



DREXEL UNIVERSITY'S INSTITUTIONAL BIOSAFETY COMMITTEE  
**BIOSAFETY PROTOCOL APPLICATION**  
*General Biohazard Form (Form A)*

**Instructions**

- Complete this form for all research activities involving biological hazards that may put research personnel at risk.
- If your research includes the use of Pathogenic Organisms or Human/Primate Samples but does not involve recombinant DNA (rDNA), hazardous chemicals, or animals, the **General Biohazard Form** (this form) is the only form required to submit your protocol for approval.
- If your research involves the use or generation of rDNA, you also need to complete the **Recombinant DNA Registration Addendum (Form B)** and attach it to this application form.
- If your research involves the use of chemical carcinogens or cytotoxic agents, you also need to complete the **Hazardous Substance Addendum (Form C)**.
- If your research involves the use of biohazardous agents in animals, you also need to complete the **Animal Use Addendum (Form D)**.
- Changes to an approved biosafety protocol must be made by filing a **Protocol Amendment Form (Form E)** for the Institutional Biosafety Committee review.
- If you have questions about this form or the application process, please contact us by phone (215-762-7147) or e-mail ([biosafety@drexel.edu](mailto:biosafety@drexel.edu)).

**1. PROJECT INFORMATION**

Project Title (Must exactly match the grant title if externally funded)	Sponsor
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**2. INVESTIGATOR PROFILE**

Principal Investigator Name		Degree
Department	Location of Lab(s)	
College or School		
Phone Number	Fax Number	Pager or Cell Number
E-mail address		
Name of Co-Principal Investigator (if applicable)		Degree

3. PROJECT HAZARDS (check all that apply):		
<input type="checkbox"/>	Recombinant and synthetic nucleic acid molecules, pathogenic organisms, cytotoxic agents, and carcinogens/mutagens	- complete this form
<input type="checkbox"/>	Recombinant and synthetic nucleic acid molecules (generation, <i>in vivo</i> or <i>in vitro</i> use of rDNA)	- also complete Form B
<input type="checkbox"/>	Chemical carcinogens/mutagens or cytotoxic agents	- also complete Form C
<input type="checkbox"/>	Biohazardous agents or rDNA in animals	- also complete Form D

#### 4. SAFETY TRAINING

In the following table, provide the names of Drexel University personnel involved in this study (including the Principal Investigator). All personnel must have completed BioRAFT-based laboratory safety training within the last 12 months. Please note that:

- Because the PI is responsible for all biosafety aspects of the project, the PI must complete all relevant laboratory training.
- When entering information in the “Role and tasks” column, be specific as to the major tasks to be performed. For example, a project involving the collection of patient blood samples for cytokine analysis might include “blood collection,” “sample processing,” and “ELISAs” as tasks.
- The training completion date should be entered in the mm-dd-yy format.
- If the “Shipping Biological Materials” and/or “Recombinant DNA Materials” courses were completed through BioRAFT within the last 12 months, check the appropriate box(es) for each person listed in the table.

To complete laboratory safety training, go to <https://drexel.bioraft.com/> and log in using your DrexelOne user ID and password. *(Please note: If you are using MS Word on a PC, you will likely need to copy the link directly into your web browser. This is a MS Word issue with no work-around.)*

Name of investigator, student, or coordinator	Role and tasks to be performed	Date of BioRAFT training	rDNA Course Completed	Biohazard Material Shipping Course Completed
	PI		<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>

#### 5. RESEARCH DESCRIPTION

Provide a brief description of the proposed research in the field below. If this is an externally funded project, please attach an abstract or Specific Aims page from your grant application or proposal.

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#### 6. BIOHAZARDS AND RISKS

a. Provide a brief description of the biohazards/risks associated with the proposed work. List any pathogenic organisms, and list human or non-human primate tissues, cells or cell lines, or biological fluids that will be used, their sources (e.g., commercial, patient-derived, collaborator), and their potential for carrying infectious pathogens. In addition, list any recombinant or synthetic nucleic acid molecules (rDNA) to be used or involved in the work. **Note: any work involving rDNA will also require the submission of Form B.**

For each pathogen (or pathogenic product of rDNA use), indicate the Risk Group Classification, as defined under Exhibit V-a (“Classification of Human Etiologic Agents on the Basis of Hazard”) in the Drexel University Laboratory Safety Manual (May 2011).

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b. List all locations where biohazardous material will be manipulated or stored. For each location, indicate the highest level of biological containment (Biosafety Level or BSL) to be used. Describe equipment available for the containment of biohazardous material.

<i>Location (building, room)</i>	<i>BSL</i>	<i>Containment Device/Equipment</i>
	Select one	

**7. RISK MANAGEMENT**

**Note:** In the event of a needle stick or any other injury resulting from exposure to contaminated sharps, employees should, in accordance with the Drexel University Bloodborne Pathogens Compliance Plan, take the following actions:

- Immediately cleanse the affected area with soap and water. Be sure to use plenty of soap and a strong stream of water. If the eyes, nose, or mouth are exposed, rinse heavily with water only (no soap).
- After cleansing, notify your supervisor immediately and seek medical care at WorkNet Occupational Health (located on the first floor of the Bobst Building on the Center City campus) for post exposure evaluation. This facility is open Monday through Friday from 8 am until 5pm. If WorkNet is not available or if exposure occurs after hours or on the weekend, please proceed to the nearest emergency room.
- Complete and fax an Employee Injury Report to Risk Management and the Department of Environmental Health and Safety (EHS) within 24 hours. EHS will conduct an accident investigation after any exposure incident.

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a. List any special groups of workers (e.g., pregnant, immune-compromised, allergic) at greater risk for infection or disease from the use of this biohazardous material. In addition, describe any additional precautions that will be implemented to protect these special groups. If there are no special groups of workers at greater risk, type “None” in the text block.

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b. Are any preventative medical services required (e.g. special vaccinations, serum testing) that exceed those provided by Drexel University’s standard program? If so, describe the required services below. **Note:** If you are uncertain about the requirements or if you have questions regarding occupational health services, please contact the Department of Environmental Health and Safety

Yes  No

(EHS) at 215-895-5919.	
c. Are special post-exposure prophylaxis or medical management services needed in case of accidental exposure? If so, please describe them.	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. Describe decontamination procedures that will be used after a spill or exposure. If none, please explain.	

<b>8. FACILITY AND PRECAUTIONS CHECKLIST</b>	
If your work requires containment at Biosafety Level 3 or higher, please contact the Institutional Biosafety Committee at (215) 762-7147 for additional reporting requirements.	
a. Are doors kept closed during experiments?	<input type="checkbox"/> Yes <input type="checkbox"/> No
b. Are work surfaces cleaned on a daily basis and immediately following spills? Work surfaces potentially contaminated with biological hazards should be decontaminated immediately after use with appropriate agents [e.g., 70% ethanol or 10% bleach (Clorox)].	<input type="checkbox"/> Yes <input type="checkbox"/> No
c. Are all biohazardous wastes disposed of as Biohazard Waste? If your answer is <b>No</b> , describe (below) the nature of waste and method of decontamination.	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. Is the laboratory kept neat and clean?	<input type="checkbox"/> Yes <input type="checkbox"/> No
e. Are materials to be decontaminated at a site away from the laboratory placed in durable, leak-proof, and sealed containers before removal?	<input type="checkbox"/> Yes <input type="checkbox"/> No
f. Are other contaminated materials (e.g., glassware, animal cages, lab equipment) decontaminated before washing, reuse, or disposal? If your answer is <b>Yes</b> , describe the procedure(s) used for decontamination (e.g., incineration, autoclave).	<input type="checkbox"/> Yes <input type="checkbox"/> No
g. Is all pipetting performed using mechanical devices?	<input type="checkbox"/> Yes <input type="checkbox"/> No
h. Is there clear and obvious signage prohibiting eating, drinking, and smoking in the laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No
i. Are foods for human consumption stored in the laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No
j. Are handwashing facilities available within the laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No
k. Are biohazardous materials used in procedures that can produce aerosols (e.g., sonication or centrifugation)? If your answer is <b>Yes</b> , please describe (below) aerosol containment methods (e.g., laminar flow hoods, aerosol-safe leak-proof centrifuge buckets, or sealed secondary containers) used during these procedures.	<input type="checkbox"/> Yes <input type="checkbox"/> No
l. Is there a biological safety cabinet (i.e., tissue culture hood, laminar flow hood) available for use in the laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
If so, what class? (check one)	I <input type="checkbox"/> II/A1 <input type="checkbox"/> II/A2 <input type="checkbox"/> II/B1 <input type="checkbox"/> II/B2 <input type="checkbox"/> III <input type="checkbox"/>

Date of last certification		
The cabinet is used with (check all that apply):	Biologicals <input type="checkbox"/>	Toxic Chemicals <input type="checkbox"/> Radioactive materials <input type="checkbox"/>
Is there a chemical fume hood available for use in the laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
Date of last certification		
The chemical fume hood is used with (check all that apply):	Biologicals <input type="checkbox"/>	Toxic Chemicals <input type="checkbox"/> Radioactive materials <input type="checkbox"/>
m. Is access to the laboratory limited to persons advised of the nature of the biohazardous material used in this research?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
n. Is an insect and rodent control program in the laboratory needed? For information on available programs, contact University Facilities Management at (215) 895-1700. If a control program is necessary, describe (below) the provisions that have been made.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
o. Are additional engineering controls (e.g., glove box, filtration systems) required to handle the biohazardous materials? If your answer is <b>Yes</b> , please list and describe (below) the required equipment.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
p. Will respiratory protection (e.g., masks, respirators) be required to handle the biohazardous materials? If your answer is <b>Yes</b> , list and describe (below) the personal protective equipment to be used. <b>Note:</b> If respiratory protection will be required, you must contact the Department of Environmental Health and Safety (EHS) about specific equipment needs and training (including respirator fit testing).	<input type="checkbox"/> Yes <input type="checkbox"/> No	
q. Will gloves be used to handle the biohazardous materials? If your answer is <b>Yes</b> , specify the type of glove to be used. <b>Note:</b> Some laboratory personnel may be allergic to latex.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
r. Are animals allowed in the laboratory? If your answer is <b>Yes</b> , describe (below) their relationship to the research involving biohazardous material. A completed Animal Use Addendum (Form D) may also be required.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
s. Are hypodermic needles and syringes used?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
If your answer is <b>Yes</b> , are they handled appropriately and disposed of in an approved sharps container?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
t. Are experiments of lesser biohazard potential being carried out concurrently in the laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
If your answer is <b>Yes</b> , are experiments of different biohazard potential kept carefully separated?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
u. Are protocols describing the hazards involved in the research available to all laboratory personnel?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
v. Are all personnel in the laboratory aware of the emergency plan concerning accidental spills and personnel contamination?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

w. Will this work involve transport of biohazardous material to or between areas outside of the laboratory? If your answer is <b>Yes</b> , indicate which of the following best describe how the material will be transported (check all that apply). <b>Note:</b> All biohazardous materials should be transported in appropriate, leak-proof biohazard containers.		<input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/> Carrying material to another laboratory or area on the same floor or wing of building <input type="checkbox"/> Carrying material to another laboratory or area on a different floor or in a different building	<input type="checkbox"/> Transporting material to another campus, facility, or institution in a private vehicle <input type="checkbox"/> Transporting material to another campus, facility, or institution via commercial courier	

9. HUMAN STUDIES		
Does the biohazard involve human studies? If your answer is <b>Yes</b> , please complete the questions in the following section. <b>Note:</b> Standard Precautions must be followed when handling all human samples.		<input type="checkbox"/> Yes <input type="checkbox"/> No
a. Has a protocol been submitted to the University IRB?		<input type="checkbox"/> Yes <input type="checkbox"/> No
b. Sample collection will be performed at the following locations (check all that apply):	<input type="checkbox"/> Clinical setting (i.e., doctor's office, clinic, clinical lab, patient room) <input type="checkbox"/> Non-clinical setting <input type="checkbox"/> Subject's home or office, research lab, another institution <input type="checkbox"/> Not applicable	
c. Indicate the location (building and room) where samples will be stored.		
d. Indicate the sample storage temperature.		
e. Provide a typical sample size (e.g., 1 mL or 2 cubic cm)		
f. Indicate the information used to label and identify the samples.		
g. Are samples being collected from individuals known to be infected with any infectious disease pathogens? If your answer is <b>Yes</b> , describe (below) the samples and list the infectious pathogens.		<input type="checkbox"/> Yes <input type="checkbox"/> No
h. Proposed sample use (check all that apply):		<input type="checkbox"/> Clinical lab for testing <input type="checkbox"/> Research lab for testing <input type="checkbox"/> External entity (sponsor) <input type="checkbox"/> Other (please specify below)
i. Type of sample material to be collected (check all that apply):		<input type="checkbox"/> Body fluids (e.g., blood, urine) <input type="checkbox"/> Body parts and/or tissue <input type="checkbox"/> Biopsy material, including fresh or frozen samples (fixed or embedded slides are not included)

**10. SELECT AGENTS**

Select Agents are 65 biological agents determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. The Federal Select Agent Program oversees the use of Select Agents. For a list of select agents, go to:

<https://www.selectagents.gov/SelectAgentsandToxinsList.html>

Are you using or does your project include the use of any Select Agent?

Yes  No

If yes, please contact the Department of Environmental Health and Safety (EHS) at 215-895-5919.

**11. DUAL USE RESEARCH**

Dual Use Research describes investigations that yield new technologies or information with the potential for both benevolent and malevolent applications. Dual Use Research of Concern is research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment or materiel. For more information on Dual Use Research, go to <https://osp.od.nih.gov/biotechnology/dual-use-research-of-concern/>.

Can any part of your project be classified as Dual Use Research? If your answer is **Yes**, indicate the nature of your research below. Check all that apply.

Yes  No

Enhances the harmful consequences of a biological agent or toxin

Disrupts immunity or the effectiveness of an immunization against of a biological agent

Confers to a biological agent or toxin resistance to drug treatment

Makes a useful vaccine ineffective

Increases pathogen virulence or transmissibility

Interferes with or facilitates evasion of diagnostic or detection methods

Facilitates weaponization of a biological agent or toxin

**12. ADDITIONAL INFORMATION**

Use this text field to provide any additional information pertinent to your work and this biosafety protocol form.

**GENERAL EMERGENCY PROCEDURES**

The Principal Investigator is responsible for complying with the following general emergency procedures:

- In the event of accidental exposure or contamination, all personnel involved will wash thoroughly with soap and water. Clothing will be changed as necessary.
- Work surfaces will be cleaned immediately after contamination by biohazardous materials.
- All contaminated materials will be discarded as biohazard waste.
- The Department of Environmental Health & Safety (EHS) will be promptly notified of all spills or incidents of consequence.
- In the event of an incident that poses a risk of infection or other collateral consequences, affected personnel will be counseled to seek appropriate medical attention.

**ACKNOWLEDGEMENT OF RESPONSIBILITIES**

The Principal Investigator understands that he/she must follow all applicable University and governmental regulations for the safe collection, transportation, storage, and use of biohazardous materials to minimize the risk of exposure, by aerosols or other means, to research personnel. The Principal Investigator and involved personnel have discussed the hazards and procedures to be followed with the Biological Safety Officer or his designee and have received training in Standard Precautions. The Principal Investigator ensures that all personnel involved in this work have previous training and/or experience in the safe handling of biohazardous materials. The Principal Investigator is also responsible for notifying Drexel University's Institutional Biosafety Committee of any changes or amendments to this protocol.

**CERTIFICATION BY THE PRINCIPAL INVESTIGATOR**

I affirm that, to the best of my knowledge, the information I have provided is complete and accurate. I understand my responsibilities as noted in this form. No changes will be made without prior approval of the Institutional Biosafety Committee.

Signature certifies that the principal investigator affirms that this research and the actions of all project personnel involved in conducting the study will conform with the IBC approved protocol and the provisions of the [NIH Guidelines for Research Involving Recombinant DNA](#), the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories Manual](#), the [Federal Select Agent Program Rule](#), and all associated university policies and procedures.

Signature of Principal Investigator	Date
Signature of Co-Principal Investigator (if applicable)	Date
Name of preparer (if prepared by someone other than the PI)	Position

*Once you have completed, printed, and signed this form, scan it and create an Adobe PDF file. Alternatively, convert the completed form directly to an Adobe PDF file and electronically sign the form using the E-signature feature of Adobe Acrobat. Send the completed form by e-mail as an attachment to [biosafety@drexel.edu](mailto:biosafety@drexel.edu).*