TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: Unanticipated Problems and Adverse Event Reporting**	
	Section IV: Post-Approval Monitoring and Non-Compliance	
	Number	Date
	IRB IV-005	9/13/2025

1. PURPOSE

1.1. The purpose of this SOP is to ensure adverse and serious adverse events are defined, recorded, reported, and evaluated in accordance with the requirements of the TAMUK Institutional Review Board (IRB).

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. This applies to all research involving human subjects that is conducted at TAMUK or any of its affiliate institutions.

3.2. The Principal Investigator (PI) is responsible for prompt reporting to the IRB of any unanticipated problems involving risks to participants or others.

3.3. The IRB maintains responsibility for initial assessment of the risk-benefit ratio in a research activity involving human participants.

3.4. Definitions:

3.4.1. *Adverse event*: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

3.4.2. *Serious Adverse event*: Any adverse event that: (1) Results in death, (2) Is life threatening or places the participant at immediate risk of death from the event as it occurred, (3) Requires or prolongs hospitalization, (4) Causes persistent or significant disability or incapacity, (5) Results in congenital anomalies or birth defects, or (6) results in another condition which investigators judge to represent significant hazards.

3.4.3. *Unanticipated Problems Involving Risks to Subjects or Others*: Any information that is (1) unexpected (in term of nature, severity, or frequency), (2) related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been 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.

4. RESPONSIBILITIES

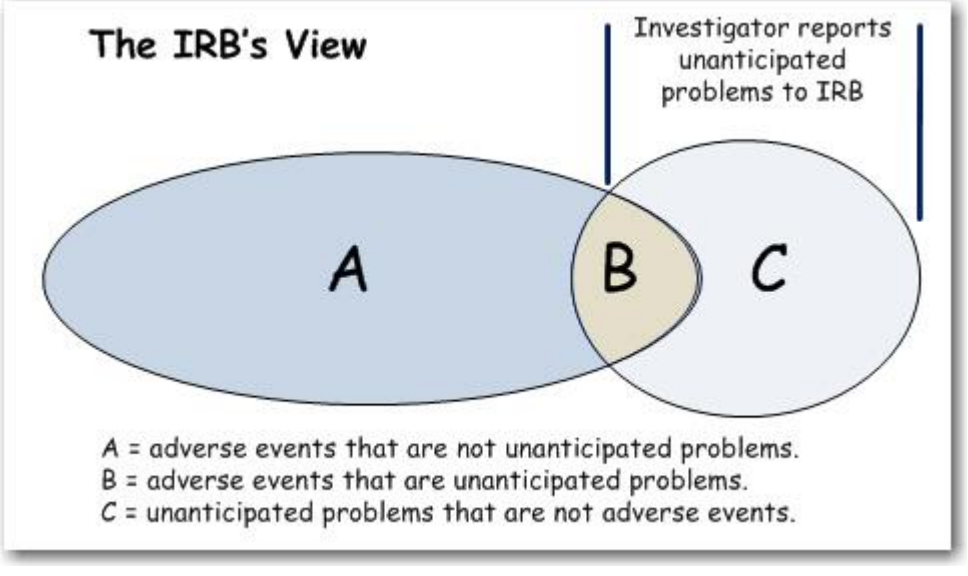
4.1. The principal investigator or designee is responsible for assessing and documenting both unanticipated problems and serious adverse events and reporting to the IRB through the Cayuse electronic system.

4.2. The research compliance staff assigned to the IRB will conduct an initial review of the report; the IRB will conduct the final review.

5. PROCEDURE

5.1. Identifying Reportable Unanticipated Problems or Adverse Events:

5.1.1. The IRB will utilize OHRP guidelines to determine what unanticipated problems and/or adverse events must be reported under 45 CFR 46 and/or other federal regulations as applicable. The Venn diagram below summarizes the general relationship between adverse events and unanticipated problems that the IRB will use when making its determination:



UNDER 45 CRF part 46: DO NOT report A, DO report (B+C)

5.1.2. This diagram illustrates three key points:

5.1.2.1. The vast majority of adverse events occurring in human subjects are not unanticipated problems (area A);

5.1.2.2. A small proportion of adverse events are unanticipated problems (area B);

5.1.2.3. Unanticipated problems include other incidents, experiences, and outcomes that are not categorized as adverse events (area C).

5.1.3. To determine whether an adverse event is an unanticipated problem, the following questions should be considered:

5.1.3.1. Is the adverse event unexpected?

5.1.3.2. Is the adverse event related or possibly related to participation in the research?

5.1.3.3. Does the adverse event suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized?

5.1.4. If the answer to all three questions above is yes, then the adverse event is an unanticipated problem.

5.2. Reporting Requirements:

5.2.1. The principal investigator or designee must promptly report all unanticipated problems or adverse events to the TAMUK IRB.

5.2.1.1. Unanticipated problems, or adverse events as defined in 3.4 Definitions (above), that occur under the oversight of any entities or investigators using the TAMUK IRB as the IRB of record for that study.

5.2.1.2. Subject deaths that the investigator has determined to be unexpected and related or possibly related to the research.

5.2.1.3. Adverse events, or a series of adverse events, external reports, or safety findings that constitute unanticipated problems. For example: (NOTE: When in doubt, if there is a possibility that the event is related to the study intervention or procedures, the event should be reported to the IRB).

5.2.2. The regulations under 45 CFR 46 require "prompt" reporting of unanticipated problems:

5.2.2.1. Unanticipated problems that are serious adverse events must be reported to the IRB. Reports should be submitted within 1 week of the investigator becoming aware of the event.

5.2.2.2. Any other unanticipated problem(s) should be reported to the IRB within 2 weeks of the investigator becoming aware of the problem.

5.2.2.3. All unanticipated problems that are also considered serious adverse events under 5.1.4 above should be reported to the appropriate institutional officials, the supporting agency head, and OHRP within one month of the IRB's receipt of the report from the investigator.

5.2.3. In some instances, the requirements for prompt reporting may be met by submitting a preliminary report to the IRB and other officials/agencies involved, with a formal follow-up report submitted at a later date when more information is available. Such determinations will be made on a case-by-case basis by the IRB Chair, investigator, or Institutional Official and/or others involved as appropriate. The primary consideration in making these judgments is the need to take timely action to prevent avoidable harm to other subjects.

5.3. Timeline Requirements:

5.3.1. If the unanticipated problem is a serious adverse event that occurred at a TAMUK research location, it must be reported to the IRB promptly. It should be reported within 1 week (7 calendar days) of recognition/notification of the event.

5.3.1.1. The principal investigator or designee is responsible for ensuring that the reporting is done.

5.3.1.2. A follow-up written report must be submitted to the IRB within 2 weeks (14 calendar days) unless the investigator has submitted a request for an extension to gather more information regarding the problem in writing.

5.3.2. If the unanticipated problem or serious adverse event occurred at an external site as part of a multi-site research project, it must be reported to the IRB of Record.

5.3.2.1. The report should also be submitted to the TAMUK IRB within one month (30 calendar days) of recognition/notification of the event, if TAMUK IRB isn't the lead IRB.

5.3.3. Any other unanticipated problem should be reported to the IRB within 2 weeks (14 calendar days) of the investigator becoming aware of the problem.

5.3.3.1. All other events should be documented and included in the continuing renewal application.

5.4. Reporting Procedures:

5.4.1. The PI or designee is responsible for assessing and documenting unanticipated problems and serious adverse events then reporting them to the IRB, regardless of who observed or became aware of the event.

5.4.2. The PI should use their judgment when determining whether an event is considered reportable. If in doubt, the investigator should contact the TAMUK IRB at tamuk.irb@tamuk.edu.

5.4.3. The event report will be submitted through the Cayuse electronic system.

5.5. IRB Actions:

5.5.1. An initial review of the unanticipated problem or adverse event will be conducted by the research compliance staff assigned to the IRB who will then:

5.5.1.1. Perform an administrative review of the report.

5.5.1.2. In consultation with the IRB chair, write an assessment to determine whether the incident constitutes a reportable unanticipated problem and/or serious adverse event, and by whom it should be reviewed (e.g., the Chair only, a subcommittee, the convened IRB).

5.5.1.3. If the reportable event needs to be reviewed by the convened IRB, schedule the review at the next regularly scheduled meeting, unless an emergency meeting is deemed necessary.

5.5.1.4. If warranted, initiate temporary suspension of the research protocol if the rights, safety, and welfare of the subjects are jeopardized until such time that the convened IRB can review the report.

5.5.2. In order to protect the ongoing safety of the research subjects due to the nature, severity, or frequency of the reported problem/event(s), the IRB may require the following actions:

5.5.2.1. Modification to the protocol of subject inclusion/exclusion criteria to mitigate the newly identified risks;

5.5.2.2. Implementation of additional procedures to monitor the research and subjects;

5.5.2.3. Modification of the informed consent process and documents to incorporate the newly identified risks;

5.5.2.4. Provision of additional information to the previously enrolled subjects;

5.5.2.5. Suspension of enrollment of new subjects;

5.5.2.6. Suspension of research procedures in currently enrolled subjects;

5.5.2.7. Suspension or termination of the entire study;

5.5.2.8. Other actions not described above.

5.5.3. If the unanticipated problem or adverse event results in an amendment of the research protocol and/or informed consent procedures/document, the amendment must be submitted to the IRB for review.

5.5.3.1. If the changes are minor, they may be handled by expedited review procedures, unless specified by the IRB.

5.5.3.2. If the changes are substantial, they must be reviewed and approved by the convened IRB.

5.5.3.3. Any proposed changes in response to an unanticipated problem or adverse event must be reviewed and approved by the IRB before implementation, unless implementation is necessary to eliminate apparent immediate hazards to subjects.

5.5.4. If the unanticipated problem and serious adverse event results in required report to OHRP, the IRB chair or designee will utilize the guidelines defined by OHRP for type of information to include in the incident report.

6. REFERENCES

6.1. 45 CFR 46

6.2. OHRP – Guidance on Reporting Incidents to OHRP

6.3. OHRP - Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events

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