Reset Form Print Form

Office of Graduate and Professional Studies

PROPOSAL APPROVAL FORM FOR
THESIS, DISSERTATION, OR RECORD OF STUDY
Full proposal should be attached

This form must be approved by OGAPS no later than 20 business days prior to submitting the Request and Announcement of Final Examination.

STUDENT INFORMATION

Name: Collin Blake
UIN: 421009584
Mailing Address: 15814 Deerpath Ct, Tomball, TX 77377
Major: Aerospace Engineering
Email Address: collin1021@tamu.edu
*Signature: Collin Blake
Date: 7/18/2018
Chair Name: Dr. John Whitcomb
Chair Email: jdw@tamu.edu

*By signing 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.

PROPOSAL INFORMATION

I submit for approval the following research proposal for my: (•) thesis ( ) dissertation ( ) record of study

Tentative Title: Detection and Resolution of Interpenetrations of Woven Tows

Check each category below and provide the requested protocol or permit numbers, if research in your proposal includes any of these items.
This is not an all-inclusive list of all possible required compliance approvals, so check the website* below for full information.

Human Subjects			Biosafety			Animals		
Yes	No		Yes	No		Yes	No	
( )	(•)	Human subjects (including survey data)	( )	(•)	Human tissue/cell lines	( )	(•)	Vertebrate animals
( )	(•)	Human tissue/cell lines	( )	(•)	Recombinant DNA (e.g., viral vectors, recombinantly modified cell lines, or transgenic animals, plants, or insects)	( )	(•)	Animal tissues/cell lines
- If yes, were the tissues/cell lines commercially available? ( )Yes ( )No						- If yes, were the tissues/cell lines commercially available? ( )Yes ( )No		
( )	(•)	Protected health information	( )	(•)	Agents infectious to humans, animals or plants			

***Please enter the protocol number below if you have answered YES to any of the questions above.**
The student's name must be included on any required IRB or IACUC protocols and/or the IBC permit if it describes BSL-2 or BSL-3 activities.

List the IRB protocol number(s) (20XX-XXXX):	List the IBC protocol number(s) (20XX-XXXX):	List the IACUC protocol number(s) (20XX-XXXX):

*Additional information can be obtained at http://rcb.tamu.edu (click on "Obtain Approval" link) or by calling the Office of Research Compliance and Biosafety, Division of Research, at 979.458.1467.

Page 2, PROPOSAL APPROVAL PAGE, Collin Blake
Student Name

COMMITTEE AND DEPARTMENTAL APPROVALS

Dr. John Whitcomb			
Chair – Name printed or typed	Dept.	*Chair – signature	Date
Dr. Darren Hartl			
Co-Chair – Name printed or typed	Dept.	Co-Chair – signature	Date
Dr. Terry Creasy			
Member – Name printed or typed	Dept.	Member – signature	Date
Member – Name printed or typed	Dept.	Member – signature	Date
Member – Name printed or typed	Dept.	Member – signature	Date
Member – Name printed or typed	Dept.	Member – signature	Date
Dr. Rodney Bowersox			
Dept. Head OR Intercollegiate Faculty Chair		*Dept. Head/IFC – signature	Date

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Research Compliance and Biosafety APPROVAL:	**Office of Graduate and Professional Studies APPROVAL:**

The Proposal Form is necessary to document the following:

1) **The approval of the research project by the advisory committee and head of the major department**
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 prior to 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 .

TEXAS A&M UNIVERSITY
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
infectious, pathogen, virulent
transgenic, recombinant, cloning, gene, mutant
DNA or RNA
biological agents (e.g. bacteria, rickettsia, fungi, viruses, protozoa, parasites, prions) that may cause disease
ATCC, AddGene
culture, decontamination, disinfection
biosafety cabinet, autoclave, incubator, centrifuge
Toxins of biological origin
aerosolization
viral vectors, plasmids
human cells, cell lines
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
case report studies*
clinical investigations
focus groups and interviews*
innovative or novel procedurings, treatment, or instructional methods*
internet research
in vitro device studies
oral histories*
pilot studies
professional recognition
quality assurance and quality improvement activities
repositories, registries, or other specimen or record-keeping mechanisms (i.e. data, specimens)*
self-experimentation
standard diagnostic or therapeutic procedures*
student-conducted research
surveys
For items with an asterick (*), please refer to HRP-093 - SOP
"Activities that Require IRB Review"

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

This document provides a list of potential key words for activities that may require compliance review. This list 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.

June 2017

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