# The University of Toledo IRE Committee
# Dual Use Research of Concern Identification Form

## 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 nonattenuated 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)

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### 2.2 Research Description (In non-scientific language, provide a narrative including goals/aims of research)

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## 2.3 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*

## 2.4 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:

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# 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 nonattenuated 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 | Highest Biosafety Level Training | DURC Training Completion Date |
|---|---|---|---|
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(If more rows needed, attach an additional sheet to the document)

## 4. Assessment by the PI for Experimental Effects

PIs are required to assess whether any research directly involving nonattenuated 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.

**NOTE: If the experiment effect listed does not apply, simply type/write "No" in the box below.**

☐ 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

What types of knowledge, information, technology, or products are anticipated to be generated through the research?

How will the results or products of the research in question be shared or distributed? (ie; Who will have access to the knowledge, information, technology or final products? Will it be shared openly or remain within the laboratory?

Can the products/results from this research be directly misapplied? If so how? If not, do the outcomes of the research need to be combined with other research, information, or technology, in order to pose a threat? If so, is that information already available?

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 by the IRE for DURC potential, the PI should submit this form again to the IRE with his/her revised assessment.

I hereby certify that the above statements are true and correct to the best of my knowledge.

Signature: _____

Date: _____

## Please submit completed forms to:

Elaine Joseph, Ph.D.
IACUC/IBC/IRE Project Administrator
2106 CCE / MS 1020
University of Toledo
419-383-4251

Email: elaine.joseph@utoledo.edu