The University of Texas at San Antonio
Institutional Biosafety Committee
Dual Use Research of Concern Policy

INTRODUCTION

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. The United States Government'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.

The responsibility for oversight of DURC at UTSA, under the United States Government's policy, is shared by the Principal Investigator (P.I.) and the Institutional Biosafety Committee (IBC). The policy covers any research involving one, or more, of the 15 listed agents or toxins. Any research involving these agents must be assessed within the scope of the seven experimental effects listed in the federal policy (http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf) thereby classifying it as DURC (see "Experiments that require DURC Oversight" section of this policy).

DURC LISTED AGENTS AND TOXINS

- Avian Influenza (highly pathogenic)
- *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 strains of *Clostridium botulinum*
- Variola major virus
- Variola minor virus
- *Yersinia pestis*

EXPERIMENTS THAT REQUIRE DURC OVERSIGHT

Any experiment that could:

1. Enhance the harmful consequences of the agent or toxin
2. Disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification
3. Confer to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that toxin or facilitate their ability to evade detection methodologies
4. Increase the stability, transmissibility, or the ability to disseminate the agent or toxin
5. Alter the host range or tropism of the agent or toxin
6. Enhance the susceptibility of a host population to the agent or toxin
7. Generate or reconstitute an eradicated or extinct agent or toxin listed above

INSTITUTIONAL REVIEW ENTITY (IRE) RESPONSIBILITIES

The UTSA Institutional Biosafety Committee will act as the Institutional Review Entity (IRE) for DURC and will designate an Institutional Contact for Dual Use Research (ICDUR) (the Assistant Vice President for Research Integrity will operate as the ICDUR)

- Review all IBC protocols to determine if the proposed research meets the criteria for DURC.
- Conduct annual reviews of any protocols that use one or more of the 15 listed agents or toxins.

If the IRE determines that research meets the criteria of DURC, or is notified by a P.I. or other UTSA entity that one or more of the experimental effects listed in the "Experiments that require DURC oversight" section of this policy have been observed, the following steps will be implemented:

- Notify the P.I. and the Institutional Contact for Dual Use Research (ICDUR) that the protocol meets the criteria for DURC.
- Consult with the BSO, and any other specialists as required, to conduct a risk assessment on the proposed research (UTSA DURC Risk Mitigation Assessment Form)
- Develop a risk mitigation plan for the identified DURC.
- Provide education and training on DURC, as needed.
- In consultation with the P.I.s, review all risk mitigation plans annually.
- Maintain the records associated with any DURC for the term of the research grant plus three years after its completion and no less than 8 years.

The IRE's decision and any other institutional decision regarding DURC may be appealed by the affected PI to the ICDUR and will be reported to the Vice President for Research who will have the final word as to all institutional decisions regarding DURC that have been appealed.

P.I. RESPONSIBILITIES

- Ensure all personnel involved with potential DURC projects complete the provided DURC online training.
- Complete the DURC section of the IBC Application in all new, renewal or amended protocols.
- Notify the IRE (ibc@utsa.edu) when research activities include one or more of the listed agents or toxins.
- Identify to the IRE any research that produces one or more of the seven listed experimental effects described in the policy.
- Work with the IRE to assess the dual use risks and develop a risk mitigation plan.
- Conduct DURC only after permission has been granted by the NIH, an IBC protocol has been approved and all risk assessments and risk mitigation plans are in place.
- Be knowledgeable of, and comply with, all UTSA and federal policies and requirements for DURC.
- Ensure that all laboratory personnel conducting DURC have been fully trained and are knowledgeable of UTSA and federal policies and requirements for DURC.
- Complete an annual review of DURC to be submitted to the IRE.
- Cease all research activities associated with DURC if an unexpected experimental result produces one of the seven listed experimental effects listed in the policy and immediately notify the IRE.

MITIGATING DURC ASSOCIATED RISKS

Following the identification of DURC the BSO will notify the funding agency within 30 days using the United States Government (USG) template for reporting (UTSA DURC Reporting Form). The IRE and BSO will consult with the funding agency to develop a risk mitigation plan within 90 days of the determination of DURC. Following submission of the draft risk mitigation plan by UTSA the funding agency will have 60 days to finalize the plan. Implementation of the plan by UTSA will occur immediately after approval is received from the funding agency.

In addition the IRE and BSO may recommend further risk mitigation measures that may include but are not limited to:

- Additional security for storage of experimental data and transmission of electronic data between entities.
- Pre-publication review by the institution and / or funding agency.
- Redaction of security sensitive information.
- Require additional training for staff working with DURC.

- Review DURC more frequently than the annual review.
- Analyze how the DURC findings inform the development of countermeasures, disease surveillance, preparedness, and response efforts.

APPENDIX A

DEFINITIONS

All definitions below were developed by the National Science Advisory Board for Biosecurity (NSABB) to assist in the consideration of the NSABB's categories of experiments that describe information, products, or technologies that, if produced from life sciences research, might define that research as meeting the criterion for being DURC.

Biological agent: As is consistent with 18 U.S.C. § 178, "any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing - (A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; (B) deterioration of food, water, equipment, supplies, or material of any kind; or (C) deleterious alteration of the environment."

Clinically and/or agriculturally useful prophylactic or therapeutic interventions: Includes first- or second-line prevention and treatment measures or alternative therapeutics used with special populations (e.g., pregnant women and pediatric patients) in the form of vaccines, antibiotics, antivirals, antiparasitics, antibodies, herbicides, fungicides, algaecides, insecticides, etc. "Agriculture" encompasses all methods of production and management of livestock, crops, vegetation, and soil. Therefore, useful prophylaxes and therapeutics would include herbicides, fungicides, algaecides, insecticides, rodenticides, etc.

Dissemination: The process by which infectious diseases or toxins are dispersed. The same routes of entry pertinent to the natural spread of diseases are also relevant when their etiologic agents are delivered intentionally (e.g., inhalation of biological agent disseminated as an aerosol or ingestion of a biological agent disseminated through a water supply).

Eradicated agent: A biological agent that has been exterminated through surveillance and containment resulting in the permanent reduction to zero of the worldwide incidence in the transmission of the agent and the infection/disease it causes; intervention measures are no longer needed. Eradicated agents are thought to no longer exist in circulation in plants, animals, or the environment. Note: Reconstituted eradicated agents of concern are those for which there are no known or widely available prophylactic or therapeutic interventions, those that could evade diagnostics, or those for which there is no known immunity.

Extinct agent: These agents are thought to no longer exist in nature or in the laboratory.

Harmful consequences: The ability of a biological agent or toxin to critically alter normal biological functions, inflict damage on public health resources, materiel, and public safety. This would include augmenting properties such as virulence, infectivity, stability, transmissibility, or the ability of the biological agent or toxin to be disseminated.

Host population: A collection of organisms that constitutes a specific group or occurs in a specified habitat. In the context of the DURC definition, this phrase implies that the misapplication

of the knowledge, products, or technologies derived from the research has the potential to broadly impact a population of host organisms.

Host range: The number of different species or populations that can become infected by a biological agent, causing disease in the host or allowing the host to become a carrier.

Immunity: Encompasses all aspects of host immunity (e.g., active, adaptive, adoptive, passive, innate, and immune modulators).

Immunization: Refers to the active or passive induction of immunity through inoculation (e.g., natural inoculation or vaccination) with an immunizing agent or with antibodies; this includes antitoxins and toxoids.

Novel agent: An agent that has not existed previously and is considered unique based on its biological or other properties and traits (e.g., genotype and phenotype). Novel agents of concern are those for which there are no known or widely available prophylactic or therapeutic interventions, those that could evade detection, or those for which there is no known immunity.

Small interfering RNA (siRNA): Also known as "short interfering RNA" or "silencing RNA"; a class of RNA molecules that play a variety of roles in biology; most notably, siRNA is involved in the RNA interference (RNAi) pathway where the siRNA interferes with the expression of a specific gene.

Stability: The ability of a biological agent to remain viable when exposed to various environmental factors, including temperature, relative humidity, atmospheric pollution, and sunlight. Stability also includes persistence in a host.

Toxin: As is consistent with 18 U.S.C. § 178, "the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever the origin and method of production, and includes: (A) any poisonous substance or biological product that may be engineered as a result of biotechnology that is produced by a living organism; or (B) any poisonous isomer or biological product, homolog, or derivative of such a substance."

Transmissibility: The ease with which an agent spreads from host to host or from vector to host, e.g., via arthropod vectors.

Tropism: The specificity of a biological agent or toxin for a particular host tissue or cell.