San Francisco State University
College of Science and Engineering
Biosafety Committee

Ver. Dec. 2008

Biological Use Registration

For Recombinant DNA, Select Agents, Biosafety Level 2 or 3 Organisms

What is a BUR? *Biological Use Registration describing a Principal Investigator's (PI's) research at San Francisco State University (SFSU) that, when approved by the Biosafety Committee (BSC), provides authorization to conduct research utilizing biohazardous agents*

What is meant by "biohazardous agent"? *A biohazardous agent is a biological toxin or is a disease-causing microorganism (bacterial, chlamydia, fungi, parasites, prions, rickettsias, toxins, viruses, etc.) capable of causing diseases in humans, animals or plants.*

Who should complete this form? *A PI who currently has or plans to possess, store, work with or transport infectious agents, human blood, tissues or blood products, and recombinant DNA. All work with rDNA, even if under CDC "exempt status" must be registered with the BSC prior to receiving the material or beginning work. If post-doctoral fellows and visiting scholars plan to work on projects with rDNA as a component, they must submit their proposals under the auspices of a SFSU PI with an existing registration*

How to submit this form. Send the completed form via email to lvadura@sfsu.edu or print out the form and send it to Linda Vadura C/O COSE Dean's office or to TH 216.

1. Requestor Information

a) **Principal Investigator#1** ☐ Faculty ☐ Visiting Scholar ☐ Staff ☐ Post-Doctoral Fellow

Name _____ Department _____ Office Location _____

Email Address _____ Office Phone _____ Lab Extension _____

New Submission ☐ Grant Renewal ☐ Revision/Resubmission ☐

2. Brief Summary of Research Objectives

Project Title _____

Funding Agency _____ **Project Dates:** _____ **to** _____

Attach a project summary describing your research in such a way that a scientist from another field will understand.

3. Location. Provide information regarding the research facilities and type of use.

Building	**Room No.**	**Type of Use** (Cold Room, Procedure Room, etc.)

Note: In circumstances where laboratory space is borrowed or shared with another lab group, the PI in charge of the other lab group must also sign the form indicating informed consent.

PRINT NAME OF PI SHARING SPACE _____ PLEASE HAVE PI SIGN HERE _____ DATE _____

Biosafety Committee Use Only

❒ Registration to work with BSL-2 (Part B)
❒ Registration to work with rDNA (Part C)
❒ Registration to work with BSL-3 (Part D)
❒ Approval to forward the request to use Select Agent(s) to University EHOS (Part E)

❒ Request Approved Biosafety Cabinet Required? ❒ YES ❒ NO
❒ Not Approved: More information needed

_____
Name of Organism(s) Approved

Notes: _____

Signature of BSC Chairperson _____ Date _____

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Part B: BSL-2

Part B BUR Application: Biosafety Level 2

☐ Yes, I am applying to work with materials designated as BSL-2
☐ No, Part B does not apply to my request.

I. Details Of Request

a) Name of Organism(s)	Form/Description	Type* (* bacteria, virus, toxin, etc.)

b) Will aerosols be generated? ☐ No ☐ Yes

c) Will a biosafety cabinet be used? ☐ No ☐ Yes

Location of biosafety cabinet

If not, please explain _____

e) Attach relevant use and storage protocols

II. Principal Investigator's Signature and Statement of Understanding

- I attest that the information contained in the attached application is accurate and complete. I agree to comply with the requirements pertaining to shipment and transfer of infectious agents. I am familiar with and agree to abide by the provisions of the current NIH/CDC Guidelines and other specific granting agency instructions pertaining to the proposed project.
- I further attest that all research personnel are familiar with and understand the potential biohazards, proposed precautions, and appropriate emergency procedures, and that the practices and techniques required to ensure safety will be followed. I agree to accept responsibility for training of all laboratory workers involved in the project.
- I hereby adopt the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories *(4th Edition)* as the basis for work in my laboratory. As a minimum, I will implement work practices in accordance with the Standard Microbiological Practices as outlined in Section II of the Biosafety Manual. I understand that a supplemental Biosafety manual, should I want to develop one, must be approved by the BSC before research can commence.
- Written reports will be submitted to the COSE Biosafety Committee through the COSE Health and Safety staff concerning:
  1. Any accident that results in inoculation, ingestion, and inhalation of infectious agents or recombinant DNA or any incident causing serious exposure of personnel or danger of environmental contamination:
  2. Any problems pertaining to operation and implementation of containment safety procedures or equipment or facility failure or security: and,
  3. Any new information bearing on the Guidelines such as technical information relating to hazards and safety procedures or innovations.
- I will not carry out the work described in the attached application until it has been filed with and accepted by BSC or, when necessary, until it has been approved by the BSC, other appropriate oversight committees and all sponsoring agency requirements have been met.

_____ _____

Principal Investigator **Date**

(Signature must be original ink signature)

Part C BUR Application: RECOMBINANT DNA

☐Yes, I am applying to work with materials containing recombinant DNA (rDNA)
☐ No, Part D does not apply to my request.

I. NIH Guidelines Exemption Statement

The following types of recombinant DNA molecules are considered "exempt" as listed in Section III-F of the NIH Guidelines. If you believe your experiment qualifies under one of these exemptions, please indicate which of these apply:

☐ III-F-1 Those that are not in organisms or viruses

☐ III-F-2 Those that consist entirely of DNA segments from a single monchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

☐ III-F-3 Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host *(or a closely related strain of the same species)*, or when transferred to another host by well-established physiological means.

☐ III-F-4 Those that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids *(but excluding viruses)* when propagated only in that host *(or a closely related strain of the same species)*

☐ III-F-5 Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. For a list of natural exchangers that are exempt, see Appendix A (I–IV), *Exemptions Under Section III-F-5—Sublists of Natural Exchangers.*

☐ III-F-6 Those that do not present a significant risk to health or the environment. See Appendix C, *Exemptions under Section III-F-6* for other classes of "exempt" experiments.

(For a copy of Appendix C, contact the Biology Stockroom or go online http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

☐ I have reviewed the NIH Guidelines and have determined that the experiments I plan to do with rDNA molecules are "**EXEMPT**" under those guidelines.

☐ I have reviewed the NIH Guidelines and have determined that the experiments I plan to do with rDNA molecules are **"NOT EXEMPT"**under those guidelines.

Signature of Principal Investigator **Date**

Instructions: Fill out Section II below regardless of whether you have determined your rDNA experiment is in the "exempt" category.

II. Brief Description of Proposed rDNA Research

1. Biological sources of DNA List Genus/Species or common name of the source organism to insert DNA

2. Nature of the inserted DNA sequences.

List gene names, biological markers, sequences, promotors	Describe the function/activity of the DNA or its product

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Part C: rDNA

(Continued)

3. Which of the following host-vector systems will be used for this research? Check box(es) and provide further details requested.

Vector

☐ Adenovirus Name strain and describe wild type deletions: _____

Is this strain replicative defective? ☐Yes ☐No

☐ Retrovirus Vector backbone: _____

☐Murine Name strain _____

☐Lentivirus: Name HIV genes present or attach map _____

Name envelope packaging system(s) _____

☐Other _____

Does the packaging cell line generate amphotrophic virus? ☐Yes ☐No

Does the packaging cell line generate ecotrophic virus? ☐Yes ☐No

☐ Adeno-associated virus _____

☐ Vaccinia virus _____

☐ Bacterial plasmids Name plasmids: _____

☐ Baculovirus Name species: _____

☐ *Agrobacterium spp.* _____

☐ Other

Host	Include bacterial host used to propagate vector plasmid which will be used to generate recombinant virus.
☐*E. coli* K12:	Name derivative or strain:
☐ Other bacteria:	Give genus/species/strain:
☐Laboratory animals:	Name species:
☐Tissue culture:	*(Check all that apply.)* Cell designation: _____ ☐Human ☐established cell line ☐primary cell culture ☐transformed cell line

4. Will you attempt to express a foreign gene? ☐No ☐Yes

If yes, what protein(s) will be produced?

5. What containment conditions will be implemented as specified in the *NIH Guidelines?*

Physical Containment: Check all that apply.

General: ☐ BSL 1 ☐ BSL2 ☐ BSL3 ☐ Other _____

Biological Containment --prokaryotic host. ☐EK1 ☐ EK2 ☐ Not Applicable

Animals: ☐ BSL1-N ☐BSL2-N ☐BSL3-N ☐ Not Applicable

6. Other rDNA research types:

☐Yes ☐No Will the recombinant DNA molecule contain greater than 2/3 of the genome of any eukaryotic virus? Section III-E-1.

☐Yes ☐No Will the research involve greater than 10 liters of culture at any one time? Section III-C-6

☐Yes ☐No Will there be deliberate formation of rDNA containing genes for the biosynthesis of toxic molecules lethal for vertebrates at an LD50 of less than 100 ng/kg body weight? Section III-B-1

☐Yes ☐No Will there be deliberate transfer of drug resistance trait to microorganisms not known to acquire the trait naturally if such acquisition could compromise the use of the drug to control disease agents? Section III-A-1-a

☐Yes ☐No Will there be transfer of rDNA into human or animal pathogens in Risk Groups 2 or 3? Section III-C-1

PART D BUR Application: BIOSAFETY LEVEL 3

☐ Yes, I am applying to work with materials designated as Risk Group 3
☐ No, Part D does not apply to my request.

I. Occupational Health

a) Building and room where experiments will be conducted _____

b) Where will stock cultures be stored? _____

c) If applicable, is a vaccine available? ☐ Yes ☐ No Vaccine is available ☐ n/a
If yes, provide the following information

Names of Vaccinated Persons	Date Vaccinated	Institution where they were vaccinated

d) Describe medical surveillance protocols (if any) for laboratory research personnel.

II. BSL-3 Work Practices

a) Autoclave is available? ☐ No ☐ Yes. It is located in _____.

Biosafety cabinet(s) will be used for all BSL-3 work ☐ Yes Location_____

b) There will be physical separation from access corridors ☐ Yes ☐ No
Functional self-closing double-door access will be installed ☐ Yes ☐ No
Lab doors will remain closed when BSL-3 work is done ☐ Yes ☐ No

c) Negative airflow into the laboratory will be in place? ☐ Yes ☐ No
Will exhausted air be re-circulated? ☐ Yes ☐ No

d) How will lab clothing be decontaminated (before laundering)? (or attach protocols)

e) Will baseline serum samples of lab personnel be collected? ☐ Yes ☐ No

- I understand that BSL-3 agents are indigenous or exotic agents with potential for aerosol transmission; disease may have serious or fatal consequences.
- BSL-3 work will require some remodeling of laboratory space to provide the required ventilation and security upgrades. Approval of this registration request does not mean that work may be started before the required upgrades are in place and functional.

Principal Investigator Signature **Date**

PART E BUR Application Select Agents

☐ Yes, I am applying to work with materials designated as "Select Agents"
☐ No, Part E does not apply to my request.

Background

As part of its response to the events of September 11, 2001, Congress passed the USA Patriot Act ("the Act"). The Act became effective immediately upon being signed into law by the President on October 26, 2001. Part of the Act expands restrictions on the possession, use and access to biological agents, toxins and delivery systems.

A Principal Investigator (PI) may not possess or use, receive from outside the United States, or transfer from within the United States, any biological agent or toxin listed as a Select Agent by DHHA or the USDA until they have been approved to use the biological agent or toxin by SFSU EHOS and have been granted a certificate of registration by the DHHA Secretary of the USDA Secretary.

Prior to possession, use or transfer of any Select Agent, a principal investigator (PI) must register with the appropriate federal agency (CDC and/or APHIS). The PI must complete **SFSU's Select Agent Registration Form,** in its entirety. Application packets are available at the following websites:

DHHS CDC packet USDA APHIS packet

Instructions

1. The PI must complete the appropriate agency registration packet in coordination with the University Environmental, Health, and Occupational Safety Office (EHOS).
2. If you intend to use Select Agents in your research, please attach the required approval from EHOS to this BUR.
3. Contact Linda Vadura, COSE Health and Safety Specialist or Michael Fong for more information.

Acknowledgement

- I understand that the use of a biological material on the "Select Agents" list involves registration and approvals with outside government agencies and the involvement of the University Environmental, Health, and Occupational Safety Department (EHOS).
- I realize that the security upgrades, background checks and government authorization required to use "Select Agents" may take several months or longer.
- The Biosafety Committee will only approve registration once the University has obtained the required permits.
- I agree that I will not acquire or bring such materials to University property until all the permits and registrations procedures are complete.

Signature of Principal Investigator **Date**