TEXAS A&M UNIVERSITY
SAN ANTONIO

INSTITUTIONAL REVIEW BOARD (IRB) STANDARD OPERATING PROCEDURE (SOP)

SOP #: 200	**Version:** 1	**Effective Date:** June 27, 2024
Title: Activities that Require IRB Review		
Approved by: Dr. Vijay Golla, PhD Vice Provost for Research and Health Sciences		**Date:** June 27, 2024

1. Purpose

1.1 This SOP establishes the process to determine which activities require IRB review.

2. Scope

2.1 This SOP covers all human subjects' research including preparatory to research activities that involve interventions or interactions with living individuals (e.g. advertising for research, recruitment of study participants, and/or screening of potential subjects for research) and/or accessing or obtaining identifiable, private information or biospecimens from or about living individuals for the purpose of conducting research (e.g., review of existing records).

3. Responsibilities

3.1 Investigators perform these procedures.

3.2 When there is any question about whether an activity is Human Subjects Research, the investigator will send a request for a Human Subjects Determination.

4. Procedures

4.1 Investigators should review guidance on whether an activity is human research. See TAMUS *HRP-310- WORKSHEET - Human Research Determination*.

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

4.3 Investigators should submit their activities to the IRB for a determination when they anticipate that correspondence from the IRB will be required to satisfy funding agency requirements or for presentation and publication purposes.

4.4 The following table is 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.

4.5 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 deceased individuals does not require IRB oversight.	**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**

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	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**
	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**
Internet Research	Online websites set up for the purposes of collecting human data regarding a particular topic. 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	**YES**

	when the research involves no identifiers, and the biological materials cannot be linked to any identifying information.	
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 TAMU involved in human research projects carried out at other locations when the services performed merit professional recognition or publication privileges.	**YES**
Program Evaluation	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.	
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**
	Proposed activity involves accessing unrestricted **PUBLICALLY** available data/information, public use files (PUFs) or biospecimens that are available to the general public.	**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**
	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 is intended for dissemination or contribution to generalizable knowledge.	**YES**
	There is an alteration in patient care or assignment for research purposes or the alteration is in a way that standard diagnostic or therapeutic procedures are not completely up to the discretion of a practitioner.	**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**

5. References

5.1 HRP-093 SOP: Activities that Require IRB Review

5.2 DHHS: 45 CFR §46.102 (Pre -2018 and 2018 requirements)

5.3 FDA: 21 CFR 50.3; 21 CFR §56.102 and 56.103; 21 CFR 312.3(b); 21 CFR 812.3(h)

5.4 WORKSHEET: Human Research (HRP-310).

6. Revisions

6.1 June 2024