

Dual Use Research of Concern – How we do things at St. Jude

Philip Potter, Ph.D.
DURC (IRE) Chairman
V. Chair, IBC
St. Jude Children's Research Hospital

Why does DURC affect St. Jude?

- NIAID Centers of Excellence for Influenza Research and Surveillance; WHO Collaborating Center for Studies on the Ecology of Influenza in Animals
- Influenza-positive samples (of unknown genotype) submitted to St. Jude from all around the world
- Highly pathogenic avian influenza (HPAI) virus is one of the organisms regulated by DURC
- Sequencing, biochemical, and in vivo studies are performed on derived virus
- Swapping of viral segments into low risk category virus is frequently undertaken to assess role of identified mutations
- Relatively small group of faculty that work with HPAI
- HPAI is the only agent subject to DURC used at St. Jude

How is DURC research identified at St. Jude

- PIs use an online submission process for IBC protocols and amendments
- One section addresses the NSABB concerns
 - Does the proposed research have the highest potential for yielding knowledge....
 - Will the research enhance the harmful consequences of a biological agent or...
 - Does the research have the potential of disrupting the immunity....
 - Can the proposed research confer to a biological agent resistance to....
- Answering 'Yes' to any of these questions (regardless of pathogen) triggers review by BSO and DURC (IRE) chairman
- Any member of the IBC can suggest DURC review of a protocol
- We (St. Jude) err on the cautious side, i.e., we review all HPAI research to consider the possibility of DURC

How we evaluate potential DURC science

- Ad hoc DURC (IRE) subcommittee with expertise from different disciplines
 - Chair (V. Chair IBC), 2-4 faculty experts, BSO (ICDUR), Director EH&S, Chief Compliance Officer, scientific editing, legal counsel
- PI delivers detailed proposal to committee in advance
- 1-2 hr meeting for PI presentation and Q&A
- Specifically asked to address the DURC issues based upon the 15 + 7 'algorithm'
- In camera discussion with vote
- Chair of DURC subcommittee writes memo to IBC with summary of discussion and result of vote
- PI is required to submit an update if any unexpected events occur and an annual update coincident with IBC reapproval

DURC subcommittee (IRE) – IBC relationship

- DURC (IRE) is a subcommittee of the IBC
- Meetings scheduled separate for IBC meeting (frequently held 'back to back' so that any members of IRE can attend IBC)
- Limits public dissemination of sensitive information
- Overlap of personnel
- IRE Chair (and others) provides overview of science and discussion at IBC meeting

The good and the bad

Good

- Expectations are clear
- Criteria are easy to interpret (except one!)
- PI has to explain proposed studies to non-scientists
- Institution has sufficient expertise to evaluate science without conflicts of interest
- Non-scientist members clearly add value to the DURC committee

Bad

- Wording in DURC policy has led to significant ambiguity of interpretation by PI and committee
- Policy not all encompassing
- Increased workload (mainly for BSO, EH&S)

Problems interpreting the 'algorithm'

- In general, following the DURC policy algorithm works well, however there are two areas where we, as a committee, struggle

‘5. **Alters** the host range or tropism of the agent or toxin’

- A decrease in these properties triggers DURC review
- We realize that the criteria will evolve over time, but currently H7N9 virus is not subject to DURC
- We recently reviewed studies that proposed to evaluate the biology of H7N9 virus and concluded that this was durc (not DURC), i.e., that the results may be enabling, but since HPAI was not used (H7N9 is not an HPAI/DURC agent), technically it may not be covered by the guidelines

DURC Algorithm

