Institutional Research Entity (IRE)

DURC Policy and Procedures Guidelines

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1.0 POLICY FOR INSTITUTIONAL OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN

1.1 LSU Health-NO Responsibilities

Louisiana State University Health Sciences Center – New Orleans (LSU Health-NO) acknowledges and accepts responsibility for complying with the United States government (USG) policy on life sciences research categorized as Dual Use Research of Concern (DURC). This LSU Health-NO Policy is effective Sept. 24, 2015.

1.2 Guiding Principles

Despite its value and benefits, certain types of life sciences research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called dual use research. Dual use research *of concern* (DURC) is a subset of dual use research defined as: "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. The *United States Government Policy for the Oversight of Life Sciences Dual Use Research of Concern (March 29, 2012)* *[http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf]* and The *United States Government Policy for* ***Institutional*** *Oversight of Life Sciences Dual Use Research of Concern (September 24, 2014)* *[http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf]* articulate the practices and procedures required to ensure that dual use research of concern is identified at the institutional level and risk mitigation measures are implemented as necessary. Additional guidance is available on the Public Health Emergency, Science Safety Security website at *http://www.phe.gov/s3/dualuse/Pages/default.aspx*.

Nothing in the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (September 24, 2014)* should be read as superseding U.S. Department of Health and Human Services or Department of Agriculture statutory authority to regulate the possession, use, or, transfer of biological agents and toxins that have the potential to pose a severe risk to public health and safety, animal and plant health or animal and plant products; or provisions of the select agent regulations found at 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331; nor the export control regulations at 15 CFR Parts 730-774 (known as the Export Administration Regulations (EAR), and 22 CFR Parts 120-130 (known as the International Traffic in Arms Regulations (ITAR). Note that the term dual use should not be interpreted to indicate which regulations govern the export of these items, and for example, that some of the DURC agents/experiments are controlled by the ITAR and not the EAR.

1.3 Definitions

Definitions - For the purpose of this Policy the following terms are defined:

A. “Dual use research” is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes.

B. “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, materiel, or national security.

C. “Institutional Contact for Dual Use Research (ICDUR) is an individual designated by the institution to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC as well as the liaison (as necessary) between the institution and the relevant USG funding agency.

D. “Institutional Review Entity” (IRE) is the committee established by LSU Health-NO empowered to execute the requirements of this policy.

E. “Life sciences” pertains to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, microbiology, synthetic biology, virology, molecular biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches to understanding life at the level of ecosystems, populations, organisms, organs, tissues, cells, and molecules.

F. “National Science Advisory Board for Biosecurity” (NSABB) is a USG advisory committee established to advise the USG on dual use research issues as requested.

G. “Principal Investigator” (PI) is an individual who is designated by the research institution to direct a project or program and who is responsible to the funding agency or the research institution for the scientific and technical direction of that project or program. There may be more than one PI on a research grant or project within a single or multiple institutions.

1.4 Scope of Research Requiring Oversight

Consistent with the USG March 2012 DURC Policy, research that uses one or more of the following agents or toxins and produces, aims to produce, or can be reasonably anticipated to produce one or more of the effects listed below in "Categories of Experiments" will be evaluated for DURC potential.

A. Agents and Toxins

The 15 agents and toxins listed below in this Policy are subject to the select agent regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121), which set forth the requirements for possession, use, and transfer of select agents and toxins, and have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products. It is important to note, however, that the Federal Select Agent Program does not oversee the implementation of this Policy or the *March 2012 DURC Policy*.

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin (For the purposes of this Policy, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.)
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*

B. Categories of Experiments

1. Enhances the harmful consequences of the agent or toxin.
2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification.

3. 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.

4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin.
5. Alters the host range or tropism of the agent or toxin.
6. Enhances the susceptibility of a host population to the agent or toxin.
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed above.

2.0 COMPONENTS OF THE REVIEW AND OVERSIGHT SYSTEM FOR DURC

2.1 Principle Investigator Responsibility

A. The PI, of life sciences research, must identify in the LSU Health-NO Institutional Biosafety Committee application that the research involves one or more of the 15 agents or toxins listed above.

B. The PI must accept the responsibility for the safe conduct of work with the study at the Biological Safety Level practices and procedures assigned by the IBC and the IRE.

C. PI must inform all personnel, who may be at risk of potential exposure of the conditions of this work and assure that all personnel will receive adequate training to perform all activities safely and proficiently.

D. PI will not carry out the work under DURC until it has been approved by the IBC and the IRE and that all risk mitigation plans have been met.

2.2 Institutional Review Entity (IRE) Responsibility

A. The Chairperson of the IRE will review all IBC applications to determine whether PIs have correctly identified one of the 15 agents or toxins relevant to this policy. If such agents are identified, the Chair will make an initial assessment whether research that uses one or more of the agents or toxins listed above also produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed above in “Categories of Experiments” above.

B. The IRE will review protocols listing one of the agents or toxins relevant to this policy and make a determination as to whether the research is anticipated to produce at least one of the seven effects mentioned above and

make a final determination of whether the research meets the definition of DURC. Risk assessment will underpin the determination of DURC. Resources listed in *Section 8A* of the United States Government DURC policy may be used for this assessment.

1. Identification of the anticipated benefits of the research identified as DURC will be made by the IRE. The anticipated benefits will be considered in conjunction with the previously identified risks in order to develop a draft, risk mitigation plan to guide the conduct and communication of the DURC. The risk mitigation plan will be submitted for approval by the USG funding agency sponsoring the research. Plans will be evaluated by the IRE at least annually and modified as necessary for the duration of the research. The LSU Health-NO Office of Environmental Health and Safety (EH&S) and the IRE are responsible for ensuring that the DURC is conducted in accordance with the risk mitigation plan.

2. Notification of the results of this review process will be made to the relevant USG funding agency and, in instances when the research is determined to be DURC, provision of the draft, risk mitigation plan by the institution will be submitted to the USG funding agency. For non-USG funded research, notification of the results of the review process and the risk mitigation plan will be submitted to the NIH Program on Biosecurity and Bio-safety Policy of the National Institutes of Health (NIH) at DURC@od.nih.gov. This NIH office will receive the notification for administrative purposes and will in turn refer the notification to an appropriate agency based upon the nature of the research.

3. Risk mitigation plans will be reviewed by the IRE on an annual basis and modified as necessary for the duration of the research.

2.3 Composition of the IRE

A. LSU Health-NO will designate an Institutional Contact for Dual Use Research (ICDUR) to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of research that falls within the scope of this policy and/or meets the definition of DURC. If questions arise regarding compliance, implementation of this Policy, or the *March 2012 DURC Policy*, or when guidance is needed about identifying DURC or developing risk mitigation plans, the ICDUR serves as the liaison (as necessary) between the institution and the relevant program officers at the USG funding agencies, or for non-USG funded research, between the institution and NIH (or the USG agency to which NIH refers the institution).

B. LSU Health-NO will establish and maintain a committee, Institutional Review Entity (IRE), to execute the requirements for review of agents designated in this policy and types of research conducted with these agents and where

required develop a risk mitigation plan.

1. The IRE will be composed of at least five members and who/will:

    a. Be sufficiently empowered by the institution to ensure it can execute the requirements of this policy;

    b. Include persons with sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at a given research facility;

    c. Include persons with knowledge of relevant USG policies and understanding of risk assessment and risk management considerations, including biosafety and biosecurity. The IRE may also include, or have available as consultants, at least one person knowledgeable in the institution's commitments, policies, and standard operating procedures;

    d. On a case by case basis, recuse any member of an IRE who is involved in the research project in question or has a direct financial interest, except to provide specific information requested by the review entity; and

    e. Engage in an ongoing dialogue with the PI of the research in question when conducting a risk assessment and developing a risk mitigation plan.

2. Maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

3. Provide education and training on DURC for individuals conducting life sciences research with one or more of the agents or toxins listed in this Policy, and maintain records of such education and training for the term of the research grant or contract plus three years after its completion. LSU Health-NO may also address dual use topics in existing courses on research ethics or the responsible conduct of research. LSU Health-NO may require additional record keeping and will designate an individual responsible for maintaining documentation.

2.4 Compliance with this policy

A. LSU Health-NO certifies that the institution will comply with this Policy.

B. LSU Health-NO will ensure compliance with this Policy and with approved risk mitigation plans. The Institution will report instances of non-compliance with this Policy, as well as mitigation measures undertaken by the institution to prevent recurrences of similar noncompliance, within 30 calendar days to the

USG funding agency. In the case of non-USG funded research, reports should be made to the USG agency designated by NIH for oversight.

C. In some situations, elements of a potential DURC project may be carried out at multiple institutions through a subaward with LSU Health-NO which directly receives a grant or contract from a USG funding agency. In some cases LSU Health-NO may collaborate with another institution receiving a grant or contract form a USG funding agency. In cases of such collaborations involving multiple institutions via a sub-award, the primary institution will be responsible for notifying the funding agency of research that falls within the scope of this Policy or of the DURC policy of the primary institution and, if that research is determined to be DURC, providing copies of each institution's risk mitigation plan. Furthermore, the primary institution will ensure that DURC oversight is consistently applied by all entities participating in the collaboration.

D. Non-compliance with this Policy may result in suspension, limitation, or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research.

E. Sanctions may be brought by the Institution against individual investigators who are non-compliant with this Policy. These sanctions may include but are not limited to: warning, reprimand, censure, suspension of authority to conduct research at this Institution or other disciplinary action up to and including termination of employment.