Dual Use Research of Concern Review Process:

Any individual working with any of the non-attenuated 15 DURC Agents should immediately notify the Institutional Review Entity (IRE) via the “Internal DURC Report Form”

The IRE reviews research using VCU’s “DURC Risk Assessment Guidelines” to determine if the research meets the definition of DURC

Experimental effects not involved, the IRE still must notify and has 30 calendar days to notify the appropriate USG funding agency of the outcome of the review (use VCU’s 30-Day USG DURC Report Form)

The Internal DURC Report Form is appropriately marked and signed by the IRE and the researcher agrees in writing to notify the IRE if the research changes in a way that may involve one of the 7 Experimental Effects

The IRE and researcher establish a plan for a periodic review of the research moving forward

Experimental effects involved, the IRE has 30 calendar days to notify the appropriate USG funding agency of the outcome of the review (use VCU’s 30-Day USG DURC Report Form)

The IRE considers the previously identified risks and the anticipated benefits in order to develop a draft risk mitigation plan (use VCU’s IRE DURC Risk/Benefit Assessment Guidelines)

The IRE works with the USG funding agency to complete the draft risk mitigation plan within 90 calendar days of the IRE’s initial determination that research is DURC

The USG funding agency finalizes the risk mitigation plan within 60 calendar days of receipt of the draft plan

VCU and the IRE implement the approved risk mitigation plan and provide ongoing oversight of DURC

7 Experimental Effects:
1. Enhances harmful consequences of agent or toxin
2. Disrupts immunity or effectiveness of immunization without clinical/agricultural justification
3. Confers resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions or facilitates ability to evade detection methodologies
4. Increases the stability, transmissibility, or the ability to disseminate the agent
5. Alters the host range or tropism
6. Enhances the susceptibility of a host population
7. Generates or reconstitutes an eradicated or extinct agent or toxin previously listed