INSTITUTIONAL BIOSAFETY COMMITTEE SAN JOSÉ STATE UNIVERSITY BIOLOGICAL USE AUTHORIZATION APPLICATION

Attachment E. Toxins

Check all that apply:				
	We will be performing procedures with toxin amounts that could be lethal for a person			
	We will purposefully be generating aerosols with the toxin			
	We will be using the toxin with live animal models (Complete Attachment G)			
\boxtimes	We will be using a Select Toxin			
	We will be working with a dry form (other than reconstituting lyophilized toxin in a sealed vial)			

A Standard Operating Procedure (SOP) must be attached that describes the work with biological toxins and/or select toxins. Describe from where the material will be obtained. 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. Include the preparation/dilution/reconstitution protocols (if applicable) and the steps that will be conducted in a biological safety cabinet. Consult the SOP template for other required components.

Toxins								
Toxin	Purchasing	Maximum	LD ₅₀	Target organ	Dilution	Neutralization/		
Common Name	source	quantity			procedure, if	inactivation		
		on hand			applicable	procedure		
Anthrax	Thermo Fisher	1 ng	8,000-50,000	skin	Diluting via	2% Dichlor or		
	Scientific		spores		adding diluent	5% hydrogen		
			(estimated)		through septa	peroxide for 10		
					of lyophilized	min		
					stock.			

□N/A	Regulated Select Toxins See <u>link for list of Select Toxins</u> , <u>exclusions</u> and <u>permissible toxin amounts</u> . If toxin is not eligible for					
	exemption or exclusion, list the agents below and submit a copy of the Select Toxin registration application					
	to the IBC					
Name of Toxin and Strain						
Bacillus anthracis Pasteur strain						

Risk assessment.

If you are using a toxin that affects plants or animals, discuss the possible consequences of a release into local agricultural areas or natural ecosystems

Animals are susceptible to Bacillus anthracis, and infected animals can easily spread the disease-causing spores to humans, other animals, or contaminate the soil with spores which could cause future outbreaks. As such, preventing release of spores into the environment is vital. All work with anthrax will rely heavily on properly functioning engineering controls (including a certified biosafety cabinet and HEPA-filtered equipment), and appropriate decontamination of all surfaces, materials, and solutions that may have come in contact with the toxin. See SOP for detailed procedures we will implement to substantially reduce the chance of release of Bacillus anthracis into local agricultural or natural ecosystems.