IBC Study No. [Assigned by RCA Office]

Indiana University Purdue University at Indianapolis
INSTITUTIONAL BIOSAFETY COMMITTEE
Protocol Submission Form
For new protocols or those involving the use of recombinant DNA in research

INSTRUCTIONS:
All submissions must be typed. Submit to: Sponsored Research Services, Research Compliance Administration, via email to resnew@iupui.edu. Call 274-8289 for additional forms and information. Keep a copy for your records.

SECTION I. – GENERAL PROJECT DETAILS

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

Title of Protocol:

Funding: ☐ Internally funded

☐ Externally funded. Source:
Grant/sponsor number:

Type of Proposal:

☐ New Study
☐ 5 year resubmission or major amendment
Original study number:
☐ Overlaps with another project reviewed by the Institutional Biosafety Committee, number

Other Institutional Reviews/Approvals Related to this Protocol:

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

☐ Animal Research (IACUC)
☐ Previously approved:
Protocol number: Most recent approval date:

☐ Pending
Date submitted:

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.

Provide a basic description and rationale for your project.

Describe what systems you plan to use, including your endpoint and what type of manipulations you plan to use to achieve that goal. If applicable, incorporate a description of any animal work, including athymic and syngeneic animals which will be used for research purposes.

List the building and room numbers where the research will be conducted. 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 lab numbers and procedures specific to each.

SECTION III. ABBREVIATIONS

Include a list of abbreviations (with definitions) that are used in this study application.

Abbreviation	Definition

SECTION IV. LAB PERSONNEL

Name	Title	Responsibilities	Signature*
	Principal Investigator		Email submission must be sent from or copied to the PI's University email account. This will serve as an electronic signature.

*** Personnel must provide the IBC with documentation that they have read the proposal. This can be accomplished by having each individual submit an email to the IBC (resgen@iupui.edu) acknowledging their participation in the protocol.**

SECTION V: REGULATORY CONSIDERATIONS

Please choose the appropriate section(s) of the *NIH Guidelines* (http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm) under which your research falls (check all that apply):

III-A: Experiments that require IBC approval, RAC review, and NIH Director approval before initiation

- ☐ III-A-1-a: The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromised the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. (Note that antibiotic resistance markers used for selecting and propagating plasmids in *E.coli* are not included)

III-B: Experiments that require NIH/OBA and IBC approval before initiation

- ☐ III-B-1: Experiments involving the cloning of toxin molecules with LD50 of <100ng per kg body weight

III-C: Experiments that Require IBC, IRB, and RAC review before research participant enrollment

- ☐ III-C-1: Experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from rDNA, into one or more human research participants

III-D: Experiments that require IBC approval before initiation

- ☐ III-D-1: Experiments using Risk Group (RG) 2, 3, 4, or restricted agents as host-vector systems
- ☐ III-D-2: Experiments in which DNA from RG 2, 3, 4, or restricted agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems
- ☐ III-D-3: Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA Viruses in the presence of helper virus in tissue culture systems
- ☐ III-D-4: Experiments involving whole animals
- ☐ III-D-5: Experiments involving whole plants
- ☐ III-D-6: Experiments involving >10 liters of culture

III-E: Experiments that require IBC notice simultaneous with initiation

- ☐ III-E-1: Experiments involving the formation of rDNA molecules containing no more than two-thirds of the genome of any eukaryotic virus
- ☐ III-E-2: Experiments involving whole plants
- ☐ III-E-3: Experiments involving transgenic rodents

Appendix K: Physical containment for large scale uses of organisms containing recombinant DNA molecules

- ☐ K-III, BL1
- ☐ K-IV, BL2
- ☐ K-V, BL3

☐ Appendix M: Points to consider in the design and submission of protocols for the transfer of recombinant DNA molecules into one or more human participants

☐ Appendix P: Physical and biological containment for rDNA research involving plants

☐ Appendix Q: Physical and biological containment for rDNA research involving large animals

☐ Other:

SECTION VI. RISK ASSESSMENT
Choose all that apply.

☐ Whole Plants
Species:

☐ Transactive or infectious proteins; http://www.iupui.edu/%7Eresgrad/spon/min-tat.htm
Protein: Agent:

Cellular Target: Hazards of Exposure:

☐ Prion protein
- ☐ Review, sign and return the following with the completed application: http://www.iupui.edu/%7Eresgrad/spon/prion_forms.pdf
- ☐ Human-derived prion or BSE = Biosafety Level 3 containment
- ☐ Prion research without above components = Biosafety Level 2 containment

☐ This project involves transgenic/knockout/knockin animals:
- ☐ Purchase or transfer of animals only at Biosafety Level 1 – **PROCEED TO SECTION VI**
- ☐ This project involves transgenic/knockout/knockin animals as well as other recombinant materials – **COMPLETE ENTIRE APPLICATION.**
- ☐ This project involves transgenic/knockout/knockin animals as well as human or primate cell lines (no other recombinant materials) – **COMPLETE SECTIONS VII, X, XI, XII. A LABORATORY INSPECTION FROM THE BIOSAFETY OFFICER WILL BE REQUIRED.**

☐ This project involves infectious agents, plasmid and/or viral vectors (no transgenic/knockout/knockin animals) – **PROCEED TO SECTION VIII**

☐ This project involves human gene therapy - **PROCEED TO SECTION VIII. SUBMIT INFORMED CONSENT STATEMENT(S), RESPONSES TO APPENDIX M, POINTS TO CONSIDER IN THE *NIH GUIDELINES* (http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm), AND ANY APPENDICES WITH THE SUBMISSION**

SECTION VII. TRANSGENIC/KNOCKOUT/KNOCK-IN ANIMAL STUDIES

List the specifics regarding each animal strain utilized for this research project.

Strain	Vendor/ Origin	Gene product[1]	Knockout (KO), Knock-In (KI) or Transgene (T)	Oncogenic? (yes/no)	Potential Hazard? (Yes[2]/No)	TAT fusion? (Yes[3]/No)	Knock-out of gene product or transgene			
							Tissue specific? (Yes/No)	Regulatable (R) / Conditional (C)	Inducing agent? (Yes/No)	Hazards? (Yes[4]/No)

[1] **Most work with transgenic, knock-in and knockout animals will be conducted at Biosafety Level 1. However, certain vectors used to produce the transgenic or knockout may necessitate a higher Biosafety level (e.g., transgenic mice derived from lentivirus-based vectors). If this is the case, please list the gene product/vector and its associated higher Biosafety level:**

[2] **Describe potential hazard for any gene product (if marked "Yes" above):**

[3] **Describe TAT fusion for any gene product (if marked "Yes" above):**

[4] **Describe hazards of the knockout of the gene product or transgene (if marked "Yes" above):**

Does this project also involve the use of infectious agents, plasmids, and/or viral vectors?

☐ **Yes – Proceed to Section VIII.**

☐ **No – Proceed to Section XI.**

SECTION VIII. 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 IX. RECOMBINANT DNA/VECTOR STUDIES

1. Please describe the species/source of rDNA(s):

☐ Organism Literature citation if available:

☐ Clone bank Literature citation if available:

2. Please list and describe the nature of the rDNA(s):

Genes/Genomic DNA/cDNA/Other	Mutated Gene (yes/no)?	Oncogene (yes/no)?	Potentially Harmful (explain)?

3. Does this study involve the use of human gene therapy?

☐ No. Continue to question 4.

☐ Yes, attach responses to Appendix M from the NIH Guidelines, "Points to Consider," http://www4.od.nih.gov/oba/rac/guidelines_02/APPENDIX_M.htm#_Toc7255836, the informed consent statement(s), and 4 copies of all appendices (see Instructions, page 1).

3a. Does this study involve cancer-related gene therapy?

☐ Yes, submit to the Scientific Review Committee (SRC), http://iucc.iu.edu/intranet/forms/SRC/SRC_Guidelines_and_Routing_Sheet-2005_02_10.doc and attach approval.

☐ No

3b. Does this study involve non-cancer-related gene therapy?

☐ Yes, submit to the GCRC Advisory Committee, http://www.gcrc.iupui.edu/

☐ No

4. Will the experimental procedures involve the deliberate transfer of a drug resistance trait to microorganisms which may compromise the use of drugs commonly used to control disease in humans, veterinary medicine, or agriculture?

☐ No

☐ Yes, describe

5. Are adenoviral or retroviral vectors used in this study? Note: Attach maps for any non-commercial or custom-made viral vectors, or when changes have been made to the vector backbone.

☐ None of the above - continue to question 6.

☐ Adenovirus, describe
*Note that adenoviruses are always considered replication competent due to the environmental concerns and the wide propensity of wildtype serotypes; therefore, they must be handled at Biosafety Level 2.

☐ Retrovirus, describe
Is it considered replication competent?
☐ Yes
☐ No, describe validation tests to confirm replication incompetence

5a. Are you using any helper viruses or packaging cell lines?
☐ No

☐ Yes, describe

6. Are plasmid vectors used in this study? Note: Attach maps for any non-commercial or custom-made plasmid vectors, or when changes have been made to the vector backbone.
☐ No

☐ Yes, describe

7. Does the vector expand the host's range (is the product now potentially infectious in other organisms or cells not normally infected)? Note: antibiotic resistance markers used for selecting and propagating plasmids in *E. coli* are not included.
☐ No

☐ Yes, describe

8. Does this project involve large scale (>10 liters of culture) research or production?
☐ No

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

9. Are you using a lentiviral vector system?

☐ No. Continue to Section X.

☐ Yes, check the appropriate box to indicate how you will acquire the lentiviral vector (a 3rd generation system is encouraged):

- ☐ The vector will be produced in the IU Vector Production Facility
- ☐ The vector will be produced in my laboratory
- ☐ The vector will be obtained from outside supplier/vendor. Source:

☐ I have reviewed the following NIH Guidance:
http://www4.od.nih.gov/oba/rac/Guidance/LentiVirus_Containment/pdf/Lenti_Containment_Guidance.pdf

Risk Assessment:

A. Containment (choose all that apply):

- ☐ BL2: Cell culture work, delivery into animals
- ☐ BL2: Non-pathogenic/non-oncogenic gene inserts
- ☐ BL2 w/BL3 practices: Pathogenic/oncogenic gene inserts, use of sharps, large scale research (>10L)
- ☐ BL2 w/BL3 practices: Injection of lentivirus or lentivirus-transduced cells into animals engrafted with human cells that will not be tested for RCL
- ☐ BL2 w/BL3 practices: Any lentivirus that will not be tested for replication competence

B. Potential for generation of RCL (choose one):

- ☐ Not applicable (describe)
- ☐ Lentivirus-transduced cells intended for injection into animals engrafted with human cells
- ☐ Lentivirus intended for injection directly into animals.
- ☐ Utilization of other than 3rd generation lentivirus

1. If performing RCL testing, indicate how the RCL testing will be performed (choose one):
   - ☐ ELISA-based commercially available test kits
     - ☐ PI laboratory to perform (NOTE: please contact the Lentiviral Vector Core prior to test for quality assurance purposes)
     - ☐ Lentiviral Vector Core to perform
   - ☐ Certified Replication incompetent by supplier (NOTE: Certificates of analysis may be subject to audit and therefore must be retained by the investigator)
   - ☐ Other:

C. Animal Studies (choose one):

- ☐ Not applicable
- ☐ Animals engrafted with human cells or animal hosts that are permissive for HIV-1 replication maintained at **BL2 w/BL3 practices** containment (tissue harvesting).
- ☐ Following vector delivery, the containment level will be reduced from **BL2** to **BL1** (NOTE: The virus must be confirmed replication incompetent prior to injection)**.**

SECTION X: INFECTIOUS AGENTS AND PHYSICAL CONTAINMENT

1. Please list all (micro)organisms/cells/whole animals/plants/cell lines/infectious agents that will be used in the 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/Cells/Whole Animal/Cell line/Etc. **NOTE:** Work with human or primate cell lines is considered RG2/BL2	**Source/Vendor**	**Risk Group (RG1, RG2, RG3, RG4)**	**Biosafety Level (BL1/BL2/ BL2w/BL3 practices/BL3)**

2. Please check the highest 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

SECTION XI. 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: Applicable to research at Biosafety Level 2 or higher. Check all that apply.

a. Agent Hazard:
Agent(s):
Pathway(s): ☐ skin contact ☐ eye contact ☐ inhalation ☐ ingestion ☐ injection ☐ N/A
Potential 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:
In case of emergency, call: Name/number:
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. 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. Additional precautions to be implemented for BL2 w/BL3 practices risk assessment (e.g., due to lentivirus).

☐ Check here if the following BL2 w/BL3 practices containment precautions will be implemented

1. All pipetting involving the agent shall be performed in a Class II Biological Safety Cabinet (BSC).
2. All vortexing of materials shall be performed using sealed containers and only within a Class II BSC.
3. All small animal work involving the agent(s) shall be performed within a Class II BSC. This includes, but not limited to, injections, necropsy, surgery, tissue removal and cellular manipulations.
4. All centrifugation of agents and/or unfixed animal material shall be done using aerosol resistant buckets. These buckets should only be opened and loaded within a Class II BSC.
5. The PI is responsible for developing laboratory SOPs and training laboratory staff in specific procedures.
6. No plants shall be allowed in the laboratory.
7. Attention to sharps; use of safety needles when possible
8. Use of personal protective equipment intended to reduce the potential for mucosal exposure

4. Health Surveillance/Immunization Programs

Please respond appropriately regarding the following programs:

If you are working with any of the agents listed below, you must develop an appropriate health surveillance and/or immunization program for laboratory associates to ensure 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:

☐ **Human/Primate Cell Lines, Biological Products, or Other Infectious Agents:**
Bloodborne Pathogens training: HBV vaccination and declination form, post-exposure follow-up, treatment at no cost to employees, initial BBP training and annual retraining and universal precautions.

☐ **Orthopoxviruses (vaccinia and others):**
Medical screening, vaccination and contraindication awareness and training

☐ **Human disease-causing agents:**
Serum sample banking: Consult with Environmental Health and Safety

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.

Please include any additional information that you feel the Board should consider in reviewing your application.
Do not exceed one page.

SECTION XII. 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 rDNA materials, 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, the IBC and the NIH OBA of any research-related accident or illness as soon as possible after its occurrence as per *NIH Guidelines* Section IV-B-2-b-7;
- Submit in writing a request for approval from the IBC 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 IBC will be followed during the period covered by this research project. Any future changes will be submitted for IBC 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 IBC. Major changes, such as adding new infectious agents, changing organisms or transgenes which require a review of the risk assessment per *NIH Guidelines* Section II-A-3, or upgrading Biosafety levels may require a new application.

To ensure that the IBC has the most current information when reviewing a study, it has established a 5-year re-review policy for on-going non-exempt IBC studies. The policy requires principal investigators (PIs) to submit a new application to the IBC at the time of continuing review every 5 years the study remains open. I understand that this protocol will also be reviewed periodically; it is my responsibility to complete and submit the survey form used for the periodic IBC review in a timely manner. I will resubmit a full application every 5 years as is IBC policy.

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