

## Protocol Form for Recombinant DNA Research/Teaching

This form must be completed and submitted to the Institutional Biosafety Committee at least 4 weeks prior to the initiation of each independent project.

Protocol/course title:

Proposed project dates: begin: \_\_\_\_\_ end: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_ E-mail: \_\_\_\_\_

Department: \_\_\_\_\_ Telephone: \_\_\_\_\_

(check all that apply)      Faculty/Staff      Graduate student      Undergraduate student      Unaffiliated

(If the PI is a student researcher or not affiliated with Ball State University, a Faculty Sponsor must be listed below.)

Faculty Sponsor: \_\_\_\_\_ E-mail: \_\_\_\_\_

Department: \_\_\_\_\_ Telephone: \_\_\_\_\_

If this project is funded or if the investigator is seeking funding, list the agency(s) and/or sources.

(If the title of the grant application differs from the title of the IBC protocol, also specify the grant application title.)

New protocol

Requesting modifications to a currently approved protocol

Requesting continuation of a currently or previously approved protocol

Provide the IBC# of the protocol to be modified or continued: \_\_\_\_\_

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### Principal Investigator Assurance Statement

The information I have provided is complete and correct, to the best of my knowledge. I certify that I understand the University's "Policy for Research Involving Recombinant Molecules" and the NIH "Guidelines for Research Involving Recombinant DNA Molecules" as they pertain to the work I describe herein, and will conduct such work in compliance with those regulations. I will begin the work only after obtaining the approval of the Institutional Biosafety Committee, and will notify the Chairperson of that committee prior to effecting any changes in experimental procedures. I also certify that I will report any and all accidents or illnesses related to this work to the IBC and the NIH/OBA within 30 days of such incidents.

The Principal Investigator must electronically sign this study prior to submitting the protocol to the IBC for review. When you sign this study as the Principal Investigator, you are also agreeing to the terms in the Principal Investigator Assurance Statement above.

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### Faculty Sponsor Assurance Statement

As the Faculty Sponsor, I certify that I have reviewed this protocol and affirm the merit of this research project and the competency of the investigator(s) to conduct this project.

A Faculty Sponsor must electronically sign this study for all student research projects and for all persons not affiliated with Ball State University before the protocol is submitted to the IBC for review. When you sign this study as the Faculty Sponsor, you are also agreeing to the terms in the Faculty Sponsor Assurance Statement above and accepting responsibility for ensuring that the terms of the Principal Investigator Assurance Statement are met.

BALL STATE UNIVERSITY • INSTITUTIONAL BIOSAFETY COMMITTEE

List below all persons, other than the PI, who will have significant involvement in the research:

**Name:**

**Nature of involvement** (co-investigator, graduate assistant, etc.):



A. Please provide a brief abstract of the experiments and a description of the procedures involving recombinant DNA. (Attach additional pages as needed.)

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**EXPLANATORY NOTE:** To assist in completing this form, parenthetical underline notes (      ) are included. Some of these refer to the section of the NIH Guidelines (GL:) [[www4.od.nih.gov/oba/oct2000guide2.pdf](http://www4.od.nih.gov/oba/oct2000guide2.pdf)] pertinent to the particular type of work being asked about.

The information provided on this form will allow the Institutional Biosafety Committee (IBC) to assess the proposed work, as outlined in the University "Policy for Research Involving Recombinant Molecules" (Section IV), by:

- 1) determining the appropriate biosafety level and standard containment practices,
- 2) being assured that lab personnel will be informed of the level of biohazard and adequately trained in microbiological and containment techniques, and emergency plans for accidental spills and personnel contamination, and
- 3) being assured of compliance with the NIH Guidelines, including shipping requirements for recombinant molecules.

**Also, this document serves as the Registration Document for Recombinant DNA Research as required in GL: III-B.**

B. Please answer the following questions, providing information as requested. (Upload additional pages as needed.)

1. (GL: III-B) What will be the source(s) of DNA in the proposed work?

2. (GL: III-B) What are the hosts and vectors to be used?

3. (GL: III-B) Does the recombinant DNA to be used fit any of the situation described in terms a-f below, which make the work exempt from the NIH Guidelines?                       YES                       NO

(If YES, please check each of items a-f that apply to your work.)

- a. The recombinant DNA will not be used inside, or inserted into, an organism or virus.
- b. The DNA consists entirely of segments from a single monochromosomal or viral DNA source (including synthetic equivalents).
- c. The recombinant molecule consists entirely of DNA from a prokaryotic host, including its indigenous plasmids or viruses, and will be propagated only in that host (or a closely related strain of the same species) or transferred to another host by well-established physiological means.
- d. The recombinant DNA consists entirely of DNA from a eukaryotic host, including its chloroplasts, mitochondria, or plasmids (but excluding its viruses), and will be propagated only in that host (or a closely related strain of the same species).

- e. The recombinant DNA is included in the list in Appendix A of the Guidelines (or in an updated version of the list), and is therefore exempt from the Guidelines because it consists entirely of DNA segments (or synthetic equivalents) from species that exchange DNA by known physiological processes. If from an updated version of the list, please give the reference where the list that includes this class of recombinant DNA has been published:

- f. The recombinant DNA is included in the list in Appendix C of the Guidelines (or in an updated version of the list), and is therefore exempt from the Guidelines because it has been found not to present a significant risk to health or the environment. If from an updated version of the list, please give the reference where the list that includes this class of recombinant DNA has been published:

4. (GL: III-B) Will a foreign gene be expressed?  YES  NO (If NO, skip to #5)

a. What protein will be produced?

5. (GL: III-A-1) Will any recombinant DNAs containing genes for the biosynthesis of toxic molecules be constructed?  YES  NO (If NO, skip to #6)

a. What is the toxin?

- b. Is the toxin known to be lethal?  YES  NO

If YES, is the LD<sub>50</sub> less than 100 nanograms per kilogram body weight?

- YES  NO

**(Experiments involving formation of recombinant DNAs for genes coding for certain molecules toxic to vertebrates, require RAC review and NIH approval, and must be carried out under NIH-specified conditions, described in GL: Appendix F.)**

6. (GL: III-A-2) Will any organism containing recombinant DNA be released into the environment?

- YES  NO

7. (GL: III-A-3) Will a drug resistance trait be transferred to any microorganism that is not known to acquire that trait naturally?  YES  NO (If NO, skip to #8)

a. Which drug resistance trait is to be transferred?

b. What microorganism will this trait be transferred to?

- c. Would acquisition of such a trait by the microorganism compromise the use of the drug to control disease agents in human or veterinary medicine or agriculture?  YES  NO

8. (GL: III-A-4) Will any DNA, recombinant DNA, or RNA be deliberately transferred into human subjects?

YES  NO

9. (GL: III-B-1) Are either the hosts or vectors human, animal, and/or plant pathogens (Class 1, 2, 3, 4, or 5)?

YES  NO (If NO, skip to #10)

a. Which class(es) are the pathogenic agents (1, 2, 3, 4, or 5)?

**(Work with Class 5 agents requires a special USDA permit and determination of containment conditions by OBA review.)**

10. (GL: III-B-2) Does proposed work include cloning DNA from human or animal pathogens (Class 1, 2, 3, 4, or 5) in a nonpathogenic prokaryotic or lower eukaryotic host-vector system?  YES  NO (If NO, skip to #11)

a. From what source will the DNA be obtained?

b. Is it a Class 1, 2, 3, 4, or 5 agent?

**(Work with Class 5 agents requires a special USDA permit, and determination of containment conditions or OBA review.)**

c. If the source is Class 4, has it been previously demonstrated that the recombinant DNA is a totally and irreversibly defective fraction of the Class 4 agent's genome?  YES  NO

**If NO, BL4 containment should be used. If YES, the work can be done at BL2, or the IBC may lower the containment level to BL1, or the experiment may be exempt from the Guidelines according to GL: III-D-4 and GL: III-D-5.**

11. (GL: III-B-3) Does the proposed work involve using infectious animal or plant viruses, or defective animal or plant viruses in the presence of helper virus, in the tissue culture?  YES  NO (If NO, skip to #12)

a. Are the proposed experiments likely to enhance the pathogenicity (e.g., insertion of a host oncogene) or to extend the host range (e.g., introduction of novel control elements) of a viral vector under conditions that permit a productive infection?  YES  NO

**If YES, the IBC may increase the containment level.**

b. Is the virus or defective virus a Class 1, 2, 3, 4, or 5 agent?

**(Work with Class 5 agents requires a special USDA permit and determination of containment conditions by OBA review.)**

c. Does defective nucleic acid represent less than 2/3 of the viral genome?

YES  NO

If YES, has it been shown that the cells in which this defective nucleic acid will be propagated and maintained are free of helper virus for the specific Family of viruses being used?

YES  NO

**(When greater than 2/3 of the genome of any one virus is used, and if helper virus is present, procedures under GL: III-B-3 should be used, according to GL: III-C.)**

12. (GL: III\_B-4) Does the proposed work involve the transfer of recombinant DNA to whole animals or plants?  
 YES       NO      (If NO, skip to #13)

a. Which animal or plant will be involved?

b. If the recombinant molecule to be transferred is a fraction of the genome of any eukaryotic virus, has it been shown that it does not lead to a productive infection?       YES       NO

c. Will the transferred nucleic acid represent greater than 2/3 of any eukaryotic viral genome?  
 YES       NO

13. (GL: III-B-5) Does the proposed work involve more than 10 liters of culture?  
 YES       NO

14. What Biosafety (containment) Level have you determined is appropriate for conducting the proposed work?

BL:

Exempt work should still be done at a BL appropriate for the host or recombinant organism; also according to GL: III-C, experiments not covered in GL: III-A, -B, or -D may be carried out at BL1 containment.

15. Will all personnel participating in this work be apprised of the biohazard involved and trained appropriately in microbiological techniques and precautions necessary for them to maintain the appropriate containment level, and will they be instructed in emergency plans for accidental spills or personnel contamination?  
 YES       NO

16. Will there be any shipping of recombinant or infectious materials to or from other sites in the course of this project?  
 YES       NO      (If NO, skip to C)

a. (GL: Appendix H) Will requirements for shipping of etiologic agents, as described in the NIH Guidelines be strictly followed?  
 YES       NO

C. Briefly, but specifically, describe the location where this work will be done, and special containment equipment and laboratory facilities (e.g., biosafety cabinets, negative airflow animal facilities, autoclaves) which will be used to adhere to the appropriate Biosafety Level: