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 cn sd.c s	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:

☐ Mask	☐ Gloves	☐ Lab coat
☐ Shoe covers	☐ Head cover	☐ Disposable Gown
☐ Safety Glasses	☐ Respirator	☐ Other

5. Describe risk of infection, clinical symptoms, and any recommended medical surveillance and preventive laboratory practices to be used:

6. How do you plan to inactivate the toxin(s) prior to disposal?

7. How do you plan to dispose your biological wastes:

Waste disposal method: ☐ Autoclave ☐ Biohazardous waste/red bag(incineration)

☐ other, please describe:

8. Indicate training status of all personnel involved in the project:

Completed Bloodborne Pathogens (BBP) training ☐ Yes ☐ No

**Note: training is required annually; contact EHS to schedule training

9. Do you have an emergency spill response plan in place? ☐ Yes ☐ No

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.

Supplemental information:

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