



Dual Use Research of Concern: Challenges in Management

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Introduction

- Institutions have developed policies to meet the U.S. Government (USG) United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
- The policies and procedures include initial, and continuing, review of proposed projects and identification of potential DURC
- Most challenges associated with this process seem to have been identified and addressed



Introduction (*continued*)

The following are statements from the U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern :

- “Funders of life sciences research and the institutions and scientists who receive those funds have a shared responsibility for oversight of DURC and for *promoting the responsible conduct and communication of such research....*”
- “The *free and open conduct and communication* of life sciences research is vital to a robust scientific enterprise and will continue to be the goal of the USG. It also should continue to be the goal of institutions engaged in life sciences research”.
- “Communication of research and research findings is an essential activity for all researchers, and occurs throughout the research process, not only at the point of publication. Researchers planning to communicate DURC should do so in compliance with the approved risk mitigation plan”.

Responsibilities of the USG In accordance with this Policy:

C. Provide guidance to institutions on the sharing of DURC research products and on the communication of DURC.



NIH Guidance for Communication

The USG has clearly stated that: *“It is the expectation of the USG that the vast majority of DURC findings will be communicated. The goal of the risk mitigation process is to promote the responsible conduct of DURC and communication of its results, not the restriction of such research”*.

The following guidance is provided:

- Consider changing the timing, mode, or venue of communication for the DURC in question.
- Establish a mechanism for prepublication or pre-communication review by the institution and/or the appropriate USG funding agency.
- Consider the need to redact specific information in light of security concerns.
- When communicating the DURC, emphasize the biosafety and biosecurity measures that were in place throughout the course of the research.
- Emphasize the public health or broader significance of the DURC. For example, describe specifically how the findings may inform the development of countermeasures, disease surveillance, preparedness, and response efforts

Source: Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide



Management Challenges

- **Uniqueness for each research:**
 - Each research proposal that is categorized as DURC is different and poses unique issues related to the implications of the information, materials, or technologies that may result from the research. Therefore, it is not possible to develop a single review process that can be used for all cases.
- **Who Determines?**
 - NIH- Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern assigns the responsibility to the “Institutional Review Entity” (IRE): *“The IRE should consider how the concerns about dual use associated with the research in question may be mitigated by developing a plan for responsible communication of its findings”*.



Management Challenges (cont'd)

- **IRE Considerations**

- IRE's risk tolerance is a reflection of the institution and *its* risk tolerance
 - Multi-Institutional Collaboration
 - Multi-National Collaboration
- Members have concerns regarding making the “right decision”
- Who can “misuse the results”?
- How can the results be misused-how is easy is it?

- **Freedom to publish**

- Almost all institutions have policies for freedom of publication to preserve their “fundamental research” exemption for Export Control regulations. The concern is related to:
 - Note 2* to paragraph (a): There are instances in the conduct of research, whether fundamental, basic, or applied, where a researcher, institution, or company may decide to restrict or protect the release or publication of technical data contained in research results. Once a decision is made to maintain such technical data as restricted or proprietary, the technical data becomes subject to the ITAR.

* International Traffic in Arms: Revisions to Definitions of Defense Services, Technical Data, and Public Domain; Definition of Product of Fundamental Research; Electronic Transmission and Storage of Technical Data; and Related Definitions [Federal Register / Vol. 80, No. 106 / Wednesday, June 3, 2015]



Summary

- Academic institutions are committed to ensuring responsible conduct of research and the publication of results, but are uncertain about the ambiguities related to which results fall under the “rare exceptions” requiring communication/publication restrictions.
- A national, and preferably international, approach to the subject would be greatly welcomed. Possible elements should include:
 - Role of scientific journals in identifying concerns
 - A national/international panel to review and provide guidance
 - Availability of any redacted details for researchers who ask for it (e.g. for replication purposes)
 - How to determine legitimate requests?
 - Preserving fundamental research exemptions



Questions?

A black marker is shown drawing a curved line under the word 'Questions?' on a piece of white lined paper. The marker is positioned at the bottom right of the frame, with its tip pointing towards the end of the line.