BUA#:
BioSafety Level:
Expiration:
Approval
(BSO Signature)

BIOLOGICAL USE AUTHORIZATION APPLICATION (BUA)

Section 1: Principal Investigator			
Name and Title		Office Room #	
Email		Phone (office)	
Department		Phone (mobile)	
Biosafety Training Certification Date		Lab Room (s)	
Additional information on researcher proficiency and experience related to the project application may be provided:			

Section 2: Co-Principal Investigator			
Name and Title		Office Room #	
Email		Phone (office)	
Department		Phone (mobile)	
Biosafety Training Certification Date		Lab Room (s)	
Additional information on researcher proficiency and experience related to the project application may be provided:			

Section 3: Category of Experiments from the NIH Guidelines Check ALL that apply. For more detailed information on the categories, see Section III of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html)
IBC approval, RAC review, NIH Director approval:
○ Deliberate transfer of drug resistance into microorganisms; Do not check for using selectable markers in E. coli (A1)
NIH/OBA and IBC approval:
○ Cloning genes encoding toxin molecules $LD_{50} \leq 100$ μg/kg (B1)
IBC, IRB and RAC Review:
○ Gene transfer into human research participants (C1)
IBC approval prior to initiation:
○ Experiments with pathogenic agents as host-vector systems (viruses, bacteria, protozoa, other pathogens) (D1)
○ Cloning DNA from pathogenic agents into nonpathogenic or lower eukaryotic host-vector systems (D2)
○ Use of infectious virus, or defective viruses in the presence of helper virus, in tissue culture systems (D3)
○ Experiments involving recombinant DNA in whole animals (D4)
○ Experiments involving recombinant DNA in whole plants (D5)
○ Large scale (> 10 liters) cell culture (D6)
○ Experiments with influenza viruses (D7)
IBC notice simultaneous with initiation:
○ Experiments with < 2/3 of any eukaryotic viral genome (E1)
○ Experiments with recombinant-DNA modified plants and small animals, or recombinant-DNA modified arthropods with plants, containable at biosafety level 1 (E2)
○ Creation of transgenic or knock-out rodents, or breeding of those rodents, containable at animal biosafety level 1 (E3)
Applications for the use of these biological materials are also reviewed by the IBC:
○ Primary human and/or primate cell lines and tissues, e.g., human blood
○ Human pathogens
○ Toxins with an $LD_{50} \leq$ μg/kg body weight

Section 4: Project Description		
New application or renewal of BUA#	Date of Approval:	Date of previous renewal or approval:
Project Title:		
Project Objectives Provide a brief summary of the goals of the proposed research.		
Experimental Procedures Summarize the experimental procedures used in the project.		
If renewal, how long has project been going?		

Section 5: Biological Materials			
Part 5A: Recombinant or Synthetic Nucleic Acids			
○ This project does not involve work with recombinant DNA.			
Source of DNA Specify the source organism and whether it is isolated, purchased from or synthesized by a vendor (organisms, company name or lab, catalog #, lot #)	**Nature of DNA** State the gene names and give the function or activity of the DNA or its product	**Host** (e.g., *E. Coli,* HEK293 cells)	**Vector** (e.g., plasmid name, lentiviral, adenoviral)

Potential Hazards Indicate whether the gene products encode known or potential oncogenes (e.g., transcription factors), toxins, virulence factors, silence tumor suppressor genes, affect the known treatment for infection, etc.

Viral Vectors Provide information on the genetic basis of attenuation, viral particle replication competency, host range and tropism. As applicable, include details on the packaging cell line(s), whether and how recombinant particles will be concentrated, or information on the vector core facility to be used.

Part 5B: Human or Primate Cell Lines and Tissues			
○ The project does not involve work with human/primate cell cultures or tissues.			
Give the status of IRB or ESCRO oversight as applicable			
Description	Vendor or Source (e.g., ATCC, NDRI)	Screen for bloodborne pathogens	In vivo use in animals
			Yes/No
			Yes/No
			Yes/No
			Yes/No
ATCC began testing all new production lots of human cell lines for the presence of virus in January 2010. The ATCC test panel includes: HIV, Hep B, HPV, EBV, and CMV. Test results are provided on the Certificate of Analysis (CoA) for each product, showing either a "negative" or "positive" specification/result for the assay. (Some cell lines are known to carry a particular virus, e.g., HeLa cells. These cells are infected with HPV and as such the cells will be positive for HPV and ATCC screen. ATCC still distributes the cells because this was a normal characteristic of this cell line)			
If the cells or tissues from other vendors or collaborators are screened for bloodborne pathogens, summarize the test panel below or provide an example of the Certificate of Analysis.			

Part 5C: Infectious Agents: Bacteria, Fungi, Parasites, Prions and Viruses			
○ This project does not involve work with infectious agents.			
Agent name, strain	Vendor or source agent	Biosafety Level	In vivo use in animals
			Yes/No
			Yes/No
			Yes/No
			Yes/No
Additional information on the agents listed above may be provided below.			

Part 5D: Toxins			
○ This project does not involve work with toxins having an $LD_{50} \leq 100$ μg/kg body weight.			
Toxin name	Maximum amount to be stored	Vendor or source toxin	In vivo use in animals
			Yes/No
			Yes/No

			Yes/No
Additional information on the agents listed above may be provided below.			
Part 5E: Animal Experimentation			
○ The project does not involve whole animal experimentation as covered by the NIH guidelines for the introduction of biological agents into animals (http://osp.od.nih.gov/sites/default/files/TableAnimalResearchCoveredUnderNIHGuidelines-Aug2011.pdf)			
○ The project involves whole animal experimentation as covered by the NIH Guidelines. IACUC Protocol Number:_____			
Housing Conditions and Use			
Part 5F: Large Scale (> 10 L) Cell Culture			
○ The project does not involve large scale cell culture.			
If this project entails cell culture in excess of 10 liters volume, then provide a rationale below.			

Section 6: Containment

Part 6A: Facilities

State the purpose of each room, i.e., experimental, storage only, and specify whether the room is shared with other users

Building	Room #	Purpose

Part 6B: Engineering Controls

- Biohazardous sharps waste containers
- Biosafety cabinet(s)

Building	Room #	Class, type, (e.g., IIA2)	Certification date

- Other:

Part 6C-1: Safe Work Practices

The following procedures shall be employed during the course of the research project:

- Wash hands upon contact with anything potentially infectious, after work, after removing gloves and before leaving the laboratory
- Gloves are replaced as soon as practical when contaminated, torn, punctured, or when their ability to function as a barrier is compromised
- Perform all procedures in a manner that minimizes splashes, the creation of droplets or aerosols
- Perform procedures that may generate infectious aerosols in a biosafety cabinet
- Use mechanical pipetting device at all times
- Disinfect work area and lab equipment daily and after use (as detailed in Section 7 below)
- Transport biological agents between buildings using rigid, leak-proof, double container systems lined with enough absorbent material to absorb liquid leaks.
- Employ Universal Precautions when handling human and nonhuman primate tissues or cleaning and decontaminating the work area (http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf) (page 66)
- Restrict access to shared spaces during experimental procedures involving potentially infectious materials
- Post appropriate warning signs to entryways of shared spaces immediately prior to

and for the duration of all such experiments

- Entry ways to work areas, containers of biohazardous waste, refrigerators and freezers used with potentially infectious materials shall have labels with the work "BIOHAZARD" and the universal biohazard symbol in orange-red with lettering and symbols in a contrasting color
- Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas
- Food and drink will not be stored in laboratory refrigerators, freezers, shelves, cabinets, or bench tops that contain research material(s)
- Do not bend, break, shear or remove needles from disposable syringes
- Dispose of contaminated sharps in a single-use, disposable container that is rigid, leak proof, puncture resistant, and labeled with the biohazard symbol and "SHARPS WASTE"; close the container when not in use
- Place sharps waste containers as near the point of use as appropriate for immediate disposal and do not exceed the sharps container fill line at 2/3 full
- Other:

Part 6C-2: Additional Safe Work Practices Specific to the Project:

Part 6D: Personal Protective Equipment

At a minimum, long pants and closed toe shoes are to be worn when occupying a lab. For your reference, please see the Whittier College Policy on Personal Protective Equipment. Contaminated lab coats are handled as little as possible. Under no circumstances will employees be expected to take home laboratory coats for laundering.

- A lab coat and disposable latex or nitrile gloves are worn when handling potentially infectious materials
- Barrier lab coats that are impervious to small volumes of liquids are used for work with human blood or other potentially infectious body fluids
- Safety glasses or goggles, with an accompanying face shield for handling large volumes, are worn for biohazardous liquid handling outside of a biosafety cabinet
- Other:

Section 7: Disinfection and Sterilization

Part 7A: Spill Response

Review the procedures below and edit as necessary

Disinfectant:	10% (vol/vol) freshly diluted household bleach
Contact time:	10 minutes

- For spills contained within a biosafety cabinet, keep the cabinet blower on.
- Replace any contaminated personal protective equipment.
- Obtain or prepare a fresh solution of disinfectant.
- Cover spill with paper towels to prevent aerosols and splashing, and apply disinfectant to the area.
- Wait 10 minutes.
- Use paper towels to absorb the spill, working from the outside in.
- Use tongs to collect the paper towels if sharps are involved.
- Bag the clean-up materials as solid waste, discard the gloves and wash your hands thoroughly.

For larger spills outside of a biosafety cabinet, notify colleagues and vacate the premises for 30 minutes to allow time for aerosols to settle and for a few room air exchanges.
Post a sign at the door warning of the spill and advising of the proper re-entry time.
Before or upon re-entry, don clean personal protective equipment and proceed as described above.

Part 7B: Surface and Equipment Decontamination

List the equipment to be decontaminated daily and after experimentation:

Part 7C: Solid Liquid and Solid Medical Waste

Handling, storage, treatment and disposal of all regulated medical waste shall be in accordance with the California Medical Waste Management Act, Health and Safety Code Chapter 6.1, Sections 117600 through 118360 (https://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/MedicalWasteManagementAct.pdf), other applicable regulations and Whittier College policy.
Regulated waste generated from the laboratory is placed in containers that are labeled with the biohazard symbol, color-coded red, leak-proof, and snuggly lidded when not in use. For your reference, consult the Whittier College Medical Waste Management Plan.

Part 7D: Liquid Waste Disinfection and Disposal

State what type(s) of liquid waste will be generated and how it will be deactivated. Give dilution or concentration of disinfectant, contact time and procedure.

Part 7E: Solid and Pathological Waste Indicate the method(s) used to disinfect and dispose of solid biohazardous waste.
○ Red biohazard bag and autoclave prior to disposal, minimum 121 °C and 15 psi for 30 minutes.
○ Clear autoclave bag and autoclave, e.g., for transgenic fruit flies
○ Biohazardous sharps disposal per Whittier College guidelines
○ Other:

Section 8: Incident Protocol

Part 8A: Symptoms of Infection

Summarize the symptoms of infection post-exposure to the infectious agents used in lab or those potentially encountered via field sampling.

Part 8B: Post Exposure Procedures

Review and modify the procedures below as necessary.

1. Clean the affected area. Wash needlesticks and cuts with soap and water, flush splashes to the nose, mouth or skin with water, and irrigate eyes with clean water or sterile saline. The laboratory sink, emergency shower and eye wash stations will be used as necessary to flush affected areas with water for several minutes.

2. Report the incident. The exposure must be reported to the PI and Biosafety Officer immediately. Employees and personnel on College pay status must call the Biosafety Officer at (562) 907-4844 and the Department of Campus Safety at (562) 907-4211 to report the incident and complete the incident report form.

Seek treatment. Healthcare personnel treating exposed patients must be informed of the biological materials involved in the exposure. Students will be directed to seek immediate treatment at Whittier College Student Health and Wellness Center, Hamilton House, 13612 E. Philadelphia St., Whittier, CA 90601 (562) 464-4548. Employees and personnel with complete the Post-Exposure Response Form and arrange for treatment at:

HealthFirst Medical Group – South
13440 E. Imperial Highway, Santa Fe Springs, CA 90670
(562) 926-3440

3. Document the incident. The post-exposure evaluation will include an explanation of the circumstances, route of exposure and type of inoculum. Percutaneous injuries from contaminated sharps will be recorded on the OSHA 300 Log and the Sharps Injury Log, and these logs will be maintained by Human Resources.

Section 9: Biosafety Training Checklist of Operations and Procedures.
Please utilize the Biosafety Training Checklist template and customize this for your lab for the safe use of particular instruments and procedures you and your research students will be doing on the research project. You will need to train each student on the proper use of each instrument and procedure and check this off on the checklist. Finally, submit the completed checklist as an appendix to this application.

Section 10: Additional information may be provided to the IBC in the space below. If the work described herein is covered by the Bloodborne Pathogens Standards (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051) or the Aerosol Transmissible Disease Standard (http://www.dir.ca.gov/title8/5199.HTML), then any additional information on the corresponding exposure control plan is below.

Section 11: Application Certification

Part 11A: Principal Investigator's Certification

By signing below, I certify that I have read the following statements and that I am responsible for the enforcement. As the Principal Investigator, I will:

1. Certify that the information contained in this application is correct and accurately reflects my proposed research.
2. Read, understand and comply with the current Whittier College Biological Safety Policy and the NIH Guidelines and accept the Principal Investigator responsibilities listed therein.
3. Ensure that all personnel on the proposed project will have received relevant training and are informed of the potential biohazards, appropriate precautions, and post exposure procedures.
4. Report to the Biosafety Officer jwiedenm@whittier.edu and Campus Safety campussafety@whittier.edu (a) any research-related illnesses, exposures or accidents and (b) the loss or breach of containment within 24 hours after the occurrence.
5. Neither initiate nor modify any recombinant or synthetic nucleic acid research that requires IBC approval prior to initiation until IBC approval is given.
6. Ensure that equipment that requires servicing or shipping will first be decontaminated as necessary. If decontamination is not feasible, a readily observable "BIOHAZARD" label will be placed on the equipment and the portions of the equipment that remain contaminated will be noted.

_____ _____

Principal Investigator Signature Date

_____ _____

Co-Investigator Signature Date

_____ _____

Co-Investigator Signature Date

_____ _____

Department Chair Signature Date

Part 11B: Researcher Training on the BUA Application

Personnel listed on this BUA shall print, date and sign their name below after the application has been approved by the Whittier College Biosafety Committee and after they have been trained on the protocols and safety procedures outlined in this application. A copy of the signed page shall be delivered to the Whittier College Biosafety Officer.

Printed Name	Signature	Date