

Working with the Institutional Biosafety Committee (IBC) and the Office of Biosafety

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Office of Biosafety

- Includes three distinct (overlapping programs): Biosafety Program, Biosafety Occupational Health Program, and the Select Agent Program
- Serves as a liaison between the research community and the Institutional Biosafety Committee (IBC) and provides administrative support to the IBC
- Provide compliance interface with other offices including SRS, Export Controls, AWO, & HRPP
- Protects the Institution and promotes the safety of researchers and the community by ensuring compliance with all applicable laws and regulations applying to the use of biohazards



Institutional Oversight of Biohazards

Requires compliance with:

- **System Regulation 15.99.06: Use of Biohazards in Research, Teaching and Testing**
- **University Rule 15.99.06.M1: Use of Biohazards, Biological Toxins, and Recombinant DNA and Dual Use Research of Concern**

Activities (i.e., research, teaching or testing) with biohazards require Institutional oversight in the form of Institutional Biosafety Committee (IBC) review and approval.

At TAMU, the IBC must review and approve all activities involving the use of biohazards **prior to their initiation.**



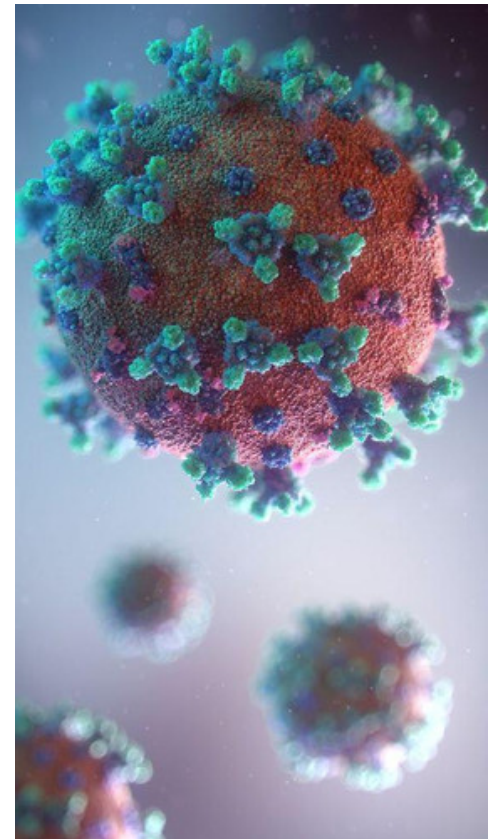
Activities with biohazards must be conducted following criteria established in the most current versions of federal or state documents, requirements and laws including:

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*)
- PHS/CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories” (BMBL)
- Federal Select Agent Regulations
 - » 42 CFR Part 73 (Public Health)
 - » 7 CFR Part 331 (Agriculture)
 - » 9 CFR Part 121 (Animals and Animal Health)



Biohazardous materials are defined as:

- Bacteria, viruses, parasites, fungi, protozoa and prions that may cause disease in humans, animals or plants
- Toxins of biological origin (as defined in the BMBL)
- Human (and non-human primate) blood, tissues, or cell lines, including commercially available cell lines
- Recombinant DNA, RNA, or synthetic nucleic acids (as defined in the *NIH Guidelines*), including the creation of transgenic plants or animals





On behalf of the Institution, the TAMU IBC is responsible for reviewing research involving recombinant DNA and/or biohazards conducted at or sponsored by Texas A&M for compliance with all applicable rules and guidelines.

Two review processes:

i. Administrative Review

- Non-recombinant or exempt recombinant studies
- IBC Chair may approve the submission on behalf of the IBC
- <30 days

ii. Full Committee Review

- Non-exempt, recombinant activities, activities requiring BSL-3 containment, etc.
- Requires review during a monthly meeting
- 30 – 60 days

IBC Compliance and funding

- Proposals are not generally reviewed
- Funded awards, with biosafety compliance items identified by the PI, are reviewed by Biosafety
 - Awards not flagged by the PI are reviewed, too
- If the grant includes the use of biohazards, IBC approval is required
 - Any discrepancies between the grant and the IBC permit must be reconciled prior to approval of the permit and sign-off on the award.
 - If activities are sponsored by the TAMU PI, and occurring at another institution, IBC approval at the recipient institution is verified & documented.
 - Compliance items will be updated by Office of Biosafety in Maestro.



Material Transfer Agreements (MTAs)

Reviewed by Office of Biosafety if the transfer involves biological materials – to ensure the necessary approvals are in place.

MTAs define the parameters under which the materials may be used – do they align with the PI's IBC approval?

If yes, we can approve.

If no, an amendment will be necessary.



Reminders to help our Researchers

- Activities with biohazards require an application to be submitted by the Principal Investigator for review by the Institutional Biosafety Committee (IBC).
 - Principal investigators must be faculty members
 - Students, post-docs, etc. may participate but cannot be PIs
 - Others may initiate the application on behalf of the PI
- Submit complete applications (or amendments)
 - Don't wait until the last minute; request approval ahead of time
- Respond to IBC and Biosafety related correspondence:
 - Lab inspections
 - Training
 - Occupational Health
- Stick to the terms of the approved protocol



What else can we do?

- Notify the Office of Biosafety when new faculty are hired
- Notify the Office of Biosafety when faculty leave
- Assist faculty with compliance issues:
 - e.g. Biosafety cabinet inspection and certification
- Encourage questions
 - Request an official determination
- Join the Biosafety Compliance Network



Take Advantage of Biosafety Resources

- ❖ Website: <https://rcb.tamu.edu/biohazards>
- ❖ Biosafety Manual: <https://rcb.tamu.edu/biohazards/biosafety-manual>
- ❖ Do I need IBC Approval?:
<https://rcb.tamu.edu/biohazards/resources/do-i-need-ibc-approval>
and <https://rcb.tamu.edu/biohazards/resources/transgenic-animals-and-plants-approval>
- ❖ Biohazard Waste Disposal Guidelines:
<https://rcb.tamu.edu/biohazards/resources/biohazardous-waste-handling>
- ❖ PI Checklist for Work with Biohazards:
<https://rcb.tamu.edu/biohazards/resources/biosafety-checklist-for-new-researchers>



Office of Biosafety Contact Information

ibc@tamu.edu

For assistance with iRIS, general questions related to IBC compliance, help with submissions, status updates, etc.

biosafety@tamu.edu

For questions about biosafety, assistance with training and outreach, scheduling lab inspections, reporting incidents, approval of MTAs, questions related to funded awards, etc.

bohpc@tamu.edu

For questions about occupational health enrollment & services, incident reporting, pre- and post-exposure risk mitigations, fit testing, etc.

Prefer talking to a person? Come visit our zoom office hours and chat with biosafety staff members.

Tuesdays: 10:00 AM – 11:00 AM

Thursdays: 4:00 PM – 5:00 PM

Email ibc@tamu.edu for the zoom connection information.



Office of Biosafety Team

Associate Biosafety Officers:

Dr. Jessica Bourquin (Assistant Director of Biosafety)

Dr. Ruchira Mitra

Dr. Charlotte Hieke

Ms. Susan Gater, MS (Responsible Official/Select Agent Program)

IBC Coordinators:

Mr. Jeffrey Lane

Ms. Bea Velez

Biosafety Occupational Health Program (BOHP)

Ms. Lauren Horton, MS, Manager

Ms. Jenifer Mathews



High Containment Lab Managers:

Ms. Wendy Wright

Mr. David Perez

Ms. Jessica Cobos, MS

Lab Facilities Management:

Mr. Frank Cox

Mr. Cliff Perry

Select Agent Program Manager:

Mr. Todd Wisner, MS, ARO



Questions?



DIVISION OF RESEARCH

RESEARCH COMPLIANCE & BIOSAFETY

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