# Biohazards in Research:
## Overview and Oversight

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TEXAS A&M UNIVERSITY

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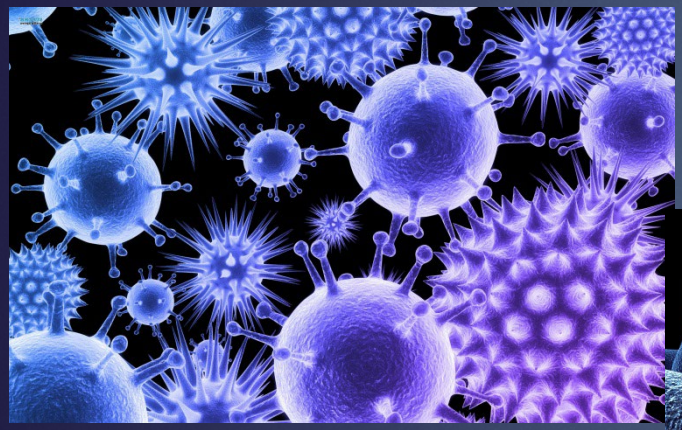
# Agenda

- Biohazards/Biosafety Awareness
- Federal Oversight, System Regulation, University Rule, etc.
- IBC review and approval process

# Biohazard

An agent or material of biological origin that is potentially hazardous to humans, animals, plants, or the environment



# Biohazardous Materials

*Pathogens or potential pathogens of humans, animals or plants (*bacteria, rickettsia, fungi, viruses, protozoa, parasites, and prions*)*

*Toxins of biological origin (e.g., pertussis toxin)*

*Human (and non-human primate) blood, cell lines, and tissues*

*Recombinant or synthetic nucleic acid (i.e., DNA, RNA, etc.) molecules*

*Genetically modified animals and plants*

# Biosafety

- Addresses safe handling and containment of biohazardous materials
- Protects researchers, support staff, the environment, and the public
  - Work  practices
  - Safety equipment
  - Personal protective equipment (PPE)
  - Facility design

# Risk Groups & Biosafety Levels

**Risk Groups (RGs)**

- Classification scheme for microbiological agents based on their association with /severity of human disease
- RGs are one factor (among many) used to determine the biosafety level at which work will be conducted with a given agent
- Biohazardous agents are categorized into four risk groups

**Biosafety Levels (BSLs)**

- Combinations of lab practices/techniques, safety equipment, lab facility design, and training geared to working safely with biohazards
- Like risk groups, there are four biosafety levels
- Applied to operations performed with a given agent, based on level of hazard; does not always correlate with the RG

# Classification of Biohazards by Risk Group (RG) and Biosafety Level (BSL)

| | Agent Risks | Containment Concerns | | Containment Methods |
|---|---|---|---|---|
| RG1 | Not associated with disease in healthy adult humans | Negligible or low individual and community risk | BSL1 | Work is typically conducted on the open bench |
| RG2 | Associated with disease<br>Can be serious<br>Preventative measures or treatment often available | Moderate individual risk<br>Low community risk<br>Most common for clinical research | BSL2 | Personnel require specific training<br>Aerosol generating procedures are confined to a Biosafety Cabinet (BSC) |
| RG3 | Associated with serious or lethal disease through inhalation<br>Preventative measures or treatment may be available | High individual risk<br>Moderate community risk | BSL3 | All procedures are confined to a BSC<br>Labs have special engineering and design features |
| RG4 | Likely to cause life threatening or lethal disease<br>Preventative measures or treatment are not usually available | High individual risk<br>High community risk | BSL4 | BSL-4 labs have special engineering and design features to prevent any release<br>• A cabinet laboratory<br>• A suit laboratory |

# Federal Oversight

**Department of Health and Human Services (HHS)**

– National Institutes of Health (NIH)

– Centers for Disease Control and Prevention (CDC)

# Federal Oversight

**National Institutes of Health** – Office of Science Policy (OSP)

- **Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids Molecules (*NIH Guidelines*)**
  - Must have an **Institutional Biosafety Committee** if recombinant research is conducted
  - **Terms and conditions of funding**
    - Even if the institution has only one NIH funded research project, **all researchers** must comply with the NIH Guidelines

# Federal Oversight


**Centers for Disease Control**

- ***Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6th ed.**
  - *Is not a regulatory document*
  - *Risk Assessment; Principles of Biosafety; Laboratory Biosafety Levels; Occupational Health; Agent Summary Statements; Appendices A – L (disinfection/decontamination, transportation, pest management, working with toxins, etc.)*

- 42 CFR Part 73: **Possession, Use and Transfer of Select Agents and Toxins**
  - Specific governmental list of agents; bacteria, viruses and toxins, potential bioterrorist agents

# Institutional Oversight

- TAMU System Regulation 15.99.06: *Use of Biohazards, Biological Toxins and Recombinant DNA*
  - *Each System member must have an IBC*
  - *Each System member must establish a rule for carrying out the regulation*
  - *Faculty, staff and students are responsible for the safe and compliant use, storage and disposal of biohazards*

# Institutional Oversight

- UNIVERSITY RULE 15.99.06.M1: *Use of Biohazards, Biological Toxins and Recombinant DNA* applies:
  - To all activities (research, teaching, and testing) involving biohazardous materials
  - 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

# TAMU Institutional Biosafety Committee (IBC)

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

# IBC Functions

- Setting containment level(s) as required by the NIH Guidelines
- Reviewing the facilities, practices, training and expertise of personnel involved in the research
- Periodically reviewing research conducted at the institution
- Adopting emergency plans covering accidental spills and personnel contamination
- Reporting any significant violations of the NIH Guidelines
- Reporting any research related accidents or illnesses to the appropriate institutional official and to NIH within 30 days
- May not authorize the initiation of experiments not explicitly covered by the NIH Guidelines

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


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

PIs must be faculty members or hold a faculty equivalent title

Students participate but are ineligible to serve as PIs.

Application information includes:

- Lay & Technical descriptions
- All biological agents in use
- Recombinant activities
- Location(s) of work
- Waste disposal/disinfection description
- Any ancillary permits

# *TAMU IBC approval process*


*ABSOs gather information:*
*Literature review*
***Grant review***
*Risk assessment/Risk mitigations*
*Schedule & conduct the lab inspection*
*Assign the submission to a meeting agenda, as needed*

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

# IBC Training Requirements

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

<u>For work with human pathogens: PIs and all personnel, including students, must complete:</u>

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

# TAMU IBC permits

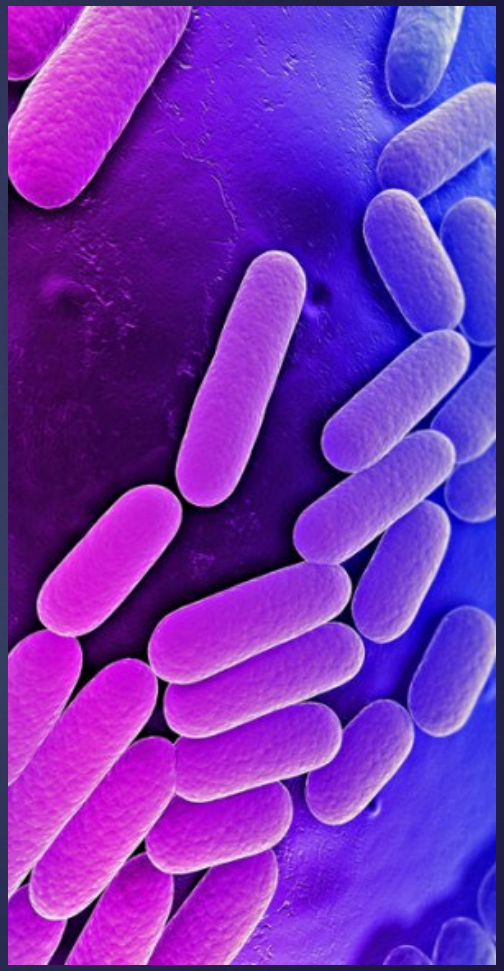

Valid for three years

- Annual reviews are performed
- IBC permits must be amended if adding new:
  - Agents,
  - Locations,
  - Scope of work with biohazards, or
  - Personnel (BL2 or higher)

## *Funded awards are reviewed*

- Awards describing work with biohazards must have IBC approval, *before the funds may be released and before the work may commence*.
  - Experiments described in the grant must be described in the IBC permit.

- If activities or projects are funded or sponsored by the University but occur in other locations and/or if University faculty, staff or students are participating in activities utilizing biohazardous materials or rDNA, the University rule applies.



# *Office of Biosafety Contact Information*

- **Email:**
  - biosafety@tamu.edu
  - ibc@tamu.edu
- **Phone:**
  - (979)-862-4549 (Biosafety)
  - (979)-862-4688 (IBC)
- **Website:** http://rcb.tamu.edu/biohazards

Director, BSO: Dr. Jessica Bourquin

Biosafety Professionals: Ms. Merissa Bruns, Ms. Susan Gater*, Ms. Melissa Hinga, Dr. Ruchira Mitra, Mr. Grant Severson, and Dr. Megan Shoff**

IBC Coordinators: Mr. Jeffrey Lane, Ms. Beatriz Velez, and Ms. Jennifer Wier

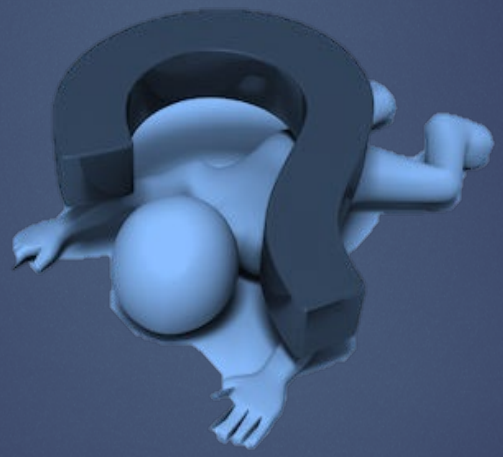
Occupational Health: Ms. Catherine Carey, Ms. Athena Cherry, Ms. Lauren Horton**, and Ms. Jenifer Mathews

* Responsible Official **Program manager

# Resources

- TAMU Biosafety Manual (and more)
  - https://rcb.tamu.edu/biohazards/resources
- CDC/NIH BMBL, 6th ed.
  - https://www.cdc.gov/labs/BMBL.html
- NIH Office of Biotechnology Activities
  - https://osp.od.nih.gov
- Dual Use Research of Concern
  - https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/
- ABSA, International: The Association of Biosafety and Biosecurity
  - https://absa.org/
- World Health Organization
  - https://apps.who.int/iris/handle/10665/337956/
- Federal Select Agent Program
  - http://www.selectagents.gov/

# Questions?



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# Radiological Safety

*Radioactive Materials, Radiation Producing Devices, Lasers*

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# Radioactive Materials

- Nuclear Regulatory Commission (NRC) is the regulatory authority for radioactive materials, nuclear materials, etc (Atomic Energy Act of 1954, as amended)
  - The NRC is the authority in those states that do not have an agreement with the NRC (11 + Territories)
  - In some cases, the NRC has ceded regulatory authority for certain materials to individual states (so called “Agreement States”, 39)
- Note that some small sources are authorized under a “General License”.

# Radioactive Materials

- Requires a Radiation Safety Officer (RSO) named on the license
- RSO is contact for interactions with the licensing agency RSO is qualified by knowledge and experience and must be approved the licensing agency
- Purchasing certain materials requires a license, in some cases portions of the license may be redacted due to security

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# Radiation Producing Devices

X-ray machines, accelerators, etc. Machines can be medical,

industrial, or research Registered

by State Regulatory body

Will have a point of contact or RSO listed on registration

Machines likely will require registration within days of installation, e.g. 30 days

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# Lasers

- Laser light can be visible (400-700 nm) or invisible
- In general, there are four laser classes, 1 through 4
  - Class 1 is an enclosed system which can contain higher powered laser
  - Class 2 and Class 3A(3R) are often pointing devices
- Class 3B & 4, are higher energy and are registered by State Regulatory body
- Will have a point of contact, Laser Safety Officer (LSO) listed on registration
- Laser class may be indicated on vendor documents

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# Occupational Safety and Health Administration (OSHA)

- Affects all facilities using hazardous chemicals (even those using small quantities)
- Chemical Hygiene Plan (CHP) –written program stating the policies, procedures and responsibilities that protect workers from the health hazards associated with the hazardous chemicals used in that particular workplace.
- Safety Data Sheets (SDS) required to be provided that communicates hazardous chemical information to users; formerly Material Safety Data Sheets (MSDS)

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# Questions?