CALIFORNIA STATE UNIVERSITY, FRESNO
BIOHAZARD USE AUTHORIZATION APPLICATION

Instructions:

Please use this form to register your work with biohazardous material and/or recombinant DNA.

You will need to reference the most current applicable guidelines.

- Download the NIH guidelines for work with recombinant DNA via the following link: *http://oba.od.nih.gov/rdna/nih_guidelines_oba.html*

- Download the CDC publication "Biosafety in Microbiological and Biomedical Laboratories (BMBL) via the following link: *http://www.cdc.gov/biosafety/publications/bmbl5/*

If you have any questions regarding the registration process, contact Environmental Health and Safety/ Risk Management at extension 8-7422.

SECTION A:

Date of Application: _____

Type of application: New_____ Addendum _____

Principal Investigator/Instructor: _____

Phone # _____ Email _____

Department/Mail Stop #: _____

Location of Instruction/Work/Storage Locations (Building, Room Numbers): _____

List of activities:

(use additional pages if necessary)

SECTION B:

- **Does your work involve the generation of recombinant DNA?**

  Yes _____ **No** _____ (Skip to Section C)

Please select all of the exempt categories below that apply to your recombinant DNA work.

☐ rDNA molecules that are not in organisms or viruses

☐ rDNA molecules that consist entirely of DNA segments from a single non-chromosomal or viral DNA source

☐ rDNA molecules that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host or when transferred to another host by well established physiological means

☐ rDNA molecules that consist entirely of DNA from a eukaryotic host, including its chloroplasts, mitochondrial DNA, or plasmids when propagated only in that host or a closely related strain of the same species

☐ rDNA molecules that consist entirely of segments from different species that exchange DNA by known physiological processes, though one or more may be a synthetic equivalent; see Appendices A-I through A-VI of the NIH *Guidelines* for sublists of natural exchangers.

☐ rDNA molecules that are not a significant risk to health or the environment as determined by the NIH Director; see Appendix C of the NIH Guidelines for a detailed explanation of the following exemptions, and please indicate which of the categories below apply to your work:

- ☐ Recombinant DNA in tissue culture (Appendix C-I and C-IA)
- ☐ *Escherichia coli* K-12 host-vector systems (Appendix C-II and C-II-A)
- ☐ *Saccharomyces* host-vector systems (Appendix C-III and C-III-A)
- ☐ *Kluyveromyces* Host-Vector Systems (Appendix C-IV and C-IV-A)
- ☐ *Bacillus subtilis* or *Bacillus lichenformis* host-vector systems (Appendix C-V and C-V-A)
- ☐ Extrachromosomal elements of gram positive organisms (Appendix C-VI and C-VI-A)
- ☐ Purchase or transfer of transgenic rodents that require biosafety level1 (BSL 1) containment (Appendix C-VII)
- ☐ Generation of BL1 transgenic rodents via breeding (Appendix C-VIII)

Experiments that require specific approval by both the NIH and the Institutional Biosafety Committee (IBC) *before initiation:*

☐ Transfer of a drug-resistance trait to microorganisms if such transfer might compromise use of the drug therapeutically (see Section III-A-1-a for further information and examples).
Note: IBC, NIH Recombinant DNA Advisory Committee (RAC) review, and NIH Director review andapproval are required before initiation.

☐ Experiments Involving the Cloning of Toxin Molecules with LD_{50} of Less than 100 nanograms per Kilogram Body Weight (see Section III-B-1 for further information and examples).
Note: IBC approval and NIH review for containment determinations are required before initiation.

Experiments that require Institutional Biosafety Committee and Institutional Review Board approvals and RAC review before research participant enrollment

☐ Experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into one or more human research participants (see Section III-C for further information and examples).

Experiments that require approval by the IBC *before initiation:*

☐ Experiments using human or animal pathogens (Risk Group 2-4 or restricted agents) as DNA source or pathogenic host/vector systems (see Section III-D-1 for further information and examples).

☐ Experiments in which human or animal pathogens (Risk Group 2-4 or restricted agents) are cloned in nonpathogenic prokaryotic or lower eukaryotic host-vector systems (see Section III-D-2 for further information and examples).

☐ Experiments involving the use of infectious animal or plant viruses or defective viruses in the presence of a helper virus in a tissue culture system (see Section III-D-3 for further information and examples).

☐ Experiments involving whole animals or plants (see Section III-D-4 and see Section III-D-5 for further information and examples).

☐ Experiments involving more than 10 liters of culture (see Section III-D-6 for further information and examples).

☐ Experiments involving influenza viruses (see Section III-D-7 for further information and examples).

Experiments that require IBC notice *simultaneous with initiation of experiment:*

☐ Experiments involving the formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus (see Section III-E-1 and Section III-F for further information and examples).

☐ Experiments involving whole plants (except those covered in the Section above; see Section III-E-2 and Section III-F for further information and examples).

☐ Experiments involving transgenic rodents (see Section III-E-3 and Section III-F for further information and examples).

SECTION C

Complete this section if your work involves the use of the following biohazardous materials: bacteria, fungi, viruses, including oncogenic viruses, chlamydiae, parasites; human blood, blood products or human tissues, primary human cell cultures, non-human primate blood or tissues; infected animals and animal tissues; toxins (bacterial, plant fungi, etc.).

- **Does your work involve the use of above-mentioned biohazardous materials?**

  Yes _____ **No** _____ (Skip to Section D)

- **Is your work with biohazardous materials limited to Biosafety Level 1?**

  Yes _____ **No** _____
  (Only complete item 1 below) (Please complete items 1 – 7 below)

1. Name of biohazardous agent(s) (if known) or source of biohazardous source.

2. Brief description of human diseases caused by agent(s), if known.

3. Brief description of the research and use/manner in which agent(s) will be handled.

4. Proposed biosafety level and description of techniques.

5. List standard practices, equipment and facility requirements used to ensure containment (BSL 2 or above) (see Appendix A for BSL2 checklist from BMBL, 4th edition; for all other BSL levels refer to BMBL, 4th edition).

6. The method used for disinfection and disposal of the biological materials(s) and waste.

7. Please list largest volume, highest titer and frequency of use.

8. Does this project involve the use of experimental animals? ☐ Yes ☐ No

SECTION D

Your signature below indicates that you acknowledge all requirements and restrictions of the most current NIH/CDC guidelines for the biosafety level you have indicated above; that you accept responsibility for the safe conduct of the experiments conducted at this biosafety level and that you have informed all associated personnel of the conditions required for this work.

Signature of Investigator/ Instructor _____ Date _____

SECTION E

I acknowledge that I have seen the Biohazard Use Authorization Application document and I agree to exercise due diligence in ensuring compliance with the University's Biosafety Policy.

Signature of Department Chair _____ Date _____

SECTION F (Institutional Biosafety Committee only)

Comments:

Registration Accepted: ☐ Yes ☐ No

Application Approved: ☐ Yes ☐ No

_____ _____
Chairperson, Institutional Biosafety Committee Date

Please return completed form to the Office of Environmental Health and Safety/Risk Management, Mail Stop PO-140, fax to extension 8-1153, or email to lisak@csufresno.edu.

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Appendix A

The following standard practices, safety equipment, and facility requirements apply to BSL-2:

Standard Microbiological Practices

- ☐ The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
- ☐ Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
- ☐ Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas.
- ☐ Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
- ☐ Mouth pipetting is prohibited; mechanical pipetting devices must be used.
- ☐ Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
  - ☐ Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
  - ☐ Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
  - ☐ Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
  - ☐ Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.
- ☐ Perform all procedures to minimize the creation of splashes and/or aerosols.
- ☐ Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
- ☐ Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method.
- ☐ Depending on where the decontamination will be performed, the following methods should be used prior to transport.
  - ☐ Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
  - ☐ Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
- ☐ A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. Posted information must include: the laboratory's biosafety level, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory. Agent information should be posted in accordance with the institutional policy.

☐ An effective integrated pest management program is required.

☐ The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

Special Practices

☐ All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.

☐ Laboratory personnel must be provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory.

☐ Each institution should consider the need for collection and storage of serum samples from at-risk personnel.

☐ A laboratory-specific biosafety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible.

☐ The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.

☐ Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.

☐ Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.

☐ Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.

☐ Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.

☐ Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety manual. All such incidents must be reported to the laboratory supervisor. Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.

☐ Animal and plants not associated with the work being performed must not be permitted in the laboratory.

☐ All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment devices.

Safety Equipment (Primary Barriers and Personal Protective Equipment)

☐ Properly maintained BSCs, other appropriate personal protective equipment, or other physical containment devices must be used whenever:

☐ Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.

- ☐ High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.

☐ Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Remove protective clothing before leaving for non-laboratory areas, e.g., cafeteria, library, and administrative offices). Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that laboratory clothing not be taken home.

☐ Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses in laboratories should also wear eye protection.

☐ Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. In addition, BSL-2 laboratory workers should:

- ☐ Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
- ☐ Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
- ☐ Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.
- ☐ Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.

Laboratory Facilities (Secondary Barriers)

☐ Laboratory doors should be self-closing and have locks in accordance with the institutional policies.

☐ Laboratories must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.

☐ The laboratory should be designed so that it can be easily cleaned and decontaminated. Carpets and rugs in laboratories are not permitted.

☐ Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.

- ☐ Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
- ☐ Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.

☐ Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they must be fitted with screens.

☐ BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.

☐ Vacuum lines should be protected with liquid disinfectant traps.

☐ An eyewash station must be readily available.

☐ HEPA filtered exhaust air from a Class II BSC can be safely recirculation back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.

☐ A method for decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).