

INSTRUCTIONS TO PRINCIPAL INVESTIGATORS FOR COMPLETING BIOLOGICAL USE AUTHORIZATION (BUA) APPLICATION FORMS

1. **What is a BUA?** A BUA is a document describing a Principal Investigator's (PI's) research at UCSF. When approved by the Biosafety Committee (BSC), it provides authorization for you, the PI, to conduct that research.
2. **Who must apply for a BUA?** If your research involves recombinant DNA materials or technology, infectious agents, toxins, transgenic animals, human gene transfer, humans, sheep or Old World primates or their source materials, you must have a BUA approved by the BSC before beginning laboratory research. Please see Chapters 3 and 4 of the UCSF Biosafety Manual for more information. The Manual and all other BUA forms are available on the [OEHS website](#).
3. **How to complete the Application.** Please download, print, and use the following BUA Application Checklist to assist you in completing the application. All of the items on the checklist must be addressed prior to submission (when applicable). Application approval may be delayed if items are not adequately addressed.

[BUA APPLICATION CHECKLIST](#) – **CLICK TO VIEW**

[IMPORTANT DATES FOR APPLICATION REVIEW](#) – **CLICK TO VIEW**

4. **Assistance.** The UCSF Biosafety Manual provides a wealth of information to help you complete your application. Your Departmental Safety Advisor (DSA) is your primary source of assistance. Please submit your initial application to your DSA for a pre-submittal review. Your final completed, signed, and dated application must be submitted to the Biosafety Officer at Box 0942 for review and subsequent submission to the Biosafety Committee (BSC). The BSC meets on the second Wednesday of each month; only applications received at least 45 days prior to a meeting can be assured of consideration at that meeting.
5. **Modification of Existing BUAs.** Approval of changes to existing BUAs must be requested on the [Universal Use Authorization Modification Request Form](#). Because approval processes differ, a separate copy of the form should be submitted for each type of authorization (BUA, RUA, etc.). The form is self-explanatory for simple changes. For more complex changes, such as the addition of an infectious agent, modification of a procedure or increase in biosafety level, the form must be accompanied with a justifying narrative that provides enough technical detail to permit an assessment of any new risks posed by the change. The addition of labs or other spaces involves a site review of the spaces to be added. Submit modification requests via your DSA.

PRINCIPAL INVESTIGATOR

Name _____
Last First M.I.

Project Title _____

Application Status: Initial Renewal of BUA# _____
(Please complete the Principal Investigator Information Sheet and submit it with this application.)

FUNDING

Will this study be funded? Yes No (check all below that apply)

Federal government Other government (state,city,WHO) Pharmaceutical/device Co.
 Other private Campus/University-wide programs Departmental

Funding source name (and grant/contract #, if known) _____

SPECIFIC LOCATIONS WHERE RESEARCH WILL BE PERFORMED

Location(s) of biohazardous materials _____
Location(s) of biosafety cabinet(s) _____
Location(s) of autoclave(s) _____

PRINCIPAL INVESTIGATOR'S CERTIFICATION

By signing below, I certify that I have read the following statements and agree that I and all listed participants will abide by those statements and all UCSF policies and procedures governing the use of recombinant DNA, infectious agents and other biological materials, as outlined in this application and in the UCSF Biosafety Manual. I will:

- Ensure that listed personnel have received or will receive appropriate training in safe laboratory practices and the procedures for this protocol *before any work begins on this project* and at least annually thereafter. In addition, all listed personnel who have occupational exposure to bloodborne pathogens will attend *annual* bloodborne pathogen training sessions conducted by EH&S.
- Follow the health surveillance practices as approved for this protocol and inform those working on the protocol about appropriate emergency assistance information for their location(s).
- Inform the Biosafety Officer at 476-2097 of any significant research-related accident or illness as soon as possible after its occurrence.
- Submit in writing a request for approval from the BSC of any significant modifications to the study, facilities or procedures. (Call the office of the Biosafety Committee at 476-2198 for information.)
- Adhere to the UCSF biosafety guidelines referred to in this application.

Signature of Principal Investigator _____ Date _____

Continue with Part A - Recombinant DNA

APPROVAL

FOR BSC/BSO USE ONLY

BSC-level approval _____
Biosafety Committee Chair

BSO-level approval _____
Biosafety Officer

BUA# _____ Approval date _____ Expiration date _____

Comments _____

PART A
RECOMBINANT DNA

1. Please indicate "Yes" or "No" for each of the statements below:

- a. I am inserting foreign DNA into a vector or organism for the purpose of cloning or expressing it. Yes No
- b. The DNA to be cloned:
 - is from a Risk Group (RG) 3 agent; Yes No
Note: For Risk Group classification of agents see UCSF Biosafety Manual, Appendix A2.
 - represents more than two-thirds of the genome of a RG1 or 2 organism; Yes No
 - encodes a known oncogene; Yes No
 - encodes molecules known to be toxic to vertebrates at concentrations less than 1 mg/ml. Yes No
- c. The vector I am using for introduction of foreign DNA into the host:
 - is from a RG3 agent; Yes No
 - is a RG1 or 2 virus that infects eukaryotic cells and contains more than two-thirds of the viral genome; Yes No
- d. The host into which I am introducing foreign DNA is a cell or organism other than *E. coli* K12 or its derivatives, *Saccharomyces cerevisiae*, *S. uvarum*, *Bacillus subtilis* or *B. licheniformis*. Yes No
- e. This protocol will be submitted to NIH for Human Gene Transfer Proposal approval. Yes No

2. If you indicated "Yes" for any of the above statements, please complete the following Recombinant DNA Information; otherwise, continue with Part B - Infectious Agents and Toxins.

HOST/VECTOR/GENE INFORMATION	Risk Group (1,2,3)
Please provide specific names:	
Host(s) _____	_____
_____	_____
_____	_____
Vector(s) _____	_____
_____	_____
_____	_____
Gene(s) to be Cloned _____	_____
_____	_____
_____	_____
DNA Source(s) _____	_____
_____	_____
_____	_____

RESEARCH DESCRIPTION

3. Please attach one paragraph descriptions of the following:

- The experimental design and goals of the research, including a brief description of the experimental procedures - please provide sufficient detail to allow the BSC to assess the hazardous potential of the experiments;
- Assessment of the hazardous potential of cloning any DNA segments encoding pathogenic, oncogenic or toxic substances, and
- Containment conditions that will be implemented.

PART B
INFECTIOUS AGENTS AND TOXINS

1. Please indicate "Yes" or "No" for each of the statements below:

- a. I am working with a RG1 organism and producing less than 10 liters of culture. Yes No
Note: For Risk Group classification of agents see UCSF Biosafety Manual, Appendix A2.
- b. I am working with a RG1 organism and producing more than 10 liters of culture. Yes No
If you intend to use the UCSF Fermentation Facility, please complete the attached *Application for the Use of the Fermentation Facility* and submit it with this application.
- c. I am working with a RG2 or 3 organism (include replication-defective agents). Yes No
- d. I am obtaining, receiving, or handling, for research purposes, any of the following: Yes No
 - Human tissue, including scrapings, secretions, body fluids, bones or teeth Yes No
 - An organ culture or primary cell line derived directly from human tissue Yes No
 - An established cell line derived from human tissue Yes No
 - Human blood or blood products such as serum, plasma or cell preparations Yes No
- e. I am working with sheep, sheep tissue or sheep cell lines. Yes No
- f. I am working with Old World primates or their tissues or cell lines. Yes No
- g. I am working with toxins known to affect humans and/or animals. Yes No

2. If you indicated "Yes" for any of the above statements, please complete the following Infectious Agents and Toxins Information; otherwise, continue with Part C - Standard Operating Procedures for All Applicants.

Note: If you will be drawing, processing, using, working with or storing:

- human blood or blood products; unfixed tissues; body fluids; or human organ or cell cultures, write the name(s) of the potential bloodborne pathogens, the specific material being used, and enter "2" under Risk Group;
- sheep; sheep blood, organs, tissues, body fluids or excreta; or sheep organ or cell cultures, write "*Coxiella burnetii*," the specific material being used, and enter "3" under Risk Group.

INFECTIOUS AGENT (S) AND TOXIN(S)	Risk Group (1,2,3)
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

RESEARCH DESCRIPTION

3. Please attach one paragraph descriptions of the following:

- The experimental design and goals of the research, including a brief description of the experimental procedures - please provide sufficient detail to allow the BSC to assess the hazardous potential of the experiments;
- An assessment of the hazardous potential, including a brief description of the agents, its hosts, modes of transmission to humans and animals, and pathogenicity. Also describe the implications if the organism were to be released outside the laboratory;
- The methods by which the safe conduct of the experimental procedures will be ensured.

USE OF DHHS
SELECT AGENTS

4. Please indicate "Yes" or "No" for the statement below:

- a. I will use one or more of the DHHS Select Agents in this study. Yes No
Note: A list of the DHHS Select Agents is shown in the UCSF Biosafety Manual, Appendix N.
 - If "Yes", please attach one-paragraph descriptions of the agent(s), the quantities in which you will be handling and storing them, storage locations, security precautions and mechanisms by which you will ensure their safe usage and disposal.

STANDARD OPERATING PROCEDURES FOR INFECTIOUS AGENTS

5. For each of the elements below, please indicate whether or not you will be following the UCSF standard operating procedures for infectious agents. If you indicate "Yes," then you agree to and must follow the standard procedures. If you answer "No," please attach a brief description of the procedures that you will follow and include a justification for deviating from the standard procedures.

- a. Decontamination Procedures: I will use 0.5% sodium hypochlorite (a 1:10 dilution of household bleach) to decontaminate equipment and work surfaces. In locations where bleach would cause corrosion, I will decontaminate with an iodophor (e.g., Wescodyne). Yes No
- b. Local Transport of Infectious Materials: I will follow the procedures outlined in the UCSF Infectious Agents Transport Policy. All infectious materials transported to and from my laboratory will be enclosed in a primary container with sealed lid or top, which will then be enclosed in a secondary leak-proof, non-breakable container (such as a Coleman cooler) appropriately labeled with the biohazard symbol. Any specimens transported to and from off-campus satellite facilities will be escorted by a responsible lab employee. Yes No
- c. Storage: All infectious materials to be stored will be clearly labeled with the universal biohazard symbol as will the storage space (e.g., freezer, refrigerator). Yes No
- d. Bloodborne Pathogens: If I am using human blood or blood products, unfixed tissue, body fluids or organ or cell cultures of human origin, I will follow the procedures outlined in the *UCSF Exposure Control Plan Summary*. Yes No
- e. Human Organ and Cell Culture: If I am using human organ or cell cultures (primary cultures, cell strains, cell lines), I will follow the procedures outlined in the *UCSF Cell Culture Guidelines*. In addition, I will handle all such cultures under BSL2 conditions and in accordance with the Bloodborne Pathogen Standard unless the Biosafety Committee has specifically approved a lower standard of containment. Yes No

HEALTH SURVEILLANCE/IMMUNIZATION PROGRAM

6. If infection of humans involved in this research is possible, please determine the most appropriate health surveillance and/or immunization program needed for the safe conduct of your protocol. If you need assistance or advice, please consult with Employee Health Services at 885-7580 (for all UCSF campuses) or the Biosafety Officer at 476-2097.

I will place in effect the following UCSF health surveillance/immunization programs and critical elements (see *UCSF Biosafety Manual* for details.)

- Bloodborne Pathogens (HBV vaccination/declination and post-exposure follow-up and treatment at no cost to employee, vaccination record retention by PI, initial BBP training and annual retraining, universal precautions)
- Q-Fever (per Cal-OSHA Special Orders - annual medical exams, serologic testing, vaccine use when available, respiratory protection, training)
- Orthopoxviruses (vaccinia and others) (medical screening, vaccination and contraindication awareness, training)
- Prion Research (training and special procedures for exposure reporting, decontamination and records handling)
- Herpesvirus simiae (Monkey B or Herpes B virus) (post-exposure follow-up and treatment at no cost to employee, training)
- Custom health surveillance/immunization program will be in effect: please attach a one paragraph description of this program.

PART C
STANDARD OPERATING PROCEDURES FOR ALL APPLICANTS

- 1. For each of the elements below, please indicate whether or not you will be following the UCSF standard operating procedures for biosafety. If you indicate "Yes" then you agree to and must follow the standard procedures. If you answer "No" please attach a brief description of the procedures that you will follow and include a justification for deviating from the standard procedures.**
- a. Biohazardous Spills: I will follow the procedures outlined in the *UCSF Biological Spill Emergency Procedures*. In case of a spill or accident involving employee exposure, I will contact the 24-hour Blood and Body Substance Exposure Hotline pager 719-3898 at all campuses except SFGH, or 469-4411 at SFGH. Yes No
- For spills which my staff is able to clean up safely, a person wearing protective equipment (gloves, goggles, long-sleeved lab coat) will first disinfect the area with a 1:10 dilution of household bleach or an iodophor (e.g., Wescodyne) before wiping up the spill with disposable paper towels and disposing of all spill materials properly. Broken glass will only be handled by remote means such as tongs or forceps. Yes No
 - For spills which my staff may not be able to clean up safely, the room will be evacuated and people will be prevented from entering the area. During working hours, I will immediately contact EH&S at 476-1300 for emergency assistance. After 5 p.m., I will call UC Police at 9-911. Yes No
- b. Shipment of Biological Materials: I will follow University Policy and all applicable Federal and international regulations whenever I ship biological materials domestically and internationally. I will also obtain the proper importation or exportation permits/licenses through the Biosafety Office (476-2097) before shipping to or receiving from any international location any biological material. Yes No
- c. Containment of Aerosols and/or Splashes: All manipulations having a potential for generating aerosols (e.g., homogenization, centrifugation, sonication) will be conducted in a properly certified biosafety cabinet or in a centrifuge equipped with sealed rotor heads or safety cups. Screw-cap centrifuge tubes will be no more than three-fourths filled. Yes No
- d. Disposal: I will post in my laboratory and follow the procedures outlined in these flyers:
- *UCSF Medical Waste Policy and Procedures* Yes No
 - *UCSF Proper Handling Procedures for Sharps* Yes No
 - *UCSF Biological Spill Emergency Procedures* Yes No
 - *UCSF Infectious Agent Transport Policy* Yes No

Continue with Part D - Other Biological Materials

PART D
OTHER BIOLOGICAL MATERIALS

- 1. Please indicate "Yes" or "No" for each of the statements below:**
- a. I am using animals or the facilities or services of the Laboratory Animal Resource Center Yes No
- If "Yes", contact Marsha C Potolo, LARC Veterinary Nursing Manager (502-1242) and complete the Animal Involvement in the Laboratory Animal Resource Center form with her assistance. In addition, provide a concise narrative describing your animal use in this study.
- b. I will import from or export to one or more foreign countries agents, samples, diagnostic specimens or other biological materials related to this protocol. Yes No
- If "Yes", please attach a one-paragraph description of the material to be shipped or received, its country of origin or destination, and whether it's a one-time only shipment or part of a series of shipments. Such shipments must be in accordance with the UCSF Infectious Agents Transport Guidelines.