

UNIVERSITY OF DELAWARE
REGISTRATION FORM FOR RECOMBINANT DNA RESEARCH

Instructions: 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 DOHS web site: <http://www.udel.edu/OHS/>. For questions, please contact the Biosafety Officer at 831-8475. Be sure to attach a description of the recombinant DNA procedures to this form.

Section I

1. Principal Investigator: _____

2. Department: _____

3. Address: _____

4. Phone Number: _____ Fax: _____

5. Labs to be used: _____

6. Project Title: _____

or for exempt work: General Work Description: _____

7. Expected start date for research: _____

Section II

Check the appropriate registration category for experiments covered by the NIH Guidelines:

All categories are defined in the NIH Guidelines

A. Experiments which are exempt and do not require registration.

- Examples include: Cloning of all other DNA in *E. coli* K12, *S. cerevisiae*, and *B. subtilis* host-vector systems (with the exception of DNA from Class 3, 4, or 5 pathogens); introduction into cultured cells of any recombinant DNA containing less than half of a eukaryotic viral genome (with the exception of Class 3, 4, or 5 pathogens).

If work is exempt, attach a description of the recombinant DNA procedures performed in the lab then go to Section IV.

B. Experiments that Require IBC Approval, Recombinant DNA Advisory Committee Review, and NIH Director Approval Before Initiation

1. Major Actions (See Section III-A-1 of the NIH Guidelines)
2. Deliberate transfer of a drug resistance trait to a microorganism that is not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture

C. Experiments that Require NIH/ORDA and IBC Approval Before Initiation

1. Experiments involving the cloning of toxin molecules with LD₅₀ of less than 100 nanograms per kilogram body weight

- D. Experiments that Require IBC Approval, Human Subjects Approval, and NIH/ORDA Registration Before Initiation. Submit completed Appendix M, I-V from the NIH Guidelines along with this document
- 1. Experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects (human gene transfer)
- E. Experiments that Require IBC Approval Before Initiation
- 1. Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems
 - 2. Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic Host-Vector Systems
 - 3. Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems
 - 4. Experiments involving recombinant DNA in animals or transgenic whole animals
 - 5. Experiments involving whole plants
 - 6. Experiments involving more than 10 liters of culture
- F. Experiments that Require IBC Notice Simultaneous with Initiation
- 1. Experiments involving the formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus.
 - 2. Experiments involving whole plants (if not included in Category E5 above)

Section III

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. If the recombinant contains viral DNA, does the insert represent more than 2/3 of the viral genome? YES NO
4. What is the biological activity of the gene product or sequence inserted?

5. Will a deliberate attempt be made to obtain expression of the foreign gene encoded in the recombinant DNA? YES NO
6. Host strain for propagation of the recombinant (give genus, species, and parent strain):

7. Is a helper virus required? YES NO If yes, specify: _____
8. Is a vector required? YES NO If yes, identify specific phage, plasmid, or virus.

9. If viral vector, what percent of the viral genome remains? _____
10. 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 _____
11. Proposed biosafety level for project (circle one): 1 2 3
12. Has all personnel involved in this project been trained to the appropriate biosafety level?
YES NO

Section IV

Your signature below indicates that you acknowledge all requirements and restrictions of the most current NIH Guidelines for the biosafety level you have indicated above, 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.

Signature of Investigator: _____

Date: _____

UBC Action

Acceptance: _____ Rejection: _____

Signature of UBC Representative: _____

Date: _____

UNIVERSITY OF DELAWARE
CHECKLIST FOR REVIEW OF RECOMBINANT DNA REGISTRATION

Principal Investigator: _____

General Work Description: _____

Project Title: _____

- 1. Project/work exempt from recombinant DNA *Guidelines* (Make sure Work Description is attached. No further information necessary.)
- 2. Project/work requires registration according to the NIH Guidelines.
- 3. The appropriate registration category has been selected (A-E on Registration Document).
- 4. The Principal Investigator has conducted a comprehensive risk assessment, and the appropriate containment level has been assigned.
- 5. The Principal Investigator and appropriate staff have a copy of/ access to the NIH Guidelines and are familiar with its contents.
- 6. The Principal Investigator and appropriate staff have a copy of the CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories" Manual and are familiar with its contents.
- 7. The Principal Investigator and staff have proper training in good microbiological practices.
- 8. The Principal Investigator has proper equipment to conduct planned work.
- 9. The Principal Investigator's group has appropriate facilities to conduct work.
- 10. A copy of the Abstract has been attached to the Registration Form.
- 11. A list of all individuals participating in this project has been submitted.
- 12. All required information has been submitted and reviewed.

The following signatures indicate provisional approval of 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 committee at the next meeting. Non-exempt work covered under this approval can not begin until final approval is received.

UBC Member Conducting Review: _____ Date: _____

Biosafety Officer Signature: _____ Date: _____

Expiration Date: _____

This section to be signed when submitting form with the grant application.

I certify that the work to be performed with this grant is consistent with that approved by the University Biosafety Committee. I understand that any work that is not approved through this permit may be subject to the loss of grant money.

Principal Investigator's Signature _____

MUST be an original signature