**Application for Biosafety Approval**

**Institutional Biosafety Committee - Western Kentucky University**

*revised January 2014: ver 6*

Instructions: Please check the appropriate boxes, add any needed narrative, print and sign the form, and submit to the Office of Research Integrity. Please attach additional pages or supporting material as necessary. Please visit the WKU-Office of Research Integrity website for relevant documents (i.e. [Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)](http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html) [Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition (CDC-NIH)](http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm%20)

CITI Program Training Completion: Contact Dr. Rodney King, IBC Chair. All applicants must complete the following CITI training modules, (1) Introduction to Biosafety and (2) any others deemed relevant to the proposed research. All individuals who conduct IBC approved research must also attend the annual Biology Department safety seminar. This seminar is offered at the beginning of the fall semester.

|  |
| --- |
| Proposal Title:  |
| Funding Agency (if relevant) |
| Principal Investigator: |   | Co-Principal Investigator: |   |
| Department: |   | Department: |   |
| Campus Address: |   | Campus Address: |   |
| Campus Phone: |   | Campus Phone: |   |
| E-mail Address: |   | E-mail Address: |   |

## Section 1. Check one: [ ] Research Proposal; [ ] Standing Teaching Initiative; [ ] Standing Research Initiative

**Section 2. Check all applicable boxes that describe the type of work:**

[ ]  Recombinant DNA

[ ]  Culturing of microorganisms

[ ]  Handling or culturing of agents infectious to plants, humans, or animals

[ ]  Cultures of tissues, organs, and cells of human origins

[ ]  Select Agents as defined by U.S. federal agencies

[ ]  Human gene therapy

## Section 3. Recombinant DNA

Are any of the recombinant DNA sources from a Risk Group 2, 3, or 4 organism? [ ]  Yes [ ]  No

* 1. If No: Identify all Risk Group 1 organisms that will be included in your recombinant DNA research.
	2. If Yes: Identify each organism from which genetic material is to be cloned, describe the genes or sequences to be cloned, and whether a deliberate attempt will be made to obtain expression of foreign genes or gene fragments.
	3. Identify the vectors to be used.
	4. Are there any potential human health risks or significant risks to the environment associated with these particular rDNAs the IBC should be made aware? [ ]  Yes [ ]  No If yes, please explain.
	5. The work will be conducted in Building/ Room # \_\_\_\_\_\_\_

## Section 4. Culturing of Microorganisms

Are any of the microorganisms to be cultured included in Risk Group 2, 3, or 4? [ ]  Yes [ ]  No

* 1. If No:
		1. Identify all Risk Group 1 microorganisms to be cultured.
		2. Use of Risk Group 1 microorganisms requires BioSafety Level 1 (BSL1) containment.

Do your facilities meet these standards? [ ]  Yes [ ]  No Building/ Room # \_\_\_\_\_\_\_

If No explain:

* 1. If Yes:
		1. Identify all Risk Group 2 microorganisms to be cultured, Risk Group 3 or 4 organisms are not supported at WKU.
		2. Use of Risk Group 2 microorganisms requires BioSafety Level 2 (BSL2) containment.

Do your facilities meet these standards? [ ]  Yes [ ]  No Building/ Room # \_\_\_\_\_\_\_

If No explain:

* 1. To your knowledge, are there any potential human health risks or significant risks to the environment associated with these organisms? [ ]  Yes [ ]  No If yes please explain.
	2. The work will be conducted in Building/ Room # \_\_\_\_\_\_\_

**Section 5: Agents infectious to plants, humans, and animals.**

Explain the nature of the work, your assessment of the health risk to humans, animals, and plants as well as any biological containment and pertinent laboratory policies and procedures in place.

 The work will be conducted in Building/ Room # \_\_\_\_\_\_\_

**Section 6: Cultures of tissues, organs, and cells of human origins.**

If your work involves culturing human-derived tissues, organs, or cells, please describe the methods with particular attention to the risk of infectious agents to human participants. Also, describe policies and procedures in place to minimize risk to human participants and/or respond to incidents of exposure.

1. The work will be conducted in Building/ Room # \_\_\_\_\_\_\_

2. Does this work require Institutional Review Board approval? [ ]  Yes [ ]  No

If yes, describe the status of the IRB application.

**Section 7: Select Agents**

If this work includes Select Agents, in whole or in part, the applicant should contact WKU Environmental Health and Safety for assistance.

**Section 8: Human Gene Therapy**

 Western Kentucky University does not support human gene therapy studies.

**Section 9. In regard to biosafety or compliance with federal law, are there any other aspects of this work in which the committee should be informed?** [ ]  Yes [ ]  No If yes, explain.

***Section 10: Certification of Awareness of NIH and CDC Guidelines***

1. *I certify that I have read and understand the NIH guidelines and CDC guidelines concerning Risk Groups and appropriate containment.*
2. *I further certify that I have instructed all of my research students and research workers in proper microbiological methods and laboratory safety.*
3. *I ensure my laboratory (-ies) will observe the appropriate level of containment indicated here.*

P.I Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Received\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Received by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

For Committee Use Only

[ ]  IBC Review; [ ]  Fast-Track Review: Reviewer\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Approved

[ ]  Unapproved

[ ]  Approved pending modification

Comments: