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 documents, to include DURC Notification Form
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!