NORTH CAROLINA AGRICULTURAL AND TECHNICAL STATE UNIVERSITY

SEC. V— RESEARCH COMPLIANCE AND ETHICS 1.0

LIFE SCIENCES DUAL USE RESEARCH OF CONCERN

UNIT POLICY—DORED

I. INTRODUCTION

The goal of life sciences research is to produce significant advances in agricultural and environmental domains, public welfare and national security. The same results if the intent is wrong, can be used to cause significant threats and broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. Proactively, the United States Government (USG) has mandated additional oversight of certain types of life sciences research. A list of select agents, toxins and experiments that could pose a threat to society when misused has been identified such that Institutions and research sponsors are required to conduct risk assessments and develop mitigation plans in addition to existing regulatory requirements.

II. DUAL USE RESEARCH OF CONCERN DEFINED

Dual Use Research of Concern (DURC) is 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. The USG's oversight of DURC is aimed at preserving the benefits of life sciences research while

minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

III. SCOPE

The USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (Policy for Institutional DURC Oversight) and the USG Policy for Oversight of Life Sciences Dual Use Research of Concern (March 2012 DURC Policy) apply to the oversight of life sciences DURC that is either funded by the U.S. Government or taking place at institutions receiving funding from the USG for life sciences research.

Under this Policy, a review will focus on research that involves one or more of the agents or toxins listed in Section (III.1) of this document, which pose the greatest risk of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence, and produces, aims to produce, or is reasonably anticipated to produce one or more of the experimental effects listed in Section (III.2) of this document (excluding attenuated forms of the agents listed and inactive forms of botulinum neurotoxin):

1) **Agents and toxins**
   a) Avian influenza virus (highly pathogenic)
   b) *Bacillus anthracis*
   c) Botulinum neurotoxin (in any quantity)
   d) *Burkholderia mallei*
   e) *Burkholderia pseudomallei*
   f) Ebola virus
   g) Foot-and-mouth disease virus
   h) *Francisella tularensis*
   i) Marburg virus
   j) Reconstructed 1918 Influenza virus
   k) Rinderpest virus
   l) Toxin-producing strains of *Clostridium botulinum*
   m) Variola major virus
   n) Variola minor virus
   o) *Yersinia pestis*

2) Experimental Effects of Agents and Toxins:
   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 their ability to evade detection methodologies;
d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
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; or
g) Generates or reconstitutes an eradicated or extinct agent or toxin listed above.

IV. THE PROCESS FOR DURC OVERSIGHT

The effective oversight of DURC is based on identifying DURC and its associated risks, then devising ways to mitigate these risks. The identification of DURC-related risks and the management of those risks begin with the Principal Investigator (PI) identifying research that directly involves non-attenuated forms of 1 or more of the 15 listed agents/toxins. Any such research that is identified must then be assessed for whether the research produces, aims to produce, or can be reasonably anticipated to produce one or more of seven listed experimental effects.

Principal Investigators must indicate on the Institutional Biosafety Committee (IBC) application upon initial submission if the following is applicable:

- Their research involves one or more DURC agents
- The use of the agent(s) in their research will produce, aim to produce, or can be reasonably anticipated to produce one or more of the above listed experimental effects
- His or her research with nonattenuated forms of one or more of the listed agents that also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects may meet the definition of DURC and should be considered (or reconsidered) by the IBC for its DURC potential

PIs must work with the IBC to assess the dual use risks and benefits of the DURC and to develop risk mitigation measures. All work must be done in accordance with the developed risk mitigation plan. In addition, they must comply with all organizational and USG policies and requirements for DURC oversight. Once identified as DURC research, the PI must ensure that laboratory personnel working with DURC are trained on the policy and the risk mitigation measures in place to alleviate possible ill-effects of the research. The PI must also ensure that the assessment of potential DURC occur prior to work begins. Risk mitigation plan and measures must be in place before work begins when the research is DURC

The Institutional Biosafety Committee (IBC) serves as the Institutional Review Entity (IRE) for DURC. Responsibilities of the IRE (IBC) include:

- Verifying that the research identified by the PI directly utilizes nonattenuated/active forms of one or more of the listed agents/toxins
- Reviewing the PI's assessment of whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the listed experimental effects and the final determination of whether the research meets the scope of the Policy for Institutional DURC Oversight
- Conducting a risk assessment and determine whether the research meets the definition of DURC (for research that the IRE determines meets the scope of the Policy for the Institutional DURC Oversight)
- Developing a draft risk mitigation plan for the identified DURC
- Reviewing, at least annually, ALL active risk mitigation plans at the institution.
- Providing education and training on DURC for individuals conducting life sciences research with one or more of the agents listed and maintaining records of such education and training for the term of the research grant or contract plus three years after its completion.
- Maintaining compliance with this policy and reporting instances of noncompliance, as well as mitigation measures undertaken by the organization to prevent recurrences of similar noncompliance, within 30 calendar days to the USG funding agency.

Responsibilities for the IBC Research Compliance Officer includes:

- Serving as Institutional Contact for DURC for questions regarding compliance with and implementation of requirements for the DURC oversight policies
- Assisting the Office of Sponsored Programs (OSP) in notifying the USG funding agency of any research with agents or toxins that may produce one or more of the experimental results within 30 calendar days of the review.
- Maintaining records of institutional DURC reviews and completed risk mitigation plans for the duration of the research grant and then three years after its completion, but no less than eight years, unless law or regulation requires a shorter period.
- Notifying USG funding agency within 30 calendar days of the IRE (IBC) identifying any changes within the status of a DURC project (including that the project no longer meets the definition of DURC).
- Notifying the USG funding agency within 30 days of any changes to a mitigation plan for a DURC project approved by the IRE (IBC).
- Notifying the Vice Chancellor of Research and Economic Development of instances of noncompliance with the DURC Policy.

V. RESOURCES

National Institutes of Health Companion Guide
http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern

DURC Policy
http://www.phe.gov/s3/dualuse/documents/durc-policy.pdf

Approved by the Chancellor

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