

**University of Texas at Dallas
Biological and Chemical Safety Advisory Committee**

Recombinant DNA Safety Plan

Instructions:

All pertinent sections must be completed. Please retain the format as near as possible and answer questions appropriately placing answers in the space provided. When you have completed the form, print a copy, then sign and date the signature page. Return a signed paper copy of the form to Kathy White, Environmental Health and Safety, campus mail stop WT 14.

If your research involves the use of rDNA, complete Parts 1, 2, 3 and 5. If your research involves the use of etiologic agents, complete part 4 in addition.

Part 1. General Information:

- a. Funding agency or fund source: _____
 - b. Date of activity From _____ To _____
 - c. Project Registration # (leave blank if new project): _____
 - d. Biosafety Level (check all that apply): BL1 BL2 BL3
 - e. Project Title: _____
 - f. Principal Investigator: _____
 - g. Department: _____
 - h. Office Phone: _____ email: _____
 - i. List personnel working on the project and experience of each person

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Part 2. Project Information:

- a. Is this project part of a course or teaching lab? YES NO

 - c. List ALL Laboratories/Facilities where the project research is to be conducted and the corresponding biosafety level: include cold/warm rooms, tissue culture rooms and animal housing if appropriate. Please indicate room(s) where biosafety cabinets (BSC) are located.
Laboratory Room # Biosafety Level
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Part 3. Project Description:

A. Outline the overall goal(s) of the project. Give enough information so the techniques used and purpose of the experiments is clear. Be as concise as possible using reasonably non-technical terms.

List of Hosts: _____

Inserts: _____

Description of study: _____

B. Specific questions, answer as appropriate.

Source of Gene, Insert or Clone:

1. Specify DNA/RNA source (or probe), nature of insert, is a protein expressed, and percent of any viral genome in construct:

2. Do any sequences code for toxins? If so, what LD50?

3. Is the DNA source from a USDA-regulated plant or animal? If the regulated organism is grown or stored at UTSWMC, please include a copy of the USDA permit.

Vectors and Host Cells:

1. Identify cloning/expression/transfection vectors used, recipient bacterial strains, and recipient host cell lines (human, mouse, plant, etc.). Provide a restriction map of vector, describe the location and type of promoters and other control sequences and percent of any viral genome in construct.

2. If using viral vectors, indicate packaging cell lines and assay system used to measure frequency of replication competent virus (background) generated. Include host range of packaged viral vector.

Large Scale Research:

1. Do experiments involve growth of more than 10 liters of culture at a time? If YES, identify culture room and type of equipment used for culture growth and handling.

Safety Procedures:

1. Outline containment equipment and personal protective equipment required to minimize exposure of laboratory personnel during all procedures requiring handling or manipulation of recombinant DNA

2. Outline procedures for decontamination of work surfaces, instruments, glassware, equipment, and liquid containing recombinant DNA materials

3. Outline disposal/decontamination procedures for biologically contaminated sharps, contaminated solid waste, tissues, pipette tips, etc.

4. Will radioactive biological wastes be generated? YES NO
Radiation Protocol # _____

5. Will hazardous chemical and recombinant DNA mixed wastes be generated? YES NO

IF YES, outline what steps are taken to kill agent before disposal of materials to radioactive waste containers. The Radiation Safety Officer and/or Committee must approve all work with radioactive compounds.

6. Are pre-project serum samples, immunization or medical monitoring or surveillance advisable? (Contact EH&S for assistance at x 4111) Is an FDA approved vaccine available if individuals working with micro-organisms involved in this research project want it?

Part 4. Infectious Agent Use:

a. Infectious agent (i.e., H. pylori, SV40, EBV, E.coli 0157) and recommended Biosafety Level (CDC):

b. Source of infectious agent (i.e., new isolate from human tissue, blood, animal, tissue culture, another laboratory, ATCC, etc.):

c. Host range:

d. Length of time agent has been maintained in laboratory culture. Is this agent periodically passaged in animals?

e. Describe disease pathology and mode of transmission. Is this a zoonotic agent?

f. Is a vaccine or therapeutic treatment available?

Experimental Procedures:

1. Describe procedures involving use of infectious agent (indicate culture volume, maximum concentration). How and at what stage of the experiment is the infectious agent inactivated or lysed?

2. Will experiments result in acquisition of new characteristics such as enhanced virulence, infectivity, drug resistance or change in host range? If so, explain:

Safety Procedures:

1. Are safety procedures the same as those listed in section 3 for recombinant DNA (above)?

YES NO

If not, describe the safety procedures used for infectious materials work.

Part 5. Animal Use

Will recombinant DNA (introduction of viral vectors, creation of transgenic animals, knockout/ins, DNA vaccinations, etc.) or infectious agents be introduced into animals? YES NO

If so, indicate introduced gene and vector or the infectious agent as well as the recipient species/mouse strain. _____

What is the expected phenotype of the animal, (e.g., immunodeficient, early disease onset/resistance, etc.)? YES NO

Please provide the following information:

- Animal Project Number _____
 - What is the animal species used in the project? _____
 - Is the biological material injected? Yes No
 - Is it inhaled as an aerosol or gas? Yes No
 - Is it applied to the skin? Yes No
 - Is it given orally? Yes No
- If yes is it given in water gavage food

Will animals show signs of clinical disease? Yes No

Will the agent(s) be shed/excreted by the infected animals? Yes No

Indicate route(s) _____

What disposal requirements are there for the animal carcasses?

What disposal requirements are there for the bedding? _____

Part 6. Certification

The information contained in this application is accurate and complete. I am familiar with and agree to abide by the provisions of the current NIH Guidelines, the NIH Guide for Grants and Contracts, other specific NIH instructions pertaining to the proposed project, UTD Policies and Procedures, and local state and federal regulations.

In addition, I agree to abide by the following requirements:

- a. I will initiate no recombinant DNA research subject to the NIH Guidelines until that research has been reviewed and approved/registered with the Biological and/or Chemical Safety Committee.
- b. I will follow appropriate biosafety level laboratory techniques in the research.
- c. I will comply with all shipping requirements for recombinant DNA materials.
- d. I will make available to the laboratory staff copies of the approved protocols that describe the potential biohazards and the precautions to be taken.

- e. I will train staff in: good microbiological practices and techniques required to ensure safety for this project, in the procedures for dealing with accidents, and in waste management procedures.
- f. I will supervise staff, and correct work errors and conditions that could result in breaches of the NIH Guidelines and UT Dallas policy.

Principal Investigator

Date

2/15//2006