

FOR OFFICE USE ONLY

Protocol No:

Approval Date:

Expiration Date:

APPLICATION FOR RESEARCH OR TEACHING PROJECT INVOLVING RECOMBINANT DNA OR BIOLOGICALLY HAZARDOUS MATERIALS

SANTA CLARA UNIVERSITY BIOSAFETY COMMITTEE

It is the instructor's or investigator's responsibility to provide complete information about teaching and research procedures involving recombinant DNA (rDNA) and/or biologically hazardous materials. The Santa Clara University Biosafety Committee (BSC) reviews all requests to conduct teaching and/or research activities involving rDNA and biologically hazardous materials. Because the persons reviewing your application may be entirely unfamiliar with the field of study involved, please present the request in non-technical terms understandable to the BSC. Please electronically submit a copy of your complete application and any other material or background information that will assist the Biosafety Committee in its review. Full links to reference materials can be found on page 6 of application.

New Application Annual Renewal :

Date of Request: Anticipated Project End Date:

Principal Investigator/ Instructor	Department (& course number, if relevant)	Phone Number: E-mail:
Other Investigators and/or staff (list all)	Address:	Phone Number(s): E-mail(s):

Project Title:
Additional Comments:

Check the appropriate box

Does the proposed teaching or research activity involve recombinant DNA? Yes No
(if you answered yes, complete sections I & III)
Reference: [Experiments Covered by NIH](#)

Does the proposed teaching or research activity involve:

a) Human Embryonic Stem Cell /Derivative? Yes No
(if you answered yes, stop and contact Research Compliance)

b) CDC-listed Biologically Hazardous Agents? Yes No *(see CDC/NIH guidelines)*

c) Human blood or other bodily fluids? Yes No
(if you answered yes to question b or c above, provide the name of the material below and complete sections II & III)

Reference: [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\), 6th edition](#)

Name of Biohazardous material(s), including any applicable cell lines:

**** if you answered no to all the above questions, no further action is required**

I am familiar with and agree to abide by the current NIH guidelines for research involving Recombinant DNA and CDC/NIH Biosafety in the Microbiological, Biomedical Laboratories manual involving Biologically Hazardous Agents and Santa Clara University Biosafety Policy and Procedures. The information in the attached application is accurate and complete.

Signature, Principal Investigator

Date

Section I: Studies Involving Recombinant DNA (rDNA)

Reference: [Experiments Covered by NIH](#)

Check all of the following that apply to your studies involving recombinant DNA. If you answer YES to any of the following conditions, Biosafety Committee approval will be required:

Reference: [Experiments Covered by NIH](#)

For Risk Groups, reference [NIH Appendix B](#) and [American Biological Safety Association Risk Group Database](#)

****NIH/Office of Biotechnology Activities (OBA) and Biosafety Committee approvals are required for the following:***

- a. Experiments involving the cloning of toxin molecules with LD50 of less than 1 mg/ kg body weight
(Section III-B-1) Yes No

*****Biosafety Committee approval is required prior to initiation of experiments that include the following:***

- a. Experiments using Risk Group 2, 3, 4, or Restricted Agents as host-vector systems
(Section III-D-1) Yes No
- b. DNA from Risk Group 2, 3, 4, or Restricted Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems
(Section III-D-2) Yes No
- c. 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
(Section III-D-3) Yes No
- d. Experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived from, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals.
(Section III-D-4) Yes No
If yes, what is the animal species?
- e. Experiments to genetically engineer plants by recombinant DNA methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant DNA
(Section III-D-5) Yes No
- f. Experiments producing more than 10 Liters of culture of organisms containing Recombinant DNA of Risk Group 1, 2 or 3.
(Section III-D-6) Yes No
- g. Experiments involving influenza viruses
(Section III-D-7) Yes No

*****(continued) Biosafety Committee approval is required prior to initiation of experiments that include the following:***

h. Experiments involving the formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus.

(Section III-E-1) Yes No

i. Experiments involving recombinant DNA-modified whole plants, and/or experiments involving recombinant DNA-modified organisms associated with whole plants

(Section III-E-2) Yes No

j. Experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived from into the germ-line (transgenic rodents). Only experiments that require BL1 containment are covered under this section

(Section III-E-3) Yes No

Complete Section III

Section II: Studies Involving Biologically Hazardous Materials

Reference: [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\), 6th edition](#)

Check all of the following that are applicable to your studies involving biologically hazardous materials. If you answer YES to any of the following conditions, Biosafety Committee approval will be required:

For reference see CDC/NIH guidelines: [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\), 6th edition](#)

- a. Viruses Yes No
 - b. Toxins (bacterial, fungal, plant) Yes No
 - c. Other infectious agents, such as prions Yes No
 - d. Infected animals & animal tissues Yes No
 - e. Human tissue, including scrapings, secretions, body fluids, bones or teeth Yes No
 - f. A primary cell culture derived from human tissue Yes No
- (For stem cell line provide source/origin/ name of cell line under section III)*
- g. Human blood or blood by-products Yes No

Complete Section III

Section III

DESCRIPTION OF THE EXPERIMENT

1. Provide a short summary of the project:

2. Technical description of the project. Explain the goal(s) and methods to be used. **Description must include any cell lines if cells are involved.**

3. Location(s) of experiments, containment equipment (i.e. bio hood) and storage of biologically active agents:

- Experiments to be conducted in room #
- Physical containment equipment to be used: Biosafety Level (BSL)
- Location of agents to be stored room #
- Location of autoclave for your use room#

4. Describe precautions to be taken when handling materials. Check applicable personal protective equipment (PPE) that will be used:

- | | | |
|---|-------------------------------------|--|
| <input type="checkbox"/> Mask | <input type="checkbox"/> Gloves | <input type="checkbox"/> Lab coat |
| <input type="checkbox"/> Shoe covers | <input type="checkbox"/> Head cover | <input type="checkbox"/> Disposable Gown |
| <input type="checkbox"/> Safety Glasses | <input type="checkbox"/> Respirator | <input type="checkbox"/> Other |

<p>5. Describe risk of infection, clinical symptoms, and any recommended medical surveillance and preventive laboratory practices to be used:</p>
<p>6. How do you plan to inactivate the toxin(s) prior to disposal?</p>
<p>7. How do you plan to dispose your biological wastes:</p> <p>Waste disposal method: <input type="checkbox"/> Autoclave <input type="checkbox"/> Biohazardous waste/red bag(incineration)</p> <p> <input type="checkbox"/> other, please describe:</p>
<p>8. Indicate training status of all personnel involved in the project:</p> <p>Completed Bloodborne Pathogens (BBP) training <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>**Note: training is required annually; contact EHS to schedule training</p>
<p>9. Do you have an emergency spill response plan in place? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>A spill kit appropriate for the materials used in the lab must be available and easily accessible. All lab personnel must know how to use it.</p>
<p>Supplemental information:</p>

All Reference Materials-

Experiments Covered by NIH: https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457034

NIH Appendix B: https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457093

Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th edition: <http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>

American Biological Safety Association Risk Group Database: <https://my.absa.org/Riskgroups>