

Dual Use Research of Concern at Colorado State University

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Acknowledgement:

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**ADDED THE DURC QUESTIONS TO OUR IBC
PROTOCOLS IN 2009, AND CONTINUES TO
UPDATE WHEN NEEDED**

CSU and DURC

2002 SEQUENCE OF 1918 INFLUENZA VIRUS

2005 CONSTRUCTION OF COMPLETE 1918 INFLUENZA VIRUS

**2009 CSU ADDED DURC QUESTION TO PROJECT APPROVAL
REQUEST FORM**

**2012 TWO PAPERS PUBLISHED ON GAIN OF FUNCTION OF
H5N1 HPAIV**

2012 USG POLICY ON DURC

2014 INSTITUTIONAL POLICY FOR DURC

2015 SEPTEMBER CSU OFFICIALLY BEGAN DURC REVIEW

What Research is Subject to the Policy?

- **RESEARCH THAT DIRECTLY INVOLVES ANY OF THE FOLLOWING 15 AGENTS AND TOXINS***

- AVIAN INFLUENZA VIRUS (HIGHLY PATHOGENIC)**
- 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***

*EXCEPT ATTENUATED STRAINS OF THE AGENTS THAT ARE EXCLUDED FROM THE SELECT AGENT LIST AND INACTIVE FORMS OF BOTULINUM NEUROTOXIN

**AGENTS THE INSTITUTION HAS WORKED WITH.

- ❖ **At CSU the “Institutional Review Entity” is our existing IBC**
 - DURC meeting is convened/adjourned prior to IBC
- ❖ **Institutional Contact for Dual Use Research (ICDUR)**
 - VP for Research
- ❖ **Institutional Review Committee**
 - Composed of at least 5 members, including persons with knowledge of US government policies and sufficient range of expertise to assess the dual use potential of research conducted at that institution
 - Define procedure for assessment and mitigation

- **At CSU the “Institutional Review Entity” is our existing IBC**
- **We ask the PI to determine whether any of the seven experimental effects apply to their research**
- **In addition: Could you envision a reasonable scenario where your research findings could be directly used by individuals with malicious intent to develop bioweapons?**
 - **Yes or No**
- **If you answered Yes to any of the above, please explain in the following textbox:**

CSU DURC Reviews: 9/2015 – 9/2017

- **As noted our official DURC review began September 9, 2015**
- **We have reviewed a total of 54 protocols, including renewals**
 - **Average 27 per year/1230 total IBC protocols = 2.2%**
- **One was thought to meet one of the 7 experimental effects**
 - **Determined not to meet the definition of DURC**
 - **Notified NIH OBA**
- **One that the sponsor determined was DURC and required a risk mitigation plan**

CSU DURC Reviews: 9/2015 – 9/2017

- Total of 15 PIs approved for select agent research
- Seven PIs are approved for DURC agents/toxins
 - Those seven accounted for the 54 DURC protocols
- Is another impact on time of those on the IRE, and the IBC Administrator (added a person half-time for assistance)
- Minimal impact on PIs
- Minimal impact on IBC/IRE

Issues to Be Resolved

- **Agents that have potential DURC but are not on the list?**
- **Gain of function (GOF) research for many agents (antimicrobial resistance)?**
- **Research issues similar to the Australian “mouse pox” research (accidental GOF)?**
- **“How to” publications such as botox in the milk supply?**

Thank You

Questions and Discussion

