TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: Activities that Require IRB Review**	
	Section I: Administrative Management	
	Number	Effective Date
	IRB I-006	9/13/2025

1. PURPOSE

1.1. This SOP outlines the process to determine which activities require Texas A&M University-Kingsville Institutional Review Board review.

1.2. The SOP begins when planning or preparing for any research activity or clinical investigation activity that involves human subjects.

1.3. The SOP concludes when IRB involvement in the TAMUK research or clinical investigation activity is determined.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. STATEMENT

3.1. This SOP applies to all human subject research, including preparatory activities such as advertising, recruitment, screening, as well as accessing or obtaining identifiable private information or biospecimens from or about living individuals for research purposes.

3.2. In this SOP, human research means any research or clinical investigation that involves human subjects as defined in TAMUK SOP: Definitions (IRB SOP I-001).

3.3. When there is any question about whether or not an activity involving human subjects or specimens is Human Research, the investigator will send a request for Human Subjects Determination. The request must be submitted through the Cayuse electronic system or the TAMUK IRB website.

3.4. The IRB is tasked with determining if something is or is not Human Research.

4. RESPONSIBILITIES

4.1. Investigators perform these procedures.

5. PROCEDURE

5.1. Investigators should submit their activities to the IRB for a determination whenever the activity involves human subjects or their identifiable private information or biospecimens.

5.2. The following tables provide a general guide that provides a list of activities that may or may not require IRB review. Other activities not on the list may also represent human subjects' research.

5.3. When unsure if the activity is or is not human subjects research, contact the IRB office.

ACTIVITY	DESCRIPTION	IRB Determination Required
Cadaver or autopsy specimens/materials	Research involving the physical interaction with the deceased or related specimens.	**NO**
Case Report Studies	**Retrospective** review of a medical or other records with intent to document a specific situation or the experience of an individual without intent to form a research hypothesis, draw conclusions or generalize findings. Data is de-identified.	**NO,** if using only 1-2 records. **YES,** if using 3 or more records.
	Prospective case study with clear intent, before recruiting or interacting with the participant, to use that data to draw conclusions and will publish or present to external groups.	**YES**
Classroom Assignments/Activities	Normal educational activities conducted by the students designed to teach students methods or demonstrate course concepts AND the activities are not designed to create new knowledge AND are not generalized or presented outside the classroom.	**NO**
Classroom Activities and Instructional Methods	Educational activities conducted by faculty or instructors in the classroom or with students and the intent is to generalize the information outside of the classroom or publish. This includes use of student records, interviews, surveys or other student data for prospective or retrospective research.	**YES**
Clinical Investigations	Experiments using an intervention, substance, or test article on one or more human subjects to evaluate the effects of those interventions, products or test articles on health related biomedical or behavioral outcomes regardless of FDA status or applicability. Products include foods (dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives), drugs for human use, medical or diagnostic devices for human use, biological products for human use, and energy emitting products used on humans.	YES

ACTIVITY	DESCRIPTION	IRB Determination Required
Focus Groups and Interviews	When discussing personal experiences or opinions and/or the focus is on people. (e.g. How do you rate your ability to handle stress? How often do you run red lights?)	**YES**
	When discussing non-human topics and the focus is on things instead of people. (e.g. Discussions on the differences between product A and product B).	**NO**
Human Factors Evaluation	Observing, recording, measuring or testing human behavior, cognition, interaction, performance, psychophysiology or anthropometry in a natural or laboratory environment for research applications.	**YES**
Innovative or Novel Procedures, Treatment, or Instructional Methods - Research	Systematic investigation of innovations in diagnostic, therapeutic procedure, or instructional methods in multiple participants in order to compare to standard of care or normal procedure. The investigation is designed to test a hypothesis, permit conclusions to be drawn, thus, to develop or contribute to generalizable knowledge.	**YES**
Innovative or Novel Procedures, Treatment, or Instructional Methods – Non-Research	The use of innovative interventions that are designed solely for therapeutic purposes to enhance the well-being of an individual patient with a reasonable expectation of success. The intent of the intervention is to provide diagnosis, preventive treatment, or therapy to an individual patient. Research is not involved.	**NO**

ACTIVITY	DESCRIPTION	IRB Determination Required
Internet Research	Online websites are set up for the purposes of collecting human data regarding a particular topic, irrespective if the data is de-identified. This may include the completion of questionnaires/surveys, personal data, etc.	**YES**
	Harvesting, mining, profiling, observing, or recording identifiable data from sites such as blogs, chat rooms, or social media postings, etc. or entering restricted or pay sites where there are restrictions of use or expectations of privacy/confidentiality.	**YES**
	Submitting information or interacting with internet sites in order to measure influence on behaviors or other outcomes.	**YES**
In Vitro Device Studies	Current FDA guidance indicates that IRB review is required for any IVD study involving human specimens/samples, even when the research involves no identifiers, and the biological materials cannot be linked to any identifying information.	**YES**
Literature Review	An assessment of a body of **published** material that addresses a research question. Identifies or summarizes what is already known about an area of study or may identify questions a body of research does not answer.	**NO**
Pilot Studies	Pilot studies that meet the definition of human research, regardless of the number of subjects enrolled or the duration of the studies.	**YES**
Professional Recognition	Employees or agents of TAMUK involved in human research projects carried out at other locations when the services performed merit professional recognition or publication privileges.	**YES**

ACTIVITY	DESCRIPTION	IRB Determination Required
Program Evaluation	The evaluation will be used for internal reporting purposes only or for funding agency reporting and will not be published.	**NO**
	Evaluation will be disseminated outside of the institution, generalized, or published.	**YES**
Public Health Surveillance Activities	Limited to those activities necessary to allow a public health authority to provide timely situational awareness or set priorities during an event or crisis that threatens public health. Researchers must have a written request, authorization, or contract from a Public Health Authority.	**NO**
Quality Assurance (QA) and Quality Improvement (QI) Activities	Systematic, data-guided activities involving humans designed to implement promising ways to improve outcomes, system performance or professional development and are intended to be generalized or used beyond the local setting **or** have research intent or address a specific deficit in scientific knowledge.	**YES**
	The proposed QA/QI activity is confined to the local setting **and the information will not be used or shared beyond the local system.**	**NO**
	Guidance: Intent is only one element considered. QI and research often overlap. A QA/QI activity often involves an iterative process that may change over time in response to ongoing feedback. The plan includes mechanisms for assessment, intervention, analysis, and implementation.	

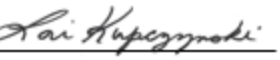
ACTIVITY	DESCRIPTION	IRB Determination Required
Records, Repositories, Registries, or other Data or Biospecimen research; and (Publicly Available Information)	Proposed activity involves accessing student, health or other private records, data banks, repositories, or any other mechanism by which identifiable human records, data, tissue, blood, or genetic materials will be obtained.	**YES**
	Proposed activity involves accessing stored human tissue, blood, genetic material or private identifiable data that will be de-identified by study personnel at the time of collection or when the investigator has access to a code or link that enables re-identification of data or specimens.	**YES**
	Private information or specimens are being collected specifically for the proposed research through interaction or intervention with living individuals.	**YES**
	Proposed activity involves accessing biospecimens or cell lines from a commercially operated or established biorepository where the investigator does not receive under any circumstances personal identifiers, or links, or codes that enable identification.	**NO**
	The proposed activity involves accessing unrestricted **PUBLICALLY** available data/information or biospecimens that are available to the general public. NOTE: If subjects are inadvertently identified when combining more than one publicly available data sets, contact the IRB immediately.	**NO**
Scholarly and Journalistic Activities (oral history, journalism, literary criticism, historical scholarship, biography, legal research)	Oral histories or journalism that focuses directly on the specific individuals about whom the information is collected, and there is no intent to generalize the information to others. Legal research must focus on the circumstances of specific plaintiffs or parties involved in a case; Legal research is not a particular field.	**NO**

ACTIVITY	DESCRIPTION	IRB Determination Required
Scholarly and Journalistic Activities (oral history, journalism, literary criticism, historical scholarship, biography, legal research)	Scholarly and Journalistic activities that involve the testing or confirmation of a hypothesis that is intended for generalization to others.	**YES**
Self - Experimentation	Any human research where the investigator is also a participant in their own study (investigator self-experimentation) requires IRB review and approval.	**YES**
Standard Diagnostic or Therapeutic procedures	The collection of data about established and accepted diagnostic, therapeutic procedures, or instructional methods that is intended for dissemination or contribution to generalizable knowledge.	**YES**
	Patient care or assignment is altered for research purposes, or the standard or therapeutic procedure changes are not entirely at the practitioner's discretion.	**YES**
	A diagnostic procedure is added to a standard treatment for the purpose of research.	**YES**
	An established and accepted diagnostic, therapeutic procedure or instructional method is performed only for the benefit of a patient and not for research purposes.	**NO**
Student Conducted Research	Thesis or dissertation projects involving human subjects research conducted to meet the requirements of a graduate degree.	**YES**
Surveys	Interacting with participants directly or through third party survey administrators to answer a research question about humans requires submission to the IRB for a determination even if not collecting identifiable information.	**YES**

6. REFERENCES

6.1. 45 CFR §46.102 (Pre-2018 and 2018 requirements)

6.2. 21 CFR 50.3; 21 CFR §56.102 and 56.103; 21 CFR 312.3(b); 21 CFR 812.3(h)

Approved by: 

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