

## University of Kentucky Institutional Biosafety Committee Proposed Plan for Compliance with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

On September 24, 2014 the United States Government (USG) issued the USG Policy for Institutional Oversight of Life Sciences Dual Use research of Concern (DURC), <http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>. This policy is complementary to the USG Policy for Oversight of Life Sciences DURC which was released on March 29, 2012, <http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf>. The institutional policy requires that institutions strengthen their review and oversight of life sciences research project that could meet the current definition of DURC.

Dual use research is defined by the USG as “research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes”. Dual use research of concern is a subset of this broader category. DURC is 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”.

These definitions could potentially encompass a number of life sciences research projects at UK, however, the current scope of the policy has been limited to the following agents and toxins and categories of experiments. Research must involve both a listed agent/toxin and a listed category to be deemed DURC.

### Agents and Toxins:

- Avian influenza virus (highly pathogenic)
- *Bacillus anthracis*
- Botulinum neurotoxin (in any amount, exempt quantities from 42 CFR Part 73 are not recognized by this policy)
- *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*

Categories of Experiments:

- Enhances the harmful consequences of the agent or toxin
- Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
- 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
- Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
- Alters the host range or tropism of the agent or toxin
- Enhances the susceptibility of a host population to the agent or toxin
- Generates or reconstitutes an eradicated or extinct agent or toxin listed above

Under the institutional policy specific responsibilities related to the review, oversight and reporting to USG funding agencies and/or the National Institutes of Health Program on Biosecurity and Biosafety Policy (NIH PBBP, <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern>) are to be shared by the Principal Investigator (PI), the Institutional Review Entity (IRE) and the designated Institutional Contact for Dual Use Research (ICDUR). If research is not funded by a USG agency and is DURC reporting to the NIH is appropriate.

The PI has the following responsibilities:

- Initially identifying life sciences research that may be DURC
- Working with the IRE to develop a risk mitigation plan
- Conducting approved DURC in accordance with the risk mitigation plan
- Being knowledgeable about DURC policies and education lab personnel accordingly
- Communicating DURC responsibly when publishing or presenting experimental findings

The IRE has the following responsibilities:

- Reviewing research projects that have been designated by the PI as potential DURC and conducting a risk assessment to determine if they are indeed DURC
- Notifying the USG funding agency and/or NIH within 30 calendar days that DURC has been identified
- Working with the PI to determine the benefits of the research and, in conjunction with the previously developed risk assessment, developing a risk mitigation plan for the research
- Providing the draft risk mitigation plan to the USG funding agency and/or NIH within 90 calendar days
- Ensuring implementation of the risk mitigation plan
- Reviewing annually all active risk mitigation plans
- Notifying the USG funding agency and/or NIH within 30 calendar days of any changes that would affect active risk mitigation plans or instances of non-compliance

- Maintaining records of DURC reviews and risk mitigation plans for at least the term of the research grant/contract plus three years but not less than eight years
- Providing education and training on DURC to research personnel
- Ensuring compliance with the policy among lab personnel

The ICDUR has the following responsibilities:

- Serving as the liaison, as necessary, between the institution and the USG funding agency and/or NIH
- Serving as the point of contact for the institution for questions regarding implementation of and compliance with the institutional DURC policy

Effective implementation of the provisions of the institutional DURC policy at UK may best be handled by the Institutional Biosafety Committee (IBC), Biological Safety Officer (BSO) and Department of Biological Safety. The current IBC is comprised of research faculty with a broad knowledge base in infectious agents, molecular biological techniques and containment strategies to mitigate risks associated with life sciences research. The current IBC registration form currently captures the listed agents and toxins and could be expanded to include the categories of experiments. This would allow the Department of Biological Safety to assist PIs in the determination of research which may be categorized as DURC. Additionally, the Department of Biological Safety has developed numerous online training modules for the UK research community and could develop a DURC training module to assist PIs with the training requirements of the policy. The IBC and BSO currently have responsibilities under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) for that are very similar to those outlined for the IRE and ICDUR in the institutional DURC policy. In Section 7.2.E of the institutional DURC policy use of an existing IBC is mentioned as an acceptable option for the establishment of the IRE. A flowchart summarizing the proposed manner in which the existing IBC would fulfill the role of the IRE is attached to this document.

The effective date of implementation required by the institutional policy for DURC is September 24, 2015. The following is a list of activities to be completed by the IBC, BSO and Department of Biological Safety prior to this date. Additional activities may be identified during this implementation process. The BSO will oversee the implementation process and assure that all required components are in place in advance of September 24, 2015.

- Additional training in DURC review for IBC members
- Online training for PIs and laboratory personnel developed and disseminated
- Revision of existing IBC by-laws to include DURC review/IRE responsibilities
- Identification of existing use of listed agents and toxins on campus that will require review for DURC potential (Currently this should be 2 PIs)
- Incorporation of the categories of research into the existing IBC registration form

PI submits online registration form to IBC/IRE identifying agents/toxins and categories of experiments which may meet the definition of DURC.

IBC Administrative Staff reviews registration form and confirms that the PI is aware that the research may meet the definition of DURC and should not be initiated.

ICDUR determines if the USG funding agency has previously notified the institution that the research is DURC under the USG policy.

Yes:

UK proceeds with implementation of the previously approved risk mitigation plan.

No:

The registration is forwarded to the next meeting of the IBC/IRE for review.

The IBC/IRE conducts a risk assessment to determine whether the research meets the definition of DURC.

Yes:

Subcommittee reports findings to IBC and registration proceeds as normal.

No:

Review and approval proceeds as per normal IBC procedures.

The IRE/ICDUR notifies USG funding agency and/or NIH within 30 calendar days.

PI conducts research per IBC approved procedures.

IRE considers previously identified risks and anticipated benefits and, with the PI, develops a draft risk mitigation plan. A subcommittee with Ad Hoc members may be developed if additional expertise is required for review.

The IRE/ICDUR submits the draft risk mitigation plan to USG funding agency and/or NIH within 90 calendar days.

Upon receipt of approved risk mitigation plan from USG funding agency and/or NIH UK proceeds with implementation of the risk mitigation plan and provides ongoing oversight of the work.

PI conducts and/or communicates research per the approved risk mitigation plan.