

IBC Registration #: \_\_\_\_\_

Initial receipt date: \_\_\_\_\_

Final revision date: \_\_\_\_\_

## University of Tennessee-Knoxville Registration for Use of Recombinant DNA Molecules

**Principal Investigator:** Please complete all applicable sections of this form. Incomplete forms will not be sent on to the IBC for review. If you choose to use acronyms or other scientific shorthand, please define these terms the first time they are used. For assistance with completion of the form, please refer the “*UT User’s Guide for Recombinant DNA Molecules*” or contact the IBC Chair or the UTK/UTIA/GSM Biosafety Officer at 974-1938 (branger@utk.edu).

### SECTION 1: PROTOCOL PROFILE

Principal Investigator:

Title:

Mailing Address:

Department:

Phone:

Email Address:

Research Protocol Title:

Applicable Grant Titles (if any)

Funding Agencies

**1. Does this project involve any of the following?**

(Check the appropriate box for each category)

	YES	NO
Deliberate transfer of drug-resistance traits to microorganisms of clinical, environmental or agricultural significance that could compromise the use of drugs to control disease		
Clinical trial of human gene therapies		
Work with human-derived materials (i.e., cells <b>including cell lines</b> , body fluids or tissues)		
Work with genetic materials from a Risk Group 2 or higher pathogen (i.e., any agent infectious to humans; refer to Appendix B of the NIH Guidelines; if YES, contact the UTK/UTIA/GSM Biosafety Officer for further documentation requirements.)		
Work with a select agent or high-consequence pathogen (Refer to current select agent list, contact the UTK/UTIA/GSM Biosafety Officer immediately if YES for this category.)		
Work with live animals (i.e., genetic modification of animals or challenge of animals with recombinant DNA or viable recombinant DNA-modified microorganisms)		
Work with live plants (i.e., genetic modification of plants or challenge of plants with recombinant DNA-modified organisms to include microbes and arthropods)		
Work involving cloning of genes that encode for toxins		
Work that will involve more than 10 liters of culture in one vessel		
Radioisotope use in conjunction with recombinant DNA use (if YES, provide an explanation of this use in your summary of techniques to be used.)		

**2. Which NIH review classification and category applies to this work?**

*Note: NIH review classifications and categories are summarized in the [“UT User’s Guide for Recombinant DNA Molecules”](#) and can also be found in Section III of the NIH Guidelines.*

Check the appropriate box for your review category and indicate the subcategory that applies to your work.

<b>Review Category</b>	<b>Subcategory</b>
	<b>III-A:</b> Requires IBC, RAC & NIH approval before initiation <b>Subcategory:</b>
	<b>III-B:</b> Requires NIH/OBA and IB approval before initiation <b>Subcategory:</b>
	<b>III-C:</b> Requires IBC and IRB approvals and RAC review before participant enrollment. (This category is for human gene therapy trials only.) <b>Subcategory:</b>
	<b>III-D:</b> Requires IBC approval before initiation <b>Subcategory:</b>
	<b>III-E:</b> Requires IBC notice simultaneous with initiation <b>Subcategory:</b>
	<b>III-F:</b> IBC registration is not required but recommended to assure that work is properly classified <b>Subcategory:</b>

**3. What Biosafety Level are you proposing to use for this work?**

*Note: Recommendations for Biosafety Levels are generally outlined under Section III of the NIH Guidelines and in the [“UT Guide for Recombinant DNA Molecule Use”](#). Full Descriptions of the Biosafety Levels are found in Appendix G for lab applications, Appendix K for large-scale use of recombinant organisms, Appendix P for plant applications, and Appendix Q for animal applications.*

Place the number of the proposed biosafety level for the recombinant DNA procedures under the appropriate box or boxes.

<b>Laboratory</b> Biosafety level	<b>Large-Scale</b> Biosafety Level	<b>Animal</b> Biosafety Level	<b>Plant</b> Biosafety level

**Note:** If Biosafety Level 2 is indicated, contact the UTK/UTIA/GSM Biosafety Officer at 974-1938 ([branger@utk.edu](mailto:branger@utk.edu)) for assistance with supplementary form preparation.

**4. Where will this work be conducted? (Rooms & Buildings)**



## SECTION 2: PROTOCOL DESCRIPTION

6. Provide a purpose statement for the protocol:

7. List all hosts, vectors and inserts used as part of this protocol in the table below. Please be as specific as possible (e.g. *E. coli* DH5- $\alpha$  rather than *E. coli* or IPTG-inducible *lac* promoter rather than inducible promoter).

<b>Hosts</b> (bacteria, yeast, cell lines, etc.; include technical names)	
<b>Vectors</b> (describe the class of vector, source organism or derivative, etc.)	
<b>Promoters</b> (include source and activity)	
<b>Insert genes</b> (name of gene or name of protein it codes for, specify natural source, activity/ phenotype)	

8. Provide a technical description of this proposed recombinant DNA protocol. Briefly describe the procedures that will result in recombinant DNA molecule generation and how these products will be used. Please include attachments if appropriate. The content of this section (at a minimum) must include information that supports the category that you selected under #2 and reflects the materials identified under #7.

\*\*\***Note:** If your proposed recombinant DNA molecule use is described under Category III-F, you do not need to complete this question.

9. Provide a non-technical summary of the recombinant DNA use for this protocol. This should be written so that a non-scientist or someone who is not an expert in your particular field can understand your recombinant DNA use.

### SECTION 3: BIOLOGICAL CONTAINMENT, HEALTH & SAFETY

*If your recombinant DNA molecule use is described under Category III-E or Category III-F, you do **NOT** need to complete this section. However, please note that the NIH Guidelines require that ALL non-exempt recombinant DNA molecule use be carried out in accordance with Biosafety Level 1 containment requirements as a minimum standard. You MUST assure that these requirements are adopted in your laboratory's standard operating procedures and that you are able to demonstrate compliance with these requirements in the event of a regulatory audit.*

*Biosafety Level 1 containment is also recommended for exempt experiments. **Please proceed to Section 4.***

10. Summarize your written biological spill response procedure for the materials covered by this protocol which has been approved by the UT Biosafety Officer. (Contact the UTK/UTIA/GSM Biosafety Officer for assistance.)
  
11. Summarize your surface disinfection procedures. Include information relative to dilution, contact time, shelf life and personal protective equipment requirements. (Contact the UTK/UTIA/GSM Biosafety Officer for assistance if needed.)
  
12. Summarize how wastes contaminated with recombinant DNA products or other biological materials will be segregated, treated and disposed of.
  
  
  
  
  
  
  
  
  
  
13. Will any biological materials be transported outside of the lab area (i.e., out of the building where the lab is located), or shipped off-site? If YES, please describe.
  
  
  
  
  
  
  
  
  
  
14. Describe any health surveillance measures that are required for personnel working on this protocol (i.e., vaccination offers, health conditions that could increase exposure or disease risk, etc.)

## SECTION 4: PRINCIPAL INVESTIGATOR/DEPARTMENT HEAD ACKNOWLEDGMENT

### Principal Investigator

**As the Principal Investigator for this protocol, I understand and acknowledge my responsibilities under the NIH Guidelines to:**

- Be adequately trained in good microbiological techniques (including standard microbiological practices) and assure that all personnel working on this protocol are also trained in these techniques;
- Instruct and train laboratory staff in the practices and techniques required to ensure safety, and the procedures for dealing with accidents;
- Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;
- Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).
- Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;
- Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).
- Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), IBC, NIH/OBA, and other appropriate authorities (if applicable);
- Correct work errors and conditions that may result in the release of recombinant DNA materials;
- Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination;
- Comply with applicable shipping requirements for recombinant DNA molecules;
- Maintain communication with the IBC including reporting of any releases, accidents or procedural modifications relative to this recombinant DNA use.

\_\_\_\_\_  
*Signature- Principal Investigator*

\_\_\_\_\_  
*Date*

### Department Head

I have reviewed this document and will assure that this work is carried out in accordance with applicable health & safety regulations and guidelines.

\_\_\_\_\_  
*Signature- Department Head*

\_\_\_\_\_  
*Date*

**Submit the final version of this form with above signatures to Brian Ranger, Biosafety Officer at 336 Ellington Plant Sciences for review and approval by the UT IBC.**

### IBC Chair's Acknowledgment

The Institutional Biosafety Committee has reviewed the proposed project involving recombinant DNA molecules and has approved the use of these research materials using the containment facilities practices outlined based on the NIH "Guidelines for Research Involving Recombinant DNA Molecules".

\_\_\_\_\_  
*Signature- IBC Chair*

\_\_\_\_\_  
*Date*