United States Gu(S)b1e/5:8.4(G)-2. TJ EMC /Link <</MCID 11 >

********** **********

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse.

All provisions in this Policy supersede those contained in the previous draft policy published on February 22, 2013 (Federal Register 78 (36): 12329-12332). This Policy and the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern, which was released on March 29, 2012 (

United States Government Policy for Institutional Oversight
of Life Sciences Dual Use Research of Concern

Contents

This Policy, the "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern," addresses institutional oversight of DURC. Oversight includes

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 (i.e., the provisions of the select agent regulations found at 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331 and 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 that some of the DURC agents/experiments are controlled by the ITAR and not the EAR.

This Policy will take effect on September 24, 2015, which is 12 months after its rele not benv001 T0(e)-1(d)

D. Oversight of DURC must recognize both the need for security and the need for research progress; as such, the degree of oversight should be commensurate with the possible consequences of misuse.

E. Effective oversight helps maintain public trust in the life sciences research enterprise by demonstrating that the scientific community recognizes the implications of DURC and is acting responsibly to protect public welfare and preserve security.

F. USG agencies that fund DURC, the recipients of those public funds, and individuals who conduct this research share the oversight responsibility.

G. It is essential to have a consistent approach to the oversight of DURC.

H. Any oversight process for DURC should be periodically evaluated both for effectiveness and impact on the research enterprise.

I. The free and open conduct and communication of life sciences research is vital to a robust scientific enterprise and will continue to be the goal of the USG. It also should continue to be the goal of institutions engaged in life sciences research.

J. Educating the scientific community about the dual use potential of life sciences research and cultivating a sense of responsibility for dual use research among life scientists is essential for promoting responsible research behavior.

K. No policy or set of guidelines can anticipate every possible situation. Motivation, awareness of the dual use issue, and good judgment are key considerations in the responsible evaluation of research for dual use potential. It is incumbent on those engaged in life sciences research to adhere to the intent of this Policy as well as to the performance standards described herein.

Section 4. Definitions

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

A. “To certify” is to attest to the USG that an institution subject to this Policy will comply with all aspects of this Policy.

B. “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.

C. “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.

D. “Institution” is any government agency (Federal, State, tribal, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity conducting research.

E. “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.

F. “Institutional Review Entity” (IRE) is a committee established by the institution as described in Section 7.2.E and empowered to execute the requirements in Section 7.2.B.i-iii, v, and viii.

G. “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.

H. “National Science Advisory Board for Biosecurity” (NSABB) is a USG

6.2.1. Agents and toxins[5]

a) Avian influenza virus (highly pathogenic)
b) Bacillus anthracis
c) Botulinum neurotoxin[6]
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

6.2.2. Categories of experiments

a) Enhances the harmful

c)

[5] The 15 agents and toxins listed 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.

[6] 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.

research, and may subject the institution to

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.

F. For institutions subject to this Policy, certify that the institution will comply with this Policy.

G. Oversight by USG funding agencies and the USG as articulated in the March 2012 DURC Policy with additional responsibilities with respect to this Policy described in Section 7.3 and 7.4 below.

Figure 1 provides an overview of the process for institutional review of life sciences research within the scope of the Policy.

ii. The PI's research with one or more of the agents or toxins listed in Section 6.2.1 also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven ef

undergo steps 7.2.B.vi, but will be subject to ongoing review and notification

the PI) responsible for the performance of the DURC; and a description of the IRE's basis for its determination.

v. Identification by the IRE of the anticipated benefits of the research identified

D. Designate an Institutional Contact for Dual Use Research (ICDUR) to serve as a institutional point of contact for questions regarding compliance with and

G. Provide education and training on DURC for individuals conducting life sciences research with one or more of the agents listed in Section 6.2.1 of 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. Institutions may also wish to address dual use topics in existing courses on research ethics or the responsible conduct of research. Institutions may require additional recordkeeping and should designate an individual responsible for maintaining documentation.

H. Ensure compliance with this Policy and with approved risk mitigation plans. Report

7.3. Responsibilities of USG Funding Agencies

A. Develop training tools and materials for use by the USG agencies and institutions implementing this Policy.

B. Provide education and outreach to stakeholders about dual use policies and issues.

C. Provide guidance to institutions on the sharing of DURC research products and on the communication of DURC.

D. Convene advisory bodies such as NSABB, as necessary, to develop re

i. The IRE requires guidance on developing an adequate risk mitigation plan in cases where the potential risks are perceived as particularly high;
ii. The IRE considers the only viable risk mitigation measure to be not conducting or not communicating the research in question;
iii. The PI does not agree with the finding of the IRE so the institution would like to request outside advice;
iv. The research in question represents a particularly complex case or appears to fall outside the scope of this Policy, but still seems to present significant concerns; or
v. Guidance is required to ensure a clear understanding of how the USG interprets and the definition of DURC and related terms.