

SAN DIEGO STATE UNIVERSITY
BIOLOGICAL USE AUTHORIZATION
Amendment Application Form

Submit a signed hard copy of the completed application to AD-222, MC1643 and an electronic copy to ibc@mail.sdsu.edu. If more space is needed please attach a separate sheet. For changes in Personnel only, fill out the Personnel Update Form.

I. Principal Investigator and Laboratory Contacts

Principal Investigator: _____ Title: _____
Department: _____ Office Location: _____ Lab Location: _____
Office Phone: _____ Lab Phone: _____ Home Phone: _____
Mail Code: _____ E-Mail Address: _____ Fax: _____

II. Project/ Course Information:

Project Title: _____
Course Name/ Number: _____
Current BUA #: _____ Current BSL: _____
Is there a change in source of funding? If yes, indicate new funding agency: _____

III. Project Summary

Provide a brief description of the original project and of the proposed Amendment and how the Amendment differs from the original project summary.

IV. Potentially Biohazardous Materials

A. RECOMBINANT DNA

1. Additional Genetically Modified Vectors *If no changes, check here*

List of Vectors (Class of Vectors)	Host Range of Vector	Infectious Particles Produced (Yes/No)	Replication Competent (Yes/No)	If Replication Deficient, Please Explain Mechanism

2. Additional Transgenes and Recombinant Proteins *If no changes, check here*

Types of Vectors from Table 1 or Biological Source of DNA (list genus/species)	Transgenes Expressed	Pathogenic Potential (Yes/No)	Oncogenes (Yes/No)	Toxins (Yes/No)	Genes or Proteins Produced Which Can Enter Cells

3. Additional Genetically Modified Vectors In-Vivo (Animals, Plants or Cell Lines) *If no changes, check here*

Vector from Section 1	Animal or Plant Species	Max Infectious Units/Dose	Max Dose Per Experiment	Method of Delivery	Specify Route(s) of Shedding/ Excretion of Infectious Agents/ Toxin or Other Hazard

B. INFECTIOUS AGENTS and TOXINS

1. Additional Infectious Agents/Pathogens *If no changes, check here*

Name and Strain of Agents	Host Range of Agent	Route of Transmission	Disease or Toxins Produced	Virulence or Toxicity

2. Additional Infectious Agents in Cells *If no changes, check here*

Agent	Cells Infected	Max Concentration	Max Volume	Used in Animals or Plants

3. Additional Infectious Agents In-Vivo (Animals or Plants) *If no changes, check here*

Agent	Animal or Plant Species	Max Infectious Units/Dose	Max Dose per Experiment	Method of Delivery	Specify Route(s) of Shedding/Excretion of Infectious Agents

C. SELECT AGENTS and TOXINS or HIGH CONSEQUENCE PATHOGENS and TOXINS *If no changes, check here*

Agent/Toxin Name	Check each agent as appropriate					
	Viable	Genomic Material	Recombinant DNA	Small Animal	Large Animal	Large Scale
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

D. HUMAN/PRIMATE or ANIMAL MATERIALS

1. Additional Human/Primate Materials (Human or primate cells, types of cell lines, body fluids, tissues, etc.) It is not necessary to list specific cell lines.
 If no changes, check here

Material	Established Cell Lines (Yes/No)	Primary Tissue (Yes/No)	Source	Known Pathogens

2. Additional Human/Primate Materials In Animals If no changes, check here

Material	Species of Recipient Animal	Expected Outcome

3. Additional Animals (Non-Primate) Materials (cells, types of cell lines, body fluids, tissues, etc.) It is not necessary to list specific cell lines.
 If no changes, check here

Material	Established Cell Lines (Yes/No)	Primary Tissue (Yes/No)	Source	Species	Known Pathogens	Zoonotic Disease

4. Additional Animal (Non-Primate) Materials In Animals If no changes, check here

Material	Species of Recipient Animal	Expected Outcome

V. Supplemental Information

A. CHANGES IN AUTHORIZED USERS/PERSONNEL AND TRAINING *If no changes, check here*
 Fill out the Personnel Update Form (Include PI, Co-PI, Lab Managers, Project Coordinators and Lab Researchers)

B. CHANGES IN LOCATION *If no changes, check here*

Laboratory Room#(s) where biohazardous materials will be used:

<u>Materials</u>	<u>Location</u>	<u>Shared Room</u>
_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No

Laboratory Room#(s) where biohazardous materials will be stored:

_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No

Laboratory Room#(s) where biosafety cabinet(s) will be located:

C. CHANGES IN BIOSAFETY CABINET *If no changes, check here*

Provide the following information for each biosafety cabinet:

<u>Make</u>	<u>Model</u>	<u>Serial Number</u>	<u>Certification Expiration Date</u>

D. CHANGES IN TRANSFER/TRANSPORTATION *If no changes, check here*

Describe change in Section VI, F.

E. CHANGES IN BIOHAZARD LABELS AND SIGNS *If no changes, check here*

Name the biohazard identified on the new biohazard sign:

F. CHANGES IN OTHER INFORMATION (Additional protocol submission may be required if this research involves changes in human or animal subjects, please contact Graduate and Research Affairs (619) 594-0905.) *If no changes, check here*

Does this research involve changes in animal subjects or tissue?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Protocol #		Expiration Date	
Does this research involve changes in human subjects or tissue?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Protocol #		Expiration Date	

VI. Biosafety Summary

A. Changes in the conditions for collection, growth, and maintenance of biohazardous materials. *If no changes, check here*

B. Changes in the experimental procedures involving biohazardous materials that are used to accomplish the objectives of your work? *If no changes, check here*

C. Changes in specific methods/procedures that will be taken to prevent exposure to biohazardous materials in each condition (described in A) and experimental procedure (described in B). *If no changes, check here*

D. Changes in biohazardous waste disposal procedures. *If no changes, check here*

E. Changes in spill decontamination procedures and terminal inactivation procedures. *If no changes, check here*

F. Changes in transfer and/or transportation procedures of biohazardous materials. *If no changes, check here*

Signature of Principal Investigator

Date