University of Louisville
Institutional Duel Use Research of Concern Committee (IDURCC)

Principal Investigator Application Form

The *Policy for Institutional DURC Oversight* requires Principal Investigators at institutions subject to the Policy to notify the IDURCC as soon as:

A) The PI's research directly involves non-attenuated forms of one or more of the listed agents; or
B) The PI's research with non-attenuated forms of one or more of the listed agents also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects; or
C) The PI concludes that his or her research with non-attenuated forms of one or more of the listed agents that also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects, may meet the definition of DURC and should be considered (or reconsidered) by the IDURCC for its DURC potential.

BIOSAFETY OFFICE USE

Protocol Number:

Protocol Status:

Initial Submission Date:

Approval Period of Risk Mitigation Plan:

SECTION A: Title and Principal Investigator

A1. Principal Investigator

Name:

UofL ID#:

Email:

Phone #:

Department:

A2. Administrative Contact

Name:

Email:

A3. Location(s) of Work Performed

Check all that apply.

HSC: ☐

Belknap campus: ☐

UofL Hospital: ☐

Robley Rex VA Medical Center: ☐

Center for Preventative Medicine: ☐

Graham Brown Cancer Center: ☐

Other: ☐

A4. Collaborators from other Institutions
Complete for each institution that will participate in this study.

Name of collaborator:

Name of institution:

Project approved by institution:

If yes, approval date:

Name of collaborator:

Name of institution:

Project approved by institution:

If yes, approval date:

Name of collaborator:

Name of institution:

Project approved by institution:

If yes, approval date:

A5. Funding Source
Complete for each source that will support the study.

Name of funding source:

Grant number:

Title:

Name of funding source:

Grant number:

Title:

Section B: Project Information

Please identify any research you conduct 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 IDURCC, per the policy of this institution.

B1. Project Title(s):

B2. Agent or Toxin Involved in Project
Check all that apply. Do not include attenuated strains.

- ☐ 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*

Research summary (as provided by PI):

Section C: 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.

Complete for each individual conduction research with non-attenuated strains of any of the above agents.

Name:

UofL ID#:

Email:

Title/Role on Project:

Completion Date(s):

Name:

UofL ID#:

Email:

Title/Role on Project:

Completion Date(s):

Name:

UofL ID#:

Email:

Title/Role on Project:

Completion Date(s):

Section D: Assessment of Experimental Effects by PI

Please indicate by checking the corresponding box 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 IDURCC for review regardless of whether any of the following experimental effects apply.

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

- ☐ Enhances the harmful consequences of the agent or toxin.
- ☐ Disrupts immunity or the effectiveness of the immunization against the agent or toxin without clinical or agricultural justification
- ☐ 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
- ☐ Alters properties of the agent or toxin in a manner that would enhance its stability, transmissibility, or ability to be disseminated
- ☐ Alters the host range or tropism of the agent or toxin
- ☐ Enhances the susceptibility of a host population to the agent or toxin
- ☐ Generates or reconstitutes an eradicated or extinct agent or toxin listed above.

If any checked above, please explain:

Certification of Principal Investigator

As Principal Investigator of the above research, I attest that:

(1) I am knowledgeable and will comply with the institutional and Federal policies for dual use research;
(2) I will ensure that all research personnel conducting this research will be educated and trained on dual use research and the safety and risks of the involved agents or toxins; and

(3) I will responsibly communicate with the Institutional Dual Use Research of Concern Committee or the Institutional Contact for Dual Use Research any changes to my research, including work that may meet the DURC definition, unanticipated problems, or incidents involving potential harm to personnel or the environment.

Principal Investigator:

Date:

IDURCC Use Only:

Risk Assessment Conducted:

Qualify as DURC:

Risk Mitigation Plan Drafted:

Funding Agency Notified (7.2(B) vii) [30 days]:

Risk Mitigation Plan provided (7.2(B) viii) [90 days]: