INSTITUTIONAL DUAL USE RESEARCH OF CONCERN COMMITTEE (IDURCC) Protocol Review Procedures

The *Policy for Institutional DURC Oversight* requires the IDURCC to undertake the following steps in its review of research:

Step 1

Verify that the research identified by the PI directly utilizes non-attenuated forms of one or more of the listed agents.

The first step of the review process is to verify that the research indeed directly involves non-attenuated forms of 1 or more of the 15 DURC-listed agents (This list will be updated as required to remain in compliance with federal regulations regarding dual use agents):

Avian Influenza Virus, *Bacillus anthracis*, Botulinum neurotoxin (in any quantity), *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*

The IDURCC application form should be submitted to the Department of Environmental Health and Safety biosafe@louisville.edu

The IDURCC will review the application supplied by the PI before addressing whether the research directly involves non-attenuated forms of the listed agents. Research involving any of the following is not currently intended for review under the *Policy for Institutional DURC Oversight*:

- The use of any of the listed agents in attenuated forms;
- The use of the genes from any of the listed agents;
- *In silico* experiments (e.g., modeling experiments, bioinformatics approaches) involving the biology of the listed agents; or
- Research related to the public, animal, and agricultural health impact of any of the listed agents (e.g., modeling the effects of a toxin, developing new methods to deliver a vaccine, developing surveillance mechanisms for a listed agent).

If the IDURCC answers "*No*" in Step 1, the research is not subject to additional institutional DURC oversight, and the entity does not need to continue with the assessment.

The PI will be informed in writing that, if at some future point his or her research does involve non-attenuated forms of any of the above-listed agents, he or she will need to notify the appropriate institutional authorities (e.g., the IRE, the ICDUR) per the policy of the institution.

Step 2

Assess whether the research produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects.

The IDURCC will examine the PI's description of the research in question, the PI's assessment of the applicability of the categories of experiments, and other relevant information, as warranted.

If *none* of the listed experimental effects (listed below) applies, the research *does not* meet the scope of the *Policy for Institutional DURC Oversight* and the IDURCC will not continue with the review. The PI will be informed in writing of the IDURCC determination, and the PI will be informed that if at any time the reviewed research produces or can be reasonably anticipated to produce one or more of the listed experimental effects, or if the reviewed research may meet the definition of DURC (see Step 3), he or she must refer it again for review.

Experimental effects

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 or agricultural justification.
3. Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates its ability to evade detection methodologies.
4. Alters properties of the agent or toxin in a manner that would enhance its stability, transmissibility, or ability to be disseminated.
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 select agent or toxin.

Step 3

For research that the IDURCC determines meets the scope of the *Policy for Institutional DURC Oversight,* **the IDURCC will conduct a risk assessment and determine whether the research meets the definition of DURC.**

Step 3a: Assess the risks of dual use associated with the research

When considering whether the research in question meets the definition above, the IDURCC will first identify the risks associated with the potential misuse of the information, technologies, or products that may be generated. Although risk assessments may be either quantitative or qualitative, the assessment process outlined below is qualitative in nature and requires the consideration and judgment of the IDURCC on the following:

- The *ways* in which knowledge, information, technologies, or products from the research could be misused to harm public health and safety, agriculture, plants, animals, the environment, materiel, or national security.
- The *ease with which* the knowledge, information, technologies, or products might be misused and the feasibility of such misuse.
- The *magnitude, nature, and scope* of the potential consequences of misuse.

Step 3b: Apply the definition of DURC

The IDURCC will consider the identified risks in determining whether the research in question meets the definition of dual use research of concern (DURC): *"…. 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."*

If the IDURCC determines that the research *does not* meet the DURC definition, the research is not subject to additional institutional DURC oversight. However, the institution must still notify the appropriate USG funding agency of the findings of the institutional review. If significant concerns about dual use remain, the Institutional Contact for Dual Use Research (ICDUR) should be informed. The ICDUR and the IDURCC may choose to consult with a representative of the USG department or agency that is funding the research in question.

If the IDURCC determines that the research *does* meet the DURC definition, the research is DURC, as defined in the *Policy for Institutional DURC Oversight* and the *March 2012 DURC Policy*, and is subject to additional DURC oversight. The IDURCC will inform the PI of its findings and proceed with the review process, which includes the development of a draft risk mitigation plan (see Steps 4-6, below). The institution, through the IDURCC and Research Oversight Administration, must notify the appropriate USG funding agency of the committee's findings within 30 calendar days of review.

Step 4

Assess the potential benefits of the DURC

The IDURCC will assess the benefits of the DURC while also considering the risks identified in the previous step.

In order to determine the acceptable level of risk associated with DURC and the best mitigation strategies, the research in question will assessed for its potential benefits. The benefits inherent to scientific research are many. Such benefits may impact various sectors of society and be realized over different time frames.

Step 5

Develop a draft risk mitigation plan for conducting the DURC and communicating its findings.

When dual use research of concern has been identified, the UofL IDURCC will work with the appropriate USG funding agency (or, for non-federally funded DURC, the NIH-designated USG agency) to develop the *draft* risk mitigation plan.

The IDURCC will submit a copy of the *draft* risk mitigation plan within 90 calendar days of the committee's determination that the research is DURC to the USG funding agency (or, for non-federally funded DURC, the NIH-designated USG agency) for review and final approval. USG

agencies are required to provide an initial response to institutions within 30 calendar days and should finalize the plan within 60 calendar days of receipt of the draft plan.

Of note, although it is the responsibility of the IDURCC to develop the draft risk mitigation plan, there may be situations that require consultation with the Federal funding agency. Such consultations may be appropriate when, for example:

> The IDURCC requires guidance on developing an adequate risk mitigation plan in cases where the potential risks are perceived as particularly high;
>
> The IDURCC considers the only viable risk mitigation measures to be not conducting the research in question or not communicating its results.

The IDURCC should work with the USG funding agency to finalize the risk mitigation plan.

The USG funding agency must finalize the risk mitigation plan within 60 calendar days of receipt of the draft plan.

Step 6

The IDURCC implements the approved risk mitigation plan and provides ongoing oversight of DURC.

Upon receipt of the approved risk mitigation plan, the investigator will conduct and/or communicate the research according to the risk mitigation plan.

The committee will review, at least annually, *all* active risk mitigation plans at the institution. If the research in question still constitutes DURC, the IDURCC will modify the plan as needed.