Instructions for Biosafety Application

Research and Sponsored Programs
201J University Hall
Wright State University
Dayton, OH 45435
(937) 775-2425

Please use the attached application for requesting a review and approval of activities involving biohazardous agents by the Wright State University Institutional Biosafety Committee (IBC). This application should be used for all activities including research, teaching, and testing. The IBC requests the information in accordance with its charge. This information is required by the Occupational Safety and Health Administration's Occupational Exposure to Hazardous Chemicals in Laboratories Standard, its Blood-Borne Pathogen Standard and/or the NIH Guidelines for Research Involving Recombinant DNA (rDNA) Molecules.

The application rules and procedures are as follows:

- Use the "Save As" function to save document on your disk.
- Please be thorough and complete all sections - please type.
  - Incomplete applications will be returned without review.
  - Hand written applications will be returned without review.
- If you need more space, attach additional sheets.
- Obtain necessary signatures.
- Allow the Biosafety Officer at least one week prior to the submission deadline for review of application.
- For procedures involving Class 1 biohazards, submit one (1) original application with original signatures and two (2) copies.
- For procedures involving Class 2 or higher biohazards, submit one (1) original application with original signatures and eighteen (18) copies.
- Submission deadlines will be strictly enforced. For a complete listing of these dates, please refer to the Office of Research and Sponsored Program's Web site at http://www.wright.edu/rsp/ or contact the IBC Facilitator as listed below.

Submit completed application(s) to:

IBC Facilitator
Office of Research and Sponsored Programs
Room 201J, University Hall
Wright State University
Dayton, OH 45435
937-775-2425/3781 (voice/fax)
rsp@wright.edu

For additional information or assistance in completing this form, please contact the Department of Environmental Health and Safety at 937-775-2215/3761 (voice/fax).

Note: The information provided may become publicly available under Ohio's Open Records Act.

Biosafety Application

Wright State University
Research and Sponsored Programs

For RSP use only:
Biosafety Protocol No.: _____
Date Received: _____

☐ This application contains proprietary/confidential information (Please attach a justification statement and any relevant documentation).

Project Title (*limit 81 characters, including spaces and punctuation*):

_____

Principal Investigator Section

PI Name/WSU username/Title: _____
Department: _____ Address: _____
Phone/Fax: _____ Email: _____

Statement of Responsibility: I accept responsibility for the safe conduct of work with the agents described in this application. The information in this application is accurate and complete.

_____ Date: _____
(Signature of Principal Investigator)

Laboratory Personnel Section (use additional sheet if necessary)

The undersigned individual(s) are involved in this project and have read this application. Please use your WSU username (for example, w001xyz) in the appropriate section.

1. Name:	username:	Title:
Signature:	Date:	Contact:

2. Name:	username:	Title:
Signature:	Date:	Contact:

3. Name:	username:	Title:
Signature:	Date:	Contact:

4. Name:	username:	Title:
Signature:	Date:	Contact:

5. Name:	username:	Title:
Signature:	Date:	Contact:

Biosafety Officer Section

I have reviewed this application and found it be suitable for IBC review:

Name: _____

_____ Date: _____
(Signature of Biosafety Officer)

PI Name: _____

1. Project Location(s) (Room/Bldg):

2. Animal Use? ☐ Yes ☐ No
AUP# Date:

3. Human Subjects? ☐ Yes ☐ No
HSP/SC# Date:

4. Select Agent Use? ☐ Yes ☐ No
If Yes, STOP here and contact the Institutional Biosafety Officer.

5. Which of the following biological agents will be used? (check all that apply)

- ☐ Recombinant DNA (rDNA)
- ☐ Nonrecombinant DNA/RNA or Prions
- ☐ Biological Toxins
- ☐ Tissue or Cell Culture
- ☐ Human or Non-Human Primate Tissue
- ☐ Microorganisms

6. What level of biocontainment will be used?
☐ BSL-1 ☐ BSL-2 ☐ BSL-2+ ☐ BSL-3

7. Recombinant DNA Section (Not Applicable ☐, next section):
   a. Are your activities exempt? ☐ Yes ☐ No
   Refer to: http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html (note exceptions)
   If Yes, list exemption category: Select _____
   If category is III-F-6, list system: Select _____
   b. Will you express any drug or immunological resistance genes? ☐ Yes ☐ No
   If Yes, list: _____
   c. Will you express any oncogenic or pathogenic genes? ☐ Yes ☐ No
   If Yes, list: _____
   d. Will you express any toxins? ☐ Yes ☐ No
   If Yes, list: _____
   e. Will you express any microorganisms or prions? ☐ Yes ☐ No
   If Yes, list: _____

   f. Please select the NIH category for your rDNA experiments.
   Refer to: http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html for complete details.
   The descriptions in parentheses are provided only as a guide.

   - ☐ Section III-A (Transfer of drug resistance genes into microorganisms that are not known to acquire the trait naturally)
   - ☐ Section III-B (Cloning of toxins with LD_{50} < 100 ng/kg body weight)
   - ☐ Section III-C (Transfer of rDNA, DNA, or RNA derived from rDNA into human subjects)
   - ☐ Section III-D (rDNA from Risk Group 2, 3, 4, or restricted agents as vector systems; Infectious or defective DNA or RNA viruses; Whole animals and plants; Large volumes)
   - ☐ Section III-E (rDNA involving < 2/3 of the genome of any eukaryotic virus in the absence of helper virus or plasmids; Whole plants; Transgenic rodents)

PI Name: _____

7. Recombinant DNA Section (continued):
   g. Complete table below using one column per construct (deletion or mutation series of a gene may be listed in one column; use additional sheet if necessary).

	Construct 1	Construct 2	Construct 3	Construct 4	Construct 5	Example
Name and Provider of Gene						Example: green fluorescent protein from Clontech
Gene Function						Example: marker
Vector Name						Example: pKH-WSU24
Vector Type / Species and Strain						Example: Viral / Adenovirus serotype 5
Expression control elements (promoters, enhancers, etc)						Example: CMV promoter
Conc/titer of rDNA (i.p./ml)						Example: 1 X 10^8 to 1 X10^{12} infectious particles/ml
Host and Strain, if applicable						Example: E. coli, Sure™, Mouse heart cells, in vivo
Largest Production Volume of Host						Example: 1 liter
Host Range (including any genetic alterations to host range)						Example: amphotropic, broad mammalian host range
Is recombinant made in your lab? If not, where?						Example: Vanderbilt Univ. Gene Therapy Center
If vector is a genome, what % has been deleted or substituted?						Example: 10%

PI Name: _____

8. Nonrecombinant or Synthetic DNA/RNA; Prions Section (Not Applicable ☐, next section)

a. Are you handling DNA or RNA from pathogenic microorganisms? ☐ Yes ☐ No
If Yes, list: _____

b. Are you handling oncogenic DNA sequences? ☐ Yes ☐ No
If Yes, list: _____

c. Are you handling DNA containing drug resistance genes? ☐ Yes ☐ No
If Yes, list: _____

d. Are you working with any prions? ☐ Yes ☐ No
If Yes, complete the following table (use additional sheet if necessary):

Name of Prion	Pathogenic PrP Isoform	Disease	Natural Host

e. If Yes to ques. 8a-d, please list the provider(s) of the agents:

f. If Yes to ques. 8a-d, please explain what safety steps you will take to avoid percutaneous and mucous membrane exposure of laboratory personnel and contamination of the environment

g. If Yes to ques. 8a-d, what types of sharps will be used and how will they be disposed of?

9. Toxins Section (Not Applicable ☐, next section):

a. Are you handling toxins of biological origin? ☐ Yes ☐ No
If Yes, list the name and provider of toxin(s):

_____

b. In what form is the toxin(s) received? _____

c. Will you reconstitute the toxin(s)? ☐ Yes ☐ No
If Yes, describe: _____

d. What is the highest concentration with which you will work or possess?

_____

e. What is the LD_{50} expressed in ng per kg body weight?

_____

f. Do you agree to comply with Appendix I of BMBL, which includes maintaining an inventory system, secure storage, and proper use of primary and secondary containment? See: http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm ☐ Yes ☐ No

PI Name: _____

10. Tissue and Cell Culture Section (Not Applicable ☐, next section):

Tissues/Cells	Provider	Catalog Number	Type	Infectious Agents? (List)	BSL
			Select		
			Select		
			Select		
			Select		
			Select		
			Select		
			Select		
			Select		
			Select		
			Select		
			Select		
			Select		
			Select		
			Select		
			Select		

Use additional sheet, if necessary

11. Human or Non-human Primate Tissue Section (Not Applicable ☐, next section):

a. Are you handling human or nonhuman primate tissue or fluids? ☐ Yes ☐ No
If Yes, list (include species):

b. What is the source and provider of the tissue(s)?

c. Are the tissues known or suspected to be infected? ☐ Yes ☐ No
If Yes, describe:

d. Has your staff taken the blood borne pathogen program? ☐ Yes ☐ No
If Yes, list names and dates:

12. Microorganism Section (Not Applicable ☐, next section):

a. Which category of microorganism is being used? (check all that apply)

☐ Bacteria ☐ Fungi ☐ Protozoa
☐ Archaea ☐ Unicellular Algae ☐ Parasitic Worms
☐ Virus

PI Name: _____

12. Microorganism Section (Continued):

b. List each agent and its risk group, biosafety level, and provider (use additional sheet if necessary). Refer to http://www.absa.org/resriskgroup.html for details.

Agent (genus, species, strain)	Risk Group	BSL	Provider

c. Are you producing or receiving vector virus? ☐ Yes ☐ No

If yes, please describe any safety features that prevent the generation of recombinant virus and methods of safety testing that have been performed or will be conducted:

13. Safety Equipment Section

Biological Safety Cabinet(s)? ☐ Yes ☐ No

Cabinet #1 Type: _____
Location: _____
Certification Date: _____

Cabinet #2 Type: _____
Location: _____
Certification Date: _____

Cabinet #3 Type: _____
Location: _____
Certification Date: _____

Sterilizer Available? ☐ Yes ☐ No

Type: _____
Location(s): _____

Hand washing sink available? ☐ Yes ☐ No

Location(s): _____

Personal Protective Equipment Used (list):

PI Name: _____

14. Safety Procedures Section

a. Will you work with biohazardous agents in any of the following aerosol-producing devices or procedures? ☐ Yes ☐ No (check all that apply)

☐ Aspirators ☐ Intranasal Inoculation ☐ Pressurized Vessels
☐ Blenders ☐ Large Volumes (≥10L) ☐ Shakers
☐ Centrifuges ☐ Necropsy ☐ Sonicators
☐ Homogenizers ☐ Pipetting Infectious Liquids ☐ Vortexers
☐ Other, please list: _____

If Yes to any of the above, describe how you will contain the aerosol:

_____

If using sonicator, how will you provide hearing protection to all workers in the area?

_____

b. Do you concentrate the biohazardous agents? ☐ Yes ☐ No (check all that apply)

☐ Centrifugation ☐ Filtration ☐ Precipitation
☐ Other, please list: _____

If Yes, which agent is being concentrated? _____

c. Are you using a vacuum supply with the biohazardous agents? ☐ Yes ☐ No

If Yes, which agent is being used? _____

If Yes, select method for protecting the vacuum source: Select _____

d. At any time during the procedures, will biohazardous agents be moved from a higher safety level to a lower one? ☐ Yes ☐ No

If Yes, provide a justification and describe method of inactivation for this step:

e. How do you generally inactivate the biohazardous agents described in this application?

f. How do you disinfect surfaces in the laboratory?

15. Waste Generation Section

a. Are you generating biological waste? ☐ Yes ☐ No

Refer to http://www.wright.edu/admin/ehs/documents/APPENDIXD.pdf for definitions.

If Yes, specify type: Select _____

b. Are you generating mixed waste? ☐ Yes ☐ No (check all that apply)

☐ Biological and Chemical Hazard ☐ Biological and Radiological Hazard
☐ Biological, Chemical, and Radiological Hazard

c. Have you notified the Department of Environmental Health and Safety? ☐ Yes ☐ No

PI Name: _____

16. Transport and Transfer Section

a. Will you transport or transfer biohazardous agents? ☐ Yes ☐ No

[*Transport* refers to packaging and shipping these agents by air, land, or sea via airplanes, motor vehicles, boats, or other means. *Transfer* refers to exchanging these agents between laboratories, generally between rooms or buildings within a facility or institute.]

If Yes, describe agents and method of transport or transfer:

_____

b. If transporting agents in my personal vehicle, I accept responsibility for the personal liability I may incur in the event of an accident. ☐ Yes ☐ No ☐ N/A

c. The transport and transfer of biological agents is governed by the Center for Disease Control (CDC) and the Federal Government. Do you agree to comply with the CDC and Federal regulations? ☐ Yes ☐ No ☐ N/A

Refer to http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm (BMBL Appendix C)
Refer to http://hazmat.dot.gov/ for Federal Hazardous Materials Transportation Law.
Refer to "Transporting Infectious Substances Safely" document.

17. Assurances Section. Please answer Yes or No.	
☐Yes ☐No	If required, Material Transfer Agreements (MTAs) will be secured for the above described biohazardous agents transferred to or from Wright State University. MTAs are administered through the Office of Technology Transfer and Development.
☐Yes ☐No	The Principal Investigator is trained for the proposed studies.
☐Yes ☐No	All personnel will receive the appropriate training in regard to safety practices and protective equipment for this work.
☐Yes ☐No	Written experimental procedures will be maintained in the laboratory.
☐Yes ☐No	Laboratory procedures will be in compliance with the *University Chemical Hygiene Plan*, the *Institutional Biosafety Manual*, the OSHA Laboratory Safety Standard, other appropriate OSHA Standards, and the Ohio Revised Code.
☐Yes ☐No	Biological safety cabinets (BSCs) shall be maintained in sound working condition at all times and shall be certified annually and after each move or maintenance procedure. Laboratory personnel are aware of the operational limits of BSCs.
☐Yes ☐No	Chemical fume hoods shall never be used to contain biohazards.
☐Yes ☐No	No employee or researcher will be asked to intentionally consume or otherwise be exposed to a biological agent as part of a research protocol.
☐Yes ☐No	All biological waste will be properly disposed in compliance with Infectious Waste Management Guidelines established by the Department of Environmental Health and Safety.
☐Yes ☐No	As applicable, employees will be offered vaccination, banking of serum or standard body material, and HIV testing. Banked material will be used for detection of compounds or serum conversion in the event of exposure.
☐Yes ☐No	Approval of this application is only for the biohazardous agents and procedures described herein. Any changes to the protocol (e.g., change of organisms, vectors, procedures, personnel, project location, etc.) must be approved by amendment prior to use or implementation.

PI Name: _____

18. Project Summary Section.

    Please provide a brief overview of the proposed research containing sufficient information to ensure adequate review of the protocol to determine compliance with Wright State University's Biosafety Program and local, state, and federal regulations. DO NOT cut and past the specific aims section from a grant application.

    a. Purpose of research (brief);
    b. Assessment of risk to personnel working with the biological agent;
    c. An outline of the procedures and techniques employed;
    d. Description of the safe practices, equipment, and facilities used to protect personnel;
    e. Describe any specific methods of inactivation or disposal of the agent not mentioned above.

Attach additional sheets as necessary.