Institutional Review Process
Dual Use Research of Concern (DURC)

Does research involve nonattenuated strain of 1 or more of 15 listed SAs?

- NO: Not DURC
- YES: PI required to update IRE of any changes that might be regulated

Does research involve or produce one or more of 7 regulated activities or outcomes?

- NO: Not DURC (ICDUR/IRE Review to confirm) No NIH notification needed, can proceed
- YES: IRE review to determine if DURC

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- NO: Not DURC Notify NIH within 30 days that work does not qualify as DURC Can proceed with research
- YES: Notify NIH within 30 days and develop Risk Mitigation Plan within 90 days Research cannot proceed until approved Risk Mitigation Plan in place

Notify NIH or USG funding agency within 30 days of any changes in status (e.g., no longer DURC)

Change in status of research?

- YES: Notify NIH within 30 days and develop Risk Mitigation Plan within 90 days Research cannot proceed until approved Risk Mitigation Plan in place
- NO: No NIH notification needed, can proceed

15 listed Select Agents
- Avian Influenza (high Path)
- Bacillus anthracis
- Botulinum neurotoxin
- 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

7 regulated activities
- Enhances the harmful consequences of the agent or toxin;
- Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
- Confers resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against the agent or toxin or facilitates their ability to evade detection methodologies;
- Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
- Alters the host range or tropism of the agent or toxin;
- Enhances the susceptibility of a host population to the agent or toxin;
- Generates or reconstitutes an eradicated or extinct listed agent or toxin

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, material or national security.”