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| TEXAS A&M UNIVERSITY KINGSVILLE | **SOP: Principal Investigator Roles and Responsibilities** | |
| | Section III: IRB Protocols | |
| | Number | Date |
| | IRB III-001 | 9/13/2025 |

## 1. PURPOSE

1.1. This SOP describes the general qualifications, roles, and responsibilities of a Principal Investigator conducting a research project with human participants.

## 2. REVISION FROM PREVIOUS VERSIONS

2.1. None

## 3. SOP STATEMENT

3.1. The principal investigator (PI) bears ultimate responsibility for the design, conduct, and reporting of the research.

3.2. The PI may delegate tasks to appropriate members of their research team, including trainees. However, PIs must ensure appropriate training and qualifications, maintain oversight, and retain ultimate responsibility for the conduct of those to whom they delegate responsibilities.

## 4. RESPONSIBILITIES

4.1. The principal investigator carries out these procedures. The PI may delegate certain tasks but retains ultimate responsibility and accountability for the research, which includes: conducting all research in compliance with the approved IRB protocol, internal policies and federal regulations including 45 CFR 46 and 21 CFR 50 – Protection of Human Participants and the ethical principles outlined in the Belmont Report,

## 5. PROCEDURE

5.1. The IRB holds the PI responsible for the overall management of an approved study, encompassing the ethical, technical, administrative, and fiscal elements of a project. Principal investigators are required to:

5.1.1. Ensure the ethical conduct of the research study and protect the rights and welfare of research participants by complying with the IRB-approved study protocol, and adhering to all university and state policies, federal regulations, and applicable guidance,

5.1.2. Ensure that all research activities have IRB approval and other approvals required by the institution before human participants are involved, and implement the research activity as it was approved by the IRB,

5.1.3. Ensure the training requirement for the protection of human participants in research (CITI on-line training modules, www.citiprogram.org) is completed by all personnel working on the study.

5.1.4. Ensure that only trained personnel listed on the approved research study participate in conducting the study, and do so in accordance with the content of the approved protocol and approved amendments,

5.1.5. Guide, mentor and advise student researchers and other trainees,

5.1.6. Report any real or potential Conflict of Interest of the PI or any study personnel in compliance with Conflict-of-Interest policies and management plans via the MAESTRO reporting system (TAMUSSO). Convened protocols will have an additional check for COI's at time of IRB review via confirmation with the Chair and discussion with the board. COI's will be reviewed using TAMUK Policy 15.01.03.K1.

5.1.7. Utilize only the IRB-approved and validated informed consent document is used to obtain consent from each participant prior to their involvement in research, in accordance with TAMUK SOP: Consent Documentation (IRB SOP III-08).

5.1.8. Maintain written records of IRB reviews, decisions, research records, and informed consent documents.

5.1.9. Obtain IRB approval for any proposed change to the research protocol *prior to* its implementation. If an immediate change is necessary to eliminate apparent immediate hazard to the participants, the IRB Chair must be informed as soon as possible once participant safety is confirmed.

5.1.10. Obtain renewed approval by reporting progress of approved research to the IRB, as described in TAMUK SOP: Approval Revie and End Dates (IRB SOP III-005).

5.1.11. Promptly report to the IRB any adverse events, protocol deviations or other unanticipated problems involving risks to participants or others. PIs should not undertake any action with an external funding agency regarding an unanticipated problem or noncompliance without first contacting the IRB to determine the correct course of action,

5.1.12. Verify that IRB approval has been obtained from all participating institutions in collaborative activities with other institutions,

5.1.13. Ensure the privacy of participants is maintained,

5.1.14. Ensure all data are collected, transmitted and stored according to the approved IRB application.

5.1.15. Use the most current version of IRB forms and document templates, which can be downloaded from the IRB website,

5.1.16. Oversee the budget and expenditures related to the study to ensure that adequate resources are available, including staff, equipment, supplies, participant incentives, storage space etc., to conduct the study at the university and any other performance site for which the PI is responsible,

5.1.17. Provide the IRB with audit reports, inspection reports, or findings issued by regulatory agencies, cooperative research groups, contract research organizations, the sponsor, or the funding agency,

5.1.18. Retain research records for 3 years after the study completion date.

## 6. REFERENCES

6.1. Belmont Report

6.2. CITI Program

6.3. 21 CFR §50

6.4. 45 CFR §46

6.5. TAMUK Policy 15.01.03.K1

Approved by: Lori Kupczynski

Lori Kupczynski, EdD
Special Assistant to the Vice President,
Office of Research and Innovation

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