Does Research involve non-attenuated strain of 1 or more of the 15 listed Select Agents

1. Avian influenza (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin (in any quantity)
4. *Burkholderia mallei*
5. *Burkholderia pseudomallei*
6. Ebola virus
7. Foot-and-mouth disease virus
8. *Francisella tularensis*
9. Marburg virus
10. Reconstructed 1918 influenza virus
11. Rinderpest virus
12. Toxin producing strains of *Clostridium botulinum*
13. Variola major virus
14. Variola minor virus
15. *Yersinia pestis*

NOT DURC

PI required to update IRE of any changes to activities that might be regulated

NOT DURC

IRE Review to determine if DURC

Answer yes to 1 or more of the 8 questions located in the BRA?

YES

NOT DURC

(IRE Review to confirm)

No NIH notification needed can proceed

YES

NOT DURC

Notify NIH within 30 days that work does not qualify as DURC. Can proceed with research.

YES

Notify NIH within 30 days & develop Risk Mitigation Plan within 90 days. Research cannot proceed until approved Risk Mitigation Plan in place.

NOT DURC

Notify NIH or USG funding agency within 30 days of any changes in status (ex: no longer DURC)

8 Questions on Biological Research Authorization (BRA):

1. Enhance the harmful consequences of the agent or toxin
2. Disrupts immunity or effectiveness of an immunization without clinical and/or agricultural justification.
3. Confer to a biological agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against the agent or toxin.
4. Facilitate their ability to evade detection methodologies.
5. Increases the stability, transmissibility, or the ability to disseminate a biological agent or toxin.
6. Alter the host range or tropism of a biological agent or toxin.
7. Enhance the susceptibility of a host population.
8. Generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent.

The March 2012 DURC Policy and the Policy for Institutional Oversight of Life Sciences DURC define "dual use research of concern," as:

"Life Sciences research that, based on current understanding, can be reasonable anticipated to provide knowledge, information products, or technologies that could be directly misapplied to pose significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security."