

**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](mailto: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](mailto: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 University of Technology Sydney Subject or Population Description: Collected from research volunteers under ethics approval Specimen: buccal swabs, blood samples Volume/Amount: ~5,000 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 type="checkbox"/> Cell lines	Designation and provider of each cell line (e.g. HeLa-ATCC #CCL-13):  Tested for HIV, HBV, and HCV? <input 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 tumorigenic? (Y/N)	Recipient of Microbe? (Y/N)	Will these be cultured? (Y/N)
			(Y/N)	If yes, purchased from where?					
Human	Buccal cells	Y	N		N	N	N	N	N

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.