

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

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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 (PIs Drs. Webby and Schultz-Cherry)
- Influenza-positive samples (of unknown genotype) submitted to St. Jude from all around the world
- Highly pathogenic avian influenza 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

How is DURC research identified at St. Jude?

- PIs use an online submission process for IBC protocols/amendments
- One section addresses the NSABB concerns

National Security Advisory Board for Biosecurity(NSABB)

Certain research projects that do or do not involve Select Agents may be considered dual use research depending on the nature of the particular experiments and the potential for misuse of the results and/or technology. The National Security Advisory Board for Biosecurity(NSABB) provides advice regarding biosecurity oversight of dual use research. Therefore, identification of such technologies/applications at the local level is critical. For that reason and to prevent the use of technology that could be misapplied to threaten public health or national security, it is necessary that the following additional questions be addressed so that an appropriate determination can be achieved.

1.0 * Does the proposed research have the highest potential for yielding knowledge, products, or technology that could be misapplied to threaten national security?
 Yes No

1.5 * Will the research enhance the harmful consequences of a biological agent or toxin?
 Yes No

2.0 * Does the research have the potential of disrupting immunity or the effectiveness of an immunization?
 Yes No

3.0 * Can the proposed research confer to a biological agent or toxin, resistance to clinically, and/or a method of detection against that agent or toxin or facilitate their ability to evade detection methodologies?
 Yes No

- Answering 'Yes' to any of these questions (regardless of pathogen) triggers review by BSO and DURC 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

- DURC subcommittee with expertise from different disciplines
 - 2-4 faculty experts in proposed research area
 - BSO
 - Director, EH&S
 - IRB coordinator
 - scientific editing
 - legal counsel
- PI delivers detailed proposal to committee in advance
- 1-2hr meeting for PI presentation and Q&A
- Specifically asked to address the DURC issues based upon the 'algorithm'
- In camera discussion with vote
- Chair of DURC subcommittee writes memo to IBC with summary of discussion and result of vote

Problems interpreting the algorithm

- In general, following the DURC 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

