

The US Government Approach to Communication of Dual-Use Research of Concern: Challenges and Options

Elisa D. Harris

Nonresident Senior Research Scholar

Center for International and Security Studies at Maryland

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DURC Communication Goal

- ▶ **Not** to impede flow of fundamental research results
- ▶ Instead, limit communication only in **rare** instances where threat to public health outweighs benefits:
 - ▶ NSABB: reviewed 6 manuscripts
 - ▶ Journal editors: rejected 2 manuscripts
 - ▶ Redactions: few

Challenge: Definition of DURC

- ▶ USG definition: “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be *directly misapplied* [emphasis added] to pose a significant threat with broad potential consequences....”
- ▶ Significant threat from misapplying research to *deliberately* cause harm
- ▶ But **also** from misapplying research and *unintentionallyy* causing harm

Challenge: Scope of Application

- ▶ Current USG DURC policies do not apply to:
 - ▶ Classified Research
 - ▶ Research not involving one of fifteen select agents
 - ▶ Research at institutions not receiving USG funding for life sciences research
- ▶ Two pose risk of deliberate misuse
- ▶ All pose risk of unintentional misuse

Challenge: Inconsistent Requirements

- ▶ 2012 DURC policy for government agencies: covers proposed research not yet funded
- ▶ 2014 DURC policy for research institutions: covers research already funded
- ▶ Inconsistency confusing for researchers/institutions
- ▶ 2014 policy less effective?

Challenge: Knowledge & Experience

- ▶ USG communication guidance for researchers, IREs, journal editors – can they identify, assess, mitigate risks?
- ▶ 2004-2008 interactive seminars with 3,000 scientists in North/South America, Europe, Asia: little knowledge of DU risks
- ▶ 2011 survey of journal editors: only 11 of 127 have biosecurity review experience

Challenge: Conflicts of Interest

- ▶ Researchers: conduct/publish ground breaking work → funding, advancement
- ▶ IRE members: don't complicate other researchers' plans
- ▶ Journals: protect scientific freedom
- ▶ USG funding agencies: solicit or fund relevant research
- ▶ NSABB: funded/staffed by NIH →key research sponsor

Challenge: Harmonization

- ▶ USG communication guidance “optional”
- ▶ No uniform approach by institutions/journals
- ▶ National but also international problem: global nature of research

Challenge: Journal Focus

- ▶ USG communication guidance focuses on final stage of research process: publication in scientific journal
- ▶ Multiple points when DURC communicated: inception, funding, conduct of work, journal submission
- ▶ Multiple ways to communicate DURC: conversations, meeting presentations, online postings, journals

Challenge: Competing Priorities

- ▶ Limiting access to sensitive research results competes with other public health or policy goals
- ▶ Example: H5N1 and virus sharing under Pandemic Influenza Preparedness Framework

Option: Funding Conditions

- ▶ Clarify USG Policy: require institutions to include R/B assessment, risk mitigation, communication plan in funding proposal
- ▶ Include prepublication review provisions in funding arrangements

Option: Journal Editors' Policy

- ▶ Scientists & international publishing organizations develop uniform DURC policy:
 - ▶ Reject manuscripts from authors who ignore risk assessment, risk mitigation requirements
 - ▶ Seek voluntary prepublication redaction of sensitive information

Option: Export Control Policy

- ▶ Restricting/redacting scientific information could trigger export license requirement: not “fundamental research” if results not broadly shared
- ▶ Controversial, but...license requirement ≠ no approval
- ▶ Orderly, legal process for assessing information sharing: whether, whom?

Option: National Advisory Body

- ▶ RAC-like board to assist journal editors identify, assess, mitigate risks, or
- ▶ Independent body with authority, separate from government agencies

Option: International Guidance

- ▶ Need for global guidance on identification & management of DURC, including communication:
 - ▶ International advisory board
 - ▶ On-line resources: expert lists, best practices, case outcomes
 - ▶ WHO forum: stakeholders, governments, international organizations develop globally harmonized approach

Option: International Review Body

- ▶ Post-H5N1 interest in international body:
 - ▶ Decide on handling DURC
 - ▶ Broader powers to assess, handle DURC, including provide access on need to know basis: avoids perception USG dictating DURC policy/denying research results to other countries

Concluding Observations

- ▶ No option addresses all challenges
- ▶ Those with greatest potential → most difficult to implement: engage broad range of actors, complex technical, legal, political, practical issues
- ▶ Conduct of DURC and communication of DURC linked: more effective approach to communication = more effective DURC oversight, nationally/globally