3364-70-29 Dual Use Research of Concern (DURC) – Research involving select agents or toxins that provides knowledge but can also be misapplied.

(A) Policy statement

The university of Toledo "UT" is committed to safe, legal and ethical use of biologically-derived materials in research. Some research, conducted for legitimate purposes, can yield materials or knowledge that can be used for both beneficial and harmful purposes. Such research can be dual use. Research is categorized as dual use research of concern "DURC" as per federal regulation and guidance in the United States government policy for institutional oversight of life sciences DURC.

(B) Purpose of policy

This policy outlines the UT institutional review and oversight process for research involving certain high-consequence pathogens and toxins in order to identify DURC and mitigate associated risks.

(C) Definitions

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

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, material, or national security.

Institutional contact for dual use research "ICDUR:" an individual designated by the institution to serve as an institutional point of contact for questions regarding compliance with the implementation of the requirements for the oversight of DURC. The ICDUR is appointed by the vice president for research "VPR." The VPR or his/her designee will serve as the institutional official "IO" and report to the relevant federal funding agencies as required.

Institutional biosafety committee "IBC:" a committee established by the institution to review all biohazardous, recombinant and synthetic nucleic acid research as per rule 3364-70-06 of the Administrative Code.

Institutional review entity "IRE:" a sub-committee of the IBC appointed by the vice president for research to review all research with dual use potential. The IRE will include a minimum of five persons with sufficient expertise to assess the research and risk mitigation. Ad hoc members may be added to the IRE as needed to provide specific expertise for any matter under review. Ad hoc members will have voting rights.

Principal investigator "PI:" an individual who is designated by UT to direct a project or program and who is responsible for its scientific and technical direction.

(D) Scope

All research directly involving the biological agents and toxins listed below in (1) is subject to additional review and oversight. PIs are ultimately responsible for ensuring that all research involving these agents is submitted to the IBC which may refer the research to the IRE for review of dual use research potential.

Research that directly involves non-attenuated[1] forms of 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 (2)) must be evaluated for DURC potential.

(3) Agents and toxins

(a) Avian influenza virus (highly pathogenic)
(b) *Bacillus anthracis*
(c) Botulinum neurotoxin[2]
(d) *Burkholderia mallei*
(e) *Burkholderia pseudomallei*

[1] The only forms of the listed agents and toxins that are considered to be attenuated can be found in the Select Agent and Toxin Exclusions list under "Attenuated Strains of HHS and USDA Select Agents and Toxins" at http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html. If an attenuated form of any of the listed agents is subjected to any manipulation that restores its virulence or toxic activity, the resulting agent or toxin will be subject to oversight.

[2] There are no exempt quantities of botulinum neurotoxin at UT for research or clinical trials. Research or clinical trials involving any quantity of botulinum neurotoxin must be reviewed by the IRE and evaluated for DURC potential.

(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*

(4) Effects of Concern

(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 and/or agricultural justification;
(c) 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;
(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;
(g) Generates or reconstitutes an eradicated or extinct agent or toxin listed above

(E) Responsibilities

(1) PIs

(a) Prior to initiation of research, submit a protocol to the IBC for any research involving infectious agents, recombinant or synthetic DNA, bacteria, viruses, plasmids, fungi, parasite, protozoa, live cell analysis, human tissues, fluids or cell lines (including stem cells), nanomaterials with biological properties, and select agents and toxins or biological tissues.

Notify the IBC of the use of select agents or toxins or effects of concern (section D).

(b) If the IBC identifies a DURC, the protocol will be referred to the IRE:

(i) No work can be conducted until a risk mitigation plan has received approval from the NIH or U.S. government funding agency and final approval is obtained from the IRE.

(ii) The PI will work with the IRE to assess the dual use risks and benefits of the DURC and develop risk mitigation measures.

(iii) The PI will ensure that laboratory personnel conducting research determined as DURC by the IRE have received instruction and training in DURC and work in accordance with an approved risk mitigation plan.

(iv) If changes are needed in an IRE-approved risk mitigation plan, the PI will work with the IBC and IRE to revise the plan. Prior to implementation of any changes, the IO will provide such changes to the U.S. government funding agency or NIH for review and approval.

(2) Institutional responsibilities

(a) Establish and recommend policies and practices that provide for the identification, oversight and mitigation of risk of DURC.

(b) The IBC will screen all IBC protocols for dual use potential.

(i) If the protocol involves any of the agents/toxins in section D(1) of this rule, the IRE will determine if the

proposed research meets the federal definition of DURC.

(ii) If the protocol does not involve one of the agents or toxins in section D(1) of this rule, but does produce or is reasonably anticipated to produce one or more of any of the effects listed in section D(2) of this rule, IBC will refer the protocol to the IRE to analyze the risk/benefit and develop a risk mitigation plan when necessary.

(c) Within thirty calendar days of the IRE's determination of that the research meets the definition of DURC, provide notification to the applicable federal funding agency (sponsor) of any research that involves one or more of the fifteen agents and toxins and one or more of the seven experimental effects listed above. The IO will provide notifications to the U.S. government funding agency or NIH for review, approval or other required reporting. For non-federally funded or unfunded research, notification will be made to NIH, which will in turn refer the notification to an appropriate federal agency, based upon the nature of the research.

(d) Within ninety calendar days of the IRE's determination that the research meets the definition of DURC, provide a copy of the draft risk mitigation plan developed by the IRE and PI to the applicable federal agency for its review and approval;

(e) Within thirty calendar days of any change in status of a DURC project (including when the research is determined by the IRE to no longer meet the definition of DURC) or any proposed change to the risk mitigation plan, provide notification of the change to the applicable federal agency.

(f) Within thirty calendar days, provide notification of instances of non-compliance with this rule, as well as mitigation measures undertaken to prevent recurrences of similar non-compliance to the applicable federal agency.

(g) The IRE will review research which involves non-attenuated forms of one or more of the above listed agents and toxins for DURC potential. The environmental, health and radiation safety department will provide guidance on review, risk mitigation, and training: http://www.utoledo.edu/depts/safety/Dual%20Use%20Research%20of%20Concern.html

Appendix A: resources

Tools for identification, assessment, management, and responsible communication of dual use research of concern: a companion guide to the United States government policies for oversight of life sciences dual use research of concern. Available from: http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf

United States government policy for institutional oversight of life sciences dual use research of concern. Available from: http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

United States government policy for oversight of life sciences dual use research of concern. Available from: http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf

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