# INSTITUTIONAL BIOSAFETY COMMITTEE

# SAN JOSÉ STATE UNIVERSITY

# BIOLOGICAL USE AUTHORIZATION APPLICATION

# Attachment C. Human or Non-Human Primate Organ, Unfixed Tissue or Cell Cultures (OTCC)

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| Check all that apply: | |
|  | We will be drawing human blood |
|  | We will be working with human blood, blood products, or spinal fluid |
|  | We will be working with human body fluids such as urine, saliva, or feces |
|  | We will be working with potentially infectious human materials such as brain, central nervous system tissues, lymphoid tissues, gut, and bone marrow |
|  | We will be working with human or non-human primate tissue or cell cultures. |
|  | We will be introducing recombinant/synthetic nucleic acids into OTCC. (Complete [Attachment A](https://www.sjsu.edu/research/research-compliance/ibc/ibc-bua.php)) |
|  | We will be introducing infectious materials into OTCC. (Complete [Attachment B](https://www.sjsu.edu/research/research-compliance/ibc/ibc-bua.php)) |
|  | We will be introducing this material into one or more human research participants (contact the IBC at [biosafety@sjsu.edu](mailto:biosafety@sjsu.edu)) |
|  | We will be handling or culturing volumes of 10 liters or more at any one time (contact the IBC at [biosafety@sjsu.edu](mailto:biosafety@sjsu.edu)) |

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| A Standard Operating Procedure (SOP) must be attached that describes your methods for work with OTCC. A detailed step-by-step protocol is not necessary, but 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. Include the steps that will be conducted in a biological safety cabinet (including reagent and construct preparation). Consult the SOP template and the sample OTCC SOP for other required components. |

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| Unfixed Human and Non-Human Primate Source Material\* | |
| Material | Characterization |
| Blood, serum, plasma, or other body fluids | Source (Provide Organization & Location):  Subject or Population Description:  Specimen:  Volume/Amount:  Tested for HIV, HBV, and HCV?  Not Tested  Tested negative  Positive for: |
| Blood-derived product | Source (Provide Organization & Location) :  Subject or Population Description:  Specimen:  Volume/Amount:  Tested for HIV, HBV, and HCV?  Not Tested  Tested negative  Positive for: |
| Tissue | Source (Provide Organization & Location):  Subject or Population Description:  Specimen:  Volume/Amount:  Tested for HIV, HBV, and HCV?  Not Tested  Tested negative  Positive for: |
| Cells - primary | Designation and provider of each cell type/line:  Source (Provide Organization & Location):  Subject or Population Description:  Specimen:  Volume/Amount:  Tested for HIV, HBV, and HCV?  Not Tested  Tested negative  Positive for: |
| Cell lines | Designation and provider of each cell line (e.g. HeLa-ATCC #CCL-13):  Tested for HIV, HBV, and HCV?  Not Tested  Tested negative  Positive for: |

\* Note - Samples being provided by (but not purchased from) an outside entity will require a material transfer agreement. All non-human primate materials require a CDC import permit (42 CFR 71.53(t)(2)). Human samples require an import permit if they are infectious (42 CFR 71.54) but non-infectious samples can be shipped with a certification statement on official letterhead.

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| OTCC Modifications Complete the table for all unfixed human and non-human primate sourced material | | | | | | | | | |
| Source (species of origin) | Cells/ Tissues/ Organs/ Specimens  (provide technical name or commercial name) | Primary Material?  (Y/N) | Established and characterized cell lines? | | Administer to animals (vertebrate or invertebrate) in vivo?  (Y/N) | Recipient of recombinant/synthetic nucleic acids?  (Y/N) | Potentially tumor-igenic?  (Y/N) | Recipient of Microbe?  (Y/N) | Will these be cultured?  (Y/N) |
| (Y/N) | If yes, purchased from where? |
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| N/A | Microbial agents in cells | | | | | | | |
| Microbe Source | | Procedures Performed | Recipient of recombinant/synthetic nucleic acids? (Y/N) | Cell type used | Max conc | Max volume | Method of delivery | Route of shedding/excretion and interval |
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| OSHA Bloodborne Pathogens Standard All labs using [human sourced materials, including cell culture lines](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=21519), are subject to the [Bloodborne Pathogen Standard](https://www.dir.ca.gov/title8/5193.html). |
| **Exposure Control Plan:**  We will follow the Exposure Control plan in the [SJSU Bloodborne Pathogen Program](https://www.sjsu.edu/fdo/docs/EHS_280_Bloodborne_Pathogens_Program.pdf) and our attached SOP.  **Hepatitis B Immunization:**  OSHA considers anyone who reasonably anticipates contact with blood or other potentially infectious materials to be at risk of Hepatitis B infection. Hepatitis B vaccination is recognized as an effective defense against Hepatitis B infection.  Hepatitis B immunization is required by the California State University system for students 18 or younger on the first day of their first term. The 3-shot series is available to students at the Student Wellness Center for a fee.  All employees with reasonable exposure to human sourced materials must submit a [Hepatitis B Vaccine Form](https://pdp.sjsu.edu/fdo/docs/EHS_280_Bloodborne_Pathogens_Program.pdf) to EH&S ([lisa.torralba@sjsu.edu](mailto:lisa.torralba@sjsu.edu?subject=Hepatitis%20B%20Vaccine%20Form)) to declare their status. |