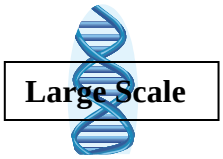
Registration #: _____



University of Delaware
Department of Environmental Health & Safety
Large Scale Recombinant DNA Registration

Directions: Please complete this form to register recombinant DNA research with the University Biosafety Committee (UBC) as required by the most current "Guidelines for Research Involving Recombinant DNA Molecules" (NIH *Guidelines*) and University Policy 7-19.

Submit a separate form for each project. **A copy of the current *Guidelines* is available at the EHS web site: http://www.udel.edu/ehs/. For questions, please contact the Biosafety Officer at 831-8475.**

Section I- to be completed for all projects

Principal Investigator:
Department:
Address:
Phone Number: Fax:
Email:
Labs to be used: 239A DBI other:
Project Title:
Proposed start date for project:
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 UBC, 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 the Biosafety Officer and the UBC of any adverse events, including research-related accidents and illnesses. The Principal Investigator certifies that the work description is accurate. Any work performed which is not approved under this permit may be subject to the loss of grant funds. This registration must be updated annually. Signature of Investigator: Date:

Section II- to be completed for all projects

Check the appropriate registration category for experiments covered by the NIH Guidelines:
All categories are defined in the NIH Guidelines

E. Experiments that Require IBC Approval Before Initiation ☐ 6. Experiments involving more than 10 liters of culture

Section III- to be completed for large-scale projects

1. Names of individuals participating in project, with job title:
2. Source(s) of DNA/RNA sequences (include genus, species, gene name and abbreviation):
3. Is a vector required? **Yes** ☐ **No** ☐ If yes, identify specific phage, plasmid, or virus**:** Virus vector: Adenovirus ☐ Retrovirus ☐ Other ☐ Defective: **Yes** ☐ **No** ☐ Replication competent: **Yes** ☐ **No** ☐ If viral vector, what percent of the viral genome remains?
4. If the recombinant contains viral DNA, does the insert represent more than 2/3 of the viral genome? **Yes** ☐ **No** ☐
5. Is a helper virus required? **Yes** ☐ **No** ☐ If yes, specify**:**
6. What is the biological activity of the gene product or sequence inserted?
7. Will a deliberate attempt be made to obtain expression of the foreign gene encoded in the recombinant DNA? **Yes** ☐ **No** ☐
8. Host strain for propagation of the recombinant (give genus, species, and parent strain):
9. Target recipient of recombinant DNA (indicate species or cell lines used): Animals: Tissue Culture: Plant cells: Plants: Gene therapy: Specify target host(s) - human, animal species:
10. Proposed biosafety level for project (check one): Good Large Scale Practice ☐ 1 ☐ Intended culture volume:
11. Description of biohazard and how the hazards will be managed (containment, PPE, disinfection, etc):
12. Other additional information we should know:

13. Have all personnel involved in this project been trained to the appropriate biosafety level?
Yes ☐ **No** ☐

14. Dual Use Research- Check any categories below that apply to your project:
☐ Renders a useful vaccine ineffective
☐ Adds antibiotic resistance affecting response to a clinically useful drug
☐ Enhances pathogen virulence
☐ Increases pathogen transmissibility
☐ Widens a pathogen's host range
☐ Enables a pathogen to evade diagnostic or detection modalities
☐ Weaponization (e.g. environmental stabilization of pathogens)
☐ None of the above

Section IV- For UBC Use Only

☐ Project/work requires registration according to NIH *Guidelines*. The PI and staff can safely perform this work with the training, work practices, and lab facilities listed.

The following signatures indicate provisional approval by the University Biosafety Committee for this project involving recombinant DNA technology. The work is to be performed according to NIH requirements. Final approval for projects that are NOT exempt from the NIH *Guidelines* will not be granted until after review by the entire UBC at the next meeting. Non-exempt work covered under this approval cannot begin until final approval is received.

UBC Member Conducting Review
Print Name:

Signature:

Date:

Biosafety Officer
Print Name:

Signature:

Date:

Expiration date:

Final UBC approval date:

UBC Representative Signature:

UBC Comments: