

Research Compliance IBC/Biosafety Approval at TAMU



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What?

Why?

How?

*Important information for
Investigators, students and their advisors*

What needs TAMU Institutional Biosafety Committee (IBC) approval?



Biohazardous material is defined as -

- *bacteria, viruses, parasites, fungi, protozoa and prions infectious to humans, animals or plants;*
- *biologically active agents (e.g. toxins of biological origin);*
- *Human (and non-human primate) blood, cell lines, and tissues; and*
- *Recombinant DNA, RNA, or synthetic nucleic acids (as defined in the NIH Guidelines).*



Biological materials you may not consider to be biohazardous may be regulated as biohazardous materials. Consult with OBS.

IBC approval is required prior to initiation.

Why do you need IBC approval? Federal Requirements for Research with Biohazards

- *NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules (NIH Guidelines)*
 - http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf
- *Select Agents Regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121)*
 - <http://www.selectagents.gov/Regulations.html>

Why do you need IBC approval? System Regulations and University Rule for Research with Biohazards



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UNIVERSITY RULE 15.99.06.M1 *Use of Biohazards, Biological Toxins and Recombinant DNA*

(<http://rules-saps.tamu.edu/PDFs/15.99.06.M1.pdf>)

This rule describes:

- The review and approval process for activities involving the use of biohazards at TAMU; and
- Roles and Responsibilities of the PI (& the BSO, the RO, and the IO)



UNIVERSITY RULE 15.99.06.M1 *Use of Biohazards, Biological Toxins and Recombinant DNA*



This rule applies:

- to all University employees, **students** and visitors who utilize rDNA and/or biohazardous agents or materials in the context of their research, teaching and/or testing activities.
- to these activities when they occur in University facilities, other locations if the projects are funded or sponsored by the University, and/or if University faculty, staff or **students** are participating in activities utilizing biohazardous materials or rDNA.



UNIVERSITY RULE 15.99.06.M1 *Use of Biohazards, Biological Toxins and Recombinant DNA*

These requirements are also applicable to all activities involving the use of biohazards and/or recombinant DNA for which the University is responsible, regardless of source of funding or whether the activity is funded.



TAMU Institutional Biosafety Committee (IBC)

- Reviews and approves recombinant (and non-recombinant) research utilizing biohazards that occurs on TAMU campuses, in CS and around the state.



HOW? The IBC approval process at TAMU (one permit – one PI)



Application information includes:

Lay description

Technical description

List of agents and inserts, as applicable

Risk assessment/Risk Mitigation

Location(s) of work

Waste disposal description

The first step is to submit an application using the on-line submission software iRIS.

PIs must be faculty members, or faculty equivalent title

TAMU IBC approval process



Once the submission is received, it will be assigned to a biosafety professional for review.

ABSOs:

Gather information

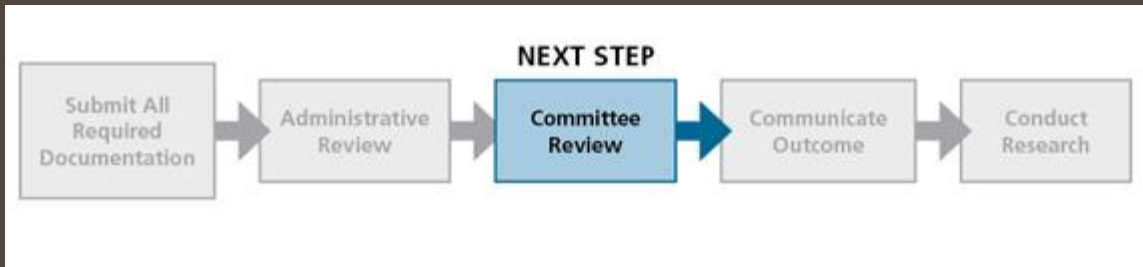
Literature review

Risk assessment/Risk mitigations

Schedule & conduct the lab inspection

Assign the submission to a meeting agenda, as needed

TAMU IBC approval process



IBC:

Review submission and take action:

Approve, or approve pending minor modifications

Table

Not approve

Not all submissions require review by the full committee; such applications may be approved by the IBC Chair on behalf of the committee.

The next step is committee review; PI is invited to attend. BSO/ABSO will present the review.

IBC Training Requirements

NIH Guidelines and University Rule training – must be completed by all PIs

For work with human pathogens: PIs and all personnel, including students, must complete:

- *Biosafety training – provided by the Biosafety Program*
- *Bloodborne Pathogen Training – provided by the Biosafety Program*
- *Biosafety Cabinet online training*
- *Enrollment in Occupational Health*
- *Lab/agent specific training – provided by the PI*



IBC approval process



IBC approval letters:

- *are agent and location specific,*
- *list lab entry requirements (including training and PPE) and*
- *document any special provisos or conditions stipulated by the committee for the conduct of the research.*

Written approval is required before the work may commence.



TAMU IBC permits



Valid for three years

- Annual renewals and laboratory inspections are required.
- IBC permits must be amended if adding new:
 - agents,
 - locations,
 - recombinant work, or
 - personnel (BL2 or higher)



Graduate student proposals are reviewed

- Proposals describing work with biohazards must have IBC approval, *prior to initiation*.
 - Experiments described in the proposal must be described in the IBC permit.
- If working with human pathogens, student must be listed on the permit and must complete all required trainings.



Case study – classic example...

Tentative Title: One-pot Enzymatic Pretreatment of Lignocellulosic Biomass for Bioenergy Production

Verification of research regulatory compliance: Check each category below if included in any research reported in the final document and provide the requested protocol or permit numbers, if relevant. *The study name must be included on any required IRB or IACUC protocols and/or the IBC permit.* This is not an all-inclusive list of all possible required compliance approvals, so check the website* below for full information.

<u>Yes</u>	<u>No</u>		<u>If you checked yes at left:</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Human subjects, including survey data	Provide the IRB protocol #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Human tissue/cell lines	Provide the IRB protocol #: _____ and the IBC permit #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Protected health information (human subjects)	Provide the IRB protocol #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Vertebrate animals	Provide the IACUC protocol #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Animal tissues/cell lines	Provide the IACUC protocol #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Recombinant DNA/transgenic animals, plants	Provide the IBC permit #: _____
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Agents infectious to humans, animals or plants	Provide the IBC permit #: _____

Objective and Hypothesis

Objective. To produce high crude lignocellulosic degrading enzymes to improve degradation of untreated lignocellulosic biomass

Hypothesis: Improved degradation of untreated lignocellulosic biomass can be achieved through a one-pot enzymatic hydrolysis with crude enzymes-lignin peroxidase, cellulase, and xylanase. Crude enzymes can be produced by over expression of proteins in genetic engineered *Escherichia coli*.

Task 1: Clone lignocellulosic degrading genes into plasmid and transformation of recombinant plasmid into *Escherichia coli*.

Task 2: Induce expression of lignocellulosic degrading genes in *Escherichia coli*.

Task 3: Determine sugar released from one-pot enzymatic hydrolysis of untreated lignocellulosic biomass using crude enzymes.

Task 4: Perform cost analysis of utilizing crude enzymes versus traditional methods to hydrolyze lignocellulosic biomass.

Consequences

- Incidents of noncompliance:
 - Will be reported to the IBC; (investigation and corrective action)
 - May be reportable to federal agencies; (reputational harm to PI and Institution)
 - May result in a loss of research data (data not publishable)
 - May result in significant delays (thesis defense, graduation)



Office of Biosafety Contact Information

- ❖ Email: biosafety@tamu.edu or IBC@tamu.edu
- ❖ Phone: (979)-862-4549 (Biosafety)
- ❖ (979)-862-4688 (IBC)
- ❖ Fax: (979)-862-3176
- ❖ URL: <http://rcb.tamu.edu/biohazards>

Director, BSO/RO: Dr. Christine McFarland

Associate Biosafety Officers: Dr. Ruchira Mitra, Dr. Jessica Bourquin and Mrs. Susan Gater

IBC Coordinators: Mr. Jeffrey Lane and Mrs. Debbie Perry

Occupational Health: Mrs. Sherri Evans and Mrs. Lauren Horton