Biological Safety Program

Recombinant DNA

Form

Registration for Recombinant DNA Experiments

Section A: Basic Information (To be completed for <u>all</u> projects, by Principal Investigator [PI]). Please type or print clearly. Note: Fill out Sections A-D only. Return the completed form to IBC Chair and EHS.	
Project Title/Proposal:	
Proposed Start Date for Research:	Registration Number (to be completed by IBC Chair/EHS):
PI Name:	Phone:
Department:	Building & Laboratory Room:

Your signature below indicates that you acknowledge all requirements and restrictions of the most current NIH Guidelines for the biosafety level you have indicated, unless modified by the IBC, that you accept responsibility for the safe conduct of the experiments conducted at this biosafety level and that you have informed all associated personnel of the conditions required for this work. It is the Principal Investigator's responsibility to follow the NIH Guidelines and notify EHS and the IBC of any adverse events, including research-related accidents and illnesses. The Principal Investigator certifies that the work description is accurate. Any work performed that is not approved under this permit may be subject to the loss of grant funds. This registration must be updated every three years.

Signature, Principal Investigator	**Date**
Signature, Department Chair	**Date**

Experiments which are exempt and do not require a full registration:

Examples include rDNA that is: not in organisms and viruses; DNA segments entirely from a single non-chromosomal or viral DNA source; entire DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host or when transferred to another host by well-established physiological means; entire DNA from a eukaryotic host when propagated only in that host or a closely related strain of the same species; entire DNA segments from different species that exchange DNA by known physiological processes; or DNA that is not a significant risk to health or the environment. NOTE: Any large-scale work greater than 10 liters is NOT considered exempt, even if it fits any of the above criteria.

SECTION B: Details of Work (To be completed for covered [non-exempt] projects only)

1. Source(s) of DNA/RNA sequences (include genus, species, gene name, and abbreviation):

2. Is a vector (virus, plasmid, phage, or any other) used? □ Yes □ No

a. If yes, identify specific phage, plasmid, or virus: _____

b. If a viral vector: □ Adenovirus □ Retrovirus □ Other □ None

c. If a viral vector, is it defective: □ Yes □ No □ N/A

d. If a viral vector, is it replication competent: □ Yes □ No □ N/A

e. If a viral vector, what percent of the viral genome remains?

f. If a viral vector is used, provide evidence or documentation to substantiate replication incompetence and method to ensure that replication-competent virus is not generated. (Please attach document(s))

g. if a viral vector is used, and if packaging cells are used with murine retroviral vectors, does this broaden the host range of the virus (e.g. ecotropic to amphotropic)? Explain (include packaging cell line, tropism, and added risk of a broadened host range, if applicable). (Please attach document(s))

3. If the recombinant DNA contain viral DNA, does the insert represent more than 2/3 of the viral genome? □ Yes □ No □ N/A

4. What is the biological activity of the gene product or inserted sequence?

5. Will a deliberate attempt be made to obtain expression of the foreign gene encoded in the recombinant DNA? □ Yes □ No

a. If expression is obtained, protein, or RNA name:

6. Name host strain for propagation of the recombinant DNA (give genus, species, and parent strain):

a. Is host strain pathogenic? □ Yes □ No □ N/A

7. Is there transfer of a drug resistance gene? □ Yes □ No

a. If yes, what is the gene?

b. If yes, is the drug resistance trait acquired naturally by the microorganism? □ Yes □ No

c. If yes, will the acquisition of the trait compromise the use of the drug control disease agents in humans, veterinary medicine, or agriculture? □ Yes □ No

8. Does work involve cloning toxin molecules with an LD_{50} of < 100 ng/kg of body weight?

a. If yes, what specific precautions are used to prevent accidental release of toxin? (Please attach document(s))

9. Is there a target recipient of this recombinant DNA? □ Yes □ No

a. If there is a recipient organism, indicate species or cell lines:

Animals: Tissue Culture (See Question 11):

Plant Cells: Plants:

Yeast: Bacteria:

Other:

Specify target host (s):

b. If target is a plant or animal, is there the possibility of any form of horizontal transmission outside the laboratory setting? □ Yes □ No

c. If target is a plant of animal, what precautions are taken to prevent release of recombinant organisms into the wild? (Please attach document(s))

10. Is there production of transgenic organisms? □ Yes □ No a. If yes, what precautions are taken to prevent release of animals to the wild?
11. Is the work in cell or tissue culture? □ Yes □ No □ N/A a. If yes, do the recombinant DNA molecules contain greater than half of any eukaryotic viral genome? □ Yes □ No b. If yes, identify cells or cell lines being used:
12. Relevant Section of NIH Guidelines:
13. Proposed Biosafety Level for Project (Check one): □ Biosafety Level 1 (BSL-1) □ Biosafety Level 2 (BSL-2)
14. Physical Containment:
15. Have all personnel involved in this project been trained to the appropriate biosafety level? □ Yes □ No
SECTION C: Risks and Safety (To be completed for covered [non-exempt] projects only). List the potential risks associated with the research and the safety precautions utilized to address those risks.
Potential Risks:
Safety Precautions:
SECTION D: An abstract of the research and objectives in layman's terms must also be submitted by PI on a separate page. Some proposals may require an additional form "Registration of Materials (Potentially) Infectious for Humans" to be completed.
(Section Intentionally Left Blank)
SECTION E: (To be completed by IBC Chair/EHS)

The laboratory was certified at BSL-____ on (Date) _____	**The registration was approved on (Date) _____**
Signature	**Signature**