Stakeholder Workshop – DURC September 25 - 26, 2017 Warwick Allerton Hotel Chicago, IL

SESSION VIII – Research Investigator Perspectives on Implementation of the Institutional DURC Policy

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- 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

- 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.

- 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 <u>Concern.</u>
 - 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.

- 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

- 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