Use of Biohazardous Materials at Texas A&M: Working with the Institutional Biosafety Committee and the Biosafety Program

Presented by

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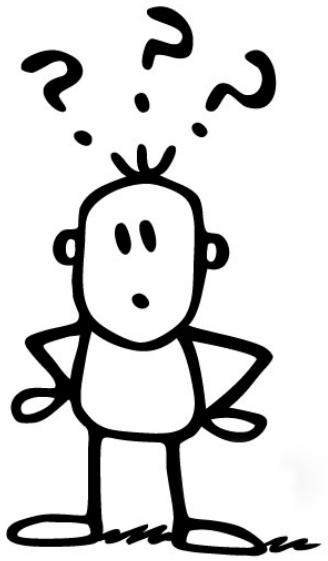
TEXAS A&M UNIVERSITY

Agenda

- Materials requiring Institutional Biosafety Committee oversight and approval
- Why is IBC approval necessary?
- How to obtain IBC approval?
- Not on the agenda: Principles and practices of Biosafety



Work with biohazardous agents is subject to Federal and local (institutional) oversight.

- The extent of Federal or Institutional oversight depends on the type and risk of activities and agents and institutional policies.

- At Texas A&M, the possession and use of all biohazardous agents requires review and approval by the Institutional Biosafety Committee prior to initiation.

Federal Guidelines and Regulations

TAMU adheres to the following:

- The NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules
- The CDC's Biosafety in Microbiological and Biomedical Laboratories
- USDA regulations controlling the use of biohazardous materials and/or rDNA
- The Select Agent Regulations
  - 42 CFR 73: Public Health
  - 7 CFR 331: Agriculture
  - 9 CFR 121: Animal Health and Animal Products

Compliance 101

Rules are in place for a reason.

Following the rules is not always convenient.

- more steps, more time, requires discipline and consistency

Not knowing about or understanding the rules are not excuses for not following the rules.

Not following the rules can be costly:

- Be reportable to federal authorities
- Result in a loss of funding to the institution
- Result in damage to the institution's reputation
- Result in exposure and illness

Compliance is a team sport

Researchers identify their activities with biohazards and rDNA.

The Institutional Biosafety Committee reviews proposed activities with biohazards and locations of such work and sets containment, training, and PPE requirements.

The Office of Biosafety serves as a liaison between the research community and the Institutional Biosafety Committee, provides administrative support to the IBC, conducts outreach and inspections and responds to incidents on behalf of the IBC.

IBC approval at Texas A&M

IBC approval is required prior to initiation of teaching, testing or research activities with:

- Biologically viable agents (e.g. bacteria, viruses, fungi, etc.) infectious to humans, animals or plants
- Human (and non-human primate) blood, tissues, and cell lines, including commercially available cell lines
- Biologically active agents, i.e. toxins of biological origin
- Recombinant/synthetic DNA, including the creation of transgenic animals or transgenic plants

IBC approval is required prior to initiation of activities with these agents.

Why is IBC approval necessary?

- **NIH Guidelines for Research Involving Recombinant or Synthetic DNA Molecules *(NIH Guidelines)***

- The purpose of the NIH Guidelines is to specify practices for constructing and handling:

  - (i) recombinant deoxyribonucleic acid (DNA) molecules

  - (ii) organisms and viruses containing recombinant DNA molecules

NIH Guidelines

- *NIH Guidelines* for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*)

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- Conditions of Funding – if an institution receives any money from NIH for recombinant work, then the entire institution agrees to abide by these guidelines, regardless of the source of funding for other projects.

System Regulation

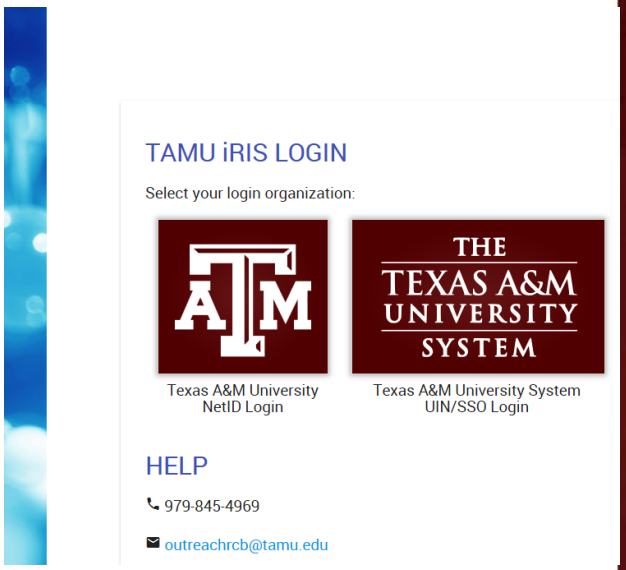
Texas A&M University System Regulation 15.99.06 –

Use of Biohazardous Material in Research, Teaching and Testing

- Sets policy for member institutions
- Defines what constitutes a “biohazard” for the system
- Requires member institutions to establish a Rule for carrying out the regulation

How to get IBC approval

- **Principal Investigators** must submit an application for review by the Institutional Biosafety Committee (IBC).
  - https://iris.tamu.edu
  - Principal investigators must be faculty or have a faculty equivalent title and cannot be students.
  - Graduate students, undergrads, post-docs may not be PIs but participate.
- The IBC must review and approve all activities involving the use of biohazards in research, testing, or teaching **prior** to the initiation of work.



IBC approval at Texas A&M

Aren't sure?

- Do I need IBC approval?

(https://rcb.tamu.edu/biohazards/resources/do-i-need-ibc-approval)

- Working with Transgenic Animals or Plants?

(https://rcb.tamu.edu/biohazards/resources/transgenic-animals-and-plants-approval)

- Request a determination on-line in iRIS

IBC review & approval process

Prior to initiation of work:

- ✓ Ensure PI, students, and staff complete all training(s) required by the IBC
- ✓ Prepare for a successful laboratory inspection
- ✓ Obtain IBC approval before beginning work

IBC applications must be complete and include:

- ✓ Description of proposed experiments including all *in-vitro* and *in-vivo* activities
- ✓ Include all biohazardous agents to be used
- ✓ All location(s) of work
- ✓ Genetic modifications
- ✓ Description of Decontamination/Waste disposal methods
- ✓ Risks and risk mitigations
  - ➢ Personal Protective Equipment (PPE) and safety equipment

IBC Review and Approval Process

Two review processes

- Administrative Review (non-recombinant or exempt recombinant studies)
  - Office of Biosafety staff review the submission
  - The IBC Chair, or Vice Chair, may approve the submission on behalf of the IBC

- Full Committee Review (recombinant, non-exempt studies)
  - The committee reviews the protocol during a convened meeting
  - The committee votes to approve, table, or deny approval

IBC Training Requirements

***NIH Guidelines* training – must be completed by all PIs using recombinant materials.**

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

- *Biosafety (BSL-2 or BSL-3) training*
- *Biosafety Cabinet training*
- *Medical Questionnaire for participation in Biosafety Occupational Health*
- ***Lab/agent specific training* – provided by the PI**

For work with materials of human (or NHP) origin: PIs and all personnel must complete:

- *Bloodborne Pathogen (BBP) training*

TAMU IBC permit terms and conditions

Valid for three years

- Annual reviews are required
- Annual laboratory inspections are scheduled.

- IBC permits must be amended if adding new:
  - agents,
  - locations,
  - recombinant work, or
  - personnel (BSL-2 or higher)
  - Aren't certain? Contact Office of Biosafety for guidance

Responsibilities of the PI during the conduct of work:

- Know what is in the approved application and stick to the approved application
- Submit proposed modifications to the IBC to gain approval
- Mentor, train and supervise staff and students
- Maintain safe and compliant laboratories – maintain equipment in good repair.
- Correct departures or issues identified by the IBC and Biosafety staff during lab site visits
- Provide adequate PPE and enforce use.
- Report accidents or incidents involving potential exposures of personnel to the IBC and Biosafety.

The IBC and the Biosafety Program: A shared mission

- Protect faculty, staff, students, visitors, the general public and the environment from exposure to biohazardous materials and recombinant DNA.

- Ensure all activities and facilities used to conduct work with biohazardous materials and rDNA are in compliance with federal, state and institutional guidelines.

- Facilitate safe science and reduce the risk of its misuse.

In Summary….

- **Research activities describing work with biohazards typically requires institutional oversight. At TAMU, such approval is required *prior to initiation*.**
- **Compliance with federal regulations is not optional.**
  - **The NIH Guidelines aren't just guidelines….**
- **Risk assessment and risk management is an on-going and shared responsibility.**
- **The purpose or goal of biosafety and IBC compliance is to ensure personnel safety, public health safety, and environmental safety.**
- **Incidents of noncompliance may be costly:**
  - **Be reportable to federal authorities**
  - **Result in a loss of funding to the institution**
  - **Result in damage to the institution's reputation**
  - **Result in exposure and infection**

Office of Biosafety Contact Information

- For questions related to Biosafety: biosafety@tamu.edu
- For questions related to IBC permits: IBC@tamu.edu
- Contact me, Jeff Lane: jeffreyrlane@tamu.edu
- Visit our website:

http://rcb.tamu.edu/biohazards

Thank you.
Questions?

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