

NC STATE UNIVERSITY BIOSAFETY COMMITTEE
INSTRUCTIONS: REPORTING RECOMBINANT DNA EXPERIMENTS

This is a selective guide to the recombinant DNA (r-DNA) proposal registration forms. It is not meant to be comprehensive. In the NIH Guidelines for Research Involving Recombinant DNA Molecules experiments are classified according to their potential for biological hazards. Before completing the registration form, check the Guidelines and ascertain the classification of your work. http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm

Your work may include experiments that fall into more than one class of the Guidelines. For instance, E. coli cloning work is mostly Class III-F-5, expression of r-DNA genes in cell culture may be III-D or III-E and animal work will be III-D-4a or b. You are asked to report each Class of experiment separately. Some work of minimal hazards (i.e., Class III-F-5) is exempt from the Guidelines, however it must be reported.

1. Registration Documents.

Any r-DNA proposals involving animals must be reviewed and approved by the IACUC and the NCSU BIOCUM before being submitted to the IBC for final review and approval. Submission to the IACUC and NCSU BIOCUM should be made at the same time. r-DNA experiments involving animals cannot be initiated before IBC approval is granted.

Any pathogens/human blood/OPIM¹ used in r-DNA experiments must also be registered with the NCSU BIOCUM.

Exempt work includes:

- (A) r-DNA containing less than 1/3 of a eukaryotic viral genome propagated in cell culture. (Class III-F-5 and Appendix C I)
- (B) Work involving E. coli K12 host-vector systems. (Class III-F-5 and Appendix C II)
- (C) Work involving Saccharomyces cerevisiae host-vector systems. (Class III-F-5 and Appendix C III)

Non-Exempt work includes:

- (A) Experiments including human or animal pathogens as host- vector systems. (Class III-D-1)
- (B) Experiments involving infectious virus or defective virus plus helper in tissue culture. (Class III-D-3)
- (C) Experiments involving animals. This includes the use and creation of transgenic animals. (Class III-D-4)
- (D) Experiments not included in Class III-A, III-B, III-C, III-D and III-F are classed III-E. They include the following:
 - (i) r-DNA molecules containing less than 2/3 genome of an eukaryotic virus propagated in tissue culture, no helper virus being present.
 - (ii) The NCSU BIOCUM place experiments involving the use of defective retrovirus vectors with an enabling packaging cell system in Class III-E. Where there is the potential for infection of human cells, experiments will be performed at BL-2.

2. Amendments to the Recombinant DNA Registration Document. The NC State Biosafety Specialist and Committee (NCSU BIOCUM) should be notified, in writing, when there are any changes made to the r-DNA registration document. In some cases, a new Registration Form will need to be completed.

In instances where nonexempt r-DNA changes are proposed, review by the NCSU BIOCUM will be initiated and, if approved, submitted to the NCSU BIOCUM for approval. Where animal protocols are proposed as an amendment, review and approval by both the IACUC and NCSU BIOCUM is required.

These amendments include:

- (A) Changes in the materials being used. These include upgrading host-vector systems (from "Exempt" to "Non-Exempt"), changes in the amount, type and manipulation of virus being used and the use of mammalian cell culture, pathogens or OPIM.
- (B) Changes in protocol that reclassify "Exempt" experiments as "Non-Exempt" (mentioned above).
- (C) Initiation of animal protocols associated with materials registered.
- (D) Personnel additions and/or deletions.
- (E) Terminations of registered r-DNA programs and/or a change in the principal investigator(s) associated with these programs.

¹"Other potentially infectious materials" means:

- (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
- (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
- (3) HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture medium or other solutions, and blood, organs or other tissues from experimental animals infected with HIV or HBV.

Please call if you have questions, call Safety at x5-6858

Form can be filled out online and saved using MS Word. Send signed hard copy to Biosafety Specialist EHS Box 8007. **Only** type written applications will be accepted. Hand written forms will be returned.

REGISTRATION OF RESEARCH WITH RECOMBINANT DNA MOLECULES

BSC#:

DATE RECEIVED: _____

APPROVAL DATE: _____

DO NOT WRITE IN ABOVE SPACE

**

1. Principal Investigator: _____ Telephone: _____
Bldg/Rm: _____ Organization: _____ Program: _____
Project Title: _____

2. Briefly describe the objective of the proposal. (Attach additional sheets as necessary) Include in your description the following items: agent characteristics; types of manipulation planned; sources of the inserted DNA sequences; nature of the DNA sequences (structural gene, oncogene); Host(s) and vector(s) to be used; whether an attempt will be made to obtain expression of a foreign gene and the protein that will be produced; Containment conditions to be implemented.

3. Name of organism(s) used as host (cloning vehicle):

a) Prokaryotes: (e.g., E. coli K12)

b) Eukaryotes: (e.g., mammalian cell lines)

c) Higher animals: (e.g., mice)

Animal Study Proposal#

(Attach copy)

4. a. Describe use of animals: (if applicable)

b. Does the possibility of recombination with endogenous virus exist YES NO

5. Nature of gene sequences inserted in the recombinant (give detailed description, attach catalogue description if obtained commercially).

6. If virus is used, check appropriate statement(s):

a) Quantity: Whole virus <2/3 viral genome <? Viral genome

b) Use: Vector Donor of genetic information Explain what the genetic materials is to do in this experiment:

c) Is virus replication competent? YES NO

d) Is virus capable of infecting human cells? YES NO

e) Classification:

Prokaryotic virus Name

Eukaryotic virus Name

Oncogenic virus Name

Risk level: High Moderate Low

Infectious agent Name

Risk level: BL1 BL2 BL3

7. Vector(s): List specific phage, virus or plasmid and the function of each:

8. Are plant or animal cells to be exposed to the recombinant?

YES NO

a) If yes, describe the potential hazards:

b) List cells or cell lines to be used:

c) What infectious virus, oncogenic agents or toxins will be produced during this work?

9. Is a deliberate attempt made to obtain expression of foreign gene(s) in the cloning vehicle?

YES NO

If yes: What proteins?

10. Are recombinant organisms/molecules?

a. What NIH Classification does this project fall in?

b. Genetically modified microorganisms or genetic elements from organisms listed on the CDC List of Select Agents (42 CFR 72.6, Appendix A) shown to produce or encode for a factor associated with a disease? YES NO

c. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed on the CDC List of Select Agents (42 CFR 72.6, Appendix A), or their toxin subunits? YES NO

11. Describe **potential hazards** associated with this protocol:

12. Describe the equipment and procedures used to safely conduct this protocol which address any potential hazards:

13. Have all personnel associated with this protocol (including animal caretakers) been instructed and trained in the practices and techniques required to ensure safety and the procedures for dealing with accidents?

YES NO

If yes, please attach a roster of all personnel with signatures indicating that they have been informed of potential hazards, safe work practices, availability of medical surveillance and that they understand and will follow approved laboratory practices and procedures.

14. List building and room(s) where work will be conducted (including animal work to support this protocol):

If an individual room has been designated for work at more than one Biosafety Level (i.e., BL1 and BL2), the highest degree of physical containment and work practice should apply at all times.

	Lab	Animal Facility
a) BL1		
b) BL2		
c) BL3		

I attest that the information contained in this application is accurate and complete. I agree to comply with the NIH requirements pertaining to shipment and transfer of recombinant DNA materials. I acknowledge my responsibility for the conduct of this research in accordance with Section IV-B-4 of the NIH Guidelines.

I will not carry out the work described in the attached application until it has been filed with the IBC or, when necessary, until it has been approved by the Committee and all requirements have been met.

Principal Investigator _____

Date

DO NOT WRITE BELOW THIS LINE

This Registration Document is approved by the NC State University Biosafety Committee

Chairman, NCSU BIOCUM

DATE

Note: Return Completed form to Biosafety, Box 8007