

**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)

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 introducing recombinant DNA into OTCC. (Complete [Attachment A](#))
- We will be introducing infectious materials into OTCC. (Complete [Attachment B](#))
- We will be introducing this material into one or more human research participants (contact the IBC chair at laura.miller.conrad@sjsu.edu)
- We will be handling or culturing volumes of 10 liters or more at any one time (contact the IBC chair at laura.miller.conrad@sjsu.edu)

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.

Unfixed Human and Non-Human Primate Source Material

Material	Characterization
<input checked="" type="checkbox"/> Blood, serum, plasma, or other body fluids	Source (Provide Organization & Location): Collected at SJSU Health Center Subject or Population Description: Collected from research volunteers under IRB approval Specimen: buccal swabs (saliva), blood samples (fingerpicks) Volume/Amount: 1,000 samples Tested for HIV, HBV, and HCV? <input checked="" type="checkbox"/> Not Tested <input type="checkbox"/> Tested negative <input type="checkbox"/> Positive for:
<input type="checkbox"/> Blood-derived product	Source (Provide Organization & Location) : Subject or Population Description: Specimen: Volume/Amount: Tested for HIV, HBV, and HCV? <input type="checkbox"/> Not Tested <input type="checkbox"/> Tested negative <input type="checkbox"/> Positive for:
<input type="checkbox"/> Tissue	Source (Provide Organization & Location): Subject or Population Description: Specimen: Volume/Amount: Tested for HIV, HBV, and HCV? <input type="checkbox"/> Not Tested <input type="checkbox"/> Tested negative <input type="checkbox"/> Positive for:
<input type="checkbox"/> 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? <input type="checkbox"/> Not Tested <input type="checkbox"/> Tested negative <input type="checkbox"/> Positive for:
<input checked="" type="checkbox"/> Cell lines	Designation and provider of each cell line (e.g. HeLa-ATCC #CCL-13): MCF 10A (ATCC # CRL-10317) Tested for HIV, HBV, and HCV? <input checked="" type="checkbox"/> Not Tested <input type="checkbox"/> Tested negative <input type="checkbox"/> Positive for:

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 in vivo? (Y/N)	Recipient of rDNA construct ? (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?					
Human	Saliva (Buccal epithelial cells)	Y	N		N	N	N	N	N
Human	Blood (Leucocytes, erythrocytes and other blood components)	Y	N		N	N	N	N	N
Human	MCF 10A (ATCC # CRL-10317)	N	Y	ATCC	N	N	Y	N	Y

<input checked="" type="checkbox"/> N/A	Microbial agents in cells							
Microbe Source	Procedures Performed	Recipient of recombinant DNA (Y/N)	Cell type used	Max conc	Max volume	Method of delivery	Route of shedding/excretion and interval	

OSHA Bloodborne Pathogens Standard

All labs using [human sourced materials, including cell culture lines](#), are subject to the [Bloodborne Pathogen Standard](#).

Exposure Control Plan:

We will follow the Exposure Control plan in the [SJSU Bloodborne Pathogen Program](#) and our attached SOP.

Hepatitis B vaccine series:

All personnel with reasonable exposure to human sourced materials must have a Hepatitis B vaccine or must submit a [Hepatitis B vaccine declination form](#) to EH&S.

