

Stakeholder Workshop – DURC
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Warwick Allerton Hotel
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SESSION VIII – Research Investigator Perspectives on Implementation of the Institutional DURC Policy

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Questions:

1. **At what point(s) in the research life-cycle do you consider your research for potential DURC and what, if any, steps have been taken?**
 - *PI identifies work as potentially DURC in UGA IBC form*
 - *ICDUR refers protocols IRE*
 - *If DURC, work with PI to develop risk mitigation's plans*
 - *Report DURC review findings and risk mitigation's plans to USG*
 - *Education/training on DURC, review mitigation plans annually*
 - *Maintains records of education and training on DURC for three years after the term of research project*
 - *Notify funding agencies of any change in the status of a DURC project*

Questions:

1. **At what point(s) in the research life-cycle do you consider your research for potential DURC and what, if any, steps have been taken?**
 - *After 2005, reconstitution of 1918 H1N1 – help us place our own work in context*
 - *Before the H5N1 transmission publications – priority on fundamental mechanisms that control respiratory droplet transmission*
 - *After the H5N1 transmission publications,*
 - *Every potential project undergoes an internal risk assessment analysis (prior to submission of IBC registration)*
 - *In addition to institutional policies and requirements, annual/refresher training on agent specific training, biosafety, biosecurity, and DURC for lab personnel provided by the PI*
 - *Training of personnel in biosafety and animal resources about work with influenza viruses – DURC is addressed and discussed*

Interspecies Transmission of H9N2 LPAIV avian influenza viruses

Interspecies Transmission of H7N1 HPAIV avian influenza virus

Studies follow a common theme: Introduce mutations in avian influenza viruses by either site-directed mutagenesis, or reassortment with human influenza viruses and/or adaptation in a mammalian animal model (ferret)

Major goal: To determine the minimal changes necessary to produce a virus that can transmit by respiratory droplets (in ferrets).

Why? Because the mechanisms that control airborne transmission of avian influenza viruses in mammals is poorly understood and a comprehensive analysis of the factors involved in this process help us with risk assessment analysis of the pandemic potential of these strains.

Questions:

2. Describe your experiences working with the IRE, ICDUR, funding agency and, if relevant, journal editors regarding the potential for research to be DURC.

- My most relevant experience comes from the work with mammalian transmissible HPAIV H7N1 (Sutton et al, JVI 2014)
 - IBC approves the registration “Mechanisms of Transmission of Influenza in Mammals and Birds”; it considers the work to have dual use potential but NOT to be Dual Use Research of Concern.
 - However, IBC asks for a risk/benefit analysis and risk mitigation plan to address dual use potential. IBC approves such plans.
 - Manuscript is submitted to program officer at funding agency (NIAID-NIH) which considers the work DURC and suggests inclusion of a communication strategy to “Strengthen the explanation of the benefits of this research and the reasons why the experiments were conducted”
 - Manuscript is submitted to JVI. DURC panel assembled ad hoc. Minor suggestions to help enhance the significance of findings for pandemic preparedness and vaccine development.

Questions:

3. What, if any, benefits or challenges have you or your lab experienced stemming from DURC policy implementation?

- Benefit: The research questions are contemplated in the global context of risks versus benefits
- Challenge: Like in every area of research a perceived potential benefit today may become a risk in the future (*think of passenger planes, trucks, cars as weapons*)
- Challenge: A tendency to second-guess whether more knowledge is good...not good for science

Questions:

4. Has the policy fundamentally altered the way you think about or approach your research?

- Definitely!
- In my modest opinion there are fundamental questions related to transmission, pathogenesis, and antiviral resistance of influenza viruses that are almost impossible to pursue.
- There also countless number of research questions and opportunities that must be pursued, which do not have the risks (or perceived risks) of DURC