

<b>EHS Use Only</b> Protocol#:
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Send original to:

Yale Environmental Health and Safety  
Occupational Health and Safety Section  
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New Haven, CT 06510  
Phone 785-3550 fax: 785-7588

**YALE UNIVERSITY**  
**BIOLOGICAL SAFETY COMMITTEE**  
**REGISTRATION OF RECOMBINANT DNA EXPERIMENTS**

Principal Investigator: \_\_\_\_\_ Anticipated Starting Date: \_\_\_\_\_

Faculty Rank or Research Appointment: \_\_\_\_\_

Department: \_\_\_\_\_ Telephone #: \_\_\_\_\_ Fax #: \_\_\_\_\_

Short Title of Proposal: \_\_\_\_\_

Brief summary stated in non-technical language:

I attest that the information in the attached Registration is accurate and complete. I am familiar with and agree to comply with the NIH Recombinant DNA Guidelines and accept the responsibilities listed in Section IV-B-7 as printed on the reverse side of this form, as well as any modifications of these guidelines subsequently issued by the Federal Government or Yale University.

As the Principal Investigator, I agree to accept responsibility for training all laboratory workers involved in the project. All research personnel will be familiar with and understand the potential biohazards and relevant biosafety practices, techniques and emergency procedures.

Written reports will be submitted to the Biological Safety Officer, the Biological Safety Committee, and the Office of Recombinant DNA Activities at NIH (if applicable) concerning: any research related accident, exposure incident or release of rDNA materials to the environment; problems pertaining to the implementation of biological and physical containment procedures; or violations of the NIH Guidelines.

I will not conduct the work described in the attached registration until it has been filed with, and if necessary, approved by the Biological Safety Committee.

Principal Investigator \_\_\_\_\_  
Signature

Date \_\_\_\_\_

Additional Investigator \_\_\_\_\_  
Signature

Date \_\_\_\_\_

Reviewed and Accepted \_\_\_\_\_  
Institutional Biological Safety Committee

Date \_\_\_\_\_

#### **Section IV-B-7. Principal Investigator (PI)**

On behalf of the institution, the Principal Investigator is responsible for full compliance with the *NIH Guidelines* in the conduct of recombinant DNA research.

A Principal Investigator engaged in human gene transfer research may delegate to another party, such as a corporate sponsor, the reporting functions set forth in Appendix M, with written notification to the NIH OBA of the delegation and of the name(s), address, telephone, and fax numbers of the contact. The Principal Investigator is responsible for ensuring that the reporting requirements are fulfilled and will be held accountable for any reporting lapses.

#### **Section IV-B-7-a. General Responsibilities**

As part of this general responsibility, the Principal Investigator shall:

**Section IV-B-7-a-(1).** Initiate or modify no recombinant DNA research which requires Institutional Biosafety Committee approval prior to initiation (see Sections III-A, III-B, III-C, III-D, and III-E, *Experiments Covered by the NIH Guidelines*) until that research or the proposed modification thereof has been approved by the Institutional Biosafety Committee and has met all other requirements of the *NIH Guidelines*;

**Section IV-B-7-a-(2).** Determine whether experiments are covered by Section III-E, *Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation*, and ensure that the appropriate procedures are followed;

**Section IV-B-7-a-(3).** Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable) within 30 days. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax);

**Section IV-B-7-a-(4).** Report any new information bearing on the *NIH Guidelines* to the Institutional Biosafety Committee and to NIH/OBA (reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax));

**Section IV-B-7-a-(5).** Be adequately trained in good microbiological techniques;

**Section IV-B-7-a-(6).** Adhere to Institutional Biosafety Committee approved emergency plans for handling accidental spills and personnel contamination; and

**Section IV-B-7-a-(7).** Comply with shipping requirements for recombinant DNA molecules (see Appendix H, *Shipment*, for shipping requirements and the *Laboratory Safety Monograph* for technical recommendations).

#### **Section IV-B-7-b. Information to Be Submitted by the Principal Investigator to NIH OBA**

The Principal Investigator shall:

**Section IV-B-7-b-(1).** Submit information to NIH/OBA for certification of new host-vector systems;

**Section IV-B-7-b-(2).** Petition NIH/OBA, with notice to the Institutional Biosafety Committee, for proposed exemptions to the *NIH Guidelines*;

**Section IV-B-7-b-(3).** Petition NIH/OBA, with concurrence of the Institutional Biosafety Committee, for approval to conduct experiments specified in Sections III-A-1, *Major Actions Under the NIH Guidelines*, and III-B, *Experiments that Require NIH/OBA and Institutional Biosafety Committee Approval Before Initiation*;

**Section IV-B-7-b-(4).** Petition NIH/OBA for determination of containment for experiments requiring case-by-case review; and

**Section IV-B-7-b-(5).** Petition NIH/OBA for determination of containment for experiments not covered by the *NIH Guidelines*.

**Section IV-B-7-b-(6).** Ensure that all aspects of Appendix M have been appropriately addressed prior to submission of a human gene transfer experiment to NIH OBA, and provide a letter signed by the Principal Investigator(s) on institutional letterhead acknowledging that the documentation being submitted to NIH OBA complies with the requirements set forth in Appendix M. No research participant shall be enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*); IBC approval (from the clinical trial site) has been obtained; Institutional Review Board (IRB) approval has been obtained; and all applicable regulatory authorization(s) have been obtained.

For a clinical trial site that is added after the RAC review process, no research participant shall be enrolled (see definition of enrollment in Section I-E-7) at the clinical trial site until the following documentation has been submitted to NIH OBA: (1) IBC approval (from the clinical trial site); (2) IRB approval; (3) IRB-approved informed consent document; (4) curriculum vitae of the principal investigator(s) (no more than two pages in biographical sketch format); and (5) NIH grant number(s) if applicable.

#### **Section IV-B-7-c. Submissions by the Principal Investigator to the Institutional Biosafety Committee**

The Principal Investigator shall:

**Section IV-B-7-c-(1).** Make an initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*;

**Section IV-B-7-c-(2).** Select appropriate microbiological practices and laboratory techniques to be used for the research;

**Section IV-B-7-c-(3).** Submit the initial research protocol and any subsequent changes (e.g., changes in the source of DNA or host-vector system), if covered under Sections III-A, III-B, III-C, III-D, or III-E (*Experiments Covered by the NIH Guidelines*), to the Institutional Biosafety Committee for review and approval or disapproval; and

**Section IV-B-7-c-(4).** Remain in communication with the Institutional Biosafety Committee throughout the conduct of the project.

#### **Section IV-B-7-d. Responsibilities of the Principal Investigator Prior to Initiating Research**

The Principal Investigator shall:

**Section IV-B-7-d-(1).** Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;

**Section IV-B-7-d-(2).** Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents; and

**Section IV-B-7-d-(3).** Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

#### **Section IV-B-7-e. Responsibilities of the Principal Investigator During the Conduct of the Research**

The Principal Investigator shall:

**Section IV-B-7-e-(1).** Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;

**Section IV-B-7-e-(2).** Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable) (reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax));

**Section IV-B-7-e-(3).** Correct work errors and conditions that may result in the release of recombinant DNA materials; and

**Section IV-B-7-e-(4).** Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).

**Section IV-B-7-e-(5).** Comply with reporting requirements for human gene transfer experiments conducted in compliance with the *NIH Guidelines* (see Appendix M-I-C, *Reporting Requirements*).

**I. SPECIFIC INFORMATION:**

A. Will experiment be carried out in *E. coli* or other prokaryotic host? Yes                  No

If yes, specify: \_\_\_\_\_

Host strains: \_\_\_\_\_

Vectors: \_\_\_\_\_

inserted DNA (include names of genes and organisms from which they were cloned): \_\_\_\_\_

Will whole virus or provirus be cloned? Yes                  No

NIH Guideline Section: \_\_\_\_\_ Recommended Biosafety Level: \_\_\_\_\_

B. Will experiment be carried out in eukaryotic cells? Yes                  No

If yes, specify: \_\_\_\_\_

Host cells: \_\_\_\_\_

Vectors \_\_\_\_\_

Inserted DNA: \_\_\_\_\_

Helper virus or packaging cells if used: \_\_\_\_\_

What fraction of a eukaryotic viral genome is contained in the recombinant DNA molecules (including vector and insert)? Check appropriate range:                  <1/2                  >1/2 but <2/3                  >2/3

NIH Guideline Section: \_\_\_\_\_ Recommended Biosafety Level: \_\_\_\_\_

C. Will experiment be carried out using whole plants or animals as hosts? Yes                  No

If yes, specify: \_\_\_\_\_

Plant or animal hosts: \_\_\_\_\_

Vectors: \_\_\_\_\_

Inserted DNA: \_\_\_\_\_

What fraction of a eukaryotic viral genome is contained in the recombinant DNA molecule? <2/3                  >2/3

Will transgenic plants or animals be constructed or used? Yes                  No

NIH Guideline Section: \_\_\_\_\_ Recommended Biosafety Level: \_\_\_\_\_

- II. DESCRIPTION OF EXPERIMENT:** 1) Include sufficient detail to clarify the scientific basis of the work. 2) Note approximate start date for each phase of the work. 3) Give references if appropriate.

**III. DESCRIBE THE BIOHAZARD POTENTIAL OF THESE EXPERIMENTS:** Are special medical surveillance practices recommended? Anyone who is currently pregnant or immunosuppressed must contact Employee Health (432-7978) before working with the agent in question.

**IV. LOCATION** (Buildings, Room #s):

**V. PERSONNEL** (Names, Status and Telephone):