RESEARCH PROPOSAL APPROVAL FORM FOR THESIS, DISSERTATION, OR RECORD OF STUDY

Full proposal should be attached.

Questions or concerns? Contact the Graduate and Professional School via email at gradprocessing@tamu.edu.

For MS thesis students, it is important to note that this form must be submitted to the Graduate and Professional School no later than 20 business days prior to submitting the Request and Announcement of Final Examination.

STUDENT INFORMATION

Name_____ Date _____

UIN _____

Major _____

*By completing and submitting this form, I certify that all research compliance requirements related to this proposal have been addressed prior to submission. I understand that if the research scope changes, those changes must be addressed with Research Compliance and Biosafety prior to implementation.

Email Address _____ Chair Name _____

Mailing Address_____ Chair Email _____

PROPOSAL INFORMATION

I submit for approval the following research proposal for my: Master's thesis PhD dissertation Record of Study

Tentative Title: _____

_____

Attach full proposal:

RESEARCH COMPLIANCE

Research activities involving the use of live animals (including euthanasia for tissue harvest), biohazards, or human subjects must be reviewed and approved by the appropriate TAMU regulatory research committee (i.e., IRB, IACUC, IBC) **before** the activity can commence. This requirement applies to activities conducted at TAMU and to activities conducted at non-TAMU facilities or institutions. In both cases, students are responsible for working with the relevant TAMU research compliance program to ensure and document that all TAMU compliance obligations are met **before** the study begins. Students are encouraged to reach out to the appropriate compliance office early.

For a list of activities that may require a compliance review, see the Red Flags in Research tool at https://rcb.tamu.edu/more/resourcehub/faqsresources/RedFlagOnePage.pdf

For research involving the use of human subjects, please contact IRB@tamu.edu.
For research involving the use of biohazards, please contact IBC@tamu.edu.
For research involving the use of animals, please contact animalcompliance@tamu.edu.

This is not an all-inclusive list of all possible required compliance approvals, so please check https://rcb.tamu.edu for full information.

It is strongly recommended that you complete TrainTraq course 2112557: *Introduction to Research Compliance Requirements* and review *Copyright Basics for Graduate and Professional Students* before submitting the proposal.
https://grad.tamu.edu/OGAPS/media/media-library/documents/Forms%20and%20Information/Copyright_Basics_for_Grad_Students-final-version-With-Certificate.pdf

Name: _____ UIN: _____

RESEARCH PROPOSAL APPROVAL FORM FOR THESIS, DISSERTATION, OR RECORD OF STUDY
COMMITTEE AND DEPARTMENTAL APPROVALS

Please enter the requested information and sign where indicated.

Checked and approved by
Staff Graduate Advisor: _____

_____ Chair – type and sign name	_____	_____ Dept.	Approved Not Approved	_____ Date
_____ Co-Chair – type and sign name	_____	_____ Dept.	Approved Not Approved	_____ Date
_____ Member – type and sign name	_____	_____ Dept.	Approved Not Approved	_____ Date
_____ Member – type and sign name	_____	_____ Dept.	Approved Not Approved	_____ Date
_____ Member – type and sign name	_____	_____ Dept.	Approved Not Approved	_____ Date
_____ Member – type and sign name	_____	_____ Dept.	Approved Not Approved	_____ Date
_____ Dept. Head OR Intercollegiate Faculty Chair - type and sign name	_____	_____ Dept.	Approved Not Approved	_____ Date

*By completing and submitting this form, I certify that all research compliance requirements related to this proposal have been addressed prior to submission. I understand that if the research scope changes, those changes must be addressed with Research Compliance and Biosafety prior to implementation.

Research Proposal Approval Form is necessary to document the following:

1) **The approval of the proposed research by the advisory committee and head of the department or chair of the interdisciplinary degree program.**
2) **The student's awareness and action to address any and all compliance issues for research involving human subjects, animals, infectious biohazards and recombinant DNA, with the office of Research Compliance and Biosafety while conducting research.**

PLEASE NOTE: Approved copies of this document will not be sent to the student or committee members. Please view documentation of approval in My Record through www.howdy.tamu.edu.

Graduate & Professional School:

Division of Research
Research Compliance and Biosafety
979.458.1467 phone
rcb.tamu.edu

RED FLAGS: Animals Use, Human Research, Biohazards/Select Agents, Export Controls, Good Laboratory Practices

Animals • http://rcb.tamu.edu/animals • 845.1828 • animalcompliance@tamu.edu
vertebrate animals
animal tissues or antibodies (polyclonal or monoclonal)
animal cell lines
genus or species (refer to species list in iRIS)
euthanasia or carcasses
field study or wild capture
feed lot/agriculture/livestock

Biohazards • http://rcb.tamu.edu/biohazards • 862.4549 • biosafety@tamu.edu
cloning genes, DNA or RNA
creation or use of transgenic animals or plants
use of biological agents (e.g. bacteria, rickettsia, fungi, viruses, protozoa, parasites, prions) that may cause disease in humans, animals, or plants and toxins of biologic origin
purchases from ATCC, AddGene
activities requiring the use of biosafety cabinet, autoclave, incubator, centrifuge
culture, decontamination, disinfection
use of viral vectors, plasmids
use of human cells, cell lines or non-human primate cells or cell lines
also check the list of agents in iRIS

Good Laboratory Practices • rcb.tamu.edu/glp • 845.1263 • glp@tamu.edu
FDA or EPA product approval
Product safety
Biocompatibility study
Pre-clinical trial
21 CFR Part 58 (FD&CA) Food, Drug, and Cosmetics Act
40 CFR Part 160 (FIFRA) Federal Insecticide, Fungicide, and Rodenticide Act
40 CFR Part 792 (TSCA) Toxic Substances Control Act

Human Research • http://rcb.tamu.edu/humansubjects • 458.4067 • irb@tamu.edu **See HRP-093 for a more comprehensive list at http://rcb.tamu.edu/humansubjects/forms/standard-operating-procedures-sops**
case report studies OF 3 or more
classroom research conducted by faculty
clinical investigations (therapeutic or non-therapeutic)
interviews and focus groups about human experiences, opinions, behaviors, learning, needs
identifiable data or records
identifiable human biological specimens
innovative or novel procedures ,treatment, or instructional methods that will be generalized
internet research involving humans
in vitro device studies
human factors evaluation
oral histories of 3 or more testing or confirming a hypothesis
pilot studies involving humans
professional recognition through research collaborations
quality assurance and quality improvement activities that will be generalized
self-experimentation
student research, thesis or dissertation that involves humans in one of the above activities

Export Controls • http://export-controls.tamu.edu • 862.6419 • exportcontrols@tamu.edu
Research is intended for military, nuclear, or space purposes
International collaboration
Encryption software
Use of the word(s): controlled, export controlled, classified, proprietary
International travel or transfer of technology, items, chemicals, or biologicals abroad
Transactions involving embargoed countries (North Korea, Iran, Sudan, Syria, and Cuba) or individuals or entities in these countries
Restrictions against or approvals required for foreign national participation/access
Pre-approval rights over publications reserved by the sponsor of the research beyond that which is generally permitted
Contains a 7512 Controlled Unclassified Information (CUI) clause

This document provides a list of potential key words for activities that may require further compliance review. This listdoes not include all activities and is not intended to be exhaustive, but can be used as a compliance tool. It should not be relied upon exclusively.

Questions should be directed to the appropriate research compliance and biosafety program.

1 PURPOSE

1.1 This SOP establishes the process to determine which activities require Texas A&M University 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 ends when IRB involvement in the TAMU research or clinical investigation activity is determined.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 SOP STATEMENT

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

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

3.3 When there is any question about whether or not an activity is Human Research the investigator will send a request for a Human Subjects Determination. The request must be submitted through the electronic submission system, iRIS. Requests sent through other mechanisms (email, phone, fax) will not be processed.

4 RESPONSIBILITIES

4.1 Investigators perform these procedures.

5 PROCEDURE

5.1 Investigators should review guidance on whether an activity is human research. See *SOP: Definitions (HRP-001) and WORKSHEET: Human Research (HRP-310).*

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

5.3 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.

5.4 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.

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

ACTIVITY	DESCRIPTION	IRB Determination Required
Cadaver or autopsy material or specimens	Research involving deceased individuals does not require IRB oversight.	**NO**
Case Report Studies	**Retrospective** review of a patient's medical record 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 for publication or presentation.	**YES**
Classroom Assignments/Activities	Normal educational activities 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**
Clinical Investigations	Experiments using a test article on one or more human subjects that are regulated by the Food and Drug Administration or support applications for research or marketing permits for products regulated by the Food and Drug Administration. Products regulated 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 devices for human use, biological products for human use, and electronic products used on humans.	**YES**
Focus Groups and Interviews	When discussing personal experiences or opinions and/or the focus is on people (e.g. what do you think about your supervisor's communication skills)	**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**
Innovative or Novel Procedures, Treatment, or Instructional Methods	Systematic investigation of innovations in diagnostic, therapeutic procedure or instructional method 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 data regarding a particular topic. This may include the completion of questionnaires/surveys, personal data, etc.	**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** research 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**
Oral Histories	Oral histories represent a technique that usually involves a series of taped interviews with participants regarding a particular historical event or period. When the focus is a recollection of societal or institutional events rather than the interviewees subjective perceptions then the project is not usually human subjects research.	**NO**
	Oral histories that involve the testing or confirmation of a hypothesis or the subjective perceptions of the interviewees may be human subjects research.	**YES**
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**
Quality Assurance (QA) and Quality Improvement (QI) Activities	Systematic, data-guided activities designed to implement promising ways to improve outcomes, system performance or professional development - The activity usually occurs within standard of care or normal educational or business practices confined to the local setting. Guidance: Intent is only one element considered. The activity often involves an iterative process that may change over time in response to ongoing feedback. The plan may include mechanisms for assessment, intervention, analysis and implementation. One-time activities designed to meet personal educational requirements are generally not QA or QI. Since QI and research often overlap all investigator initiated QI/QA projects should be sent to the IRB for a determination.	**YES – must have a determination**
	Proposed QI/QA activities that may have research intent, address a specific deficit in scientific knowledge or are intended to be generalized beyond the local setting require submission to the IRB for a determination.	**YES**
Repositories, Registries or other specimen or record keeping mechanisms (e.g., data, specimens)	Proposed activity involves accessing a storage site, data bank, repository or mechanism by which identifiable human tissue, blood, genetic material, records or data will be obtained.	**YES**
	Proposed activity involves accessing stored human tissue, blood, genetic material or data that will be de-identified by study personnel at the time of collection or when the investigator will retain a code or link that enables re-identification of data or specimens.	**YES**
	Proposed activity involves accessing data or specimens from a commercial or IRB controlled repository where the investigator	**NO**

	does not receive under any circumstances identifiers or links to identifiers.	
	Proposed activity involves accessing publically available specimens or data.	**NO**
Self - Experimentation	Any research were the investigator is also a subject (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 participants 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 requires IRB review even if not collecting identifiable information.	**YES**

6 MATERIALS

6.1 SOP: Definitions (HRP-001).

6.2 *WORKSHEET: Human Research (HRP-310).*

7 REFERENCES

7.1 DHHS: 45 CFR §46.102

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

7.3 AAHRPP I.1.A