

EHS Protocol #:

Send original to: Yale Environmental Health and Safety
135 College Street, Suite 100
New Haven, CT 06510
Phone 203-785-3550 Fax: 203-785-7588

REQUEST TO USE INFECTIOUS AGENTS Yale Biological Safety Committee

Principal Investigator: _____ Phone#: _____

Department: _____ Fax#: _____

Proposed Location of Work (Bldg./Room):	
Personnel Associated With the Project:	
List the Infectious Agents 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)?	
Other biological components involved in the work (cell lines, animals, etc.):	
Brief description of project:	
Check the proposed containment level: <input type="checkbox"/> BSL1 <input type="checkbox"/> BSL2 <input type="checkbox"/> BSL2+ <input type="checkbox"/> BSL3 <input type="checkbox"/> BSL3+	

Principal Investigator: _____ Date: _____
(signature)

Additional Investigator: _____ Date: _____
(signature)

Reviewed by: _____ Date: _____
(Biosafety Officer)

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 <https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research>

Will you be conducting research that directly uses nonattenuated 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:

Risk Assessment:

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):

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?

List the storage location (building/Room) and the type of storage (e.g, freezer, -80, liquid nitrogen, liquid oxygen) of the agent when not in use:

Is access limited at this location? Yes No

Where will the agent be housed (building/room) during the experiment?

Equipment & Supplies:

List below the equipment and supplies that will be used for this experiment.

EQUIPMENT (make/model)	SUPPLIES

Indicate if there will be any cell sorting or visiting other laboratories for specialized procedures and list location:

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:

Provide a set of Standard Operating Procedures that will be employed by your laboratory 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.

Insert or attach a copy of your procedures to this form.

Transporting:

Will infectious material be transported outside your laboratory? Yes No

If yes, to what location?

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What items will be used to contain the materials during transport?

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Biosafety Cabinets:

EHS requires biological safety cabinets to be used with BSL2, BSL2+ and BSL3 agents. Provide the information on the biological safety cabinet(s) you will be using.

Make/Model:	
Serial #:	
Date of last certification:	

Please note, if your work requires you to conduct your experiment outside a biological safety cabinet or other primary containment device, please provide an attachment detailing the description of the experiment and how it will be contained.

Disinfectants and Decontamination:

List disinfectant(s) and concentration(s) that will be used for decontaminating work surfaces and equipment:

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Detail the decontamination method for waste generated from the experiment:

Solids:	
Liquids:	
Other:	

Location of Autoclave:

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Will autoclave procedures be verified? Yes No

Describe the verification method:

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How will waste be transported to the autoclave?

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Animals:

Animal species: _____ #animal 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: _____ YACUC Project: _____

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

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.

Medical Surveillance:

Anyone who is currently pregnant or immunosuppressed must contact Employee Health (432-7978) before working with the agent in question.

Have all researchers involved in this work contacted the University Employee Health Physician for the required medical consultation? Yes No

Are there any restrictions for handling these agents? Yes No

If yes, what are the restrictions?

Emergency Response Procedures:

Please describe the emergency response procedures for the following incidents: (refer to the OEHS Biosafety Spill Response Guide or OEHS Biological Safety Manual for assistance).

Puncture wound or parenteral exposure:

Exposure to mucous membranes of face:

Exposure to aerosols:

Biohazard Spill:

RESEARCHER EXPERIENCE FORM

Name: _____ Job Title: _____

Principal Investigator: _____ Date: _____

Education:

Date	Institution	Major Area	Degree

Laboratory experience related to work with microorganisms or cell culture:

Date	Institution	Description of work and name of microorganisms