

Yale Environmental Health & Safety Update Form for Request to Use Infectious Agents

After reviewing the attached Request to Use Infectious Agents registration, please complete this Update Form to document your changes to your protocol and sign below. Email (Maryjo.Lanzillotta@yale.edu), fax (203-785-7588) or mail (EHS, 135 College Street, Suite 100) this update form back to Environmental Health & Safety (EHS) to update your registration with the Yale Biological Safety Committee. If you have any questions, please notify your EHS Safety Advisor or call the Biosafety Office at 785-3550.

Principal Investigator: _____ <div style="text-align: center; font-size: small;">Print Name</div>	Registration#: _____
_____ <div style="text-align: center; font-size: small;">Signature</div>	Date: _____

Status of Protocol
<p>Check the box that best applies to the attached registration:</p> <p><input type="checkbox"/> Please close out this protocol. This protocol is inactive and we will not perform these experiments in the near future. The infectious agents have been destroyed and we no longer have the agent in storage.</p> <p><input type="checkbox"/> Please close out this protocol. I am leaving the Yale University and taking my agents with me.</p> <p><input type="checkbox"/> Please close out this protocol. I'm transferring my stock of infectious agents to another PI at Yale. Please print the name of PI: _____</p> <p><input type="checkbox"/> This protocol is inactive; however, we still have the agents in storage.</p> <p><input type="checkbox"/> Please update this registration with the changes described below.</p>

Update Information Sections:

Personnel Associated with Protocol	
Names of current personnel* assigned to this protocol:	Names to delete from this protocol:

***If there are personnel added to the protocol they must complete and submit a Researcher Experience Form with this update.**

Dual Use Research

In reviewing registrations, the Yale IBC considers "dual use" potential, namely the potential for research projects with a beneficial purpose to provide knowledge, products or technologies that could be directly misapplied to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or material. For a full discussion of this topic, consult <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern>

Will you be conducting research that directly uses non-attenuated forms of one or more of the following agents? Yes No

If yes, please check the agent involved:

<input type="checkbox"/> Avian influenza virus (highly pathogenic)	<input type="checkbox"/> Marburg virus
<input type="checkbox"/> <i>Bacillus anthracis</i>	<input type="checkbox"/> Reconstructed 1918 influenza virus
<input type="checkbox"/> Botulinum neurotoxin (in any quantity)	<input type="checkbox"/> Rinderpest virus
<input type="checkbox"/> <i>Burkholderia mallei</i>	<input type="checkbox"/> Toxin-producing strains of <i>Clostridium botulinum</i>
<input type="checkbox"/> <i>Burkholderia pseudomallei</i>	<input type="checkbox"/> Variola major virus
<input type="checkbox"/> Ebola virus	<input type="checkbox"/> Variola minor virus
<input type="checkbox"/> Foot-and-mouth disease virus	<input type="checkbox"/> <i>Yersinia pestis</i>
<input type="checkbox"/> <i>Francisella tularensis</i>	

Do any of your experiments fall into any of the following experimental categories? Yes No

If yes, please check all that apply:

- Enhances the harmful consequences of the agent or toxin;
- Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/ or agricultural justification;
- Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
- Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
- Alters the host range or tropism of the agent or toxin;
- Enhances the susceptibility of a host population to the agent or toxin; and
- Generates or reconstitutes an eradicated or extinct listed agent or toxin.
- Provide other knowledge, products or technologies that could be directly misapplied to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or material.

Comment on aspects of your research, if any, with potential for dual use:

Status of Infectious Agent			
Infectious Agent	Date Left Yale Campus	Date Destroyed	Agent no longer used, but in storage. List storage location:(Building & Room#)
Infectious Agent and Other Biological Components			
<p>List additions to or changes to infectious agents used in this protocol including changes to other biological components involved in the work (cell lines, animals, etc.). If any of the listed infectious agents are drug resistant strains, list the drug(s) they are resistant to and indicate if these strains were created by the deliberate transfer of the drug resistance trait by your laboratory or another lab group? Or are these naturally occurring strains (i.e. not created by recombinant DNA technology)?:</p>			

<p>Risk Assessment for additional Infectious Agent(s):</p> <p>Describe the biohazard potential of this experiment and consider the following in your response: routes of transmission, virulence and infectivity; the severity of the disease it causes (include the signs and symptoms of exposure); natural vector; immunizations; effective therapies; and expected quantity of the agent (volume and concentration).</p>

Duration , Source of Infectious Agent,
Give the anticipated start date for the experiment:
Expected duration of project:
Where will you obtain the infectious agent?
How will the agent be transported to Yale?

Location
List the storage location (building/Room) and the type of storage (e.g, freezer, -80, liquid nitrogen) of the agent when not in use:
Is access limited at this location?
Where will the agent be housed (building/room) during the experiment?

Transporting Material Outside Your Laboratory
List building and room which material is transported to outside your laboratory:

Equipment and Supplies	
List below the additional equipment and supplies that are used for this experiment.	
Equipment (make/model)	Supplies
Autoclave Location:	

Specialized Procedure	
Specialized Procedure	Location (building/Room):
<input type="checkbox"/> Electron Microscopy	
<input type="checkbox"/> Cell Sorting	
<input type="checkbox"/> Multi-Photon	
<input type="checkbox"/> Confocal	
<input type="checkbox"/> Other Specialized Microscopy. Please Specify:	
<input type="checkbox"/> Other Please Specify:	

Standard Operating Procedures (SOP)
--

Changes to the Standard Operating Procedures: list changes in the procedures personnel will use to ensure safe handling of the infectious agent from the initiation of the experiment through decontamination and disposal of laboratory waste. List each task that will be performed, what type of physical containment devices will be used, and the type of personal protective equipment that will be worn for each task. In addition, include a description of your laboratory entry and exit procedures, and explain how access will be restricted to the lab during the experiment.

Attach a copy of your procedures to this form or insert information here.

Animals Section for Request To Use Infectious Agent Form:

YACUC Project: _____

Animal species: _____ # animals at any one time: _____

Total # animals: _____ # animals used annually: _____

Animal housing location (building/room) before infectious agent use: _____

Animal housing location (building/room) after infectious agent use: _____

Start date: _____ Completion date: _____

Route of inoculation: _____

Dose (concentration and volume): _____

Duration of experiment post-infection: _____

Indicate whether transmission of infectious agent may occur:

Transmission from animal to animal YES NO Not Known

Transmission from animal to human YES NO Not Known

Environmental transmission (to feral population) YES NO Not Known

Transmission by natural vector YES NO Not Known

If yes, name vector(s):

Route of transmission: by urine YES NO Not Known
feces YES NO Not Known
saliva YES NO Not Known

Brief description of project:

Describe the biohazard potential of the organism(s) and susceptibility to commonly used therapeutic drugs.

Describe planned containment procedures of infected animals.

Describe proposed animal waste procedures.

EHS Only:

Biosafety Officer

Reviewer:

Date

Signature

Update Approved

Update Not Approved

Comments: