INDIANA UNIVERSITY

OFFICE OF THE EXECUTIVE VICE PRESIDENT
FOR UNIVERSITY ACADEMIC AFFAIRS

University Environmental Health and Safety

Laboratory Inspection Program for Institutional Biosafety Committee Approvals

July 30, 2014

1. INTRODUCTION

1.1. Purpose

Indiana University has developed the Laboratory Inspection Program for Institutional Biosafety Committee (IBC) Approvals to ensure that all laboratories with IBC protocols are inspected and meet certain protocol specific laboratory standards before IBC approval is granted. This program is intended to promote a safe laboratory working environment and to ensure compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, the Biosafety in Microbiological and Biomedical Laboratories, 5th ed. Guidelines, and the OSHA Bloodborne Pathogens Standard 29 CFR 1910.1030.

1.2. Scope

The Laboratory Inspection Program for Institutional Biosafety Committee Approvals establishes the training and inspection elements required for all Indiana University Principal Investigators (PI) utilizing biological materials to receive IBC protocol approval. The Laboratory Inspection Program for Institutional Biosafety Committee Approvals pertains to all IBC protocols and research that fall under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, all non-recombinant DNA Biological Safety Level 2 or higher protocols, and protocols and research that have been otherwise required to be reviewed and approved by the IBC committee.

2. AUTHORITY AND RESPONSIBILITY

2.1. The Biological Safety Office is responsible for:

- Developing, updating, and promulgating inspection and training requirements;
- Maintaining inspection and training records;
- Communicating any deficiencies and working with supervisors to correct deficiencies; and
- Revising and updating the program as necessary.

2.2. Principal Investigators are responsible for:

- Ensuring that all personnel follow the specific requirements outlined in the inspection including all necessary training requirements;
- Correcting any deficiencies noted in the inspection before study approval;
- Notifying the Biological Safety Office if deviations from the inspection requirements occur; and
- Notifying the Biological Safety Office of any spills or accidental exposures.

2.3. Employees are responsible for:

- Understanding and adhering to the specific requirements outlined in the inspection;
- Completing applicable training; and
- Contacting PIs and the Biological Safety Office if deviations from the inspection requirements occur and if questions arise.

3. PROGRAM ELEMENTS

3.1. Biological Laboratories

This program applies to laboratories comprising four different biological safety levels: Biological Safety Level 1, Biological Safety Level 2, Biological Safety Level 2 with BL3 practices, and Biological Safety Level 3.

3.1.1. Biological Safety Level 1

Biological Safety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, and present minimal potential hazard to laboratory personnel and the environment.

3.1.2. Biological Safety Level 2

Biological Safety Level 2 is suitable for work involving agents associated with moderate human disease for which treatment and or vaccination is commonly available.

3.1.3. Biological Safety Level 2 with BL3 practices

Biological Safety Level 2 with BL3 practices is suitable for agents associated with moderate human disease but where the manipulations of those agents necessitate additional safety precautions to reduce the risk of aerosol exposure.

3.1.4. Biological Safety Level 3

Biological Safety Level 3 is suitable for work involving indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure.

3.2. Laboratory Inspection Frequency

Each laboratory that falls into the scope of this program shall be inspected before IBC approval is granted. Laboratory inspections are required upon the submission of a new protocol, a major amendment to an existing protocol, when the laboratory room changes or whenever an amendment is submitted that would change the risk assessment of the study. The necessity for a laboratory inspection is at the discretion of the Biological Safety Office. An annual inspection may be accepted in place of a separate IBC inspection as deemed appropriate by the Biological Safety Office.

3.3. Laboratory Inspection Requirements

Each laboratory that falls into the scope of this program shall be inspected using the "IBC Inspection Form". (See Appendix A-1)

3.4. Laboratory Inspection Follow Up

Upon inspection of the laboratory any deficiencies must be corrected or addressed before approval of the proposed IBC protocol. Deficiencies will be documented and an inspection report sent to the PI. The Biological Safety Office would be available to provide advice to the PI to address and correct any deficiencies in a timely manner for approval.

4. TRAINING & RECORDKEEPING

The training courses required for protocol approval will depend on the biological safety level of the study and the work involved. Trainings can include but are not limited to BSL1, BSL2, BSL3, animal work, viral vector, biological shipment and bloodborne pathogens. Training requirements will be stated during the study review process. The Biological Safety Office will ensure that the proper trainings are completed and records retained for reference.

5. REFERENCES

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, March 5, 2013, Department of Health and Human Services
- Biosafety in Microbiological and Biomedical Laboratories, 5th edition, U.S. Department of Health and Human Services
- OSHA Standard 29 CFR 1019.1030

6. REVISIONS

New Document: July 30, 2014

APPENDIX A-1: IBC Inspection Form

IBC LABORATORY BIOSAFETY INSPECTION

Study Number _____ BSL- _____

Principal Investigator_____Department_____

Laboratory Building/Room No._____Date_____

Biological Agent(s)_____

Health Concern_____

Inspected By:_____

YES	NO	N/A	
☐	☐	☐	This inspection is based on an Annual Inspection dated:
☐	☐	☐	Principal Investigator or research staff involved in the project were present for the inspection.
☐	☐	☐	Puncture-resistant containers are available for disposal of contaminated sharps.
☐	☐	☐	Biohazard waste remains covered at all times unless inside the biological safety cabinet.
☐	☐	☐	Durable leak proof containers are available for disposal of all non-sharp contaminated materials.
☐	☐	☐	Laboratory coats, gowns, or uniforms are available and have a place for storage in the laboratory when not in use.
☐	☐	☐	Appropriate gloves are available for the work to be performed.
☐	☐	☐	Access to the laboratory is limited by the Principal Investigator.
☐	☐	☐	A hazard warning sign is posted outside of the laboratory entry stating the following: infectious agent, name and telephone number of responsible person, and requirements for entering the laboratory.
☐	☐	☐	A Biosafety Manual and specific standard operating procedures for the infectious agent are located in the laboratory and have been read by all personnel involved in these experiments.
☐	☐	☐	Appropriate and certified biological safety cabinet(s) are available in the laboratory and have been certified within the last 12 months.
☐	☐	☐	Centrifuges used in the open laboratory have sealed heads or centrifuge safety cups.
☐	☐	☐	Vacuum lines are protected with a double-trap and in-line filter between the last trap and vacuum source.
☐	☐	☐	Each laboratory contains a sink for hand washing.
☐	☐	☐	An emergency eyewash facility is readily available.
☐	☐	☐	An autoclave for decontaminating infectious laboratory wastes is available.
☐	☐	☐	Equipment and work surfaces are appropriately decontaminated.
☐	☐	☐	All appropriate training has been completed and is up to date.

Revised: 7/30/2014