**Application for Biosafety Approval**

 **Western Kentucky University**

**Institutional Biosafety Committee**

*revised January 2018: ver 7*

**Instructions**: Please fill out the application entirely with all details of your proposed project. Check the appropriate boxes and add any needed narrative, print and sign the form, and submit to the Office of Research Integrity. Attach additional pages or supporting material as necessary. If you are applying for BSL2 status, please be advised that you may be asked to defend your proposal at an IBC meeting. If your proposed work is outside of your area of expertise, you may be asked to perform a skills analysis by the IBC committee. 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**: All applicants and all persons involved in the proposed work, must complete the following CITI training modules, (1) Basic Biosafety Training 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 in person at the beginning of the fall semester and it is available on Blackboard (a short quiz is required after viewing the online seminar). Contact Dr. Rodney King, IBC Chair for questions.

|  |
| --- |
| 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 origin

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

## 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 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. Also, identify the appropriate section of the NIH Guidelines under which your research falls (For example, is your research covered under Section III-A, III-B, III-C, III-D, or III-E?)
	3. Identify and describe the DNA vectors that will be 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

* 1. If yes, please explain in detail all associated risks both to participants in this research and those who may be inadvertently exposed. Describe in detail all containment measures, relevant SOPs (especially those designed to reduce exposure), any training to be performed, and emergency response plans to spills and any incidents of exposure. Use extra pages as necessary.
	2. The work will be conducted in Building/ Room # \_\_\_\_\_\_\_

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

* 1. Explain the nature of the work, your assessment of the health risk to humans, animals, and plants. Please explain in detail all associated risks both to participants in this research and those who may be inadvertently exposed. Describe, in detail, all containment measures, relevant SOPs (especially those designed to reduce exposure), training that will be performed, and SOPs for responses to spills and incidents of exposure.

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

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

* 1. 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 as well as those who may be inadvertently exposed. Describe in detail all containment measures, relevant SOPs (especially those designed to reduce exposure), training that will be performed, and SOPs for responses to spills and 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, what is the status of the IRB application?

**Section 7: Select Agents** [ ]  Yes [ ]  No

If Yes, describe which Select Agent and provide copies of all applicable permits from appropriate agencies.

**Section 8. PI qualifications to perform work**

Describe in detail your personal, direct laboratory experience or skills with the proposed project and provide documentation of this experience. Please only include experience you have personally performed. Your CV should accompany this application. Please be advised that if you are proposing work outside of your area of expertise/experience, the committee reserves the right to administer a laboratory skills evaluation.

**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 on separate pages.

***Section 10: Certification of Awareness of NIH and CDC Guidelines (please initial each line).***

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 all rooms used for this work will observe the appropriate level of containment indicated here. \_\_\_\_\_\_\_\_*
4. *I understand I may be asked to defend my proposal at an IBC meeting and/or perform a skills assessment.\_\_\_\_\_\_\_\_*

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

NOTE: You must include a hand written signature or digitally sign this document.

**Submission Checklist:**

[ ]  1. Completed Application (attach additional pages as necessary)

[ ]  2. Current CV

[ ]  3. SOPs

[ ]  4. Emergency Response Plan (including incident reporting protocol)

[ ]  5. Completed lab audit form

[ ]  6. Documented Completion of required training (CITI, Training Checklist for all

lab personnel)

*Failure to submit the above documents will delay approval of your application.*

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

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

**For IBC Chair or Committee Use Only**

[ ]  IBC Review; [ ]  Fast-Track Review:

Reviewer\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Approved

Approval expires on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Unapproved

**Comments:**