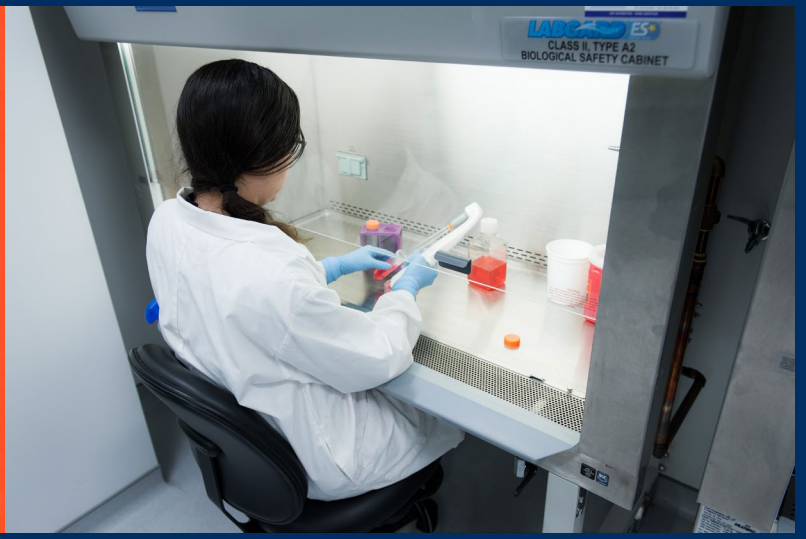
University of Nevada, Reno

Research & Innovation

Research Biosafety and IBC Oversight



Ben Owens, Associate Director

Environmental Health and Safety

Biosafety

- Biosafety addresses the safe handling and containment of hazardous biological materials
  - Infectious agents
  - Recombinant and synthetic nucleic acids
  - Biological toxins
- Goal - Protection of humans, animals, plants, and the environment

Research and Biosafety

- **Academic research areas involving biosafety – it's not just microbiology!**
  - **Biomedical Sciences**
  - **Biology – lab and field work**
  - **Environmental Sciences**
  - **Chemistry and biochemistry**
  - **Engineering fields**
  - **Human and animal clinical and diagnostic laboratories**
  - **Any work involving microbes, rDNA technology, human and NHP materials, zoonotic agents**

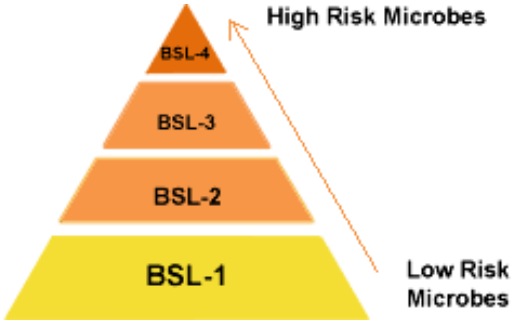
Biosafety “Regulations”

- **Guidance or Condition of Funding**
  - **(CDC/NIH) *Biosafety in Microbiological and Biomedical Laboratories* (BMBL)** https://www.cdc.gov/labs/BMBL.html
  - **(NIH) *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines)** https://osp.od.nih.gov/biotechnology/nih-guidelines/
- **Federal Regulations**
  - **(OSHA) *Bloodborne Pathogens*** https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030
  - **(CDC/USDA) *Select Agents and Toxins*** https://www.selectagents.gov/
    - **Incorporate the BMBL and NIH Guidelines as regulation**
- **Local Regulations**
  - **(Washoe County and Clark County) Biohazardous Waste**

Biosafety Levels (BSLs)

BSLs are a combination of laboratory practices, containment equipment, and laboratory design

- **BSL-1:** Microbes that are not known to cause disease in healthy adults and present minimal potential hazard to laboratorians and the environment
- **BSL-2:** Microbes pose moderate hazards to laboratorians and the environment and are associated with diseases of varying severity
- **BSL-3:** Microbes can cause serious or potentially lethal disease through respiratory transmission
- **BSL-4:** Microbes pose a high risk of aerosol-transmitted infections which are frequently fatal and without treatment or vaccines



Institutional Oversight

- **NIH Guidelines require establishment of an Institutional Biosafety Committee (IBC)**
  - **Scope of the UNR IBC includes:**
    - **Recombinant and synthetic nucleic acids (includes genetically modified animals and plants)**
    - **Microorganisms**
    - **Biological toxins**
    - **Human blood, body fluids, tissues, cells**
    - **Animal blood, body fluids, tissues, cells**
    - **Plant tissues and cells**
    - **Insect tissues and cells**
    - **Animals infected with human pathogens or as sources of zoonotic diseases**

Principal Investigator Responsibilities

- **Under the *NIH Guidelines*, PI responsibilities include (not all inclusive):**
  - **Ensuring full compliance with the *NIH Guidelines***
  - **Ensuring appropriate NIH/IBC approval based on experimental category**
  - **Proposing physical containment level and appropriate microbiological practices**
  - **Being adequately trained themselves; ensuring lab personnel are properly informed and trained**
  - **Submitting any changes to the IBC that occur after initial approval**
  - **Reporting any significant problems, violations, or research-related accidents and illnesses**
  - **Adhering to IBC approved emergency plans**

Institutional Biosafety Committee

- **The NIH Guidelines require that the Institutional Biosafety Committee membership meet the following criteria:**
  - **At least 5 members**
  - **At least 2 members who represent the community and who are not affiliated with UNR**
  - **At least 1 member with expertise in plant containment principles if work with plants is conducted**
  - **At least 1 member with expertise in animal containment principles if work with animals is conducted**
  - **If work at BSL-3, BSL-4, or at large scale (greater than 10 liters), a biological safety officer is required and must be a member of the IBC**
  - **Collectively, committee must have experience and expertise with recombinant nucleic acid technology used at the institution**

UNR IBC Membership

- **Current makeup of the UNR IBC**
  - **8 members total**
  - **2 members with animal containment expertise**
  - **3 community members**
  - **Biosafety Officer**
  - **Collective expertise in biosafety, microbiology, molecular biology, biochemistry, and animal care and containment**

Overlap With Other Committees

- IACUC
  - Many PIs conduct research that involves biological agents and research animals
  - Attending veterinarian and clinical veterinarian are both members of the IBC and IACUC
  - Biosafety officer (me) is a member of the IBC and IACUC
- IRB
  - Few studies that involve human subjects (generally limited to obtaining blood or other samples)
    - No human gene therapy studies
  - No committee membership overlap but IBC and IRB communicate as needed

IBC Biological Agent Use Protocol

- Known as Memorandum of Understanding and Agreement (MOUA)
  - Each principal investigator that uses biohazardous agents must submit a MOUA for approval by the IBC
    - MOUA includes personnel; agents used, hazards; work to be performed; safety equipment, procedures, and personal protective equipment; decontamination and disposal; incident response
- MOUA approved for three years
- Any changes to MOUA requires submittal of amendment

What Work Requires a MOUA?

- **An approved MOUA is required for use of biological agents in research or teaching**

  Research

  - **Laboratory research involving biological agents**
  - **Genetically modified animals and plants; zoonotic diseases**

  Teaching

  - **Instructional laboratories that use biological agents**

Experiments Covered by the NIH Guidelines

Section	Experiments Covered	Examples
Section III-A	Experiments that require NIH Director approval and IBC approval before initiation	Deliberate transfer of drug resistance to a microorganism not known to acquire it naturally, if such acquisition could compromise the ability to control disease in humans, animals, or agriculture
Section III-B	Experiments that require NIH OSP and IBC approval before initiation	Cloning of toxin molecules with LD_{50} less than 100 ng/kg
Section III-C	Experiments that require IBC approval and IRB approval before enrolling participants	Human gene transfer

Experiments Covered by the NIH Guidelines

Section	Experiments Covered	Examples
Section III-D	Experiments that require IBC approval before initiation	**i)** Recombinant or synthetic nucleic acids in RG2 microorganisms, **ii)** Viral vectors for gene transfer, **iii)** Transgenic animals other than rodents
Section III-E	Experiments that require IBC notice simultaneous with initiation	**i)** Recombinant or synthetic nucleic acids in RG1 microorganisms, **ii)** Experiments involving whole plants at BSL1-P
Section III-F	Exempt experiments (still require a MOUA)	**i)** Recombinant or synthetic nucleic acid that is not in organisms or viruses, **ii)** use of *E. coli* K-12 host-vector systems, **iii)** use of *Saccharomyces* host-vector systems

When is a MOUA Not Required?

- **Certain activities generally do not require a MOUA**
  - **Human health care**
  - **Veterinary medicine**
  - **Clinical laboratory analyses performed by commercial human or veterinary health laboratories**

Example 1: Blood is collected from human volunteers by a licensed HCP and then analyzed for cholesterol by a clinical lab – no MOUA required.

Example 2: Blood is collected from human volunteers by a trained HCP and then immunologically screened for *Burkholderia pseudomallei* by a research laboratory – a MOUA is required for the antibody testing.

Submittal of MOUA

- **MOUAs are submitted, reviewed, and managed using the Safety Stratus online application (LabcliQ)**
  - https://labcliq.com/l/unr/ (then IBC Module)
  - **Requires active UNR NetID**
- **IBC Coordinator:**

  Kristin Eliasen, Laboratory Safety Specialist

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MOUA Submittal and Review

- To ensure review at the next IBC meeting, the MOUA or amendment must be submitted at least 10 business days prior to the meeting
- The IBC meets every other month throughout the year
  - January, March, May, July, September, November
  - Typically on the second Wednesday of the month

IBC Contacts

IBC Chair

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UNR Web Site
www.unr.edu/ehs

then “Forms and Applications”