

The application works best in Microsoft Word. To add additional lines to any table, place the cursor in the last box and press the “tab” key. Submit the Biological Use Authorization (BUA) as a Word document by email to biosafety@sjsu.edu. The signature page should be completed by DocuSign and sent as a pdf. If more space is needed, please attach a separate sheet. If you need assistance contact the Institutional Biosafety Committee (IBC) at biosafety@sjsu.edu.

Upon approval of the BUA, Principal Investigators or Faculty will complete a BUA renewal yearly for active biosafety level 2 (BSL-2) and select agents/toxins work or every 3 years for all other work requiring a BUA (including storage only of BSL-2 materials). To amend or renew an approved BUA, first confirm that your approved application used the most recent versions of the forms. If so, apply changes directly to the approved BUA using the “Suggesting” mode in Google Docs to track changes. If not, please prepare the renewal with the most recent forms. Submit the revised BUA to biosafety@sjsu.edu.

BUA Preparer Information	
Name of Principal Investigator (PI)/Faculty:	<u>Sammy Spartan, Ph.D.</u>
Job Title:	<u>Professor</u> Department: <u>Department of School Spirit</u>
Office Room:	<u>Clark 000</u> Lab Room(s): <u>Duncan Hall 000</u>
Office Phone:	<u>408-924-0000</u> Lab Phone(s): <u>Click or tap here to enter text.</u>
Email address:	<u>Sammy.spartan@sjsu.edu</u>

Co-Investigator or Faculty:	<u>Click or tap here to enter text.</u>	
Job Title:	<u>Click or tap here to enter text.</u>	Department: <u>Click or tap here to enter text.</u>
Office Location:	<u>Click or tap here to enter text.</u>	Lab Room(s): <u>Click or tap here to enter text.</u>
Office Phone:	<u>Click or tap here to enter text.</u>	Lab Phone(s): <u>Click or tap here to enter text.</u>
Email address:	<u>Click or tap here to enter text.</u>	

Lab Supervisor/Manager:	<u>Click or tap here to enter text.</u>	
Office Location:	<u>Click or tap here to enter text.</u>	Lab Phone: <u>Click or tap here to enter text.</u>
Email address:	<u>Click or tap here to enter text.</u>	

After Hours Contacts	Name:	After Hours Phone:
Principal investigator/Faculty	<u>Click or tap here to enter text.</u>	<u>Click or tap here to enter text.</u>
Responsible Personnel (optional)	<u>Click or tap here to enter text.</u>	<u>Click or tap here to enter text.</u>
	<u>Click or tap here to enter text.</u>	<u>Click or tap here to enter text.</u>

BUA Information				
<input checked="" type="checkbox"/>	New BUA			
<input type="checkbox"/>	Renewal	Original BUA #	<u>Click or tap here to enter text.</u>	Expiration Date: <u>Click or tap here to enter text.</u>
<input type="checkbox"/>	Amendment	Apply edits to approved BUA using track changes		

<i>This section for IBC use only</i>		
<i>BUA #</i>	<i>Approval Date</i>	<i>Expiration Date</i>
<u>Click or tap here to enter text.</u>	<u>Click or tap here to enter text.</u>	<u>Click or tap here to enter text.</u>
<i>NIH Recombinant DNA Designation</i>	<i>Biosafety Level</i>	<i>Lab Audit Status</i>
<u>Click or tap here to enter text.</u>	<u>Click or tap here to enter text.</u>	<u>Click or tap here to enter text.</u>

Submission Guidelines

To prevent any delays in the approval process, consider the following:

- Review CDC [BMBL](#) and [NIH Guidelines](#)
- Refer to [Sample completed BUA application](#) for guidance
- Ensure all lab personnel have completed the appropriate safety training. See [Biosafety Training Information](#) for guidance
- Confirm that any issues noted in your last lab safety audit have been resolved.
- For BSL-2 agents: Schedule a biosafety inspection (biosafety@sjsu.edu)

Type of Activity (Check Only One):

Submit separate BUA applications for research activities and teaching activities

<input checked="" type="checkbox"/>	<p>Research</p> <p>This registration is designed to encompass the research activities involving recombinant or synthetic nucleic acid molecules and biohazardous materials occurring in the lab in a comprehensive manner, and is thus not limited to a specific grant or project. Please list below all grants/projects to be covered by this application, whether funded or not (note: all biohazardous materials related to each listed grant/project must be completely described on this application).</p>		
General Project Title: Analysis of Spartan Spirit through assays			
Grant/Project Title(s)	Grant Dates	Granting Agency/Award #	SJSU Account #
"In vivo detection of Spartan Spirit"	00/00-00/01	San Jose State Central RSCA	00-0000-0000
<input type="checkbox"/>	<p>Teaching</p> <p>This registration is designed to encompass the teaching activities involving recombinant or synthetic nucleic acid molecules and biohazardous materials occurring in the class in a comprehensive manner. If two or more sections of the course are taught with the same biological hazards and standard operating procedures, a single BUA can be submitted. For such scenarios, the department chair has the authority to designate a faculty or staff member (e.g., the course coordinator) to submit the BUA. Each instructor teaching a section of the course described in the BUA must sign the signature page. Otherwise, each class should have its own BUA.</p>		
Course Name(s)/Number(s):			
Semesters held:			

Associated Institutional/Agency Approvals

Additional protocol submissions may be required if work involves human or animal (vertebrate) subjects. Note, you can submit your BUA for approval before getting the other approvals, but work on the project cannot commence until all necessary approvals have been obtained.

Does this work involve vertebrate animal subjects or unfixed tissues? (requires IACUC approval) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	SJSU IACUC #	Approved? (Y/N)	Expiration Date
Does this work involve human subjects or unfixed tissues? (requires IRB approval) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	SJSU IRB #	Approved? (Y/N)	Expiration Date
Does this work involve regulated select agents or toxins ? (may require DHHS/USDA approval) <input type="checkbox"/> Yes <input type="checkbox"/> Yes, below DHHS/USDA threshold <input checked="" type="checkbox"/> No If yes , complete the following questions: Do you intend to culture/propagate select agents? <input type="checkbox"/> Yes <input type="checkbox"/> No Do you intend to insert DNA from a select agent or DNA encoding select toxins into another organism? <input type="checkbox"/> Yes <input type="checkbox"/> No Do you intend to isolate select toxins? <input type="checkbox"/> Yes <input type="checkbox"/> No	DHHS/USDA #	Approved? (Y/N)	Expiration Date
Does this work involve human gene therapy ? (requires FDA approval) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	FDA/IND #	Approved? (Y/N)	Expiration Date

Research/Teaching Materials

Check all that apply

- | | |
|-------------------------------------|---|
| <input checked="" type="checkbox"/> | Project involves recombinant/synthetic nucleic acid molecules, recombinant/synthetic nucleic acid-containing organisms, viruses or cell cultures. Submit Attachment A |
| <input type="checkbox"/> | Project involves potential human, animal (vertebrate), or plant pathogens or infectious agents. Submit Attachment B |
| <input type="checkbox"/> | Project involves unfixed human or non-human primate organs, tissues, or cell cultures (OTCC) with proven or potential hazard to humans. (All work with human blood, human blood products, human body fluids, or other potentially infectious human materials such as brain, CNS tissues, lymphoid tissues, gut, bone marrow, and human cell cultures fall into this category. Note: human source material that has been previously fixed is excluded and does not need a BUA.) Submit Attachment C |
| <input type="checkbox"/> | Project involves the collection and analysis of environmental samples (e.g., soil, water) where biohazardous agents will be cultured from the samples or the collection location likely contains biohazards (e.g., an area with animal waste run-off). Submit Attachment D |
| <input type="checkbox"/> | Project involves biological toxins. Toxins are toxic substances produced by bacteria, fungi, protozoa, insects, animals (vertebrates and invertebrates), or plants that have the capability of causing harmful effects when inhaled, ingested, injected or absorbed. Note: Toxins not administered to cells or animals do not warrant a BUA. Select Toxins , regardless of use, require a BUA. Submit Attachment E |
| <input type="checkbox"/> | Collection or use of animals (vertebrates and invertebrates), plants, or samples that harbor zoonotic agents (e.g., wild trap animals, farm animals, and non-human primates); or collection or cultivation of plants that produce biological toxins. Submit Attachment F |
| <input type="checkbox"/> | Project involves laboratory animals (vertebrates and invertebrates) and/or plants in conjunction with materials described above in Attachment A, B, C, or E. Submit Attachment G |
| <input type="checkbox"/> | Project involves storage only of biohazardous agents. Submit Attachment H |
| <input type="checkbox"/> | Project involves large scale production of cultures in volumes of 10 liters or more at any time, regardless of biosafety level or recombinant/synthetic nucleic acid material. Contact IBC (biosafety@sjsu.edu) |
| <input type="checkbox"/> | Project involves transfer of recombinant/synthetic nucleic acid molecules into human research subjects. Contact IBC (biosafety@sjsu.edu) |

Brief Non-Technical Summary

In lay language, provide a few sentences describing the research purpose or course objectives, including goals, objectives, and anticipated outcomes of your work

Our studies will identify the genetic basis for Spartan spirit using the fruit fly *Drosophila melanogaster*. "spartan spirit" are a newly identified naturally occurring variant strain of fruit flies isolated in Santa Clara county. A successful project will help us characterize the genetic landscape of fruit flies in Santa Clara county and to understand whether these gene functions are conserved in human cells.

Experimental Procedures and Research Methodology

Describe the experimental procedures that involve biohazardous material. Please include a work flow with all of the biohazards to help give the committee an understanding of your activities with these materials.

In addition, provide the appropriate Standard Operating Procedures (SOPs) as attachment(s). A detailed step-by-step protocol is not necessary, but provide sufficient information on your procedures so that the committee can complete a risk assessment. Identify:

- each biohazardous material (e.g., specific cell lines, recombinant plasmids, viral vectors, bacteria, plants, etc.)
- conditions of collection, growth, and transportation
- safety measures to minimize risk of exposure (i.e., PPE, biosafety cabinet or other physical containment)
- spill response plan
- exposure response plan
- use of recombinant or synthetic nucleic acid molecules, transgenic organisms, or any related concerns
- work practices and special accommodations
- level of expertise of personnel performing procedures

Examples of SOPs that may be needed based on your required attachments are listed below.

- Attachment A – Recombinant DNA SOP, BSL-1 SOP
- Attachment B, C, E – BSL-1 and/or BSL-2 SOP

Refer to the SOP template and sample SOPs for guidance on completing this section, however, feel free to combine the SOP information as appropriate onto a single document.

Include your description of your work flow and list the SOPs attached to the application below.

Our studies will identify the genetic basis for Spartan spirit using the fruit fly *Drosophila melanogaster*. “spartan spirit” are a newly identified naturally occurring variant strain of fruit flies isolated in Santa Clara County. First, we will conduct a genetic screen to identify genes that mediate the “spartan spirit” variant phenotype, where flies exhibit a blue and gold striped abdomen. We will use molecular techniques to identify the blue and gold pigment genes, including PCR and agarose gel electrophoresis. We will next subclone these genes into protein expression vectors and express the proteins in E coli BL-21 cells. We will perform enzymatic assays to characterize activity and identify inhibitors of blue and gold pigment synthesis. Finally, we will express these genes in HeLa cells to determine if their functions are conserved.

SOPs included:

recombinant DNA

BSL1 (E. coli and fruit flies)

BSL2 (HeLa cells)

Hazard and Risk Assessment	
Based on your risk assessment, what do you perceive to be the highest risk procedures involving your biohazards? (i.e., accidental aerosolization, injection risk)	Culture and maintenance of HeLa cells.
What safety measures will be instituted to minimize the risk of exposure for procedures listed above? (i.e., use of a biosafety cabinet and/or centrifuge safety cups, engineered sharps)	We will use a biosafety cabinet and BSL-2 precautions for all cell work.
Based on your risk assessment, what overall level of biosafety containment do you propose to use for this work? (Note: the overall BSL should reflect the highest level of biosafety containment to be utilized)	<input type="checkbox"/> BSL-1 <input checked="" type="checkbox"/> BSL-2 <input type="checkbox"/> BSL-2+
Biohazard Signs and Labels	Signs shall be posted at the lab entrance(s). Biohazard labels (stickers) shall be placed on refrigerators, freezers, biosafety cabinets, and incubators. BSL-2 signs will be authorized by the IBC chair.

Containment Methods
 Procedures which may result in the generation of aerosols, splash, or sprays of biological material and safety precautions that should be followed by personnel performing these procedures are as follows:

Procedures/Equipment	Agent(s)/Material(s)	Containment	
<input checked="" type="checkbox"/> Microbiological Growth	E coli with recombinant DNA	<input type="checkbox"/> Biological Safety Cabinet <input checked="" type="checkbox"/> Benchtop <input checked="" type="checkbox"/> Incubator	<input checked="" type="checkbox"/> Sealed tube/vial <input type="checkbox"/> Other: Click or tap here to enter text.
<input checked="" type="checkbox"/> Tissue Culture/Cell Culture	HeLa cells with recombinant DNA	<input checked="" type="checkbox"/> Biological Safety Cabinet <input checked="" type="checkbox"/> Incubator	<input checked="" type="checkbox"/> Sealed tube/vial <input type="checkbox"/> Other: Click or tap here to enter text.
<input checked="" type="checkbox"/> Recombinant/synthetic nucleic acid molecules in cells/organisms	Recombinant/Synthetic Nucleic Acids: blue and gold pigment genes Cell/Organism (vertebrates and invertebrates): Drosophila melanogaster, E coli (BL-21) and HeLa cells	<input checked="" type="checkbox"/> Biological Safety Cabinet <input checked="" type="checkbox"/> Other: Flies will be maintained in sealed vials inside a sealed incubator.	
<input checked="" type="checkbox"/> Centrifugation	Recombinant DNA and protein products from D. melanogaster, E coli and HeLa cells	<input checked="" type="checkbox"/> Biological Safety Cabinet <input checked="" type="checkbox"/> Sealed tube/vial <input checked="" type="checkbox"/> Sealed rotor	<input type="checkbox"/> Safety cups <input type="checkbox"/> Other: Click or tap here to enter text.
<input type="checkbox"/> Ultracentrifugation	Click or tap here to enter text.	<input type="checkbox"/> Biological Safety Cabinet <input type="checkbox"/> Sealed tube/vial	<input type="checkbox"/> Other: Click or tap here to enter text.
<input checked="" type="checkbox"/> Sonication	Recombinant proteins from E coli	<input type="checkbox"/> Biological Safety Cabinet <input checked="" type="checkbox"/> Sealed tube/vial	<input checked="" type="checkbox"/> Other: Sonicator is enclosed

Procedures/Equipment	Agent(s)/Material(s)	Containment	
<input checked="" type="checkbox"/> Vortexing	Recombinant DNA and proteins from <i>D melanogaster</i> , <i>E coli</i> and HeLa cells	<input type="checkbox"/> Biological Safety Cabinet <input checked="" type="checkbox"/> Sealed tube/vial	<input type="checkbox"/> Other: Click or tap here to enter text.
<input type="checkbox"/> Homogenization / Blender	Click or tap here to enter text.	<input type="checkbox"/> Biological Safety Cabinet <input type="checkbox"/> Sealed tube/vial	<input type="checkbox"/> Other: Click or tap here to enter text.
<input type="checkbox"/> Fluorescence activating cell analysis/sorting	Click or tap here to enter text.	<input type="checkbox"/> Live cells <input type="checkbox"/> Other: Click or tap here to enter text.	<input type="checkbox"/> Fixed cells Method of fixation: Click or tap here to enter text.
<input checked="" type="checkbox"/> Vacuum	Discarded media from cultured mammalian cells	<input checked="" type="checkbox"/> Biological Safety Cabinet <input checked="" type="checkbox"/> 0.2 µm In-line filter	<input checked="" type="checkbox"/> Disinfectant trap <input type="checkbox"/> Other: Click or tap here to enter text.
<input type="checkbox"/> Needles / Blades / Capillary Tubes	Click or tap here to enter text.	<input type="checkbox"/> Disposable <input type="checkbox"/> Engineered Sharp	<input type="checkbox"/> Sharps Waste Container <input type="checkbox"/> Other: Click or tap here to enter text.
<input type="checkbox"/> Finger Prick / Venipuncture	Click or tap here to enter text.	<input type="checkbox"/> Disposable <input type="checkbox"/> Retractable Lancet Sharps	<input type="checkbox"/> Engineered Sharp <input type="checkbox"/> Sharps Waste Container <input type="checkbox"/> Other: Click or tap here to enter text.
<input checked="" type="checkbox"/> Animal (vertebrates and invertebrates) cage changing/husbandry	fruit flies	<input type="checkbox"/> Biological Safety Cabinet <input type="checkbox"/> Laminar Workbench <input type="checkbox"/> Specific SOP	<input type="checkbox"/> Respirator/N95 mask <input checked="" type="checkbox"/> Other: Fly cultures are changed regularly by transferring adult animals into new food vials. Old vials are sealed in red biohazard bags and pickup by MSC staff upon request.
<input type="checkbox"/> Surgery or necropsy of infected animals (vertebrates and invertebrates)	Click or tap here to enter text.	<input type="checkbox"/> Biological Safety Cabinet <input type="checkbox"/> Respirator/N95 mask	<input type="checkbox"/> Needle protection device: Click or tap here to enter text. <input type="checkbox"/> Other: Click or tap here to enter text.
<input type="checkbox"/> Injection, inhalation, oral, or dermal administration to animals (vertebrates and invertebrates)	Click or tap here to enter text.	<input type="checkbox"/> Route: Click or tap here to enter text. <input type="checkbox"/> Biological Safety Cabinet	<input type="checkbox"/> Respirator/N95 mask <input type="checkbox"/> Other: Click or tap here to enter text.
<input type="checkbox"/> Other, specify procedure and describe containment: Click or tap here to enter text.			

Biohazardous Materials and Waste Disinfection/Decontamination and Disposal

(check applicable boxes)

Terminal inactivation and waste disposal. Indicate your methods for terminal inactivation of the biological agent or transgenic material (microorganisms, animals (vertebrates and invertebrates), 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., recombinant DNA, infectious, transgenic material, etc.).** If an autoclave will be used to inactivate waste (liquid or solid) from pathogens or medical waste, the autoclave must be certified by the county for decontamination. If you will be using a method that is not already described below, please use the "Other" field at the bottom and clarify the method and reason for its use.

Liquid Waste (liquid cultures, bodily fluids, etc.):

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

Disposal by college/university technical staff

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

Not generating liquid waste.

Solid Waste:

Disposal by college/university technical staff

Autoclave (121°C, 15 psi, 30 minutes) in red autoclave bags with an indicator (autoclave tape or steam indicator strip).

Medical waste stream (either through Barnett Medical Services or a Ca Dept of Public Health-approved terminal autoclave) in red a medical waste bag contained within a leak-proof, lidded, and labeled secondary container.

Animal (vertebrates and invertebrates) caging and bedding is:

autoclaved treated with disinfectant: [Click or tap here to enter text.](#)

untreated, regular trash other: [Click or tap here to enter text.](#)

Not generating solid waste.

Sharps:

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.

Not generating sharps waste.

Animal (vertebrates and invertebrates) carcasses, gross tissues, and preserved specimens:

Disposal by college/university technical staff

Incineration through Barnett Medical Services Other: [Click or tap here to enter text.](#)

Not generating carcass or tissue waste.

Other terminal inactivation or waste disposal method not already described will be discussed below:

[Click or tap here to enter text.](#)

Work surfaces, instruments, equipment. Indicate decontamination activities done by lab personnel.						
Method	Contact time	Agent(s)/ Material(s)	Benchtops	Stainless Surfaces	Equipment/ Parts	Instruments/ Glassware/ Apparatus
<input type="checkbox"/> Autoclave	Click or tap here to enter text.	Click or tap here to enter text.	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> Daily <input type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input type="checkbox"/> After Use
<input checked="" type="checkbox"/> Bleach (freshly diluted to final 10% v/v)	30+ minutes	Discarded cell culture media (mammalian cells & E. coli)	<input type="checkbox"/> Daily <input checked="" type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input checked="" type="checkbox"/> After Use
<input type="checkbox"/> Bleach + rinse with 70% alcohol	Click or tap here to enter text.	Click or tap here to enter text.	<input type="checkbox"/> Daily <input type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input type="checkbox"/> After Use
<input checked="" type="checkbox"/> Alcohol (e.g., final 70% v/v EtOH or Isopropyl Alcohol)	10 minutes	Biosafety cabinet, molecular work stations	<input type="checkbox"/> Daily <input checked="" type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input checked="" type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input checked="" type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input checked="" type="checkbox"/> After Use
<input checked="" type="checkbox"/> Quaternary Ammonium Agents (e.g., DC Gold)	10 minutes	Serological pipettes	<input type="checkbox"/> Daily <input type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input checked="" type="checkbox"/> After Use
<input type="checkbox"/> Other, specify: Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	<input type="checkbox"/> Daily <input type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input type="checkbox"/> After Use <input type="checkbox"/> After Spill	<input type="checkbox"/> Daily <input type="checkbox"/> After Use

Protective Equipment

Note: Appropriate lab attire (e.g., closed toed shoes, full leg/ankle/foot coverage (no shorts, ballet flats, sandals, etc.)) must be worn. Personal protective equipment (PPE) must be provided by the laboratory to all research personnel working in the facility

- | | |
|---|--|
| <input checked="" type="checkbox"/> Lab coat or gown | <input type="checkbox"/> Face shield |
| <input checked="" type="checkbox"/> Safety glasses or goggles | <input checked="" type="checkbox"/> Gloves (nitrile or latex) |
| <input type="checkbox"/> Other: List additional PPE used in the lab: Click or tap here to enter text. | <input type="checkbox"/> N95 Mask (requires fit test, contact EH&S to schedule; see Respiratory Protection Program) |

Laboratory Locations

List all locations (including common equipment rooms) associated with the projects listed on this application where biohazardous material will be manipulated or stored. For each location, indicate the highest level of biological containment (the highest biosafety level (BSL)) to be used in your work and list the equipment available for the containment of the agents. **It is your responsibility to inform all shared-space investigators of the nature of your work, including the identity and use of biohazardous materials.**

<input type="checkbox"/> N/A			
Laboratory Locations			
Location (Bldg/Room)	Shared room? (Y/N)	BSL	Containment devices/equipment (e.g., biosafety cabinet)
DH 000	N	2	Biosafety cabinet, Drosophila incubators
DH 442	Y	1	Closed dishes holding live tissue samples for imaging
DH 646	Y	1	Sonicator, centrifuges, bacterial DH 638 incubators
DH 638	Y	1	-80° freezers holding biological samples in tertiary containment

<input type="checkbox"/> N/A		
Biosafety Cabinet Information		
Note – list only biosafety cabinets in your research lab space (not in core/teaching facilities)		
Location	Tag #	Certification Expiration Date
DH 000	00000000	8/21/22

Laboratory Personnel

List all personnel involved with work covered under this BUA, including the principal investigator, lab manager/supervisory personnel, undergraduate/master's students, and volunteers. If additional space is needed, place cursor in last cell and press *Tab*. While you do not need to submit an amendment to the BUA each time your lab personnel changes, you must maintain a current list of laboratory personnel and training documentation that can be produced upon request of the IBC or a lab auditor. This section does need to be updated whenever an amendment or renewal is submitted. In addition, an amendment must be submitted for a course each semester if instructional personnel changes. All instructional personnel on the BUA must also sign the signature page.

Biosafety training is required for each person listed, **including principal investigators and instructional personnel**. See [Biosafety Training](#) information.

Name	Title	Email address
Sammy Spartan	PI	Sammy.spartan@sjsu.edu
Person A	Lab manager/ MS student	personA@sjsu.edu
Person B	MS student	personB@sjsu.edu
Person C	MS student	personC@sjsu.edu
Person D	MS student	personD@sjsu.edu
Person E	UG student	personE@sjsu.edu
Person F	UG student	personF@sjsu.edu

Health Status, Health Surveillance, and/or Immunization Program

Are any special groups of workers (e.g., pregnant, immunocompromised, allergic) at greater risk for infection or disease from the use of this biohazardous material? If so, list these high risk group categories below. Additional precautions may be required to protect these individuals based on a recommendation by a medical professional (e.g., occupational or personal physician). Note – completion of this section is required for work with BSL-2 materials.

Yes No

HeLa cells are infected with Human Papilloma Virus. Contact between HeLa cells and unprotected mucosal epithelia may present an opportunity for infection in immunocompromised individuals. This exposure is unlikely as cells are handled in a biosafety cabinet, and all personnel will use PPE including gloves, lab coats, and eye protection.

Are any preventative medical services recommended (e.g., Hepatitis B vaccination for human tissue culture work)? If so, describe the recommended services below.

Yes No

Hep B vaccination recommended for work with human cell lines.

Are special post-exposure prophylaxis or medical management services needed in case of accidental exposure? If so, please describe them.

Yes No

In the event that HeLa cells come into contact with unprotected mucosal epithelia, affected individuals should flush with water for 15 minutes and contact their physician.

Material Transport

“Shipping and Transporting Biological Material” training through CITI is required prior to shipment. Shipping of biological materials and other dangerous goods (e.g., dry ice, liquid nitrogen, ethanol) requires packaging by or review of packaging by an individual trained to ship such materials. The transport (shipping and receiving) of biological material may require a permit from a variety of agencies, including [USDA/APHIS](#), [CDC](#), and [DOC](#). Approved permits must be on file with the IBC

Transportation	Yes/No	Agent/Material	Permit required?	
Within campus labs	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	E. coli, cultured mammalian cells & lysates	N/A	
Domestic (local, intrastate, or interstate)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Transgenic Drosophila lines	<input type="checkbox"/> Yes, type: Click or tap here to enter text.	<input checked="" type="checkbox"/> No
International	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Transgenic Drosophila lines	<input type="checkbox"/> Yes, type: Click or tap here to enter text.	<input checked="" type="checkbox"/> No
Transport in Dry Ice	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Click or tap here to enter text.	N/A	
Transport in Ethanol	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Click or tap here to enter text.	N/A	
Transport in Formalin (Formaldehyde)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Click or tap here to enter text.	N/A	
Lab Designee responsible for material transport	Name	Dr Sammy Spartan		
	Email	Sammy.spartan@sjsu.edu		
	Phone	408-924-0000		

Acknowledgement of Responsibilities

By checking each statement below and signing the signature page, I certify that I have read the following statements and agree that I and all listed participants will abide by those statements as well as all SJSU policies and procedures governing the use of recombinant or synthetic nucleic acid molecules, infectious agents and other biohazardous materials.

- I recognize that I have a responsibility for ensuring the information provided in this application is complete, accurate and thorough by participating in the development of the BUA application and conducting a review of the protocols.
- I am familiar with and agree to abide by the University's policies for research with potentially biohazardous materials based on the provisions of the NIH Guidelines and the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition including all provisions related to the shipment, transfer, and handling of these materials.
- I understand that failure to comply with the NIH Guidelines may jeopardize my research grants and those of others at the University.
- I am trained in good microbiological techniques and I will ensure that all laboratory staff involved with this work are adequately trained in good microbiological techniques appropriate for the work and are provided with an initial lab orientation and any additional training, instruction, and supervision needed to work safely with the biological agents and materials involved.
- I understand that I am responsible to report immediately to the IBC any significant violations of the NIH Guidelines, problems with containment, and any research-related accidents or illnesses.
- I agree to notify the IBC of changes in the work described herein and will submit a revised BUA to the Committee for review prior to implementing any of the proposed changes.

By checking each guideline below and signing the signature page, I certify that I have **read** the following guidelines that are applicable and **agree** that I and all listed personnel will **adhere** to the specifics of the guidelines. Check N/A if not applicable.

- | | | |
|-------------------------------------|--|---|
| <input checked="" type="checkbox"/> | Guidelines for Working with Human Source Materials | <input type="checkbox"/> N/A |
| <input type="checkbox"/> | Guidelines for Drawing Human Blood | <input checked="" type="checkbox"/> N/A |
| <input checked="" type="checkbox"/> | EH&S Bloodborne Pathogen Program | <input type="checkbox"/> N/A |
| <input type="checkbox"/> | Guidelines for Research with Viral Vectors | <input checked="" type="checkbox"/> N/A |
| <input checked="" type="checkbox"/> | Guidelines for Creation, Importation and/or Breeding of Transgenic Organisms | <input type="checkbox"/> N/A |
| <input checked="" type="checkbox"/> | SJSU Waste Management Program | (Required) |

Signatures

This signature page of the BUA application should be signed in DocuSign and submitted as a pdf with the application. Please indicate the role of each signee (i.e., Principal Investigator, Co-Principal Investigator, Faculty member with shared research space or Faculty member to whom the laboratory space is assigned (if different from Principal Investigator), Instructor-in-charge (faculty teaching the lab), Course coordinator (faculty in charge of coordinating multiple sections of a lab), or Teaching Assistant (student teaching the lab)). Add additional signature pages if needed.

Printed Name:	Sammy Spartan
Role:	Principal Investigator
Signature:	
Date:	00/00/0000

Printed Name:	Click or tap here to enter text.
Role:	Choose an item.
Signature:	
Date:	Click or tap to enter a date.

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