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Yale Environmental Health and Safety
Occupational Health and Safety Section
135 College Street, Suite 100
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 _____

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

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.

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 Section III-A, III-B, and III-C) 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-D and 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/ORDA, and other appropriate authorities (if applicable) within 30 days (reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496-9838);

Section IV-B-7-a-(4). Report any new information bearing on the *NIH Guidelines* to the Institutional Biosafety Committee and to NIH/ORDA (reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496-9838);

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 for shipping requirements and the *Laboratory Safety Monograph* for technical recommendations).

Section IV-B-7-b. Submissions by the Principal Investigator to the NIH/ORDA. The Principal Investigator shall:

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

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

Section IV-B-7-b-(3). Petition NIH/ORDA, with concurrence of the Institutional Biosafety Committee, for approval to conduct experiments specified in sections III-A and III-B of the *NIH Guidelines*;

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

Section IV-B-7-b-(5). Petition NIH/ORDA 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, *Points to Consider in the Design and Submission of Protocols for the transfer of Recombinant DNA Molecules into One or More Human Subjects (Points to Consider)*, have been appropriately addressed prior to submission of human gene therapy experiments to NIH/ORDA.

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 Section III-A, III-B, III-C, or III-D, 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), the Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable) (reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496-9838);

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-VII, *Reporting Requirements – Human Gene Transfer Protocols*).

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):