TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: Managing Non-compliance in Human Subject Research**	
	Section IV: Post-Approval Monitoring and Non-Compliance	
	Number	Date
	IRB IV-006	9/13/2025

1. PURPOSE

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

1.2. This process begins when any potential non-compliance is reported to the IRB.

1.3. This process concludes when the non-compliance is addressed administratively, referred to the convened IRB, or the allegation is determined to be unsubstantiated.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. This SOP applies to faculty, staff, students, affiliated investigators, or other affiliated individuals who are involved in human subjects research being conducted under the auspices of the Texas A&M University-Kingsville (TAMUK), regardless of the location of the research, the funding source, or funding status.

3.2. Suspected or actual non-compliance must be reported to the IRB.

3.3. IRB members and consultants do not participate in any review in which they have a Conflict of Interest, except to provide information requested by the IRB.

3.4. Allegations of non-compliance reported to the IRB will be reviewed in a timely manner to assess their validity.

3.5. Investigators are required to respond to all inquiries, correspondence, or directives from the IRB regarding any allegations of or actual non-compliance.

3.6. The IRB will take appropriate actions, as necessary, to protect research participants, which may include the suspension or termination of the research.

3.6.1. Possible range of actions or restrictions considered by the IRB may include:

3.6.1.1. Investigator education.

3.6.1.2. Modification of the information disclosed during the consent process.

3.6.1.3. Notification of current participants when such information might relate to the participant willingness to continue to participate in the research.

3.6.1.4. Modification of the continuing review period frequency.

3.6.1.5. Monitoring of the consent process or the research.

3.6.1.6. Referral to other administrative departments.

3.6.1.7. Modification of the research

3.6.1.8. Suspension of the research.

3.6.1.9. Termination of the research.

3.6.2. In instances where there are immediate concerns with the research that are identified while completing TAMUK SOP: New Information Process (IRB SOP IV-004), the IRB Chair may call for a pause or suspension of the study pending review by a convened IRB.

3.7. Reports of non-compliance may come in the form of a complaint or from the result of a review or a monitoring activity. If a complainant does not have access to the Cayuse electronic system in which the New Information Item was generated, the report may be sent by other means available (email, fax, phone, or in-person).

3.8. The institution will notify the federal department or agency funding the research of any for-cause investigation of that research by another federal department or agency or national organization, as well as TAMUS RCO.

3.9. For federal departments or agencies funding the research, non-=compliance includes non-compliance with the requirements of that agency.

3.10. Conduct investigations of non-compliance when a New Information Item is determined to have sufficient cause to so warrant.

4. RESPONSIBILITIES

4.1. The IRB Chair or designee:

4.1.1. Appoints the members of the investigative committee based on the expertise and background needed to effectively address the issues.

4.1.2. Appoints a chair of the investigative committee.

4.1.3. Charges the investigative committee with the issues to be addressed.

4.2. The investigative committee carries out these procedures in a timely fashion, such as within 60 days.

4.3. Investigative committee members make their decisions based on a preponderance of the evidence.

4.4. Investigative committee decisions are made by a majority vote.

5. PROCEDURE

5.1. Investigations

5.1.1. Notify the investigator that an investigation is being conducted, the questions to be answered, and the time frame for completion.

5.1.2. Determine what information to gather and what individuals to interview.

5.1.3. Gather information and interview individuals.

5.1.4. If the investigative committee believes that a transcription of the interviews will be required to make a proper decision, the investigative committee may request to record all interviews.

5.1.5. Continue information gathering and interviews until a decision can be made.

5.1.6. The investigative committee prepares a written report detailing their findings and conclusions.

5.1.7. Send final report to IRB Chair or designee.

5.2. Investigators are required to report any instances of non-compliance that involve a potential risk to subjects or others, or involve failure to comply with federal regulations, state laws, Institutional policies, and/or requirements or determinations of the IRB or provisions of the approved protocol.

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

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

5.3.2. If the non-compliance necessitates review by the convened IRB, relevant provisions of this SOP will apply.

5.4. The IRB Chair or designee may request as needed:

5.4.1. Additional information from the PI.

5.4.2. Consultation with General Counsel.

5.4.3. An investigative sub-committee that may include outside expertise.

5.4.4. A member of the IRB to conduct an inquiry/review into the allegation.

5.5. The investigator will be given the opportunity to respond to the allegations of suspected non-compliance.

5.6. Upon completion of the initial investigation into the allegation, the IRB staff will prepare a written report detailing both the allegations and investigation's findings and conclusions.

5.6.1. The report will be submitted to the IRB as Reportable New Information and a copy will be provided to the investigator.

5.6.2. If the allegation involves the IRB or any other component of the institution, then the report will be forwarded to the Institutional Official.

5.7. When required, a corrective action plan will accompany the report submitted to the IRB.

5.7.1. The corrective action plan will outline what steps the investigator has taken or will take to resolve the non-compliance and provide sufficient detail to ensure adequate measures or training is taken to prevent future violations and to prevent such non-compliance from occurring in any current or future research that may be conducted by the research team.

5.7.2. The investigator may request additional input from the IRB Chair.

5.8. 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 refer the non-compliance to the IRB chair with recommendations.

5.9. Reporting to the Office for Human Research Protections (OHRP)

5.9.1. Reporting Non-Compliance to OHRP: When non-compliance is serious, ongoing, or presents an unanticipated risk to participants, it may require reporting to OHRP. The IRB will determine whether reporting is required. In such cases, the PI will be instructed not to communicate directly with OHRP.pl

5.9.1.1. Non-compliance involving unanticipated risks to participants, including serious adverse events, must be reported to OHRP within 30 days.

5.9.1.2. Serious or Continuing Non-Compliance: If the IRB determines that the non-compliance is serious (e.g., posing significant risks to participants) or ongoing (e.g., issues that have not been addressed effectively), it must be reported to OHRP within 30 days of the IRB's recognition of the issue.

5.9.1.3. Suspension or Termination of Research: If the IRB suspends or terminates the study because of non-compliance or unanticipated problems, OHRP must be notified within 30 days.

5.9.1.4. Reports to OHRP must include a comprehensive description of:

5.9.1.4.1. The nature of the non-compliance.

5.9.1.4.2. Findings from the investigation.

5.9.1.4.3. Corrective and preventive actions taken.

5.9.1.4.4. Any modifications made to the study protocol, consent process, or other measures taken to protect participants.

5.9.2. Reporting Process to OHRP:

5.9.2.1. When submitting a report to OHRP, the IRB will include the following information:

5.9.2.1.1. A detailed description of the non-compliance or unanticipated problem.

5.9.2.1.2. Any actions taken to mitigate risks to participants.

5.9.2.1.3. Steps the investigator has taken or plans to take to address the issue.

5.9.2.1.4. A corrective action plan (if applicable).

5.9.2.1.5. Any changes made to the study protocol to enhance participant safety or address the non-compliance.

6. REFERENCES

6.1. 45 CFR 46.103.b

6.2. 21 CFR 56.108 (b)(2)

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