

	<b>SOP: TAMUK Research Conducted at non-TAMUK Sites</b>	
	Section III: IRB Protocols	
	Number	Date
	IRB III-015	9/13/2025

## 1. PURPOSE

- 1.1. This SOP outlines the process for TAMUK IRB to review and approve external (non-TAMUK) sites to be included in a TAMUK-only research protocol. Multi-site protocols are addressed in TAMUK SOP: Reliance on External IRB (IRB SOP III-012). Non-TAMUK sites are any non-public locations outside the purview of TAMUK. Examples include businesses, schools, restaurants, etc.
- 1.2. The process begins when the Principal Investigator (PI) determines that he/she will utilize an external setting for any TAMUK research activities.
- 1.3. The process concludes when the IRB has determined that all site approvals have been attained as part of the IRB application.

## 2. REVISION FROM PREVIOUS VERSIONS

- 2.1. None

## 3. SOP STATEMENT

- 3.1. All TAMUK human subjects research activities, regardless of performance location, must be reviewed by the TAMUK IRB. Any TAMUK research activities that are proposed to occur at settings external to TAMUK must receive authorization from the external site in addition to TAMUK IRB approval.

## 4. RESPONSIBILITIES

- 4.1. Investigators within the purview of the TAMUK IRB shall obtain an authorization letter/email from any proposed research setting external to TAMUK prior to submitting a research proposal to the TAMUK IRB.
  - 4.1.1. The IRB will not review any proposal applications without at least one authorization letter/email from the external site(s).
- 4.2. The TAMUK IRB is responsible for reviewing research proposals and supporting documents, including submitted written authorization to conduct research at settings external to TAMUK.

## 5. PROCEDURE

- 5.1. When TAMUK research takes place at a non-TAMUK location, the PI of the proposed study will be notified by the research compliance staff assigned to the IRB that written authorization from the external site(s) will be required (Note: Written authorization does not constitute TAMUK IRB approval). The written authorization from the external site should be submitted as part of the TAMUK IRB application.
- 5.2. The PI will provide the organization signatory (e.g., owner, director, chief executive, or other official with authority to speak for the organization) with a TAMUK IRB External Site Request Letter. This letter will include the name of the study, its aims, procedures, and authorization for the investigator to conduct the study as described pending review and approval by the TAMUK IRB.
  - 5.2.1. The External Site Request Letter will include the statement: "The organization's authorization to conduct research at the setting is separate from TAMUK IRB approval to conduct research and

does not supplant the IRB's responsibility and authority to review and approve research proposals."

5.3. The organizational signatory will sign an authorization letter on the organization's letterhead confirming that they have received the External Site Request Letter as well as their understanding of its contents.

5.4. If the external site does not agree to participate in research, the TAMUK IRB will require that the protocol be modified to remove the external site from the application.

## **6. REFERENCES**

6.1. None

Approved by: 

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