



K-State Institutional Framework for Governance of DURC

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University Research Compliance Oversight

- Research involving Human Subjects (IRB)
- Research, testing, or teaching involving animals (IACUC)
- Research using recombinant or synthetic nucleic acid molecules, toxins, or infectious agents (IBC)
 - Select Agents and Toxins
- Export Controls Program
- Confidential/Sensitive Research
- Dual Use Research of Concern (IRE)

Policy Development at K-State

- Lead Office - Associate Vice President for Research, Compliance (URCO)
 - Associate VP for Research nominated as ICDUR and assigned implementation responsibilities by Vice President for Research
- Began developing new internal policies and procedures in October 2014
 - Followed Companion Guide in process development
 - Drafted internal SOPs and other proof documents, to include DURC Notification Form



FOR OFFICE USE ONLY: DURC Protocol # _____ Date: _____ Training Complete: _____

KANSAS STATE UNIVERSITY
University Research Compliance Office

Dual Use Research / Dual Use Research of Concern
Notification Form
Please send your completed document to comply@k-state.edu

INSTRUCTIONS

Be sure to save the PDF form to your computer *before* you begin completing the form. You may not be able to save your changes if you edit this form in a web browser.

Please identify any life sciences research you conduct at this institution that directly involves nonattenuated forms of one or more of the agents listed below (please use a separate form for each identified project). If none of the agents are identified, your research is not subject to institutional DURC oversight. However, PIs should be aware that, if at any time, research is initiated that involves any of the below listed agents, he or she will need to immediately notify the institutional review entity (IRE) (or appropriate institutional authority), per the policy of this institution.

Agents:

<i>Avian influenza virus (highly pathogenic)</i>	<i>Marburg virus</i>
<i>Bacillus anthracis</i>	<i>Reconstructed 1918 influenza virus</i>
<i>Botulinum neurotoxin (any quantity)</i>	<i>Rinderpest virus</i>
<i>Burkholderia mallei</i>	<i>Toxin-producing strains of Clostridium botulinum</i>
<i>Burkholderia pseudomallei</i>	<i>Varicella major virus</i>
<i>Ebola virus</i>	<i>Varicella minor virus</i>
<i>Foot-and-mouth disease virus</i>	<i>Yersinia pestis</i>
<i>Francisella tularensis</i>	

If you need help or have questions about how to complete this application, please contact the University Research Compliance Office (532-3224, or email: comply@ksu.edu).

FAILURE TO PROVIDE ALL INFORMATION REQUESTED WILL LEAD TO A DELAY IN PROCESSING YOUR REQUEST!

Please proof read and check spelling **BEFORE** submitting the form.
To use Acrobat spelling check, press F7 or select EDIT, CHECK SPELLING

PLEASE CONTINUE TO THE NEXT PAGE
TO BEGIN COMPLETING THE FORM

Version: Last Updated: 8/22/2015



Policy Implementation at K-State

- Created a completely new compliance committee
 - Mitigate administrative burden to existing IBC and committee members
 - Higher ranking members (Distinguished Professors, Deans, Directors) selected for IRE membership
 - Appointed by Vice President for Research
- IRE composed of 9 members, plus 4 *ad hoc* members on as needed basis
 - *Ad hoc* members - Communications Department, Pre-Awards Services, EH&S Department, and General Counsel



Spreading the Word

- Held one-on-one meetings with K-State Principle Investigators known to be working with DURC agents prior to implementation of official policy
 - Good working relationship with all PIs
- Emailed IBC listserv DURC Policy, K-State SOP, and other materials
- Published media blurb in K-State Today week of implementation
- All KSU researchers are required to take Collaborative Institutional Training Initiative (CITI) training on DURC as part of their routine IBC application process (training is required every 3 years)



Implications for Research

- Only a few researchers at K-State working with DURC agents
 - Some researchers chose not to pursue research with these agents because of the policy (to include Gain of Function Moratorium)
 - Benefit versus burden analysis in working with DURC agents
- Impact on K-State? - MINIMAL
 - Limited impact on existing research
 - Minimal impact on new research
 - Limited administrative burden for URCO

Could change with new funded DURC research



Lessons Learned/Challenges

- Unclear processes and steps to follow outside of guidance provided in Companion Guide
- Unclear on what/when to report to funding agency
 - After first IRE – ICDUR sent entire review package to funding agency
 - Unnecessary as research was NOT with one of experiments and did not meet definition of DURC
- Better guidance/training tools provided by regulators (ie, webinars) for IRE committee members on what is DURC, what the Policy requires, and steps to follow
- Confusion over DURC policies, Gain of Function Moratorium, and what could and could not be done



Thank You!

