UAMS INSTITUTIONAL BIOSAFETY COMMITTEE PROTOCOL FORM

for the use of Infectious Agents, Recombinant DNA, and Highly Toxic Materials

Institutional Biosafety Committee (IBC)/Occupational Health & Safety (OH&S)/Biosafety Division
Return completed form to OH&S/Biosafety Division as an email attachment to: IBC@uams.edu
Check the IBC website for the newest version of this form. New protocols that are submitted on an outdated version of the form will be administratively rejected without review.

I. REGISTRATION INFORMATION

Principal Investigator (PI): _____

Department: _____

Office phone: _____

Lab phone: _____

Email address: _____

Protocol Type: Check which applies	
New	
Amendment	
Yearly Renewal	

Protocol Title: _____

_____

II. BIOSAFETY NARRATIVE FOR THE PROPOSED PROJECT(S):

In lay terms, describe the project workflow and highlight the biosafety-relevant activities. *Do not directly paste the specific aims from a grant proposal into the space below*. Be sure to include the following information:

- General location where work is performed. Identify laboratory, animal facility, core facility, etc., as opposed to building or room number.
- General types of experiments or procedures to be performed (e.g., sample manipulation, cell culture, animal work, etc.).
- Biosafety-relevant activities include recombinant DNA, infectious agents, patient samples, organs, tissues, cell cultures, laboratory animals, and hazardous chemicals used in animals or core facilities. See Section V for more detail about biosafety-relevant activities.

III. RESEARCH FACILITIES

Location: Where are experiments performed? What is the biosafety level (BSL) of each room? Does the location have containment equipment [e.g., biological safety cabinets (BSCs), fume hoods, etc.]? **Note:** The IBC requires prior notification via written amendment for any change that affects containment (including location of laboratory or BSCs).

Building	**Room Number**	**Biosafety Level** (BSL-1, -2, or -3)	**Use of Room** (Animal housing, laboratory, surgery, necropsy, etc.)	**Protective Equipment** (Autoclave, BSC, fume hood, other)	**Protective Equipment Certification date(s)**

IV. LABORATORY/ADMINISTRATIVE PERSONNEL

List **ALL** personnel involved with research in this protocol, including investigators, students, and staff. Denote (bold and asterisk) the laboratory supervisor or staff member OH&S should contact about this protocol. The PI of the application must be included. The IBC must be notified via written amendment when personnel changes occur.

Last Name, First Name	**Job Title**	**Phone Number**

V. RESEARCH ELEMENTS (Complete only sections that apply.)

- **Complete Section A for work involving recombinant DNA (rDNA).**
- **Complete Section B for work involving infectious agents.**
- **Complete Section C for work involving patient samples, organs, tissue, or cell cultures (OTCC).**
- **Complete Section D for work involving vertebrate or invertebrate animals or plants.**
- **Complete Section E for work involving highly toxic chemicals used to elicit a biological response.**

A. Recombinant DNA: Subject to the most current version of the *NIH Guidelines for Research involving Recombinant or Synthetic Nucleic Acid Molecules*. Human gene therapy studies must address Appendix M of the *Guidelines*. Reports of adverse events attributed to human gene transfers must be submitted to OH&S/Biosafety Division. The IBC requests a copy of reports submitted to the Institutional Review

Board (IRB). List microbes (bacteria, virus, fungi, prion, parasite) used to propagate plasmids as a source of rDNA and vectors or produce foreign proteins in Section V.B.

A.i. Gene Source(s): List genes to be transferred and genes conferring antibiotic resistance. Include genes in plasmids or vectors generated in your laboratory or acquired from other sources (academic, commercial, etc.). Provide details for higher hazard genes (e.g., toxins, oncogenes, antibiotic resistance genes, etc.). Lower hazard genes such as housekeeping genes may be grouped into categories with representative examples given.

Gene Source(s) (Genus and species, strain)	**Gene Name** (Explain acronyms, e.g. GFP - green fluorescent protein)	**Nature of Insert or Protein Expressed** (Toxin, antibiotic resistance/selection marker, virulence factor, reporter, oncogene, transcription factor, etc.)	**Use of Construct** (Cloning, PCR, expression in a microbe, tissue culture, or an organism)

A.ii. Vectors: Provide details for representative examples of each category of vector. It is not necessary to provide details for every construct. Categorical descriptions used to assess risks are acceptable.

Gene Transfer Method (Transfection, transformation, transduction, etc.)	**Vector**	**Biosafety Level**	**Vector Function** (e.g., cloning, protein expression, etc.)	**Risk Attenuation** (e.g., inherent characteristics of the vector that affect biosafety)

A. iii. NIH Guidelines Assessment: Determine the appropriate physical and biological containment for recombinant DNA activities. PIs must thoroughly review the NIH *Guidelines*. Please include citations for recombinant microbes listed in Section B. State the appropriate biological safety level(s) for activities with these rDNA elements. Support your assessment by citing the relevant subsection(s) of the most current version of the NIH Guidelines. Contact OHS/Biosafety Division for assistance in this determination.

Recombinant Material & Activity	**Biosafety Level**	**Guidelines Citation**

B. Infectious Agents/Microbes: Subject to the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* guidelines. List all microbes (bacteria, virus, fungi, prion, parasite). Also include microbes used for transduction, rDNA research, or to produce foreign

proteins. Mark (Y/N) in appropriate categories and specify organisms/cells exposed to microbe. Provide strain designations when possible. Provide additional information on toxins including LD_{50} of the toxin in Section V.E.

Microbe (Genus, species, and strain)	**Biosafety Level**	**Pathogen for Humans, Animals, or Plants?** (Y/N; If Y, indicate which)	**Toxin Production?** (Y/N. If Y, specify toxin)	**Large Scale Production?** (>10 liters) (Y/N)	**Propagation of Plasmids & Vectors or Production of Foreign Proteins?** (Y/N)	**Is the Microbe Generated from Recombinant DNA or Genetically Modified?** (Y/N or Both)	**Administered To:** (e.g., mice, cells, etc.)

C. Organs, Tissue, or Cell Cultures (OTCC): Identify the organism that is the source of the OTCC, the nature of cell lines, and whether the OTCC is modified by rDNA. **Note**: Primary human samples/tissues/cells, established human cell lines, and cells from non-human primates are OTCC, considered potentially infectious, and subject to the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* guidelines. BSL-2 containment is required for handling these materials.

OTCC Source (Genus, species, strain)	**Technical Name of OTCC** (e.g. human whole blood, NIH3T3, HepG2, etc.)	**Passage** (e.g., primary, established)	**Description** (Oncogenic, helper/packaging, immortalized, etc.)	**Recipient of rDNA?** (Transient/stable)	**Intended Use** (Administered to animals, cell culture, etc.)	**Potentially Infectious?** (Y/N)

D. Vertebrates, Invertebrates, or Plants: Identify organisms and mark (Y/N) in appropriate categories. If a microbe is administered to the organism, identify the microbe (genus, species). Indicate if animals are immunocompromised.

Organism (Genus, species, strain)	**Transgenic?** (Provide source and biosafety level)	**Recipient of:**				**Animal Use Protocol?** (Provide AUP #)
		Microbe? (Genus, species)	**rDNA?** (Y/N)	**OTCC?** (Specify)	**Toxic Chemicals/Toxins** (Specify)	

E. Highly Toxic Chemicals and Toxins That Elicit a Biological Response: Identify chemicals that are potential human health hazards. Include routine uses only if the chemical is hazardous (e.g., bromodeoxyuridine, tamoxifen, doxorubicin, etc.) and is used outside the PI's immediate laboratory by non-laboratory personnel (DLAM, imaging facilities, etc.). In Section X, describe precautions used to prevent inadvertent staff exposure when handling these chemicals. Specify organisms/cells exposed to each chemical and where chemical is prepared and administered (e.g., fume hood, BSC, lab bench). Attach relevant safety data sheet(s).

Chemical Name (Avoid acronyms)	**Nature of Chemical** (Carcinogen, mutagen, teratogen, toxin, etc.)	**Where Prepared** (e.g., BSC, fume hood, lab bench)	**Maximum Amount on Hand**	**Administered To:** (e.g., mice, HeLa cells, bacteria)	**Where Administered** (e.g., BSC, fume hood, lab bench)	**Regimen for Dosing Animals: Route of Administration,** (IV, IP, etc.), **Highest Dose, # of Doses**

VI. BIOSAFETY ASSESSMENT

Assess the appropriate physical and biological containment required for infectious agent and rDNA-related activities. Infectious agents include human and non-human primate samples/tissues/cells/cell lines (OTCC), as well as any microbes used. Support your assessment by citing the relevant subsection(s) of the current *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*. Contact OH&S for assistance in this determination. Information regarding rDNA can be found in Appendix J of the BMBL.

Infectious Agent, Material, or Activity	**Biosafety Level**	**BMBL Citation**

VII. EXPOSURE PROPHYLAXIS AND RESPONSE

For each biohazardous material noted in Section V, describe prophylaxis and response procedures for accidental exposure.

Biohazard (e.g., rDNA, pathogen, cell, tissue, patient sample, chemical, etc.)	**Exposure Prophylaxis & Response Procedures** Provide expected response for each biohazard; address potential exposure routes, use of emergency equipment, notification of supervisor and OH&S, completion of Injury and Incident Report, seeking medical attention, etc.

VIII. DISPOSAL AND DISINFECTION

Describe method(s) used to inactivate hazardous materials in your research facility. If a disinfectant is used, state the name, concentration used, and exposure time. **If different methods/disinfectants are used for different agents, specify method for each.** Disposal of medical waste, including sharps, is managed under a contract with Stericycle. UAMS Operational Support Services will collect and dispose of animal tissues and carcasses from DLAM facilities. If other resources/services are used for biohazard disposal, describe them here. OH&S will pick up hazardous chemicals. See the OH&S website for requesting chemical or biohazard waste pickups.

Material to be Disinfected/Inactivated	**Disposal Procedure** (e.g., autoclave, disinfectant type, or picked up for off-site disposal)	**Disinfection/Sterilization Conditions** (Disinfectant concentration & exposure time, autoclave time & temperature, etc.)
Surfaces (counters and equipment)		
Cell lines, human samples/tissues, infected material, rDNA material		
Plastic ware and glass		
Animal bedding/wastes		
Other:		

IX. OTHER REGULATORY REQUIREMENTS

A. USDA/APHIS Permits: The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture regulates plant and animal pests and exotic organisms through a permit process. Permits often have conditions concerning the facility and containment procedures. The OH&S/Biosafety Division can assist with these stipulations. Are materials used in this protocol subject to federal permit requirements?

YES: ☐ **NO:** ☐ If **yes**, provide a copy of current permits.

B. OSHA Bloodborne Pathogens Standard: Research involving human-derived substances (e.g., blood or blood components, tissues, secretions, or human-derived cell lines) are subject to the OSHA *Bloodborne Pathogens Standard*. The UAMS Exposure Control Plan, Parts I and II can be found on the OH&S website at http://www.uams.edu/campusop/depts/ohs/divisions.aspx?listid=bio. The laboratory should have laboratory-specific operating instructions if they vary from the UAMS Exposure Control Plan. Staff should be offered appropriate vaccinations based on recommendations from Student Employee Health (686-6565). Do personnel receive annual bloodborne pathogens training?

YES: ☐ **NO:** ☐

C. Respiratory Protection: Use of certain respirators (e.g., N-95) may require fit testing, training, and medical clearance. For more information, contact OH&S (686-5536). Are staff required to wear respiratory protection?

YES: ☐ **NO:** ☐

D. Animal Experimentation: Do the biosafety aspects of this protocol involve animal experiments? If so, have personnel having contact with animals completed animal use training? If **not**, contact the Division of Laboratory Animal Medicine (686-5255).

YES: ☐ **NO:** ☐

E. Chemical Hygiene Plan: Does your laboratory have a Chemical Hygiene Plan? If **not**, contact Chemical Safety (686-5536).

YES: ☐ **NO:** ☐

F. DOT HazMat Shipping Certification: The U.S. Department of Transportation (DOT) requires personnel involved in shipping hazardous materials to be certified in proper handling of these materials. Is at least one member of your laboratory currently certified to ship and/or transport hazardous materials? If not, contact OH&S (686-5536). If you do not ship hazardous materials, indicate N/A.

YES: ☐ **NO:** ☐ **N/A:** ☐

If Yes, who is certified? Certification date:

G. Human Embryonic Stem Cells in Animals: Animals that receive human embryonic stem cells should not be bred, and investigators who administer human embryonic stem cells to animals need to confirm they will not allow animals to reproduce. Do you handle these materials or perform these procedures?

YES: ☐ **NO:** ☐

If **YES**, initial here to confirm that animals receiving human embryonic stem cells will not be allowed to reproduce:

H. Select Agents: Agents considered to be potential bioterrorism agents are regulated by the CDC and USDA http://www.selectagents.gov/SelectAgentsandToxins.html. Do you plan to use select agent materials in your laboratory?

YES: ☐ **NO:** ☐

If **YES,** identify the agent(s):

If **YES**, are you a select agent-registered user?

YES: ☐ **NO:** ☐

I. Dual Use Research of Concern (DURC): Specific select agents and toxins are subject to US Government DURC policies (http://www.phe.gov/s3/dualuse) and the UAMS DURC committee must review research activities using these agents. Do you plan to use any of the non-attenuated select agents/toxins listed below?

- Avian influenza virus (highly pathogenic), Reconstructed 1918 influenza virus, Ebola virus, Foot-and-mouth disease virus, Marburg virus, Rinderpest virus, Variola major virus, Variola minor virus, *Bacillus anthracis,* Botulinum neurotoxin (in any quantity), *Burkholderia mallei, Burkholderia pseudomallei*, *Francisella tularensis*, toxin-producing strains of *Clostridium botulinum*, or *Yersinia pestis*

YES: ☐ **NO:** ☐

If **YES,** identify the agent(s):

J. Flow Cytometry: The Flow Cytometry Core requires that sorting of unfixed samples containing human cells or rDNA be performed at BSL-2. Do you plan to use the Flow Cytometry Core for analysis of any materials classified as BSL-2?

YES: ☐ **NO:** ☐

X. RESEARCH PROTOCOL DESCRIPTION

Describe precautions used for handling materials in Section V by addressing the following points. Appropriate precautions for biohazardous materials are described in the UAMS Biosafety Manual based on the *BMBL* and *NIH Guidelines for Research Involving Recombinant DNA Molecules*. These documents are available on the OH&S website. Reference materials describing appropriate precautions for handling hazardous chemicals include TOXNET (http://toxnet.nlm.nih.gov/) and the chemical safety data sheet. A detailed manual is required for work under BSL-3 containment. Contact the UAMS Biosafety Officer for information (686-5536). Standard operating procedures (SOPs) may be provided to describe precautions.

A. Laboratory Facilities

i. Describe containment equipment (e.g., BSC, fume hood)**.**	
ii. For what procedures is containment used? What procedures are performed outside containment? What precautions are used when working outside containment?	
iii. Specify safeguards used during procedures that could generate aerosols (e.g., pipetting, aliquoting, flow cytometry, centrifugation, electroporation, etc.).	
iv. Describe precautions used to handle human samples/tissues/cells, human or non-human primate cell lines, potentially infectious materials, and rDNA.	
v. Describe the use of personal protective equipment (PPE) (e.g., eye protection, mask or respirator if required, gloves, lab coat, etc.). If PPE varies by material handled or procedures performed, specify which PPE is used for different procedures.	
vi. Is efficacy testing performed for each disinfection method [e.g., autoclave biological indicator (spore strips) or autoclave tape)]?	
vii. Describe **laboratory-specific** training of personnel for handling hazardous, infectious, or recombinant materials. Training on NIH Guidelines must include verification that the trainee understands recombinant research subject to the Guidelines and research not allowed without approval by the IBC. NIH Guidelines training is mandatory for all PIs and research staff performing rDNA research. **Indicate who provides training, how often it is provided, and how training is documented.**	
viii. Describe methods used to prevent escape of exotic and transgenic organisms into the environment.	
ix. Describe precautions used during transport of hazardous materials between laboratories within a building and between buildings.	
x. Describe precautions used for procedures that involve large volumes of microbe cultures (quantities >10 liters).	

xi. **Describe** signage used to communicate biological and/or chemical hazards in laboratory areas. Include signage content and location (e.g., work area, fume hood, biosafety cabinet, and potentially-contaminated equipment).	
xii. Describe the laboratory spill protocol(s) for hazardous materials.	
xiii. Provide any additional precautions used to mitigate biosafety risks associated with your specific projects.	

B. Animal Facilities

i. Describe containment (e.g., BSC, fume hood) and PPE (e.g., eye protection, mask if required, gloves, lab coat, etc.) used while handling animals that have been administered recombinant materials (rDNA, recombinant cell lines, recombinant microbes, etc.).	
ii. Describe containment, PPE, and safeguards used for aerosol-generating activities (e.g., administration, cage changes, necropsy, etc.) while handling animals that have been administered potentially infectious materials (e.g., microbes, human or non-human primate cell lines, human samples/tissues/cells, etc.).	
iii. Describe containment, PPE, and safeguards used for aerosol-generating activities while handling animals that have the potential to carry a zoonotic disease (e.g., Old World monkeys, pregnant sheep, reptiles, etc.).	
iv. Describe containment, PPE, and safeguards used for aerosol-generating activities while handling animals that have been administered potentially hazardous chemicals (e.g. chemotherapeutic agents, biological toxins, etc.).	
v. Describe methods used to prevent escape of hazardous materials and organisms into the environment.	
vi. Describe precautions used during transport of animals between facilities within a building and between buildings.	
vii. **Describe** signage used to communicate biological and/or chemical hazards in laboratory areas. Include signage content and location (e.g., cage cards, fume hood, BSC).	

viii. Provide any additional precautions used to mitigate biosafety risks associated with your specific projects.	

XI. INVESTIGATOR'S ASSURANCE

1. I confirm that all persons conducting this work at the University of Arkansas for Medical Sciences (to include students, fellows, technicians, collaborators, etc.) have been adequately trained in good laboratory/microbiological practices and aseptic techniques; have received instruction on the specific hazards associated with the work and are aware of the specific safety equipment, practices, and behaviors required during the course of the work and use of the facilities listed in this protocol. I also confirm that I will keep records of training for my personnel.

2. I will immediately report to the Biological Safety Officer any spill of biohazardous material, any equipment failure or facility failure (e.g., ventilation failure), and/or any breakdown in procedure that could result in potential exposure of laboratory personnel and/or the public to biohazardous material.

3. I confirm that any proposed changes to my work will be reported to the IBC before the change is implemented.

4. I confirm that no work requiring IBC approval will be initiated or modified until approval is received from the IBC.

5. I have read and understand my responsibilities as Principal Investigator outlined in section IV-B-7 of the *NIH Guidelines* and the UAMS Biosafety Manual, and agree to comply with these responsibilities.

6. I certify that, to the best of my knowledge, the information provided in this protocol is accurate. I also understand that it is my responsibility to ensure congruence between the work described in this protocol and funded research proposals.

Typed Name of Principal Investigator	**Signature of Principal Investigator**	**Date**