University Biosafety Manual
Procedure Overview
Purpose and Scope

• This procedure is to ensure a safe and compliant working environment for University biohazardous (agents and toxins) and rDNA activities.

• This procedure applies to all personnel who work in University of Notre Dame laboratories that handle and/or may be exposed to biological hazards in research and teaching laboratories.
Training Requirements

• All personnel who work in Biosafety Level 1, 2 and/or 3 labs must complete annual biosafety training in addition to general lab safety training.

• If personnel are working with human blood, tissues, cell lines or OPIM, annual Bloodborne Pathogens training is required.

• Training records shall be maintained per the University’s record retention policy.
Roles and Responsibilities
Institutional Biosafety Committee (IBC)

• Reviews all protocols involving biohazards, select agents and rDNA activities
• Keep a record of meetings, providing sufficient detail to serve as a record of major points of discussion and the committee’s rationale for particular decisions, documenting that the IBC has fulfilled its review and oversight responsibilities.
• Report any significant problems or violations of National Institutes of Health Office of Biotechnology Activities NIH OBA
• Guidelines and any significant research-related accident or illness to NIH/OBA.
Roles and Responsibilities
Office of Research

• Provides the necessary liaison between Principal Investigators, the Institutional Biosafety Committee, granting agencies, and regulatory agencies.
• Serves as the Office of Record for documentation involving the Institutional Biosafety Committee including all necessary documentation for PIs to comply with University submission requirements.
• Provides assistance to Principal Investigators and researchers regarding export control and importing of biological agents and select agents.
• Appoints Chair, IBC, and Biosafety Officer.
Roles and Responsibilities
Biosafety Officer

• Assists faculty members with establishing and maintaining a safe working environment in both research and teaching laboratories. Reports to the IBC any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses unless a report has already been filed by the Principal Investigator.

• Conducts laboratory inspections to ensure that standards and containment conditions established by the Institutional Biosafety Committee are followed.
Roles and Responsibilities
Principal Investigator (PI)

- Complies with University policies and all government regulations and guidelines that are applicable to their research including monitoring/approving the procurement, use and disposal of biological agents within the laboratory.
- Sets expectations for the completion of training and other requirements and provides lab specific training on safety equipment, devices, personal protective equipment, and apparel regarding provision, maintenance and use by individuals present in the laboratory, including personnel from other laboratories.
- Informs all employees and students working under their supervision that safety and health are priorities; and informs them about safety and health policies, rules, regulations and procedures, as well as their specific responsibilities, as identified in the unit safety plan.
- Submits an IBC Protocol and rDNA registration as appropriate for research activities involving biohazards and/or rDNA.
Roles and Responsibilities
Laboratory Personnel

• Follows established laboratory safety practices and standard operating procedures including performance and safety of equipment before use.
• Completes all required training including Biosafety and Biocontainment and BBP training annually as appropriate.
• Communicates to the PI any unsafe practices or conditions in the laboratory.
• Reports any spills accidents or injuries involving biological materials to the PI.
• Informs the PI of any changes in your health status that may be related to your work in the laboratory or that may affect your susceptibility to exposure.
IBC Submission and Review

• Submission of an electronic IBC protocol/registration document is mandatory for work with
  – blood, blood products, OPIM, or other biological agents
  – All rDNA activities.

• PI's proposing research/academic activities involving human blood, microorganisms (including exempt and non-exempt rDNA activities) and biological toxins shall complete the university's Biosafety protocol application form and submit it to Office of Research Compliance, for review and approval prior to initiation of the activity.
Personal Protective Equipment (PPE)

• Personnel working in BLS-1 or BSL-2 lab must wear:
  – Long pants
  – Closed-toe shoes with substantial sole.
  – Lab coat
  – Eye protection (except when working at a microscope).
  – Gloves when handling any biohazardous materials.

• Additional PPE may be required.
Signage and Labeling

• Warning labels, including the standard biohazard label, are affixed to equipment that is used for or with biohazardous material.
• All laboratories approved for BSL-2 activities must display a biosafety level 2 sign on the door.
Biohazardous Waste

• All waste containers must be covered. While not required, step-to-open waste containers are recommended.
• Waste shall not protrude or prohibit container from closing.
• All waste containers must have a biohazard symbol affixed and labeled waste.
• Sharps shall be placed in a sharps container.
• Wastes that have been autoclaved shall be placed in a dark bag and labeled, Safe for trash disposal.