

**FORDHAM UNIVERSITY**  
*Institutional Biosafety Committee*  
**Pathogenic Agent (human, non-human primate, animal, plant) Protocol**

**As Principal Investigator:**

I attest that the information in the registration is accurate and complete and I will submit significant changes to the Institutional Biosafety Committee before implementation.

I am familiar with, and agree to abide by, the current applicable guidelines and regulations governing my research, including, but not limited to, the NIH *Guidelines for Research Involving Recombinant and Synthetic DNA Molecules* and *Biosafety in Microbiological and Biomedical Laboratories*.

I have completed all required institutional training and I agree to accept responsibility for ensuring all laboratory personnel involved in this research have the required and necessary training on potential biohazards, relevant biosafety practices, techniques, and emergency procedures.

If applicable, I have carefully reviewed the NIH Guidelines and accept the responsibilities described therein for principal investigators (Section IV-B-7).

I will notify the Campus Safety department, the Institutional Biosafety Committee, and the Department of Environmental Health and Safety (EHS) concerning any research related accidents or exposure incidents.

I will notify the Institutional Biosafety Committee as well as the Department of Environmental Health and Safety (EHS) concerning any release of pathogens into the environment; problems pertaining to the implementation of biological and physical containment procedures; or violations of the NIH Guidelines.

I agree that no work will be initiated prior to project approval by the Institutional Biosafety Committee.

**Principal Investigator Typed/Printed Name:** \_\_\_\_\_

**Signature (PI):**

**Date:**

**Certification of Approval by IBC**

**Chair Name:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Signature** \_\_\_\_\_

**Biosafety level assigned to project:** \_\_\_\_\_

**Date of Expiration (Certification must be renewed every 3 years.):** \_\_\_\_\_

**PI CONTACT INFORMATION:**

Department: \_\_\_\_\_

Lab Address: \_\_\_\_\_

Lab Telephone: \_\_\_\_\_ E-mail Address: \_\_\_\_\_

After hours phone number (required if research is at Biosafety Level 2): \_\_\_\_\_

**1. DESCRIPTION OF PROJECT WITH PATHOGENS**

Project Title:

- a. Concisely describe the overall nature of your project regarding pathogens (e.g. injection of sepsis causing bacteria into mice... etc.) *Note: If you are planning to genetically alter any pathogens the you must complete the recombinant DNA/RNA declaration.*
- b. List and describe all the microorganisms that will be used in the project and the volumes to be produced at any one time. Please give strain and risk group information. Describe the nature of the risk to humans.
- c. List the host(s) that will be used, e.g., mammalian cell line, mouse, rat, humans, etc:
- d. Will this research involve transfer of microorganisms into human subjects? Yes            No
- e. Will this research involve transfer of microorganisms into animals? Yes    No

If yes, specify what microorganisms will be administered **and** the route of administration. ***Projects involving vertebrate animals also require IACUC approval.***

Project Description:

f. Using the table below, please indicate the highest biosafety level for your laboratory.

Biological Safety Level (BSL)	BSL1	BSL2	BSL3*	BSL4*
Appropriate for organisms with the following characteristics:	Not known to consistently cause disease in healthy adults.	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure.	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences.	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections, or related agents with unknown risk of transmission.

\* ***Currently there are no facilities at FORDHAM UNIVERSITY that can accommodate these biosafety levels.***

Please refer to “Biosafety in Microbiological and Biomedical Labs, 6<sup>th</sup> Ed.” at this URL: <https://www.cdc.gov/labs/bmbl.html>

**2. AEROSOLS**

- a. Conducting procedures that can produce aerosols containing pathogenic agents must be controlled using standard approved protocols, PPE, and engineering controls.

Is your laboratory following these practices? Yes.                      No                      N/A

- b. If you are making modifications to these best practices please describe them below. Also explain why these modifications are necessary, and describe how you will compensate to maintain a safe working environment.

### **3. SHARPS**

- a. The use of sharps in conjunction with pathogenic agents can be dangerous and should be eliminated if at all possible (e.g. the use of glass pipettes with BSL2 agents should not be done), or safer engineered sharps devices should be used.

Is your laboratory in compliance with these practices? Yes          No          N/A

- b. If you are using sharps and are deviating from the best practices please describe these deviations, explain why they are necessary, and describe how you will compensate to maintain a safe working environment below.

### **4. WASTE DISPOSAL METHODS**

- a. Minimum standard requirements must be followed when disposing of liquid waste, stocks, disposable labware, and pathological waste contaminated with biological hazards.

Is your laboratory following these practices? Yes          No

- b. Please describe any deviations or additions to the best practices below:

If there are any other types of contaminated biohazardous waste generated in your laboratory please describe it and your method of disposal here:

### **5. FLOW CYTOMETRY AND FACS**

- a. Will you be conducting flow cytometry or fluorescence activated cell sorting (FACS).  
Yes          No

If yes, you must complete and append the Flow/Cell Sorter Biosafety Information form.

- b. Is your laboratory following these standards? Yes          No

- c. Please describe any deviations or additions to the best practices below:

## **6. OTHER INFORMATION**

It is the responsibility of the principle investigator to assess the risks and ensure appropriate measures are in place to protect laboratory members and the general public. If there are any other significant potential hazards, related to pathogens used in your laboratory, that have not been sufficiently described above please do so in the space provided below. Discuss the nature of the hazard and protective measures put in place below:

## **7. TRANSPORTATION/SHIPMENT OF BIOLOGICAL MATERIALS**

- a. As per the Department of Transportation **49 CFR Parts 171-173 (7)**, some biological materials are regulated as hazardous materials and require special training of all personnel involved in shipping.

Will you be transporting or shipping any of the following off campus?

Yes      No.

*If yes, check all that apply:*

Cultures of human or animal pathogens

Environmental samples known or suspected to contain a human or animal pathogen

Human or animal material (including excreta, secreta, blood and its components, tissue and tissue fluids, cell lines, and other biohazardous materials) containing or suspected of containing a human or animal pathogen.

Have you or anyone in your lab involved in packaging, labeling, or completing/signing paper work received training to ship infectious substances or diagnostic specimens within the past 3 years?

Yes      No

If yes, please provide the following information:

Name	Date Trained	Certified Shipping Trainer

**8. PERSONNEL QUALIFICATIONS & FACILITY INFORMATION**

a. List qualifications of the PI and personnel with relevant training and experience with the pathogens described.

Name (first and last) – POSITION (Title, academic degrees, certifications, and field of expertise)	RELEVANT EXPERIENCE  (Describe previous work and training with biohazardous and/or recombinant DNA and include Biosafety Levels)
<i>Example: Bob Biohazard – Associate Professor, PhD- Microbiology</i>	<i>14 yrs. working with E. coli at BL1, Salmonella enterica at BL2, 8 yrs. working with transgenic mice</i>

b. List all the laboratories/facilities where research is to be conducted (specify building, room number and category for each):

Building	Room #	Category	Check if a new or updated biohazard door sign is needed*

**\*Biohazard signs are required for entrances to Biosafety Level 2 (including Animal Biosafety Level 2) areas. The Department of Environmental Health and Safety will provide signs.**

If an updated biohazard sign is required, please indicate the location and what agents/organisms/hazards should be listed on the sign in addition to what is being registered.

REFERENCES

1. *Biosafety in Microbiological and Biomedical Laboratories*: BMBL – 6<sup>th</sup> ed. CDC – Dept. of Health and Human Services:
2. Department of Transportation – Hazardous Materials: Standards for Infectious Substances; **49 CFR Parts 171-173**