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**Research Compliance** Student Faculty Center

3340 N. Broad Street, Suite 427

Philadelphia PA 19140

**Institutional Biosafety Committee Phone:** (215) 707-9741

**Email:** [ibc@temple.edu](mailto:ibc@temple.edu)

**Notification of the potential Dual Research of Concern (DURC)**

*The Policy for Institutional DURC Oversight requires Principal Investigators at institutions subject to the Policy to notify the IRE 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 IRE for its DURC potential.*

1. **Contact Information**
   1. Principal Investigator (PI)

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

* 1. Person Preparing This Document (If Not the PI)

|  |  |
| --- | --- |
| Name: | Phone number: |
| Email: | Fax: |

* 1. Type of Funding Source(s) for This Project

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Funding Source | Indicate “Yes” for each funding source used for this project | Funding agency  (e.g., NIH) | Grant/Contract Number  (or other project identifier) |
| 1 | Department/institutional funds |  |  |  |
| 2 | Foundation |  |  |  |
| 3 | Federal funds |  |  |  |
| 4 | Business /industry |  |  |  |
| 5 | Other |  |  |  |

# **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.*

* 1. Project Title(s)

2.2 Agent involved in project\**(check only one per application)*:

**Bacteria: Viruses:**

# Bacillus anthracis Burkholderia mallei Burkholderia pseudomallei

*Clostridium botulinum* (toxin-producing strains)

# Yersinia pestis

# Francisella tularensis

**Toxin:**

Botulinum neurotoxin (**any quantity, Botox included**)

Avian influenza virus (highly pathogenic) Influenza virus (reconstructed 1918)

Foot-and-mouth disease virus

Rinderpest virus

Risk Group 4 agents not permitted at TU:

* Ebola virus
* Marburg virus
* Variola major virus
* Variola minor virus

\* *Attenuated strains which are excluded from the Select Agent list and inactive forms of botulinum neurotoxin do not apply.*

1. **Research Purpose and Experimental Manipulations:**

# **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.*

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:

*The experiments with the agent or toxin do not include any of the aims described above.*

*I certify that the information contained in this application is accurate to best of my knowledge. Additionally, I have read and understood the “Training on the U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern” and agree to comply with all components of the Temple University Policy on Dual Use Research of Concern.*

*I will not proceed with the experiment until I have received an official notice of approval from IRE unless otherwise specified. I acknowledge that IRE approval granted by this application is non-transferable to any other Temple University researcher.*

**Principal Investigator Signature: Date:**

**For IRE use only**

**The IRE has determined that:**

this research **does not** meet the DURC definition and no additional review and oversight are required. The PI must report to the IRE any results or changes in the research such that one or more of the 7 categories of experimental effects may apply, or if the PI feels that the research may be DURC.

this research meets the DURC definition and requires additional oversight under the *USG Policy for Institutional Oversight of DURC.* Corresponding USG funding agency will be notified and a draft of the mitigation plan will be submitted within 90 days of this determination

Mitigation Plan submitted to the funding agency on

Approved Mitigation Plan on file

**IRE Comments:**

**IRE Chair** (print and signature) Date