TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: Reportable New Information Items**	
	Section IV: Post-Approval Monitoring and Non-Compliance	
	Number	Date
	IRB IV-003	9/13/2025

1. PURPOSE

1.1. This SOP outlines the process of identifying new information that must be reported to the IRB.

1.2. The process begins when an individual receives an information item.

1.3. The process concludes when the item is submitted to the IRB for review.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. New Information Items must be reported to the IRB which encompasses any IRB member or associated research compliance staff assigned to the IRB within 5 business days or less of the incident. Once any of these parties are notified, they are to forward the notification to TAMUK.IRB@tamuk.edu

3.2. This SOP applies to faculty, staff, students, residents, and affiliated investigators or other affiliated individuals who are involved in human subjects research being conducted under the auspices of Texas A&M University-Kingsville regardless of the location of the research.

4. RESPONSIBILITIES

4.1. Investigators or other individuals receiving reportable new information items carry out these procedures.

5. PROCEDURE

5.1. Use the Cayuse electronic system or equivalent to submit the reportable new items.

5.1.1. Provide the date you became aware of the problem.

5.1.2. Provide a description of the problem and determine the following:

5.1.2.1. Does this information indicate a new or increased risk or a safety issue?

5.1.2.2. Does the study need revision?

5.1.2.3. Does the consent document need revision?

5.2. Report information items that fall into one or more of the following categories to the IRB immediately or within five (5) business days.

5.2.1. Harm experienced by a subject or other individual, which in the opinion of the individual is ***unexpected*** *and* ***related*** *to the research procedures,* including unanticipated problems.

5.2.1.1. A harm is "**unexpected**" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.

5.2.1.2. A harm is "**related**" or possibly related to the research procedures if, in the opinion of the individual, the research procedures more likely than not caused the harm.

5.2.2. Information that indicates a new or increased risk or a new safety issue, including unanticipated problems. For example:

5.2.2.1. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor correspondence or report, CRO report, or investigator finding) that may indicate an increase in the frequency or magnitude of a previously known risk or uncovers a new risk.

5.2.2.2. An investigator drug brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk or describe a new risk.

5.2.2.3. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.

5.2.2.4. Protocol deviation/violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.

5.2.2.5. Subject complaint that indicates subjects or others might experience increased risk of harm or risk of a new harm.

5.2.2.6. Any changes significantly affecting the conduct of the research.

5.2.3. Non-compliance with the federal regulations governing human research, non-compliance with the requirements and determinations of the IRB, including TAMUK, or an allegation of such non-compliance.

5.2.4. Audit, inspection, or inquiry by a federal agency or any other outside entity and any resulting reports (e.g., FDA Form 483.)

5.2.5. Written reports of study monitors.

5.2.6. Failure to follow the protocol due to the action or inaction of the Principal Investigator or research staff, whether planned or unplanned.

5.2.7. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.

5.2.8. Breach of confidentiality (inappropriate disclosure of or access to confidential information).

5.2.9. Incarceration of a subject in a study not approved by the IRB to involve prisoners.

5.2.10. Complaint of a subject that cannot be resolved by the research team.

5.2.11. Premature suspension or termination of the protocol by the sponsor, investigator, or institution.

5.2.12. Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device if that

effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)

5.3. Provide a list of all studies related to the reportable new information.

5.4. Attach supporting documentation and a description of any corrective actions when required.

5.5. Submit the item to the IRB (via TAMUK.IRB@tamuk.edu) when the description of the reportable new information is complete. The IRB will then follow TAMUK SOP: New Information Process (IRB SOP IV-004)

6. REFERENCES

6.1. 21 CFR §56.108(b)

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

Guidance on Determining Unanticipated Problems

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, 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.

Ask all three of the following questions

An adverse event occurs in one or more subjects:

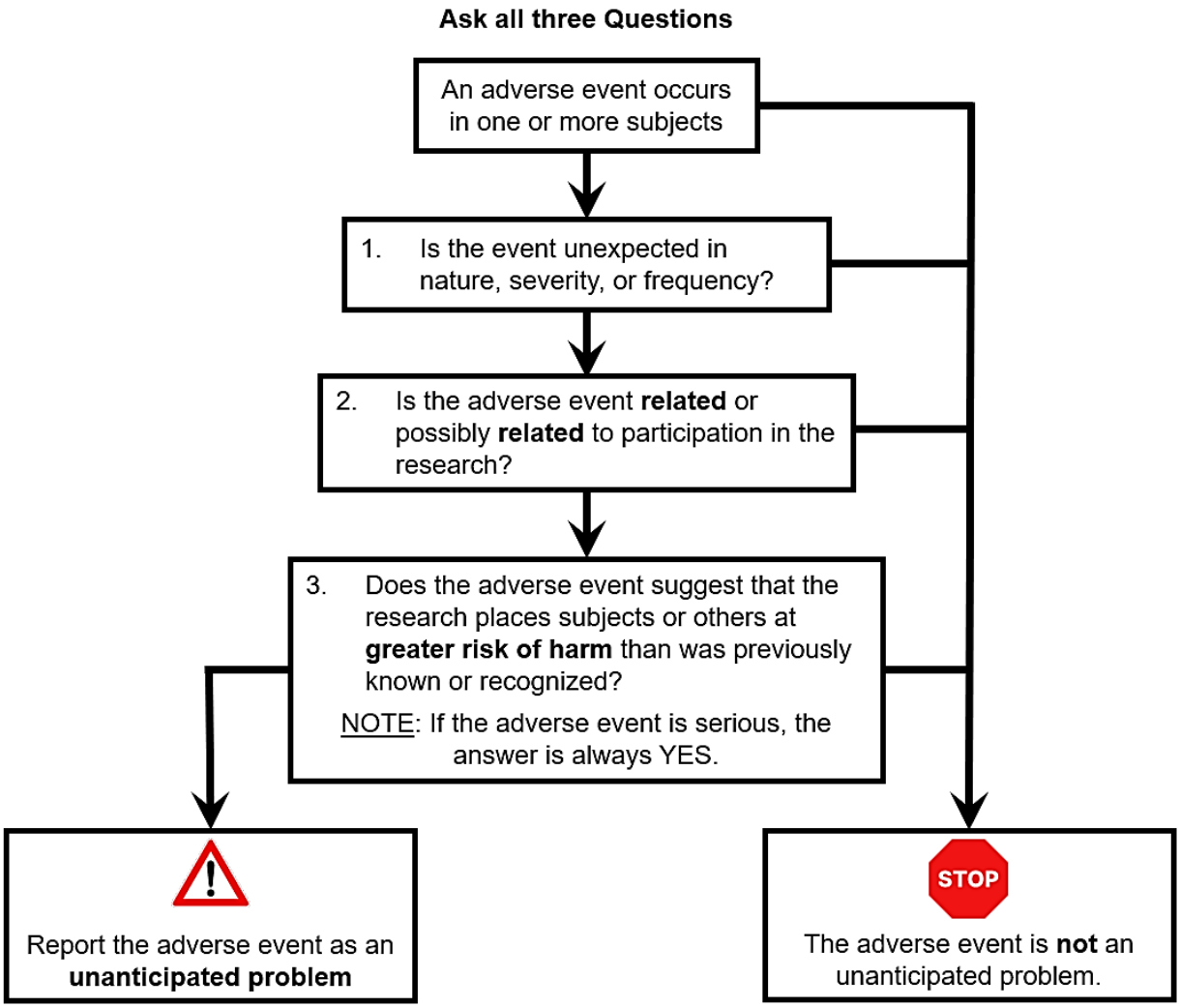
1) Is the adverse event **unexpected** in nature, severity, or frequency? If ***NO***, then the adverse event is ***NOT*** an unanticipated problem.
2) Is the adverse event **related** or possibly **related** to participation in the research? If ***NO***, then the adverse event is ***NOT*** an unanticipated problem.

3) Does the adverse event suggest that the research places subjects or others at **greater risk of harm** than was previously known or recognized? NOTE: If the adverse event is serious, the answer is always **YES**.

If ***YES***, report the adverse event as an **unanticipated problem.**

If ***NO***, then the adverse event is ***NOT*** an unanticipated problem.

Unanticipated Problem Flow Chart



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