RISK MITIGATION PLANS ASSOCIATED WITH DURC – A PI PERSPECTIVE

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DURC QUESTIONNAIRE FOR PIS



- 1. Does your research involve any of the 15 agents of special DURC interest?
 - If yes, give a brief description of the project and move to 2
- 2. Does your research falls under one of the seven DURC categories? If no, briefly explain why this is the case If yes, move to the next
- 3. Explain the scientific rationale behind your proposed experiments
- 4. Explain the benefits to conduct this research
- 5. Identify the possible DUR concerns associated with this research
- 6. Explain why the question addressed by the proposed research cannot be conducted with a pathogen outside the 15 DURC agents
- 7. Develop a DURC mitigation plan. What measures will be applied to mitigate the possible dual use of the products (agents, information).

DURC REVIEW



DURC questionnaires are reviewed by the IBC (meets every 2 months)

- IBC works with the PI to establish appropriate risk mitigation plans
- Final IBC reviewed documents are submitted to USG funding agency (NIH)
- NIH provides extra input, decides whether DURC applies or not, whether review by additional USG committees is needed, whether modifications to the research and /or the risk mitigation plan are needed and ultimately approve or not the proposed research.
- Approved DURC research requires constant monitoring from the PI to determine whether risk levels change and oversight from IBC and USG funding agency as determined in the risk mitigation plan.

DURC research involving influenza viruses is under a GOF moratorium

RISK MITIGATION PLANS

- **1. Appropriate level of biocontainment** Facility and personal practices
- 2. Appropriate level of biosecurity

In general covered by the select agent program

- **3. Evaluation of countermeasures** Antivirals, vaccines
- 4. Monitoring of changes in risk
- 5. Communication with and oversight by biosafety officer, IBC and USG commitees
- 6. Communication plan in conjunction with USG funding agency: Publications, press releases, public inquiries



<u>CHALLENGES</u> A personal perspective

1. Risk perception

Evidence based

2. Implementation time

Avoidance of red tape and unnecessary delays

3. Appropriate balance between research benefits and risks