

IBC Approval at TAMU

What? Why? How?

Biosafety Program

Presented by

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Why is *IBC* approval necessary?

- ***System Regulation 15.99.06: Use of Biohazards in Research, Teaching and Testing***
 - <http://policies.tamus.edu/15-99-06.pdf>
- ***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 is *IBC approval necessary?*

- UNIVERSITY RULE 15.99.06.M1
 - *Use of Biohazards, Biological Toxins and Recombinant DNA*
 - (<http://rules-saps.tamu.edu>)
- 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, or 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.



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).*



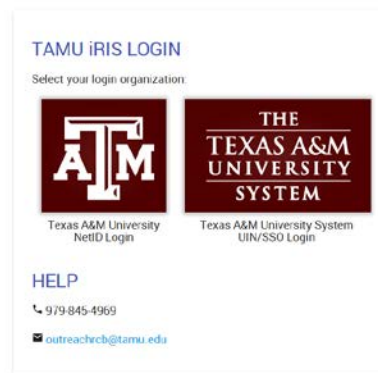
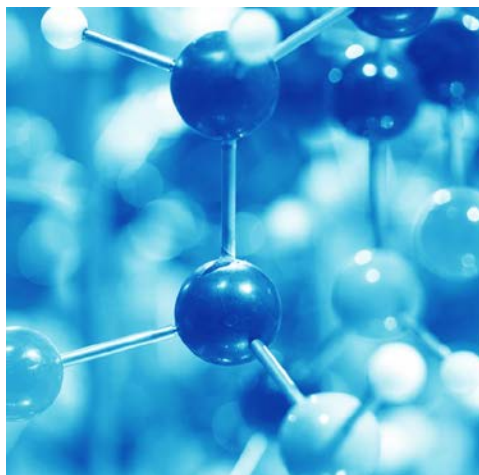
IBC approval is required prior to initiation of work.

TAMU Institutional Biosafety Committee (IBC)

- Reviews recombinant (and non-recombinant) research utilizing biohazards
- Membership: faculty, technical research staff, health and safety professionals, and community representatives appointed by the Vice President for Research
- Meets once monthly



HOW do PIs obtain *IBC approval at TAMU?*



- The first step is to submit an application using the on-line submission software iRIS: <https://iris.tamu.edu>
- NOTE: PIs must be faculty members or faculty equivalent title; students cannot submit an IBC application.



IBC approval

IBC approval letters:

- *are agent and location specific;*

If the project involves the use of infectious (to humans) pathogens, all personnel participating must be identified and listed on the permit and must complete all assigned trainings.



IBC Training Requirements

NIH Guidelines training – must be completed by all PIs.

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

- *Biosafety training – provided by the Biosafety Program*
- *BBP Training – provided by the Biosafety Program*
- *BSC training – provided by the Biosafety Program*
- *Medical Questionnaire for participation in Biosafety Occupational Health*



Lab/agent specific training – provided by the PI

TAMU IBC permits

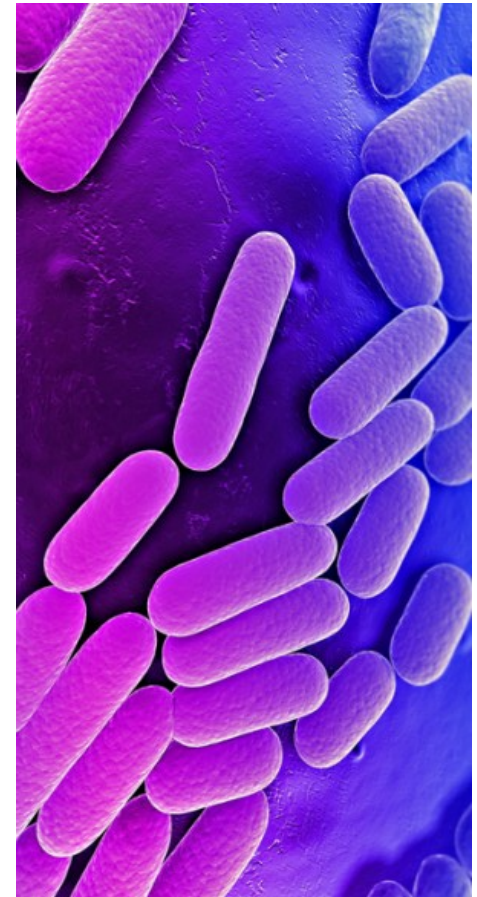
Valid for three years

- Annual renewals and annual laboratory inspections are required.
- IBC permits must be amended if adding new:
 - agents,
 - locations,
 - recombinant work, or
 - **personnel** (BSL-2 or higher)



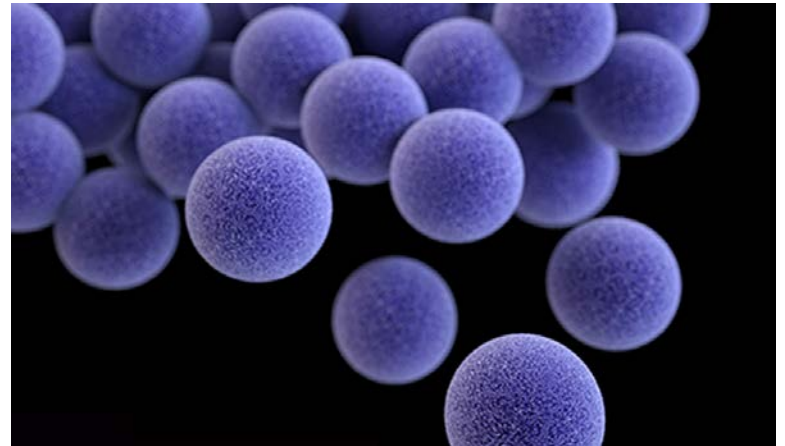
Graduate student proposals are reviewed

- Experiments 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 (s) must be listed on the permit and must complete all required trainings.



Red Flags – Key terms

- Bacteria, virus, fungus, parasite, toxin, select agent, microbes
- Scientific names: e.g. *Escherichia coli*
- Human cells, tissues, blood
- Recombinant DNA, molecular cloning, plasmid, genome, transduction, transfection, transposon
- Antibiotic resistance, cell culture
- Genetically modified, transgenic, mutant
- Infectious, pathogenic, virulent
- Decontamination, disinfection
- Autoclave, biosafety cabinet, personal protective equipment (lab coats, gloves, eye and respiratory protection)
- Zoonotic



Summary

- **Research, teaching and testing activities describing work with biohazards must have IBC approval, *prior to initiation.***
 - Experiments with biohazards described in graduate student thesis and dissertation proposals must be described in the PI's IBC permit & approved by the IBC
- Incidents of noncompliance may:
 - Result in serious or significant delays for the student;
 - Result in data that can't be published;
 - Be reportable to federal authorities;
 - Result in a loss of funding to the institution; and
 - Result in damage to the institution's reputation.



Office of Biosafety Contact Information

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

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