

**Institutional Dual Use Research of Concern Committee**

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| Principal Investigators Notification to the Institutional Review Committee |

1. **Contact Information**

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| **Principal Investigators: Name (Last, First, MI):** |
| **Department:** | **Phone number:****Emergency Phone Number (required)** |
| **Office Building and Rm #:** | **Email:** |
| **Project Start Date:** | **Project End date:** |

1. **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) – i.e. IDURC (or appropriate institutional authority), per the policy of this institution.

* 1. **Project Tittle**

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* 1. **Agent or Toxin Involved in the Project**

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| --- | --- | --- | --- | --- |
| **Agent/Toxin** | **Select**  | **Vendor** | **Total Quantity (mg)** | **Attenuated/****nonattenuated** |
| **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*** |  |  |  |  |
| Generates or reconstitutes an eradicated or extinct agent or toxin  |  |  |  |  |
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* 1. **Type of Funding Source(s) for this Project**

Department/Institutional\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Business/Industry \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Foundation \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Federal funds \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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| **Sponsor** | **UNT Proposal or Award Number** | **Title**  | **Status (Pending/approved etc.)** |
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### Assessment by the PI for Experimental Effects

3.1. 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.

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| **Question** | **Comments** |
| 1. Enhances the harmful consequences of the agent or toxin.
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| 1. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification.
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| 1. 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.
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| 1. Alters properties of the agent or toxin in a manner that would enhance its stability, transmissibility, or ability to be disseminated.
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| 1. Alters the host range or tropism of the agent or toxin.
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| 1. Enhances the susceptibility of a host population to the agent or toxin.
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| 1. Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section 2.2 of this form.
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**3.2 . In what ways could knowledge, information, technologies, or products from the research be misused to harm public health and safety, agriculture, plants, animals, the environment, materiel, or national security?**

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| **Question** | **Comments** |
| 1. What types of knowledge, information, technology, or products are anticipated to be generated through the research?
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| 1. How will the results or products of the research in question be shared or distributed? Will it be shared openly or remain within the laboratory? Who will have access to the knowledge, information, technology, or final products?
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| 1. Do any of the methods or results contain novel information or combine previously communicated methods/information in a novel fashion?
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| 1. Have the results of the research been previously described or shared? If so, at what venues and in what detail? How readily available are these results?
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| 1. Could the products of the research under consideration be applied to other more common and/or less pathogenic organisms or agents?
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| 1. Does the research highlight vulnerabilities in existing countermeasures or public health or agricultural infrastructure?
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| 1. Does the research highlight weaknesses in the ability to prepare for and/or respond to disease outbreaks that could impact public, agricultural, or environmental health?
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| 1. Does the research consolidate existing information in ways that highlight vulnerabilities in public health and/or safety preparedness?
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| 1. Does the information point out a gap in regulatory oversight (biosafety or biosecurity) or evade existing biosafety measures?
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**3.3. How easily/feasible could the knowledge, information, technologies, or products be directly misused to cause harm?**

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| **Question** | **Comments** |
| 1. Would it require a low or high degree of technical skill and sophistication to use the information from dual use research for harmful purposes?
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| 1. Would its misuse require materials, equipment, or reagents that are expensive or difficult to procure?
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| 1. Can the products, information, or technologies generated from the research be directly misapplied? If so, how?
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| 1. Could the outcomes of this research be combined with other knowledge, information, technology, or products to pose a threat? If so, is that other information already available?
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| 1. Is there concern about immediate/near-future potential use, or is the concern about misuse in the distant future?
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| 1. Given your responses to the preceding questions, how readily could the knowledge, information, technology, or products from the research be used to threaten public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security?
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**3.4. What are the potential consequences of misuse?**

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| **Question** | **Comments** |
| 1. What is the nature of the potential consequences (e.g., harm to the economy, the environment, agriculture, or public health; public terror) that might result from misuse of the research results in question?
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| 1. What is the scope and magnitude of the potential consequences? Could the impact on people, plants, and/or animals be considered minor, moderate, or major?
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| 1. Are there currently any countermeasures to help mitigate the potential consequences? (Countermeasures may include drugs, biological products, public health practices, pesticides, or devices intended for diagnosis, detection, mitigation, prevention, or treatment.)
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| 1. Are current countermeasures readily available?
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| 1. Is there potential for public anxiety, public misunderstanding, sensationalism, or other negative consequences (e.g. loss of public trust) if the information is communicated?
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**3.5 – Applying the Definition of DURC**

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| **Question** |  | **Comments** |
| Taking into consideration the risks identified above, does the research in question meet the definition of dual use research of concern (DURC): “*life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security*.” | No [ ] Yes [ ]  |  |

### Specialized Training of Laboratory Personnel

The *Policy for Institutional DURC* 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

(Please insert more rows as necessary.)

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| --- | --- | --- | --- |
| **Name** | **Title/Role** | **Title of DURC Training** | **Completion Date(s)** |
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Regular (at least once each calendar year) meetings will be scheduled to review all DURC studies and risk mitigation plans. **For research projects that have been determined to be DURC, the DURC component of the project must not be initiated until an approved risk mitigation plan is in place.**

**Submit the completed form to** **veena.naik@unt.edu**