TITLE:	**Policy for Dual Use Research of Concern (DURC) Oversight [UNMC-IBC# 42]**
OVERVIEW:	All research protocols involving biological agents or toxins specified in the US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC) are subject to review and approval by the IBC prior to project initiation. When reviewing DURC the IBC is acting as the Institutional Review Entity (IRE) and will be referred to as such.
APPLIES TO:	All faculty, staff, and students involved in life science research using one or more of the Non-attenuated Agents and Toxins of Concern listed biological below
DEFINITION(S):	***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. ***Non-attenuated Agents and Toxins of Concern*** **-** defined by federal policy include- but are not limited to: • Avian influenza virus • *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 strain of *Clostridium botulinum* • Variola major virus • Variola minor virus • *Yersinia pestis* ***—Categories of Experimental Effects*** • Enhances the harmful consequences of the agent or toxin; • Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/ or agricultural justification;

	• Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that 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; and • Generates or reconstitutes an eradicated or extinct listed agent or toxin.
PROCEDURES:	***Obligations of Researchers:*** A Principal Investigator ("PI") must identify research that involves any of the Non-attenuated Agents and Toxins of Concern listed in this policy that could involve any of the 7 listed Experimental Effects. The PI must submit this information on an "IBC Protocol for Research Involving Biohazardous Materials" form that is reviewed by the IBC. If an activity is determined by the IRE to qualify as DURC, the PI must work with the institution through the IRE to develop a risk mitigation plan and ensure that all laboratory personnel are educated and trained on DURC. The PI must conduct the research in accordance with the final risk mitigation plan. ***IRE Review:*** The IRE shall review the proposed research against the standards set forth in the U.S. Government Policy. The IRE will follow the review process as specifically outlined in the U.S Government Policy. The IRE will work with Sponsored Programs Administration office (SPA) to initially identify if the USG funding agency has notified the institution that the research is DURC. If the institution has been notified, the IRE will implement the approved risk mitigation plan and provide ongoing oversight of DURC. If the institution has not been notified by the USG funding agency, the IRE will verify that the research involves any of the agents listed in this policy and make the final determination of the applicability of the list of experimental effects. Following the completion of a risk assessment by the IRE, if it is determined that the research ***does*** meet the definition of DURC research as defined in this policy, the IRE will inform the PI of its

	findings and proceed with the development of a draft risk mitigation plan. If the research ***does not*** meet the definition of DURC, the research will be reviewed by the IBC in accordance with the review process outlined in IBC Policy #08 and the appropriate USG funding agency shall be notified of the IRE's decision. The risk mitigation plan will be reviewed by the IRE at a convened meeting. Additional ad hoc members may be added as needed based on the research under review. The IRE will follow the review process outlined in IBC Policy #08. IRE minutes will be maintained separate from the IBC minutes. All risk mitigation plans and associated research protocols must be reviewed at least annually. The IRE and Institutional Biosafety Officer will ensure that education on DURC is completed by individuals conducting life science research with a Non-attenuated Agent or Toxin of Concern. ***Reporting Plan to Funding Agencies:*** Within 30 days of the initial review, the institution, through SPA, will provide the outcome of the IRE review to the appropriate USG funding agency (or NIH, for non-USG funded research). This notification will include all information pertaining to the risk mitigation plan if applicable. If the research is DURC, the institution will work with to the USG funding agency to complete the draft risk mitigation plan within 90 calendar days of the IRE's determination. The plan will be finalized and within 60 calendar days of receipt of the draft plan.
RECORD KEEPING:	The PI must maintain a record of the approved IBC protocol including DURC review by the IRE and the approval letter in the *Laboratory Biosafety Manual.* The IBC office will maintain a copy of the DURC review and completed risk mitigation plan for eight years after the review or completion of the mitigation plan.
APPEALS	Disputes regarding interpretation of this policy or decisions made by the IRE are referred to the Associate Vice Chancellor for Academic Affairs, Regulatory Compliance, who may: deny the appeal, or request that parts of a previous decision by the IRE be reconsidered by the committee. The IRE shall reconsider the determination. After this reconsideration, the subsequent decision of the IRE shall be final.
INVESTIGATOR	University faculty, staff, and students that are found to be in

COMPLIANCE	violation of this policy may be subject to restrictions from conduct of research and/or sanctions under other university policies.
REFERENCES:	• NOT-OD-15-017 • United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (Policy for Institutional DURC Oversight) • United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (March 2012 DURC Policy) • Dual Use Research of Concern: A Companion Guide
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