**BIOLOGICAL USE AUTHORIZATION APPLICATION**

Date submitted:

Principal investigator:       Position title:

Department:       Building & room:

Phone:       Email:

**Application type:**

Requesting BUA exemption

New BUA #

Terminate BUA #

Amend BUA #

Renew BUA #

**This project involves:**

Biohazardous agents (e.g bacteria, viruses, fungi, protozoa, prions)

Human and/or nonhuman primate source material (e.g. blood, tissue, primary and established cell lines)

Recombinant or synthetic DNA or RNA

Other

**Class or Research project description.** In the space provided belowplease include the following information if applicable: BSL level, catalog/item descriptions, purpose of materials to be used, class and # of students, and room/labs were work will occur.If you are requesting a BUA exemption explain your justification here.

**OTHER RELEVANT INSTITUTIONAL APPROVALS**

Vertebrate animals (IACUC): protocol#: protocol status: submitted approved pending

Human subjects protocol (IRB): protocol#: protocol status: submitted approved pending

Other agencies: Name:protocol#: protocol status: submitted approved pending

*Attach IACUC, IRB, or other agency protocols related to the project as separate documents*

**SECTION 1 - WORK LOCATIONS**

**Building and room number:**

**Proposed use of space:**

**Type of space: Biosafety level:**

**Laboratory**  **BSL 1**

**Classroom**  **BSL 2**

**Field**

**Other:**

**Describe waste streams generated and stored in this location:**

**Building and room number:**

**Proposed use of space:**

**Type of space: Biosafety level:**

**Laboratory  BSL 1**

**Classroom  BSL 2**

**Field**

**Other:**

**Describe waste streams generated and stored in this location:**

**Building and room number:**

**Proposed use of space:**

**Type of space: Biosafety level:**

**Laboratory  BSL 1**

**Classroom  BSL 2**

**Field**

**Other:**

**Describe waste streams generated and stored in this location:**

**Autoclave use:**

**South Science, Room ---- contact Mica McCarty-Glenn (x5-3471) to schedule use**

**Medical and Sharp Waste Disposal**

**South Science, Room ---- contact to Mica McCarty-Glenn (x5-3471) request location use**

**South Science, Room ---- contact Anna Chandra @5-3527 to request location use**

**SECTION 2 - DISPOSAL & TRANSPORT PRACTICES**

*Indicate your methods for terminal inactivation of the biological agent or transgenic material (microorganisms, animals, plants, plant transformation agents, tissues, etc.). If generating multiple types of waste please clarify what waste is being disposed of in the text field after each checkbox (i.e. transgenic or infectious material, rDNA, etc.). If you will be using a method that is not already described below, use the ‘other’ field at the bottom and clarify why you are using that method.*

**LIQUID WASTE**

Not generating liquid waste

10% bleach (final conc.) with 30 min of contact time, then drain disposal

Autoclave liquids (121°C, 15 psi, 30 min), then drain dispose

Other**:**

**SOLID WASTE**

Not generating solid waste

Autoclave solids (121°C, 15 psi, 30 min) in clear autoclave bags with an indicator

Medical waste stream in red medical waste bag contained within a leak-proof, lidded, and labeled secondary container

Animal caging and bedding is: autoclaved treated with disinfectant untreated, regular trash

Other/additional information:

**SHARPS WASTE**

Not generating sharps waste

Medical waste sharps – red biohazard plastic sharps container. Sharps containers will be closed when full and transported to the medical waste accumulation site within 7 days of reaching the fill line or ¾’s full.

Non-medical waste sharps – in clear sharps containers. Sharps containers will be closed when full and transported to medical waste accumulation site.

Other/additional information**:**

**ANIMAL CARCASSES AND GROSS TISSUES**

Not generating animal carcasses or gross tissues

Incineration through biohazardous waste contractor

Other/additional information**:**

**Hazardous chemical or CHEMICAL contaminated waste**

Not generating chemical or chemical contaminated waste

Solid waste: describe

Liquid waste: describe

*Indicate any transport of biohazardous materials (human, animal, or plant pathogens), transgenic materials (cell lines, microbes, plants, etc.), and other materials, including origin and destination laboratories or other facilities, frequency of transport, and measures you will employ to prevent accidental release of biohazardous materials.*

Not shipping materials

Not transporting materials between buildings and/or rooms

When transporting materials within (or between) facilities, we will use secondary containers that are sturdy, leak-proof, lidded, labeled appropriately (with a biohazard symbol if material is handled at BSL2 or above), with enough absorbent material to absorb any spill.

For other transport or shipping conditions, please describe:

We ship/transport materials daily, weekly, monthly, annually, or

*When shipping materials contact EH&S to comply with relevant regulations.*

**SECTION 3 - RISK MINIMIZATION**

*Identify measures you will employ to contain relevant biohazardous materials and transgenic animals in such a way as to prevent researcher, community, or environmental exposure to them.*

Access to the laboratory (or facility) will be restricted while work is in progress.

We will provide general laboratory (or facility) safety training to personnel.

**SHARPS SAFETY** We will train personnel in the safe handling of sharps.  **not applicable**

Please indicate which manipulations will involve sharps

Please indicate what would happen immunologically in the event of auto-inoculation

For other sharp safety practices, please describe:

**CENTRIFUCATION SAFETY** We will train personnel in the safe handling of sharps.  **not applicable**

Please indicate what biohazardous materials will be centrifuged:

For other centrifugation safety practices, please describe:

**AEROSOL SAFETY** We will train personnel in the proper pipetting techniques. **not applicable**

Please indicate other procedures that involve the potential generation of aerosols.

Please indicate how you will contain aerosols (e.g. use of a biological safety cabinet).

**ANIMAL SAFETY**  We will train personnel in the safe handling of animals.  **not applicable**

We will use cages that prevent animal escape while in their housing or during transport.

Infected animals will be housed in cages labeled with the universal biohazard symbol.

For other animal-related safety practices not found in the IACUC, please describe:

**PLANT SAFETY** We will train personnel in the safe handling of plant materials.  **not applicable**

We will ensure that plants are labeled with PI name and identifiable as transgenic or infectious to all staff.

We employ a recordkeeping system for tracking transgenic plants from creation until terminal inactivation.

We will transport plant materials in a manner that will prevent unintentional release or establishment.

We will train all workers handling or providing care to materials regulated under applicable permit conditions.

For other plant-related safety practices, please describe:

**PERSONAL PROTECTIVE EQUIPMENT (PPE)**

Please list the appropriate PPE required for each type of work (check “No” if not working with the material). Examples of PPE: lab coat, gown, scrubs, gloves, goggles, face shield, surgical mask, respirator, hair net, shoe covers.

Recombinant DNA Yes No PPE description:

Animals Yes No PPE description:

Infectious agents Yes No PPE description:

Blood-borne pathogens Yes No PPE description:

Plants Yes No PPE description:

**EMERGENCY RESPONSE PROCEDURES**

Provide emergency procedures for exposure and spills including disinfection and decontamination procedures:

**Other risk minimization safety practices not already addressed above**:

**SECTION 4 - HEALTH PROTECTION, HEALTH SURVEILLANCE AND POST-EXPOSURE TREATMENT PROGRAMS TO BE USED IN THIS PROJECT**

*Consult EH&S BEFORE completing the BUA application. All surveillance, vaccination, post-exposure treatment, and PPE clearance and fit-testing services are to be provided at no cost to the employee. EHS will assist with Occupational Health Services consultation, implementation of the medical surveillance plan, and items listed below.*

Health surveillance is not planned for this project

Blood-borne pathogens: HBV vaccination (or declination), post-exposure follow-up and treatment, vaccination record retention by principal investigator, initial BBP training and annual retraining, and universal precautions

Occupational health surveillance will be requirement. This includes reproductive evaluation and counseling.

Respirator clearance and fit-testing

Custom health surveillance/immunization program will be adopted: Please describe the plan and work with EH&S for approval before submitting the plan to the IBC.

Other:

**SECTION 5 - RECOMBINANT DNA**

Yes No I am inserting foreign DNA or RNA into a vector or host, if yes complete section below.

Large-scale (>10L culture) experiment or production of recombinant host or vector

Introduction of a drug resistance or toxic traits into a pathogenic agent

Release of recombinant organisms to the environment

The Principal Investigator has received training on the Overview of the Current NIH Guidelines for Research Involving Recombinant DNA Molecules or has attended further specified training by EH&S

**From a Risk Group 3 or 4 agent, Select Agent, or an animal or plant pathogen normally handled at BSL 3, please discuss this project with the Biosafety Officer before submitting application**

**Please respond to the following questions regarding your proposed research. Type the requested information at the end of this document, under Section 5 – additional information.**

**1. Research project summary.** Specify your project objectives and experimental design. Briefly discuss the involvement of the genes of interest in the project objectives. Specify if your work involves gene discovery. Justify in detail any large-scale work (>10L culture). Specify any agency permits that have been issued to cover your work. Provide an overview of how all the components will be used.

**2. Sources of components.** Provide the names and sources of all hosts, vectors, and DNA species. Include commercial sources, names and addresses of collaborators supplying biohazardous materials or recombinant components. Include any pertinent information on required federal or state permits.

**3. Inserted sequence and gene information.** Specify the nature and functions of the genetic material being inserted into the host If expression of a foreign protein in a host is an objective of this research discuss the protein and identify any anticipated phenotypic changes to the host.

**4. Vector information (For work with *viral vectors* disregard this question).** Provide technical information regarding the transformed and untransformed vector, including composition and size of insert, nature and specificity of promoters and other elements, types of species targeted (*E. coli*, mammalian, etc.), and types of tissues targeted. If your vector did not originate from a commercial source, cite the original reference for its development and include a genetic map of the vector that identifies all relevant elements. If possible, provide an electronic copy of the reference.

**5. Transformation methods.** Describe your methods for transforming the vector and host. A detailed step-by-step protocol is not necessary, but please provide sufficient information on your procedures so that the committee can identify the steps that involve the greatest likelihood of worker or environmental exposure to biohazardous materials. Indicate the steps that will be conducted in a biological safety cabinet (including reagent and construct preparation).

**6. Risk assessment.** List the known or suspected biohazards of your research materials, including hazards of your gene(s) of interest, vector, and transformed host to healthy adult or immunocompromised people, or to pregnant women and to other animal species and to plants (where applicable). Describe any significant potential environmental impacts if the host escapes containment and becomes established in agricultural or natural ecosystems, whether by hybridization or by direct colonization.

**If your research involves the use of viral vectors, respond to the following questions.**

**7. Viral vector identification and source.** Identify the viral vectors to be used in your research. Specify the types of vector (as checked off in Section 2A) and the strains or other identifying designations.

**8. Viral genes remaining in vector.** Specify the native viral genes that are known to remain in the vector.

**9. Replication competence status.** Specify whether the vector is replication competent or defective, and specify the viral generation. If the vector is replication competent or is replication defective and used in conjunction with a helper virus, please justify its use in your experiments. If the vector is a replication defective construct **from a non-commercial source,** describe your methods and protocol for verifying replication incompetence at receipt and periodically thereafter. Discuss helper virus,packaging cell systems and gene complementation systems (that would yield an infectious virus) involved with your experiments.

**10. Specify the viral envelope and identify the species and cell types known to be targeted by this vector**.

**SECTION 6 – INFECTIOUS AGENTS**

Viral vectors used in recombinant experiments requires the completion of Section 5 only

I am working with Human Risk Group 2 infectious, pathogenic, or toxin-producing agents, other than viral vectors

I am working with Human Risk Group 1 biological agents that are infectious or pathogenic to animals

I am working with Human Risk Group 1 biological agents that are infectious or pathogenic to plants

I am working with human source materials

I am working with non-human primate source materials

If any of the boxes above were checked please complete the section below

**Table 2.** Infectious agents and arthropod vector information. Please provide scientific or technical names, including strain names. Be sure to include the intended host for your infectious agent, if applicable, and check all applicable boxes for each agent. Use additional sheets as necessary. The information provided here will be entered into the BUA database.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Agent / Host** | **ATP1** | **BBP2** | **BSL1** | **BSL2** |
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|  |  |  |  |  |
|  |  |  |  |  |
| **Arthropod vector** |  |  |  |  |
|  |  |  |  |  |
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1Aerosol Transmissible Pathogen (ATP) (Cal-OSHA Title 8, Section 5199)

2 Blood-borne Pathogen (Cal-OSHA Title 8, Section 5193): Human Immunodeficiency Virus (HIV), Hepatitis B and C viruses (HBV, HCV), other human pathogens that could be present in human blood, tissues, cell lines, and body fluids and could be transmitted by percutaneous exposure.

**Please respond to the following questions regarding your proposed research. Type the requested information at the end of this document, under section 6 – additional information.**

**1. Research project summary.** Describe your project objectives and experimental design. For model systems or for research involving Select Agents (42 CFR § 73), briefly state the reasons that the selected infectious agents are most appropriate for your work.

**2. Sources of agents.** Specify the sources of the individual biohazardous materials obtained from natural sources, from commercial vendors (include vendor names), or from collaborators (names and addresses). Include any pertinent information on required federal or state permits.

**3. Technical information regarding infectious agents.** Provide technical information regarding the infectious agent strain(s), including any genetic modifications, genetic recombination or drug resistance. For antibiotic drug resistant strains provide strain name, resistance factor, and source. If drug resistance traits that are being added to infectious agents are also known to be acquired naturally, reference at least one supporting publication. If your genetically altered strains did not originate from a commercial source, cite the original references for their development or specify “developed in this laboratory” as appropriate (or specify “wild-type”). Specify if you are using clinical isolates of human or animal pathogens or receiving environmental samples for isolation or identification of pathogens. For plant pathogens, specify the plant hosts, symptoms of host infection, mode of pathogen transmission (water, soil, insect or other), potential insect vectors.

**4. Arthropod vector and insectary information.** Provide technical information regarding the host-vector-agent system you will be using, including the natural history of agent-vector infection and vector-host infection. Discuss vector-host specificity and other natural limits on disease transmission (physical, geographic, and biological). Be sure to state the natural geographic distribution of the vector and natural hosts, and note any agency permits that you have been issued or are pending. Discuss in detail your insectary facilities and arthropod colony husbandry program, with special attention to your containment provisions.

**5. Risk assessment.** Specify the known and suspected biohazards of your infectious agents, including hazards to healthy adults, pregnant women or immunocompromised individuals, and to other species. If applicable, specify the symptoms of significant exposure or infection in humans. Include a one- or two-sentence review of laboratory acquired infections involving the agents you plan to use (statistics and outcome trends across all laboratories). If you are using an exotic arthropod vector system or any plant pathogen, discuss the possible consequences of a release into local agricultural areas or natural ecosystems.

**6. Experimental procedures.** Specify the experimental procedures including isolation and culture methods and conditions that involve biohazardous materials that you will use to accomplish your objectives. A detailed step-by-step protocol is not necessary, but please provide sufficient information on your procedures so that the committee can identify the steps that involve the greatest likelihood of worker, community, or environmental exposure to biohazardous materials. Indicate the procedure steps that will be conducted in a biological safety cabinet. Specify which procedures will happen in growth chambers, greenhouses or field plots, if applicable.

**SECTION 7 – AUTHORIZED USERS**

Complete this page for ***all*** personnel involved with your project. The EH&S and the IBC will keep the information on this page and on the animal care protocol page confidential.

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| **NAME** | **EMPLOYEE or STUDENT ID#** | **PHONE** | **EMAIL** |
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