UCR Institutional Review Entity for Dual Use Research of Concern

"Listed Agent" Use Authorization

PIs must submit this form prior to beginning research with Listed Agents

This form must be approved prior to performing research with these agents:

- Avian influenza virus (highly pathogenic)
- *Bacillus anthracis*
- Botulinum neurotoxin (in any quantity)
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Ebola virus
- Foot-and-mouth disease virus
- *Francisella tularensis*
- Marburg virus
- Reconstructed 1918 influenza virus
- Rinderpest virus
- Toxin-producing strains of *clostridium botulinum*
- Variola major virus
- Variola minor virus
- *Yersinia pestis*

CHANGES TO RESEARCH PLANS OR UNEXPECT RESULTS:

PIs must submit an updated version of this form if any of the following conditions are met:

- A new non-attenuated form of one or more of the listed agents is to be used in research.
- The research plan or methods are altered such that the research aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects*.
- Research with non-attenuated forms of the listed agents can be reasonably anticipated to produce one or more of the seven listed experimental effects beyond such effects already discussed in a currently approved "Listed Agent" Use Authorization.
- Unexpected results indicate that research with non-attenuated forms of the listed agents has or can now be expected to produce one or more of the seven listed experimental effects beyond such effects already discussed in a currently approved "Listed Agent" Use Authorization.
- Unexpected results indicate that research with an attenuated form of a listed agent has or can now be expected to restore or enhance its virulence or toxic activity.

* Seven listed experimental effects:

- Enhances the harmful consequences of the agent or toxin;
- Disrupts the immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;
- Confers to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates 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 a novel pathogenic agent or toxin or reconstitutes an eradicated or extinct agent or toxin listed above.

"Listed Agent" Use Authorizations are approved for one year.

"Listed Agent" Use Authorization

1. Contact Information

1.1 Principal Investigator (PI)

Name (Last, First, MI):	
Mailing address:	Phone number:
	Fax:
	Email:
Department (if applicable):	

1.2 Person Preparing This Document (If Not the PI)

Name:	Phone number:
Email:	Fax:

2. Project Information

Please identify any life sciences research you conduct at this institution that directly involves non-attenuated forms of one or more of the agents listed below (please use a separate form for each identified project). If none of the agents are identified, your research is *not* subject to institutional DURC oversight. However, PIs should be aware that, if at any time, research is initiated that involves any of the below listed agents, he or she will need to immediately notify the institutional review entity (IRE) (or appropriate institutional authority), per the policy of this institution.

2.1 Project Title(s)

2.2 Agent or Toxin Involved in Project (Check All That Apply)

- ☐ Avian influenza virus (highly pathogenic)
- ☐ *Bacillus anthracis*
- ☐ Botulinum neurotoxin (any quantity)
- ☐ *Burkholderia mallei*
- ☐ *Burkholderia pseudomallei*
- ☐ Ebola virus
- ☐ Foot-and-mouth disease virus
- ☐ *Francisella tularensis*
- ☐ Marburg virus
- ☐ Reconstructed 1918 influenza virus
- ☐ Rinderpest virus
- ☐ Toxin-producing strains of *clostridium botulinum*
- ☐ Variola major virus
- ☐ Variola minor virus
- ☐ *Yersinia pestis*

2.3 Type of Funding Source(s) for This Project

- ☐ Department/institutional funds
- ☐ Foundation
- ☐ Federal funds
- ☐ Business/industry
- ☐ Other

If project is supported with Federal funds, name of funding agency and grant or contract number:

3. Training of Laboratory Personnel

The *Policy for Institutional DURC Oversight* requires that all laboratory personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) conducting research with non-attenuated forms of 1 or more of the 15 listed agents have received education and training on DURC. Please indicate below the names of all laboratory personnel involved in this project and include the titles and dates of any DURC training.

Name	Title/Role	Title of DURC Training	Completion Date(s)

4. Assessment by the PI for Experimental Effects

PIs are required to assess whether any research directly involving non-attenuated forms of 1 or more of the 15 listed agents produces, aims to produce, or is reasonably anticipated to produce 1 or more of the experimental effects listed in Section 6.2.2 of the *Policy for Institutional DURC Oversight* (relisted below). Note: the research and this assessment must be submitted to the IRE for review regardless of whether any of the following experimental effects apply.

☐ Enhances the harmful consequences of the agent or toxin.

If checked, please explain below:

☐ Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification.

If checked, please explain below:

☐ Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates its ability to evade detection methodologies.

If checked, please explain below:

☐ Alters properties of the agent or toxin in a manner that would enhance its stability, transmissibility, or ability to be disseminated.

If checked, please explain below:

☐ Alters the host range or tropism of the agent or toxin.

If checked, please explain below:

☐ Enhances the susceptibility of a host population to the agent or toxin.

If checked, please explain below:

☐ Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section 2.2 of this form.

If checked, please explain below:

As a reminder, if there is a change in this research with respect to the applicability of any of the seven experimen-tal effects, or if the PI, for any reason, thinks the research needs to be reconsidered by the IRE for DURC potential, the PI should submit this form again to the IRE with his/her revised assessment - changes should be made in bold or highlighted.

print form

clear form