NKU NORTHERN KENTUCKY UNIVERSITY

Biohazard Agent Registration (BAR) Form
for
Infectious Agents/Materials, Recombinant DNA & Biological Toxin Registration

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Use this form for studies that fall into any of the categories below:

1. Construction and/or use of recombinant DNA, beyond accepted/standard (non-hazardous) practices in standard host-vector systems.
2. Toxins or infectious agents requiring handling conditions above Biosafety Level-1. (Biosafety Level determinations are outlined by the CDC publication *Biosafety in Microbiological and Biomedical Laboratories*).

Instructions:

- Complete all pertinent parts of the NKU Biohazard Agent Registration (BAR) Form.
- Print a copy, sign and date the signature page. Do not return these cover pages.
- To facilitate future project updates, save an electronic copy of the completed form.
- Submit the following to biosafety@nku.edu:
  - the completed and signed BAR Form,
  - a Curriculum Vitae for the Principal Investigator or Course Coordinator.

Upon receipt and review of the BAR Form, the IBC will send a memo indicating the status of the BAR as:

- Approved – allows the PI to begin immediately with experiments,
- Rejected – the researcher may not proceed with the experiment or
- Revisions Required – the PI must respond to IBC required revisions. Final approval from the IBC is required prior to starting the experiments.

Projects must be approved by the IBC before the project begins.

Every Principal Investigator or Course Coordinator performing non-standard or hazardous research with recombinant DNA, infectious agents or biological toxins must complete the following BAR Form Sections:

Part 1. General Information;
Part 2. Laboratory Information;
Part 3. Project or Course Description; and
Part 7. Certification and Signatures.

The following BAR sections should be completed if appropriate.
Part 4. If your project or course involves construction and/or use of recombinant DNA, beyond accepted/standard (non-hazardous) practices.
Part 5. If your project or course involves the use of infectious agents, potentially infectious materials, tissues, or cell cultures.
Part 6. If your project or course involves biological toxins.

If you have any questions, please contact the IBC Administrator at biosafety@nku.edu.

Resource List	
Resource	Link
NIH *Guidelines for Research Involving Recombinant DNA Molecules*	https://inside.nku.edu/content/dam/rgc/docs/ResearchCompliance/IBC/BAR/NIH_Guidelines.pdf
Risk Group (RG) Chart	https://my.absa.org/Riskgroups
CDC BioSafety Guide (5th Edition)	https://www.cdc.gov/labs/BMBL.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fbiosafety%2Fpublications%2Fbmbl5%2Findex.htm
"Select Agents" that require CDC or USDA registration BEFORE acquiring the agent or toxin	https://www.selectagents.gov/
World Health Organization Laboratory Biosafety Manual	https://www.who.int/publications/i/item/9789240011311
USDA/APHIS Biotech regulations and permits	https://www.aphis.usda.gov/aphis/ourfocus/biotechnology
USDA/APHIS Plant protection quarantine information and permits	https://www.aphis.usda.gov/aphis/ourfocus/planthealth
CDC Import Permits	https://www.cdc.gov/cpr/ipp/index.htm
Disinfection Resources	Consult the IBC Chair
NKU Institutional Biosafety Committee	https://inside.nku.edu/rgc/research-compliance/ibc.html
NKU Department of Safety and Emergency Management	https://inside.nku.edu/safety.html

Project procedures and NIH References	*NIH Guidelines* references
Using recombinant DNA/RNA (rDNA) molecules for detection purposes	III-F
Creating or using genomic libraries	III-E, III-F
Cloning and vector construction in bacteria and yeasts	III-E, III-F
Expression of rDNA products in cultured cells	III-E, III-F
The use of human cells/cell lines or tissues (e.g. human blood, 293 cell lines, CSF)	II-A-3; BBP
Using animal cells/cell lines or tissues (e.g. tissue culture research)	II-A-3; App C
Using or cloning genes from, or into a risk group 2 or 3 agent (e.g. HSV, SIV)	III-D-1 III-D-2
Administration of rDNA material into animals (e.g. transformed cells, vectors)	III-D-4
Experiments involving whole plants in research	III-D-5
Propagating culture volumes exceeding 10 liters at one time	III-D-6

Use or manipulation of infectious viruses or replication-defective viruses or viral vector(s) with helper viruses	III-E-1 III-D-3
Experiments involving influenza viruses	III-D-7
Using or cloning of toxin molecule genes (e.g. deliberate formation)	III-B-1

Research Biosafety Levels		
☐	Biosafety Level 1 (BSL-1)	For agents not known to consistently cause disease in healthy human adults.
☐	Biosafety Level 2 (BSL-2)	For agents associated with human disease or equivalent theoretical risk (i.e., human-derived agents, adenovirus, trypanosome, retroviruses, non-human primate materials, certain cell lines such as COS cells).
☐	Biosafety Level 2 Plus (BSL-2+)	For agents associated with serious human disease or equivalent theoretical risk and not transmissible via the aerosol route (i.e., lentivirus). A hybrid biosafety level utilizing BSL-3 practices and procedures in a BSL-2 laboratory. *NOTE*: Requires additional documentation, review, and notification.
☐	Biosafety Level 3 (BSL-3)	For agents indigenous or exotic with potential for aerosol transmission may have serious health effects or equivalent theoretical risk (i.e., *Mycobacterium tuberculosis*). *NOTE*: Requires additional documentation, review, notification and facility design. Please notify the site Biosafety Officer well in advance of your projected start date.

Animal Biosafety Levels		
☐	Animal Biosafety Level 1 (BSL-1-N)	Risk Group 1 (RG1) materials being administered to animals.
☐	Animal Biosafety Level 2 (BSL-2-N)	Risk Group 2 (RG2) materials being administered to animals.
☐	Animal Biosafety Level 3 (BSL-3-N)	Risk Group 3 (RG3) materials being administered to animals.

For IBC Use Only
IBC #_____ Date Received_____ Date Posted_____
☐New ☐Reply to Comments

Part 1. General Information

	Choose One	
Application Type	☐ New ☐ Three Year Renewal (with revisions) IBC # ☐ Three Year Renewal (no revisions) IBC #	☐ Revision IBC # ☐ Annual Report (with revisions) IBC #
	This protocol is (check all that apply)	Project Type
	☐ Unfunded ☐ Funded externally by ☐ This protocol is Department funded ☐This protocol is internally funded	☐ Research ☐ Classroom/Teaching Does this project require IACUC or IRB Review? ☐Yes, IACUC #_____ ☐No ☐Yes, IRB #_____ ☐No

Project/Course Title		
Principal Investigator (last name, first name)		Department
Campus Address	NKU Email	Campus Phone

Part 2. Laboratory Information

1. List all laboratories and facilities where work with biohazardous agents and toxins is to be conducted. Indicate the corresponding biosafety level, if applicable (refer to the list of biosafety levels on page 2). Include cold rooms, animal workrooms and housing, as appropriate. Also indicate rooms where biosafety cabinets (BSCs) are located.

		Check Box If Applicable						
Building and Room Number	Biosafety Level of Room	Research Lab	Teaching Lab	BSC	Equipment Room	Cold Room	Animal Work	Other, please describe
		☐	☐	☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐	☐	☐

2. Indicate all equipment used to manipulate the biohazardous materials in this project.

☐ Centrifuge(s) (note type: tabletop, floor, and or microfuge): ☐ Sonicator	☐ Plate Washer ☐ Syringes/Needles ☐ Other (list):

3. Specify protective clothing and equipment utilized in this project.

4. Specify disinfectant(s) utilized to decontaminate surfaces and equipment.

Part 3. Project Description

5. Briefly, outline the overall goal(s), or scope of the project or course and the activities to be conducted. Provide sufficient information about the techniques used, and purpose of the work for the reviewers to understand what you have planned. Please use clearly understood and reasonably non-technical (laymen's) terms. Do not insert research protocols. Please limit your description to 1-2 paragraphs.	
6. Does this study involve human blood?	☐Yes, answer 6a & 6b ☐No
a. ☐ I verify that this project will not begin until all personnel in contact with human blood have received Bloodborne Pathogen training through NKU's Department of Safety and Emergency Management.	
b. An Exposure Control Plan (ECP) is required by the *Guidelines* and must be updated annually. The project may rely on NKU's ECP or create a project-specific ECP. This project will:	☐Utilize NKU's Exposure Control Plan ☐Utilize a study-specific ECP which has been attached to this application.

Part 4. Use of Recombinant DNA

☐Not Applicable

Please complete this section if you use or generate potentially hazardous recombinant DNA.

A. Source of Gene, Insert, or Clone:

7. Specify DNA/RNA source, nature of insert, any a protein expressed, and the percent of any viral genome in the construct.

8. If any sequences code for toxins, list the toxin and corresponding LD_{50} (if known).	☐N/A ☐Unknown

9. If the DNA source is from a regulated plant or animal (e.g., USDA) and the regulated organism is grown or stored on site, indicate the regulatory agency monitoring its use and please include a copy of the regulatory permit. Consult references listed on cover page if you are not certain that the material is regulated.	☐N/A

10. Will experiments result in acquisition of new characteristics such as enhanced virulence, infectivity, drug resistance, or change in host range of the organism that is being manipulated? If so, explain.	☐ Yes ☐ No

B. Vectors and Host Cells:

11. Identify general forms of cloning/expression/transfection vectors used (e.g. bacterial plasmids, phage), recipient bacterial strains (e.g. Eschericia coli K-12), and recipient host cell lines (human, mouse, plant, etc.). Describe the location and type of promoters and other control sequences and percent of any viral genome in each construct.

12. If using viral vectors, indicate packaging cell lines and assay system used to measure helper virus titer or titer of replication competent virus (background) generated. Include host range of packaged viral vector.	☐ N/A

C. Biosafety Level covering Part 4 (check one)

13. Choose One	☐ BSL-1 ☐ BSL-2 ☐ BSL-2+ ☐ BSL-3

Part 5. Infectious Agents and Human/NHP/Animal Materials

☐Not Applicable

A. Infectious Microbial Agent(s)

Risk Group 1 (RG1)	*Not associated with disease in healthy adults.*
Risk Group 2 (RG2)	*Associated with human disease, a preventative or therapeutic intervention may be available.*
Risk Group 3 (RG3)	*Associated with serious or lethal human disease, a preventive or therapeutic intervention may be available.*

14. Name the microbial agent(s) in use or in storage, and their corresponding risk group (RG). Consult references listed on the cover page if you are not certain of the risk group and whether or not the agent is regulated under HHS/UDA or Commerce Department.

List Agent(s): (eg., Adenovirus Type 5, Helicobacter pylori, E. coli 0157)	Risk Group (i.e., 1, 2 or 3)	HHS or USDA Select Agent?	Commerce Controlled Agent?	Room Numbers for Use and/or Storage	
				Use	Storage
	☐1 ☐2 ☐3	☐Yes ☐No	☐Yes ☐No		
	☐1 ☐2 ☐3	☐Yes ☐No	☐Yes ☐No		
	☐1 ☐2 ☐3	☐Yes ☐No	☐Yes ☐No		
	☐1 ☐2 ☐3	☐Yes ☐No	☐Yes ☐No		
	☐1 ☐2 ☐3	☐Yes ☐No	☐Yes ☐No		
	☐1 ☐2 ☐3	☐Yes ☐No	☐Yes ☐No		

15. What is the host range (human, plant, animal) for each microbial agent listed? If animals are within the host range, specify each species potentially affected.

16. Describe the disease pathology and mode of transmission. Provide a copy of the most relevant publication(s), if available.

17. Is a vaccine available? If yes, will project personnel be vaccinated before project initiation?	☐Yes ☐No

B. Human and Non-Human Primate Materials and Materials from Non-Living Animals Exempt from IACUC Review

18. List the human and non-human primate materials (e.g., blood/serum, blood components, cell lines, unfixed tissues, organs, etc.), and materials from non-living animals exempt from IACUC review (sheep shoulder, bovine brain, for example). Note: Use of human source material requires the Principal Investigator to comply with all applicable facets of the Bloodborne Pathogen requirements.

C. Sources of Materials Listed in A & B

19. Example the source(s) of materials listed above in items A & B (e.g., new isolate from human tissue, blood, animal, tissue culture, another laboratory or company, ATCC).	
20. Do any of the materials listed in A & B require an import permit? Consult references listed on cover page if you are not certain that the material is regulated. If so, specify:	☐Yes ☐No

D. Experimental Procedures:

21. Briefly, describe general procedures used to manipulate materials listed in A & B, above (indicate culture volume, maximum concentration). For bacterial agents, please indicate method of culture (agar plates or liquid), size of culture and method of liquid culture (aerated or static). How and at what stage of the experiment is the infectious material inactivated or lysed? If the material is transported to another lab within NKU or outside of NKU, specify where it is being sent to and how it will be transported.

22. Will experiments result in acquisition of new phenotypic characteristics of the microorganisms being manipulated, such as enhanced virulence, infectivity, drug resistance, or change in host range? If so, explain:	☐Yes ☐No

a. Will the material(s) listed in items a/b/c be administered to animals? If yes, please describe the method of administration and dose.	☐Yes ☐No, Skip to #23
b. If yes, what is the IACUC protocol number?	

E. Biosafety Level for Part 5

23. Choose One	☐ BSL-1 ☐ BSL-2 ☐ BSL-2+ ☐ BSL-3

Part 6. Toxins of Biological Origin

☐Not Applicable

24. Name toxins (microbial and non-microbial) in use or in storage. Consult references listed on cover page if you are not certain that the agent is regulated under HHS/USDA or Commerce Department.

List Toxin(s): (eg. Ricin, Cholera Toxin, Staph. Enterotoxin B)	HHS or USDA Select Agent Toxin?	Commerce Controlled Toxin?	Room Number for Use and/or Storage	
			Use	Storage
	☐Yes ☐No	☐Yes ☐No		
	☐Yes ☐No	☐Yes ☐No		
	☐Yes ☐No	☐Yes ☐No		
	☐Yes ☐No	☐Yes ☐No		
	☐Yes ☐No	☐Yes ☐No		
	☐Yes ☐No	☐Yes ☐No		

25. Describe the procedures requiring the use of the materials listed above. If the material is transported to another lab within NKU (or outside of NKU), specify where it is being sent and how it will be transported.

26. If you store or use any of the following U.S. Department of Health and Human Services (HHS) "Select Agent Toxins" define the approximate maximum inventory (i.e. amounts) stored under your control, in your facility, at any given time. ☐N/A

Toxin	Regulatory Threshold Quantity Requiring CDC or USDA Certificate of Registration	NKU Maximum Inventory Quantity
Abrin (Plant)	100 mg	
Contotoxins (Algae)	100 mg	
Diacetoxyscirpenol (Fungi)	1000 mg	
Ricin (Plant)	100 mg	
Saxitoxin	100 mg	
Tetrodotoxin	100 mg	
Shiga-toxin like ribosome inactivating proteins	100 mg	
Botulinum neurotoxins	0.5 mg	
Clostridium perfringens epsilon toxin	100 mg	

Shiga toxin	100 mg	
Staphylococcal enterotoxins	5 mg	
T-2 toxin (Fungi)	1000 mg	

Part 7. Certification and Signatures

The information contained in this Biohazard Agent Registration (BAR) Form is accurate and complete. I am familiar with and agree to abide by the provisions of the current NIH *Guidelines* and other specific NIH instructions, and/or applicable country-specific regulations pertaining to the proposed project described above. Further, I similarly will abide by all NKU Policies, Procedures, and Guidelines, and all local, regional, and national regulations relevant to the manipulation, use and storage of all biohazardous agents and toxins. In addition, I agree to:

A. Initiate no recombinant DNA project work subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines) until the project has been reviewed and approved by the NKU Institutional Biosafety Committee. All potentially biohazardous work will be registered with and approved by the NKU Institutional Biosafety Committee.

B. Assure compliance with all appropriate national and international shipping requirements for recombinant DNA materials, biohazardous, and infectious agents.

C. Make available to all individuals listed on this protocol, copies of the approved protocols that describe the potential biohazards and the precautions to be taken.

D. Provide for the appropriate training of affected students and workers in good microbiological practices and techniques required to ensure safety for this project, including procedures for reporting accidents and incidents, housekeeping, and waste management.

E. Assure the appropriate supervision of all students and workers listed on the protocol, and to correct work conditions that could result in breeches of the *NIH Guidelines,* NKU internal regulations and procedures, and applicable local, regional or national regulations.

F. Immediately inform the NKU Institutional Biosafety Committee of any changes or anticipated changes in risk conditions affecting the biohazardous agents and toxins under my control.

G. Complete all required training pertaining to this study and biohazardous agents and toxins.

H. Verify that all staff and students working on this project have completed the required training pertaining to this study and biohazardous agents and toxins.

Principal Investigator Signature	*Date*
Biosafety Committee Review/Approval ☐*Approve* ☐*Reject* *Reviewer Signature*	*Date of IBC Approval*