in the study); and/or

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

4.7 Non-Compliance that is determined to be Serious or Continuing:

4.7.1 meeting of the IRB shall be convened to review:

4.7.2 A copy of the approved IRB protocol;

4.7.3 The minutes of the relevant IRB meeting, if the protocol warranted a full IRB review;

4.7.4 A copy of the Inquiry Committee Final Report; and

4.7.5 Any other relevant materials

4.7.6 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:

4.7.7 Obtaining more information pending final decision;

4.7.8 Requesting that the PI provide a corrective action plan;

4.7.9 Educating the respondent and the PI, if applicable, and/or all research staff;

4.7.10 Requiring for researchers to complete training courses/seminars;

4.7.11 Suspending or terminating the study;

4.7.12 Suspending all protocols of the respondent or the principal investigator (temporary or permanently)

4.7.13 Conducting random audits of the studies conducted by the respondent or the principal investigator and/or all research staff;

4.7.14 Modifying the research protocol;

4.7.15 Confiscating all data collected during the period of non-compliance

4.7.16 Notifying current subjects of the non-compliance (required when such information may relate to subject' willingness to continue to take part in the study);

4.7.17 Requiring current subjects to re-consent to participate in the study;

4.7.18 Modifying the IRB's continuing review schedule for the study;

4.7.19 Monitoring of the research or the consent process;

4.7.20 Recommending as relates to the respondent of the PI, if applicable, suspension or revoking the privilege to conduct human subject research as a PI or Co-PI or serve as a faculty advisor of student research at TAMUSA.

5. **References**

Texas A&M University. Institutional Review Board. TAMU Guidance for Continuing Review and Annual Administrative Status Report. Retrieved November 24, 2020 from: https://rcb.tamu.edu/humansubjects/revised-common-rule

Florida International University. Research and Economic Development. Standard Operating Procedure (SOP) for the Handling of Allegations of Non-Compliance with Human Subjects Protection Laws, Regulations and Policies. Retrieved November 24, 2020 from: http://research.fiu.edu/documents/irb/documents/IRB-Non-Compliance-SOP.pdf

Northwestern. Institutional Review Board Office. SOP: Handling Complaints and Allegations of Non-Compliance. Retrieved November 24, 2020 from: https://cpb-us-e1.wpmucdn.com/sites.northwestern.edu/dist/2/2819/files/2020/01/Handling-Complaints-and-Allegations-of-Non-Compliance-COMPLIANCE-095.pdf

6. **Revision History**

1.0 – This SOP has been revised JFE