TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: New Information Process**	
	Section IV: Post-Approval Monitoring and Non-Compliance	
	Number	Date
	IRB IV-004	9/13/2025

1. PURPOSE

1.1. This SOP outlines the procedure to manage new information to ensure that any incoming information that represents Non-Compliance, Unanticipated Problems Involving Risks to Subjects or Others, Suspensions of IRB Approval, and Terminations of IRB Approval are managed to protect the rights and welfare of human subjects.

1.2. The process begins when the IRB receives a new information item as described in TAMUK SOP: Reportable New Information Items (IRB SOP IV-003).

1.2.1. Information items requiring submission to the IRB are listed in TAMUK SOP: Reportable New Information Items (IRB SOP IV-003).

1.3. The process concludes when the IRB Chair or designated reviewer determines whether the information item: does not represent a problem that requires management, will be managed administratively, or will be referred to the convened IRB for review.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. Timelines and procedures for notification will follow the established funding sponsor's criteria.

3.2. In the absence of specific sponsor criteria, the institution will promptly (no longer than 30 days) notify the Federal department or agency funding the research of any cause for investigation of that research by another federal department or agency or national organization.

3.3. In the absence of specific sponsor criteria, the institution will promptly (no longer than 30 days) notify the Federal department or agency funding the research of any Unanticipated Problem Involving Risks to Subjects or Others, Suspensions, Terminations, and Serious or Continuing Noncompliance as indicated in TAMUK SOP: Post Review (IRB SOP IV-002).

3.4. For Department of Defense (DoD) research, the institution will ensure the following items are promptly (no longer than 30 days) reported to the DoD Human Research Protection Officer (HRPO):

3.4.1. Significant changes to the research protocol are approved by the IRB

3.4.2. Results of the Continuing Review

3.4.3. IRB used to review and approve the research changes to a different IRB

4. RESPONSIBILITIES

4.1. The research compliance staff assigned to the IRB carries out the Intake of New Information Items procedure as described in TAMUK SOP: Reportable New Information (IRB SOP IV-003).

4.2. The IRB Chair or designated reviewer carries out activities after the Intake of New Information is complete.

5. PROCEDURE

5.1. Review each item of information and answer the following questions.

5.1.1. Is this an Allegation of Non-Compliance?

5.1.2. Is this a Finding of Non-Compliance?

5.1.3. Is this an Unanticipated Problem Involving Risks to Subjects or Others?

5.1.4. Is this a Suspension of IRB Approval or Termination of IRB Approval?

5.2. After completing the Intake of New Information Item, assign the New Information item to the IRB Chair or Designated Reviewer.

5.3. If the IRB chair, or designated reviewer are unable to answer a question using the New Information Flowchart, initiate one of the following:

5.3.1. TAMUK SOP: Investigations, Suspensions/Terminations by the Institution (IRB SOP IV-007)

5.3.2. Request a consultant

5.3.3. If the answer is “yes” to one or more questions, then the IRB Chair or Designated Reviewer will follow the corresponding sections below.

5.3.4. Allegations of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact. See TAMUK SOP: Managing Non-Compliance in Human Subject Research (IRB IV-006) for additional information.

5.3.4.1. If yes, follow the procedures under Findings of Non-Compliance.

5.3.4.2. If no, follow the corresponding sections.

5.3.5. Findings of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.

5.3.5.1. If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.

5.3.5.2. If yes, follow the procedures under Serious or Continuing Non-Compliance.

5.3.6. Non-Serious/Non-Continuing Non-Compliance

5.3.6.1. Work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan.

5.3.6.2. If unable to work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan, consider the Non-Compliance to be Continuing Non-Compliance and follow the procedures for Serious or Continuing Non-Compliance.

5.3.7. Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others.

5.3.7.1. Place on the agenda for the next available convened IRB meeting in an IRB with appropriate scope as an item of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others.

5.4. If the new information requires immediate action necessary in advance of the meeting, the IRB Chair or other individual in accordance with TAMUK SOP: Investigations, Suspensions Termination by the Institution (IRB SOP IV-007) will consider a Suspension of IRB Approval following the TAMUK SOP: Investigations, Suspensions/Terminations by the Institution (IRB SOP IV-007).

5.4.1. A new information item that requires immediate action to protect the rights and welfare of subjects may be placed on the next IRB agenda at any time prior to the meeting.

5.5. If the notification involves a subject becoming a Prisoner in a study not approved by the IRB to involve prisoners:

5.5.1. Confirm that the subject is currently a Prisoner.

5.5.1.1. If the subject is currently not a Prisoner, no other action is required.

5.5.2. Consider whether stopping all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner would present risks to the subject.

5.5.2.1. If the subject's involvement in the research cannot be stopped for health or safety reasons, do one of the following:

5.5.2.1.1. Keep the subject enrolled in the study and review the research for involvement of Prisoners. If the research is subject to DHHS oversight, notify OHRP.

5.5.2.1.2. Remove the subject from the study and provide the study intervention as clinical care or compassionate use.

5.5.2.2. If the subject's involvement in the research can be stopped, inform the investigator that all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject must be stopped immediately until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner.

5.5.3. For Department of Defense (DoD) research, promptly report all decisions to the Department of Defense (DoD).

5.5.4. The Department of Defense (DoD) must concur with the IRB before the subject can continue to participate while a prisoner.

5.5.4.1. If the investigator asserts it is in the best interest of the prisoner-subject to continue the research while a prisoner for health or safety reasons, the IRB Chair may determine that the prisoner-subject may continue in the research until the convened IRB can review the request to approve a change in the protocol.

5.5.4.2. If the prisoner-subject's involvement in the research can be stopped, the IRB Chair shall require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can approve the change in the research protocol and until the Institution-wide IRB Chair and the DoD Component office review the IRB's approval to change the research protocol.

5.5.4.3. The convened IRB shall re-review the research protocol to ensure the rights and well-being of the human subject, now a prisoner, are not in jeopardy.

5.5.4.3.1. The IRB prisoner representative is required to attend the meeting and provide subject matter expertise.

5.5.4.4. The convened IRB may approve a change in the study to allow the prisoner-subject to continue participation in the research if the prisoner subject can:

5.5.4.4.1. Continue to consent to participate.

5.5.4.4.2. Is capable of meeting the research protocol requirements.

5.5.4.4.3. The terms of the prisoner-subject's confinement do not inhibit the ethical conduct of the research.

5.5.4.4.4. There are no other significant issues preventing continuing approval of the human subjects research.

5.5.4.5. This approval is limited to the individual prisoner-subject and does not allow recruitment of prisoners as participants.

5.6. Take any additional actions required to resolve any concerns or complaints associated with the information.

5.7. If the information does not involve Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others and a response is expected, the IRB Chair or Designated Reviewer will complete review and the research compliance staff assigned to the IRB will prepare and send notification letter per TAMUK SOP: Post-Review (IRB SOP IV-002).

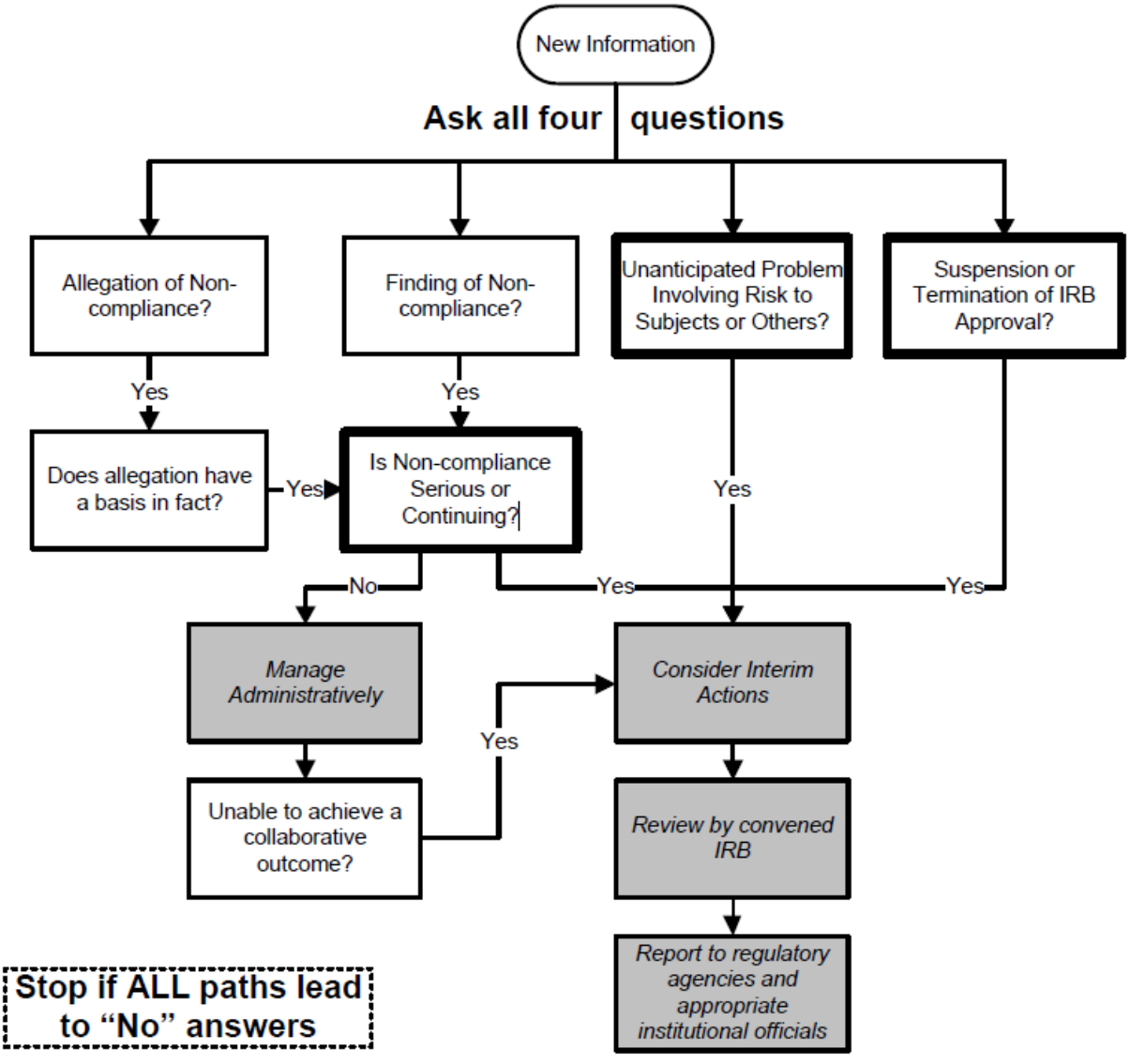
6. REFERENCES

6.1. 21 CFR §56.108(b)

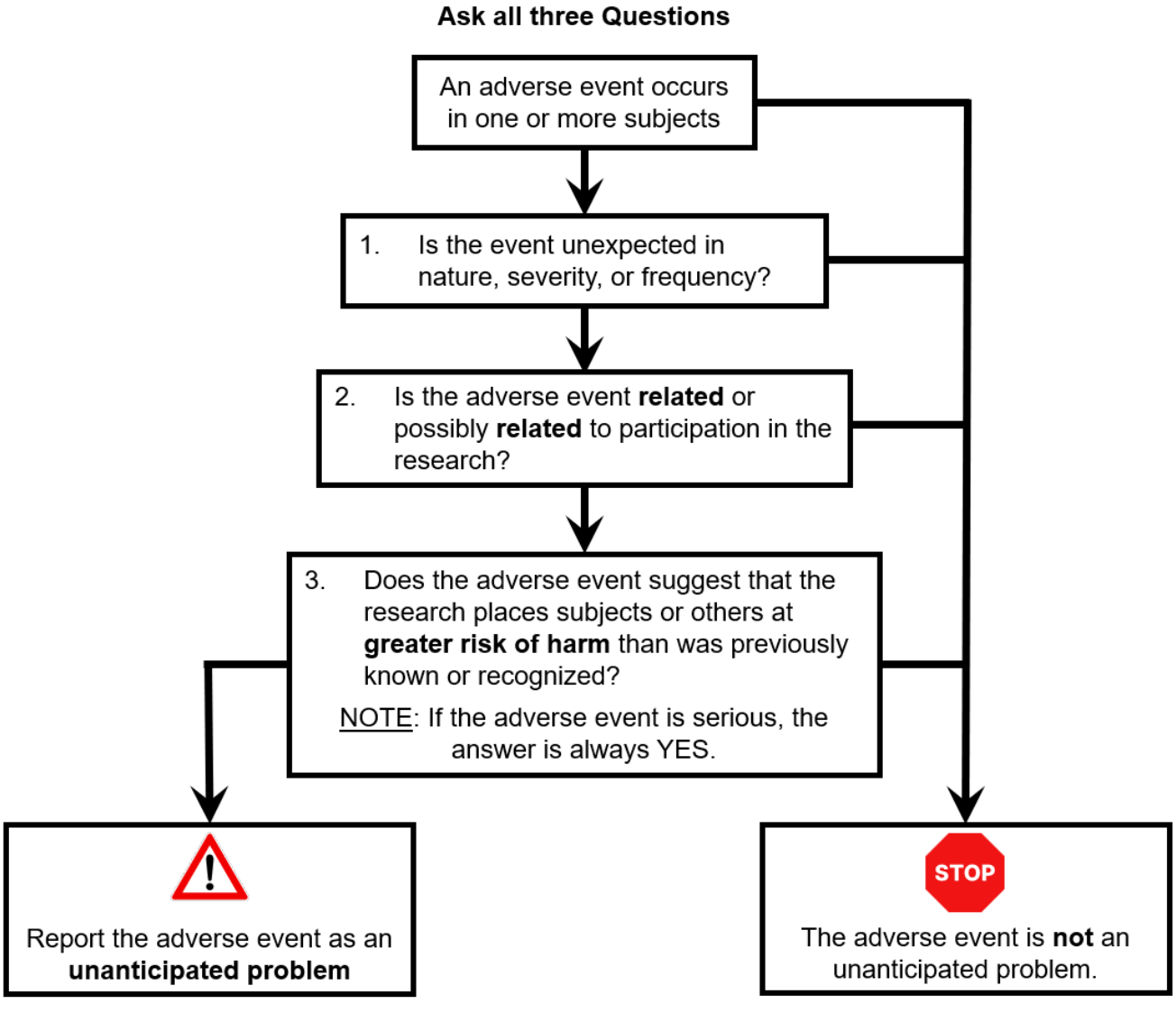
6.2. 45 CFR §46.103(b), 45 CFR §46.108(a)

6.3. DoD Directive 3216.02

New Information Flow Chart



Unanticipated Problem Flow Chart



Ask all three of the following questions

Unanticipated problems, in general, include any incident, experience, or outcome that meets **all** of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. Related or possibly related to the research (this means that it is more likely than not that the incident, experience, or outcome was caused by the procedures involved in the research); and

3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

There are other types of incidents, experiences, and outcomes that occur during the conduct of human subjects research that represent unanticipated problems but are not considered adverse events. For example, some unanticipated problems involve social or economic harm instead of the physical or psychological harm associated with adverse events. In other cases, unanticipated problems place subjects or others at increased *risk* of harm, but no harm occurs.

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