

Friendly Reminder:

It is expected that **annual committee meeting report forms** (enough for each committee member), the **completed student self-evaluation form, updated CV or Resume and all required prelim paperwork** will be brought to the meeting and available to all committee members for your prelim oral exam. After your committee meeting, please return all forms to Rafael in room 103C. All forms include:

Committee report forms

Completed student self evaluation form

Updated CV or Resume

Preliminary Examination Checklist

Report of Preliminary Examination

Proposal Approval Page

A Hard copy of your proposal

PhD Advisory Committee Annual Report

Department of Biochemistry and Biophysics, Texas A&M University

Student Name _____ Date entered PhD Program _____

Meeting Date _____ Previous Meeting Date _____

Prelim Exam Date _____

Chair _____ Co-Chair _____

****Committee Chair should collect and submit evaluation forms completed by each PhD Advisory Committee member to the Graduate Studies Office, Bio/Bio 103C ****

Name of Reporting Committee Member (please print legibly) _____

How well does the student meet your expectations in the following areas?					
Note: Expectations should represent a common level of proficiency demanded of all students in this program	Above Expectations	Meets Expectations	Needs Improvement	Not Acceptable	Not enough information
1. Progress toward degree?					
2. Exhibits understanding of discipline-specific knowledge?					
3. Applies knowledge to justify decisions?					
4. Considers a variety of sources and alternative views when critically evaluating ideas and information?					
5. Develops clear, data-supported research plans?					
6. Uses appropriate technologies to solve problems?					
7. Performs experiments with appropriate controls?					
8. Quality/reproducibility of experimental work?					
9. Proficiency in analysis of data?					
10. Communicates effectively?					

10.1 Has the student published any of her/his PhD research? Yes ___ No ___
If yes, how many publications from her/his PhD research? _____

10.2 Has the student presented at a scientific conference? Yes ___ No ___ If yes, how many presentations? _____
If yes, indicate the type of presentation(s)? Circle: Poster Platform

10.3 Has the student participated in other professional development activities? Yes ___ No ___ If yes, what activities? _____

Summarize your specific recommendations to student

Additional comments

****Committee chair should collect completed forms at the time of the meeting and turn all forms into the Graduate Programs Office, Department of Biochemistry and Biophysics, Room 103C.****

Failure to file Annual Reports with the Graduate Program Office will result in a registration block.

Annual Graduate Student Self Evaluation

Department of Biochemistry and Biophysics, Texas A&M University

The following information and a current CV/Resume is to be provided to your committee on the day of your committee meeting. Please submit the form and CV/Resume to the Graduate Programs Office in Bio/Bio 103C after your meeting.

Student _____ Date entered PhD program _____

Report date _____

Committee Chair _____ Co-Chair (if Applicable) _____

Number of publications or other major writing achievements while in current degree program.	In prep	Submitted	Accepted/ published
Refereed publications			
Non-refereed publications			
Other (specify)			
Number of oral or poster presentations at scientific meetings while in current degree program.	National International	Regional Meeting	Dept/Univ Research Competition
Oral presentations			
Poster presentations			
Grant proposals that you have submitted or have been awarded (excluding scholarships & financial aid), while in current degree program. Specify funding source and award amount.			
Departmental or other TAMU (e.g. travel grants)	Funding source	Award amount	
External			
Teaching experiences while in current degree program	Total # different courses	Total # semesters	
As Bio/Bio TA			
Other			
Research experiences unrelated to dissertation research while in current degree program, e.g. internships or Study Abroad:			
Awards (specify)	Departmental	College-level	University level
			National/International
Rate your proficiency in the following areas	Proficient	Acceptable	Developing
Literature or publication searches			
Statistical analysis			
Collaborative writing and or presentation tools			
Software & technology within your discipline			
(specify which software/technology)			



PRELIMINARY EXAMINATION CHECKLIST

The student is responsible for completing this checklist before the preliminary exam is scheduled. This checklist must accompany the report of the exam results (using the Office of Graduate and Professional Studies (OGAPS) form, "Report of Preliminary Exam"). The student should initial each appropriate blank indicating that the specified criterion has been satisfied, or where appropriate, been waived. Failure to satisfy the listed criteria will result in the given exam being disallowed in which case it will need to be retaken.

Student's Signature: _____ UIN: _____

Type or Print Name: _____

Please initial each statement in the space provided below:

1. _____ Registered for semester or 5-week term during which the exam occurs. (If the entire exam is between semesters, then the student must have been registered for the preceding term.)
2. _____ Student has an approved degree plan on file with the Office of Graduate and Professional Studies.
3. _____ GPR over all eligible courses since beginning graduate work at Texas A&M is greater than or equal to 3.000 as indicated in the degree evaluation in Howdy. (Includes 300 and 400 level courses taken while in a graduate program but does not include transfer courses.)
4. _____ GPR over all courses on the degree plan (excluding transfer courses) is greater than or equal to 3.000 as indicated in the degree evaluation in Howdy.
5. _____ All committee members have determined the format, scheduled, and agreed to attend and/or administer the exam/s or found a substitute. Only one substitute is allowed; there may not be a substitute for the chair.
6. _____ At the end of the semester in which the exam is given, there are no more than 6 hours of course work remaining on degree plan. (Does not include 691s)

If no, waiver approved by Department Head: _____

Approved:

Sign: _____ Sign: _____ _____

Advisory Committee Chair
Print/type Name:

Department Head OR
Intercollegiate Faculty Chair Print
/type Name:

Date:



Report of the Preliminary Examination

The undersigned duly appointed examining committee has conducted the preliminary examination of _____ . We have examined the candidate for a mastery of all fields in the program and for an adequate knowledge of the literature in these fields, and an understanding of the research problem and the appropriate methodological approaches.

Record of Vote for Pass or Failure: (*Votes are to be tallied, e.g., 3 pass; 1 no pass. A positive vote by all members of the graduate committee with at most one dissentation is required to pass.*)

_____ Number of Pass Votes _____ Number of No Pass Votes

If the exam was not passed: The committee, with no more than one member dissenting, (**does**) (**does not**)* recommend that this student be given one re-examination, when adequate time has been given to permit the student to address the inadequacies emerging from this examination. The examination committee will document and communicate the time-frame and feedback within 10 working days of the exam that was not passed.

* *Please strike through the inappropriate words.*

Date: _____

Signature: _____ **Chair**
 Type/Print Name:

Signature: _____ **Co-Chair or Member**
 Type/Print Name:

Signature: _____ **Member**
 Type/Print Name:

Signature: _____ **Member**
 Type/Print Name:

Signature: _____ **Member**
 Type/Print Name:

Signature: _____ **Member**
 Type/Print Name:

_____ **Substitute for** _____

Please sign AND print your name:

In compliance with the Texas Open Records Law, the student will be allowed to review this form upon written request.

PLEASE MAKE A COPY FOR YOUR RECORDS AND RETURN ORIGINAL TO THE OFFICE OF GRADUATE AND PROFESSIONAL STUDIES

FOR OFFICE OF GRADUATE AND PROFESSIONALS STUDIES USE ONLY

1. Residence requirement complete: Yes _____ No _____

2. Research proposal approved: Yes _____ No _____

3. Formal course work completed: Yes _____ No _____

4. Other course work remaining:

 May be admitted to candidacy upon completion of item(s):

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 _____	UIN _____
Mailing Address _____	Major _____
Email Address _____	*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.
*Signature _____	
Date _____	
Chair Name _____	Chair Email _____

PROPOSAL INFORMATION

I submit for approval the following research proposal for my: __thesis __dissertation __record of study

Tentative Title: _____

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

***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-XXX): _____	List the IBC protocol number(s) (20XX-XXX): _____	List the IACUC protocol number(s) (20XX-XXX): _____
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*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.

COMMITTEE AND DEPARTMENTAL APPROVALS

Chair – Name printed or typed	Dept.	*Chair – signature	Date
Co-Chair – Name printed or typed	Dept.	Co-Chair – 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
Member – Name printed or typed	Dept.	Member – signature	Date
Dept. Head OR Intercollegiate Faculty Chair		*Dept. Head/IFC – signature	Date

*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.

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 .

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 procedures, 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
<i>For items with an asterick (*), please refer to HRP-093 - SOP</i>
<i>"Activities that Require IRB Review"</i>

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.

	SOP: Activities that Require IRB Review		
	NUMBER	DATE	PAGE
	HRP-093	5/30/17	Page 1 of 4

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.



SOP: Activities that Require IRB Review

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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



SOP: Activities that Require IRB Review

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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

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	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 where 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