Indiana University Purdue University at Indianapolis
BIOHAZARD COMMITTEE
Protocol Submission Form
For new protocols or those involving the use of biohazardous agents in research

INSTRUCTIONS:

All submissions – must be typed or completed on the computer. Submit one original signed hard copy of the application to Research and Sponsored Programs, UN 618. If off campus, submit to 620 Union Drive, Room 618, Indianapolis, IN 46202-5167. Call 274-8289 for additional forms and information. Submit an electronic copy of the application either on disk to the address above or email to resrisk@iupui.edu. Keep a copy for your records.

Definition – ň - A biohazardous agent is defined in the IUPUI Biosafety Manual as a pathogen capable of replication and is a disease-causing microorganism (bacterial, Chlamydia, fungi, parasites, rickettsias, viruses, etc.), or is a non-replicating protein (prions) or a biological toxin capable or causing diseases in humans, animals, or plants. For activities involving the use of recombinant DNA, please follow the appropriate application procedures for the Institutional Biosafety Committee found on the Research and Sponsored Programs Website, www.iupui.edu/~resgrad/spon/download2.htm instead of applying to the Biohazard Committee. To register human or primate cell lines only, please use the abbreviated Biohazard Committee Human/Primate Cell Culture Registration Form.

Instructions – This authorization form must be completed by an IUPUI-affiliated PI who currently has or who plans to possess, store, work with or transport infectious agents listed as Biosafety Level 1, 2, or 3 in the IUPUI Biosafety Manual. All work with biohazardous agents must receive authorization by the IUPUI BHC or Biosafety Manager prior to receiving the material or beginning work.

Complete all sections, as appropriate, for the use of infectious agents and select agents and toxins. If medical surveillance is required for your research, ensure that all elements of the program are implemented. Failure to answer each question thoroughly and completely will impede the review process. Please submit all necessary supportive data as necessary.

SECTION I. – GENERAL PROJECT DETAILS

Investigator Name:	Department:
Campus Address:	Phone:
Email:	Fax:
Primary Contact:	Campus Address:
Email:	Phone:

Title of Protocol:

☐ New Study

☐ 5 year resubmission or major amendment
Original study number

☐ Internally funded

☐ Externally funded. Source:

Grant/sponsor number:

☐ Overlaps with another project reviewed by the Biohazard Committee, number

SECTION II. RESEARCH SUMMARY

Please summarize the proposed research. Limit your discussion to one page. Note that "See Attached" with the attachment of a grant narrative is unacceptable. Describe your research in such a way that the language may be understood by persons without expertise in your field. Provide enough information so that Committee members can evaluate the work for the purpose of making a Biohazard risk assessment.

Provide a basic description and rationale for your project.

Describe the source of the agent, an assessment of the biohazardous potential, why the selected organism is the most appropriate for the project, the method of terminal inactivation of the biological agent, your endpoint, and what type of manipulations you plan to use to achieve that goal.

List the room number, containment conditions and transportation procedures. If the experiment is conducted in more than one room, or if different phases are going to be conducted at different Biosafety Levels, describe each component separately, listing containment conditions and transportation procedures specific to each.

SECTION III. LAB PERSONNEL

Name	Title	Years Experience	Responsibilities
	Principal Investigator		

SECTION IV. OTHER INSTITUTIONAL REVIEWS/APPROVALS

☐ Human Subjects Research (IRB)
Protocol number: Most recent approval date:

☐ Animal Research (IACUC)
Protocol number: Approval date:

SECTION V. RISK ASSESSMENT

☐ Whole Plants
Species:

☐ Transactive or infectious proteins
Protein:

Agent:

Cellular Target:

Hazards of Exposure:

☐ Biohazardous Agents/Toxins

☐ Blood or components / Other Potentially Infectious Material (OPIM)

☐ CDC & USDA-regulated materials

SECTION VI. SELECT AGENTS AND TOXINS

☐ I am not using any select agents or toxins ☐ I am using the following selects agents or toxins:

VIRUSES
- ☐ Crimean-Congo (BL-4)
- ☐ Eastern Equine Encephalitis virus (BL-2)
- ☐ Ebola viruses (BL-4)
- ☐ Hendra virus (BL-4)
- ☐ Lassa fever virus (BL-4)
- ☐ Marburg virus (BL-4)
- ☐ Rift Valley fever virus (BL-3)
- South American haemorrhagic fever viruses: (BL-4)
  - ☐ Flexal ☐ Guanarito ☐ Junin ☐ Machupo ☐ Sabia
- Tick-borne encephalitis complex (flavi) viruses: (BL-4)
  - ☐ Central European encephalitis ☐ Far Eastern encephalitis
  - ☐ Russian spring/summer encephailits ☐ Kyasanur forest disease
  - ☐ Omsk hemorrhagic fever
- ☐ Variola major virus (Smallpox virus) (BL-4, Restricted)
- ☐ Variola minor virus (Alastrim) (BL-4, Restricted)
- ☐ Venezuelan Equine Encephalitis virus (BL-3)
- ☐ Cercopithecine herpesvirus 1 (Herpes B virus) (BL-3/4)
- ☐ Monkeypox virus (BL-3, BL-2 if vaccinated)

USDA PATHOGENS
- ☐ African Horse Sickness Virus
- ☐ African Swine Fever Virus
- ☐ Akabane Virus
- ☐ Avian Influenza Virus (highly pathogenic)
- ☐ Blue Tongue Virus (exotic)
- ☐ Camel Pox Virus
- ☐ Classical Swine Fever Virus
- ☐ *Cowdria ruminatum* (heartwater)
- ☐ Foot & Mouth Disease Virus
- ☐ Goat Pox Virus
- ☐ Japanese Encephalitis Virus
- ☐ Lumpy Skin Disease Virus
- ☐ Malignant Catarrhal Fever Virus
- ☐ Menangle Virus
- ☐ Newcastle Disease Virus (VVND) (BL-2)
- ☐ Nipah Virus (BL-4)
- ☐ Peste Des Petits Ruminants Virus
- ☐ Rinderpest Virus
- ☐ Sheep Pox Virus
- ☐ Swine Vesicular Disease Virus
- ☐ Vesicular Stomatitis Virus (exotic) (BL-3)
- ☐ *Mycoplasma capricolum*/ M.F38/*M. mycoides capri*
- ☐ *Mycoplasma mycoides mycoides*
- ☐ Bovine Spongiform Encephalopathy Agent (BL-3)

RICKETTSIAE
- ☐ *Coxiella burnetii* (BL-3)
- ☐ *Rickettsia prowazekii* (BL-3)
- ☐ *Rickettsia rickettsii* (BL-3)

FUNGI
- ☐ *Coccidioides immitis* (BL-3)
- ☐ *Coccidiodes posadasii* (BL-3)

TOXINS (29 CFR 1910.1450 and 1910.1200)
- ☐ Abrin
- ☐ Botulinum neurotoxins
- ☐ C. perfringens ε toxin
- ☐ Conotoxins
- ☐ Diacetoxyscirpenol
- ☐ Ricin
- ☐ Saxitoxin
- ☐ Shigatoxin
- ☐ Shiga-like ribosome inactivating proteins
- ☐ Staphylococcal enterotoxins
- ☐ Tetrodotoxin
- ☐ T-2 toxin

BACTERIA
- ☐ *Bacillus anthracis* (BL-3)
- ☐ *Brucella abortus, B. melitensis, B., suis* (BL-3)
- ☐ *Burkholderia (Pseudomonas) mallei* (BL-3)
- ☐ *Burkholderia (Pseudomonas) psuedomallei* (BL-3)
- ☐ *Clostridium botulinum* (BL-3)
- ☐ *Francisella tularensis* (BL-3 if vaccinated)
- ☐ *Yersinia pestis* (BL-3)

PLANT PATHOGENS
- ☐ *Liberobacter africanus*
- ☐ *Liberobacter asiaticus*
- ☐ *Peronosclerospora philippinensis*
- ☐ *Phakospora pachyrhizi*
- ☐ Plum Pox Potyvirus
- ☐ *Ralstonia solanacearum* race 3, biovar 2
- ☐ *Schlerophthora rayssiae* var *zeae*
- ☐ *Synchytrium endobioticum*
- ☐ *Xanthomonas oryzae*
- ☐ *Xylella fastidiosa* (citrus variegated chlorosis strain)

Many of the USDA Animal and Plant Pathogens have specific bio-containment requirements. Please contact the Biosafety Manager or the USDA for details.

SECTION VII. INFECTIOUS AGENTS AND TOXINS

1. If you checked "Yes" to any of the select agents above, please describe the agents, the quantities in which you will be handling and storing them, the storage locations, security precautions, and the mechanism by which you will ensure their safe usage and disposal:

Agent:
Quantity:
Storage Location:
Security Precautions:
Safety Mechanisms:

2. Please list all microorganisms/cell lines/infectious agents that will be used in this research:

Refer to the most recent NIH guidelines http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html
Or CDC guidelines http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4/toc.htm
Or ABSA Risk Groups http://www.absa.org/resriskgroup.html

Infectious Agent/(Micro)Organism/Cell line/Etc. **NOTE:** Work with human cell lines is considered RG2/BL2	**Source**	**Risk Group (RG1, RG2, RG3, RG4)**	**Biosafety Level**

3. Please check the appropriate physical containment for this protocol.

Refer to the most recent NIH guidelines http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html
Or CDC guidelines http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4/toc.htm
Or ABSA Risk Groups http://www.absa.org/resriskgroup.html

☐ BL1 ☐ BL2 ☐ BL2 w/BL3 practices ☐ BL3

4. Does this project involve large scale (>10 liters of culture) research or production?

☐ Yes, additional guidelines apply. Contact the Biosafety Officer at 274-2830.

☐ No

5. Dual Use Research: Please check any that apply to your study**. If None apply, check here**: ☐

☐ Renders a useful vaccine ineffective.
☐ Enhances pathogen virulence.
☐ Increases pathogen transmissibility.
☐ Adds antibiotic resistance affecting response to a clinically useful drug.
☐ Widens a pathogen's host range.
☐ Lets a pathogen evade diagnostic or detection modalities.
☐ Weaponization. (e.g. environmental stabilization of pathogens)

SECTION VIII. BIOSAFETY LEVELS

1. Biosafety Level 1 or higher: The following guidelines apply to all biological research, regardless of the designated Biosafety Level at IUPUI.

- **a. Handwashing:** Hands must be washed immediately or as soon as feasible after removing gloves or other personal protective clothing.
- **b. Personal Protective Equipment (PPE):** PPE such as gloves, safety glasses and a laboratory coat should be worn whenever biological work is conducted in the laboratory. No sandals are allowed in the laboratory.
- **c. Use of Sharps:** Minimize the use of and exposure to sharps in the workplace. Never recap, bend or shear needles. As often as possible, replace glassware with less damaging materials such as plastic. Keep sharps containers readily available in all locations where sharps waste may be generated. In order to avoid accidental injury, do not overfill sharps containers.
- **d. Food and Beverage:** Eating, drinking, storing food and drink for human consumption, smoking, applying cosmetics or lip balm and handling contact lenses in the laboratory or other work areas is prohibited. This prohibition shall be well posted.
- **e. Aerosol Generation:** Any procedures that could potentially generate aerosols or other inhalation hazards must be performed in a manner that will minimize airborne pathogen transmission.
- **f. Proper Labeling:** Place a color-coded label incorporating the universal biohazard symbol on any potentially contaminated equipment or work surface to warn others of biohazard contamination that may not be easily visible. This includes freezers, refrigerators and incubators.
- **g. Autoclave Safety:** Always wear heat-resistant gloves, goggles or safety glasses, and a laboratory coat when opening an autoclave. Be sure to allow the superheated steam to exit before attempting to remove the contents.
- **h. Spills:** Always clean spills from the periphery of the spill towards the center, after placing paper towels over the spill. Make sure that the cleaning materials are disposed of in an appropriate manner.
- **i. Mouth Pipetting:** Mouth pipetting may lead to accidental ingestion of biological specimens and is strictly prohibited.
- **j. Decontamination Procedures:** A fresh 0.5 – 1 percent sodium hypochlorite (a 1 to 10-20 dilution of household bleach) will be used to decontaminate equipment and work surfaces. In locations where bleach would cause corrosion, an iodophor (e.g., Wescodyne) will be used to decontaminate.
- **k. Local Transport of Infectious Materials:** All infectious materials transported to and from the laboratory will be enclosed in a primary container with a sealed lid or top, which will then be enclosed in a secondary leak-proof, rigid container (e.g., a Coleman cooler) appropriately labeled with biohazard symbol. A responsible lab employee shall escort any specimens transported to and from off-campus satellite facilities. Packaging and labeling must comply with the IATA dangerous goods or DOT hazardous materials regulations.
- **l. Storage:** All infectious materials to be stored will be clearly labeled with the universal biohazard symbol as will the storage space (e.g., freezers and refrigerators).
- **m. Bloodborne Pathogens:** All PIs using human blood or blood products, unfixed tissue, body fluids or organ or cell cultures of human origin will follow the procedures outlined in the IUPUI Bloodborne Pathogen Exposure Control Plan.
- **n. Transport of Select Agents/Toxins:** EH&S must be notified of all transfers or shipments off campus.

Are there proposed deviations from these standard procedures?

☐ **Yes, describe**

☐ **No**

2. Biosafety Level 2 or higher: The following statements apply to research at Biosafety Level 2 or higher and must be completed by the Principal Investigator. Check all that apply.

a. Agent Hazard:
Agent(s):
Pathway(s): ☐ skin contact ☐ eye contact ☐ inhalation ☐ ingestion ☐ injection ☐ N/A
Dangers:

b. Laboratory Access:
☐ Limited to personnel directly involved with research and who have been trained on protocol
☐ Locked laboratories with limited public access
☐ Other

c. Personal Protective Equipment and Practices:
☐ Lab Coats ☐ Latex gloves ☐ Face shield ☐ Safety glasses ☐ Masks ☐ Biosafety cabinet
☐ Other

d. Surveillance for infections:
☐ Sero-testing ☐ Baseline serum sampling ☐ N/A ☐ Other
Describe program

e. Disinfection procedures: (Note: solutions from stock concentrations must be assigned an expiration date)
☐ 10% bleach (<24 hours old) ☐ 70% ethanol ☐ 1% SDS ☐ Iodophor ☐ Cidex ☐ Other

f. Disposal methods:
☐ Animals: animal carcasses will be disposed of by the LARC facility.
☐ Solid biohazardous waste: will be autoclaved prior to disposal
☐ Liquid biohazardous waste: will be treated with bleach prior to disposal
☐ Other

g. Oversight: Day-to-day supervision of laboratory operations and personnel in PI's absence
Name/Campus address/phone:

h. Transportation of animals:
☐ Conducted in approved cages and only with animals directly involved with the research performed
☐ Other
☐ Not applicable

i. Transportation of Biohazardous Materials:
☐ Labeled, rigid, leakproof containers
☐ Other
☐ Not applicable

j. In case of emergency, call:
Name/number:

k. Aerosol containment:
☐ Vortexing/mixing/centrifugation performed in tightly capped tubes
☐ Centrifugation performed in aerosol containment capsules for BL3 containment
☐ Pipetting or other procedures performed in Biosafety cabinet
☐ Other
☐ Not applicable

3. BL3 Facility Biocontainment Procedures (if applicable). Describe in detail the specific physical and technical aspects of containment for the proposed BL3 research.

4. Health Surveillance/Immunization Programs

If you are working with any of the agents listed below, you must develop an appropriate health surveillance and/or immunization program for the safe conduct of your protocol. If you need assistance, please contact the Biosafety Officer at 274-2830.

The following IUPUI health surveillance immunization programs/requirements will be implemented:

Bloodborne Pathogens: HBV vaccination and declination form, post-exposure follow-up, treatment at no cost to employees, initial BBP training and annual retraining and universal precautions. This training must be offered when human cell lines or human infectious agents are employed. ☐ Yes ☐ N/A

Orthopoxviruses (vaccinia and others): Medical screening, vaccination and contraindication awareness and training ☐ Yes ☐ N/A

Serum sample banking: Consult with Environmental Health and Safety ☐ Yes ☐ N/A

If a custom health surveillance/immunization program will be in effect, please attach a one-paragraph description of this program. Be sure to consult Employee Health Services first.

SECTION IX. INVESTIGATOR STATEMENT

The Principal Investigator is responsible for providing adequate training and supervision of staff in microbiological techniques and practices required to ensure safety and for procedures in dealing with accidents. The investigator is responsible for enforcing federal regulations regarding laboratory safety for all persons who work under his/her direction. The investigator is responsible for correcting work errors and conditions that may result in the release of biohazardous materials or infectious agents and ensuring the integrity of the physical containment. Any work related injury or exposure must be reported to Occupational Health Services. The investigator is also responsible for ensuring that co-investigators, if any, employ the necessary safeguards to protect laboratory personnel, students, and the community from potential hazards posed by the project. The investigator must ensure that staff has read this protocol and the Biosafety manual.

I certify that I have read the above statements and agree that I and all listed participants will abide by those statements as well as all IUPUI policies and procedures governing the use of infectious agents and other biological materials as outlined in this application and in the IUPUI Biosafety Manual. In addition, I will:

- Abide by the General Duty Clause of OSHA and take full responsibility to ensure that listed personnel have received or will receive appropriate training in safe laboratory practices and procedures for this protocol before any work begins on this project and at least annually thereafter. Also, all listed personnel who have occupational exposure to bloodborne pathogens will be trained annually;
- Follow the health surveillance practices as approved for this protocol and inform those working on the protocol about appropriate emergency assistance information for their location(s);
- Inform Employee Health Services of any research-related accident or illness as soon as possible after its occurrence;
- Submit in writing a request for approval from R&SP of any significant modifications to the study, facilities or procedures; and;
- Adhere to IUPUI Biosafety guidelines referred to in this application as well as comply with the requirements of the Biosafety Manual.

I understand my responsibility with regard to laboratory safety and certify that the protocol as approved by the BHC will be followed during the period covered by this research project. Any future changes will be submitted for BHC review and approval prior to implementation.

Minor changes, such as adding co-investigators, cell lines, or transgenic animals may be submitted by downloading the amendment form from the IUPUI R&SP website at http://www.iupui.edu/%7Eresgrad/spon/amendmen.rtf and submitting a minor amendment to the BHC.

Major changes, such as adding new infectious agents or upgrading Biosafety levels may require a new application.

I understand that this protocol will be reviewed periodically; it is my responsibility to complete and submit the survey form used for the periodic BHC review in a timely manner.

Signature of Investigator:	Date:
Signature of Authorized BHC Representative:	Date:
Signature of Biosafety Officer:	Date: