## Appendix B

## Assessment by the IRE

**Date of Review:**

**Person Preparing this Document:**

**Principal Investigator:**
**Department:**

**Project Title:**

Prior dates of reviews or assessments by the PI of research for DURC potential. For each date, a copy of the review or assessment is included:

**Non-attenuated Agent or Toxin directly involved in the Project:**

### 1. Assessment by the IRE for Experimental Effects

Below identifies whether this research project aims to produce, or can be reasonably anticipated to produce any of the following experimental effects and an explanation of the assessment for any answered yes:

A. Enhances the harmful consequences of the agent or toxin.

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

C. 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.

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

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

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

G. Generates or reconstitutes an eradicated or extinct agent or toxin under consideration.

**If *none* of the above experimental effects applies,** the research does not meet the scope of the *Policy for Institutional DURC Oversight,* and the IRE does not need to continue with this assessment.

## 2. Risk Assessment by the IRE and Determination of DURC

The points below were considered to assess the potential risks associated with conducting the research in question or communicating its results.

**The ways in which knowledge, information, technologies, or products from the research could be misused.**

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

B. How will the results or products of the research in question be shared or distributed? *Knowledge, information, technology, or products that are freely available and widely distributed may be more easily accessed by individuals with harmful intent.*
   - Who will have access to the knowledge, information, technology, or final products?
   - Will it be shared openly or remain within the laboratory?

C. What is the novelty of the information provided by the research or of the research methods? *Research that adds novel information or consolidates information in novel ways may be of greater concern, whereas information that is already widely available is generally of lower concern.*
   - 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?

D. Are the products of the research under consideration applicable to other more common or less pathogenic organisms or agents? *Knowledge, information, technology, or products generated from research that could be applied to more commonly available organisms to increase their associated risks may be of greater concern.*

E. Does the research highlight vulnerabilities in existing countermeasures for public health or agricultural infrastructure?
   - Does the research highlight weaknesses in the ability to prepare for and respond to disease outbreaks that could impact public, agricultural, or environmental health?
   - Does the research consolidate existing information in ways that highlight

vulnerabilities in public health and/or safety preparedness?

**The ease with which the knowledge, information, technologies, or products might be directly misused and the feasibility of such misuse.**

A. Consider the technical expertise and/or physical resources that would be needed to apply the knowledge, information, technology, or product for malevolent purposes. *The risk of misuse may be lower for knowledge, information, technologies, or products that would be expensive, difficult to procure, or that require a high degree of technical skill to facilitate such misuse.*
   - Would it require a low or high degree of technical skill and sophistication to use the information from dual use research for harmful purposes?
   - Would its misuse require materials, equipment, or reagents that are expensive or difficult to procure?

B. Consider whether the products of the research in question could be directly misused to pose a threat to public health and safety, agriculture, plants, animals, the environment, materiel, or national security. *The risk of misuse may be higher for research information that can be directly misused than for research information that requires significant additional scientific advances to facilitate its misapplication.*
   - Can the products, information, or technologies generated from the research be directly misapplied? If so, how?
   - If not, do these outcomes of the research need to be combined with other knowledge, information, technology, or products in order to pose a threat? If so, is that other information already available?

C. Consider the time frame in which information from the research might be misused. *Information that can be misused in the near term may be of greater concern.*
   - Is there concern about immediate or near-future potential use, or is the concern about misuse in the distant future?

D. 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?

**Potential consequences of misuse.**

A. Consider 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. *Information that could be misused to harm numerous sectors of society or the environment may be of greater concern.*

B. Consider the scope and magnitude of the potential consequences. *Research or research information that could be misused to cause severe harm, disease, or consequences is generally considered to be of greater concern.*
   - Could the impact on people, plants, and/or animals be considered minor, moderate, or major?

C. Consider the available countermeasures. *Adequate countermeasures may help to decrease concern about the consequences of misuse. Countermeasures may include drugs, biological products, public health practices, pesticides, or devices intended for diagnosis, detection, mitigation, prevention, or treatment.*
   - Are there currently any countermeasures to help mitigate the potential consequences?
   - Are they readily available?

**Apply the DURC Definition:**

**If the IRE determines that the research *does not* meet the DURC definition,** the research is not subject to additional institutional DURC oversight and the appropriate USG funding agency will be notified of the findings of the institutional review.

**If the IRE determines that the research *does* meet the DURC definition,** the research is DURC, as defined in the *Policy for Institutional DURC Oversight* and the *March 2012 DURC Policy*, and is subject to additional DURC oversight. A draft risk mitigation plan will be developed and the appropriate USG funding agency will be notified within 30 calendar days.

## 3. Risk-Benefit Assessment of DURC

A. Are there potential benefits to the public's health and/or safety from the research?

B. Are there potential benefits of the research for agriculture, plants, animals, the

environment, materiel, or national security?
    - What potential solution does it offer to an identified problem or vulnerability?

C. Will this research be useful to the scientific, public health, or public safety communities? If so, how?
D. Because scientific research can have broad impacts, it is important to consider the scope of the potential benefits.
    - Will the knowledge, information, or technology generated from the research be broadly applicable (e.g., to human health, multiple scientific fields, populations of organisms)?
    - What populations of plants or animals might be positively affected?

E. If a benefit has been identified, in what time frame (e.g., immediate, near future, years from now) might this research benefit science, public health, agriculture, plants, animals, the environment, materiel, or national security?

**Points to Consider for Weighing the Risks and Benefits of the DURC**

A. Could the information of concern be more readily applied to improvements in surveillance or to the development of countermeasures than to malevolent applications? What reasons or evidence support the answer to this question?

B. What is the time frame in which potential benefits or anticipated risks might be realized?

C. How might the potential benefits and the anticipated risks be distributed across different populations (humans and animals)?
    - Who or what will be the likely beneficiaries of the potential benefits? Will the potential benefits be distributed equally or disproportionately across different populations?
    - Who or what will bear the anticipated risks? Is it likely that one or more specific populations will bear the burden of the anticipated risks?
    - Is it likely that the distribution of the anticipated risks and the potential benefits will be fair or just?

D. Considering the anticipated risks in tandem with the potential benefits, are the risks of such a feasibility and magnitude that they warrant proceeding after developing and implementing a risk mitigation plan? Are the potential benefits of significant magnitude to warrant proceeding despite the risks? What is the most responsible way to proceed?