

National Institute of Allergy and Infectious Diseases

**Committee on Dual Use Research of Concern:
Options for Limited Communication**

NIAID DURC Processes & Lessons Learned: A Program Perspective

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NIAID

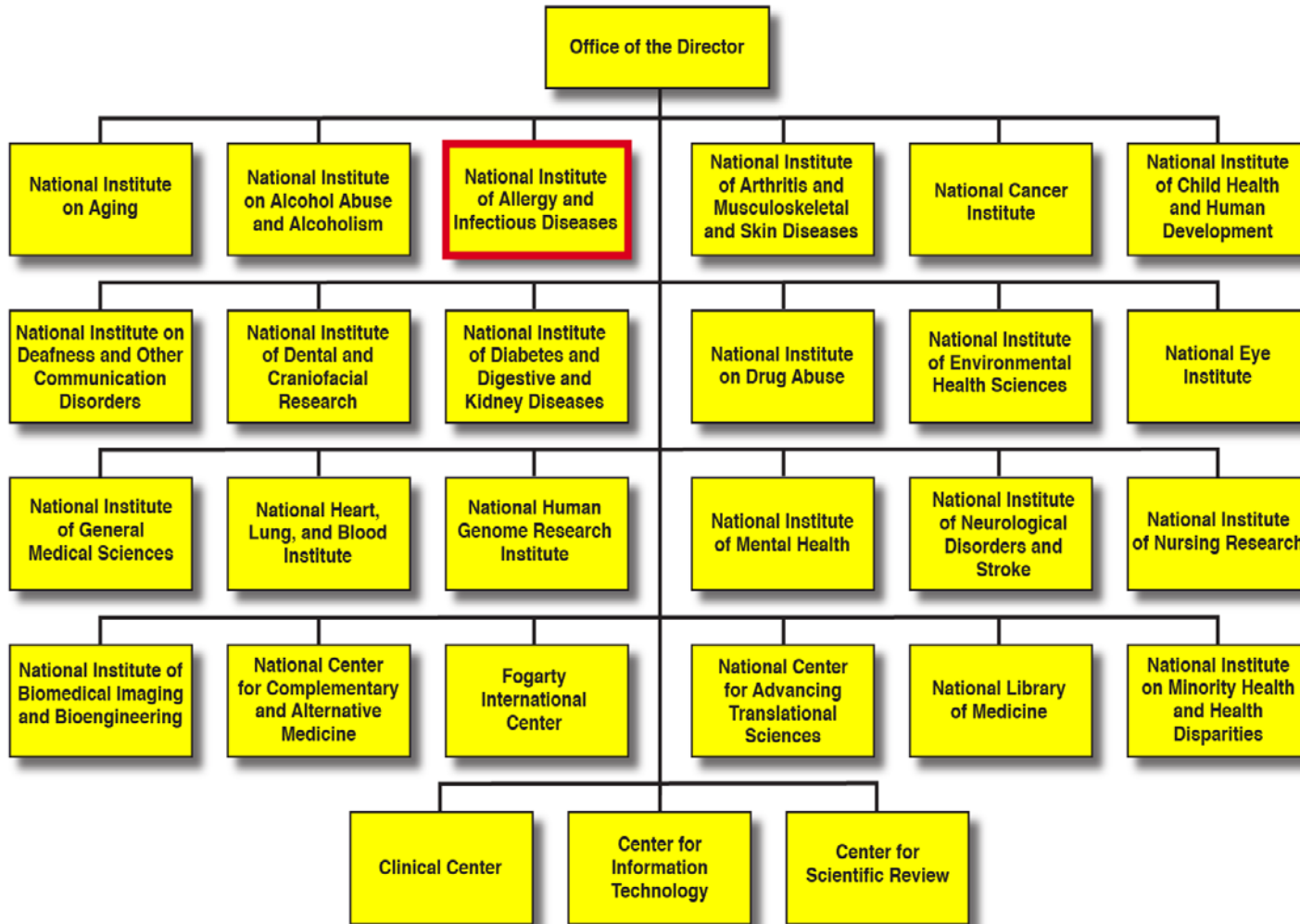


National Institute of
Allergy and
Infectious Diseases

Outline

- NIAID background
- NIAID DURC review and oversight processes
- DURC communications
- Lessons learned
- Challenges

National Institutes of Health



National Institute of Allergy and Infectious Diseases (NIAID)

- Conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases

Division of Microbiology and Infectious Diseases (DMID)

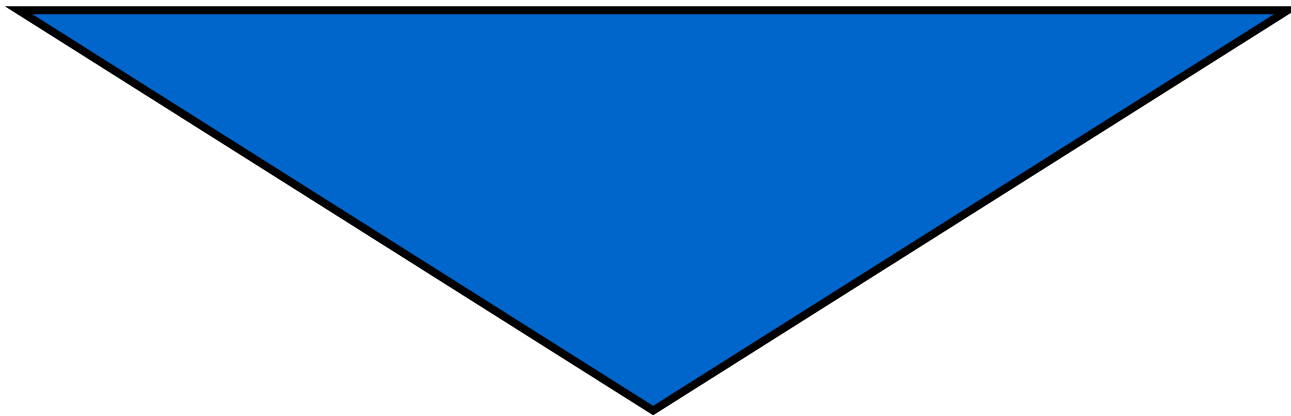
- Supports extramural basic through applied research to control and prevent diseases caused by virtually all human infectious agents except HIV

NIAID Infectious Disease Research: A Dual Mandate

**Maintain and “grow”
a robust basic and
applied research
portfolio in
microbiology,
immunology, and
clinical research**

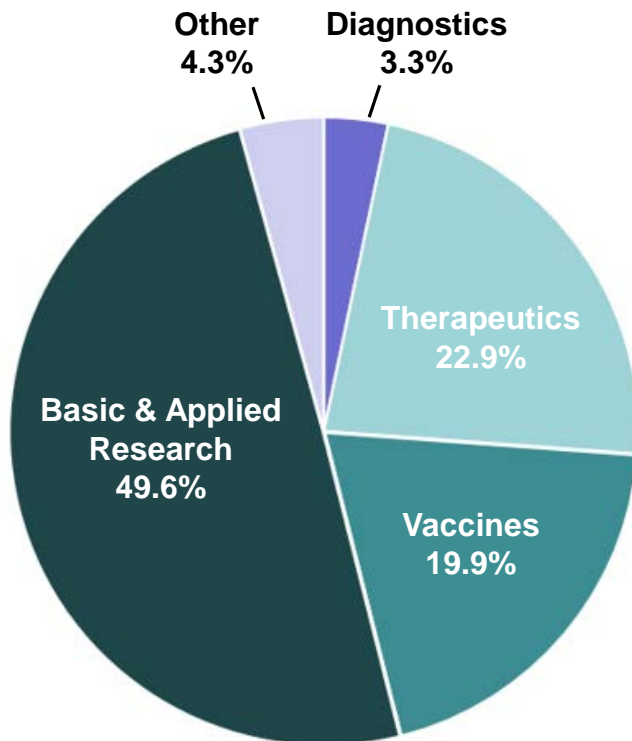


**Respond rapidly
to new infectious
disease threats**



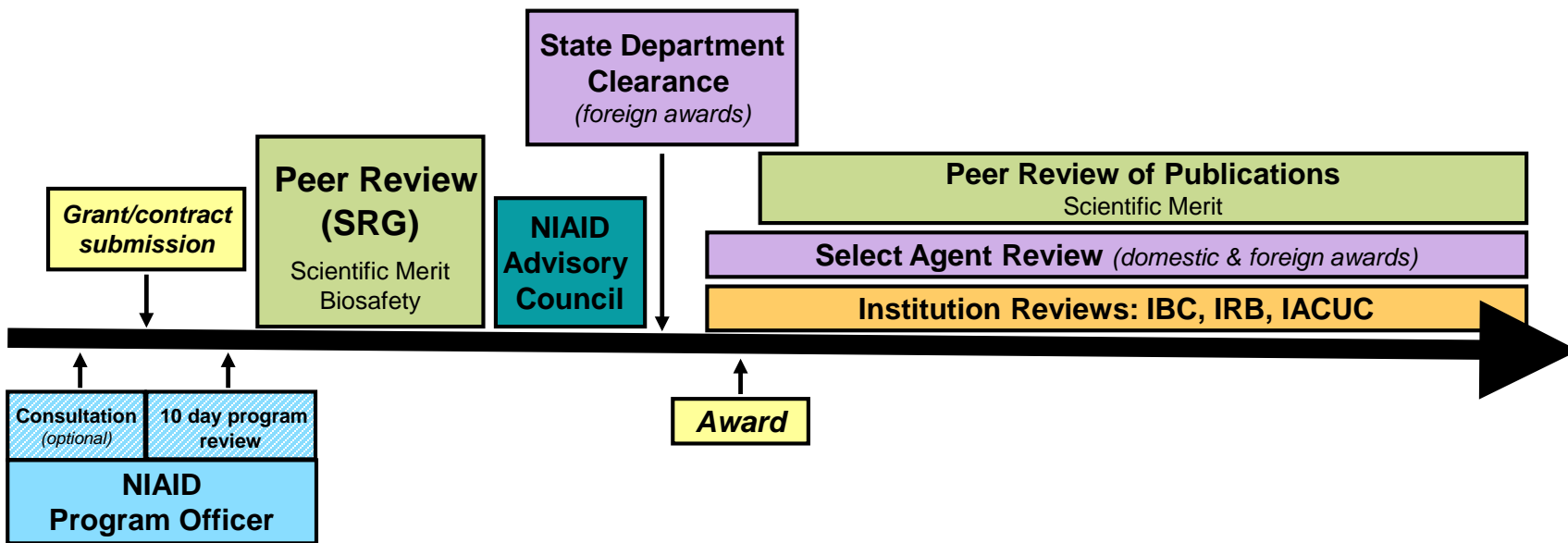
NIAID FY2015 Portfolio

FY2015 NIAID Budget: \$4.4B

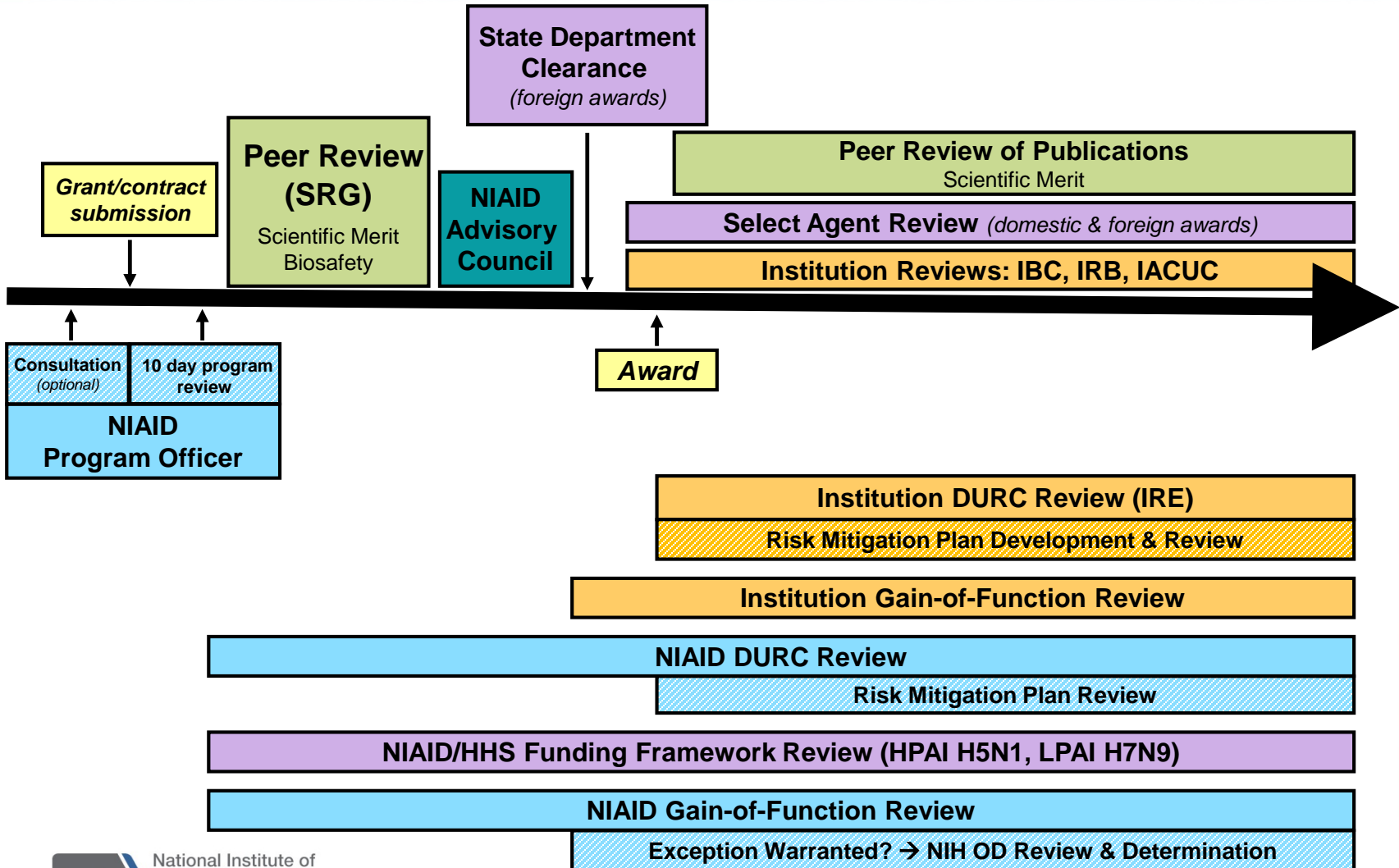


- <0.3% of NIAID's total FY15 budget supported projects that involve DURC

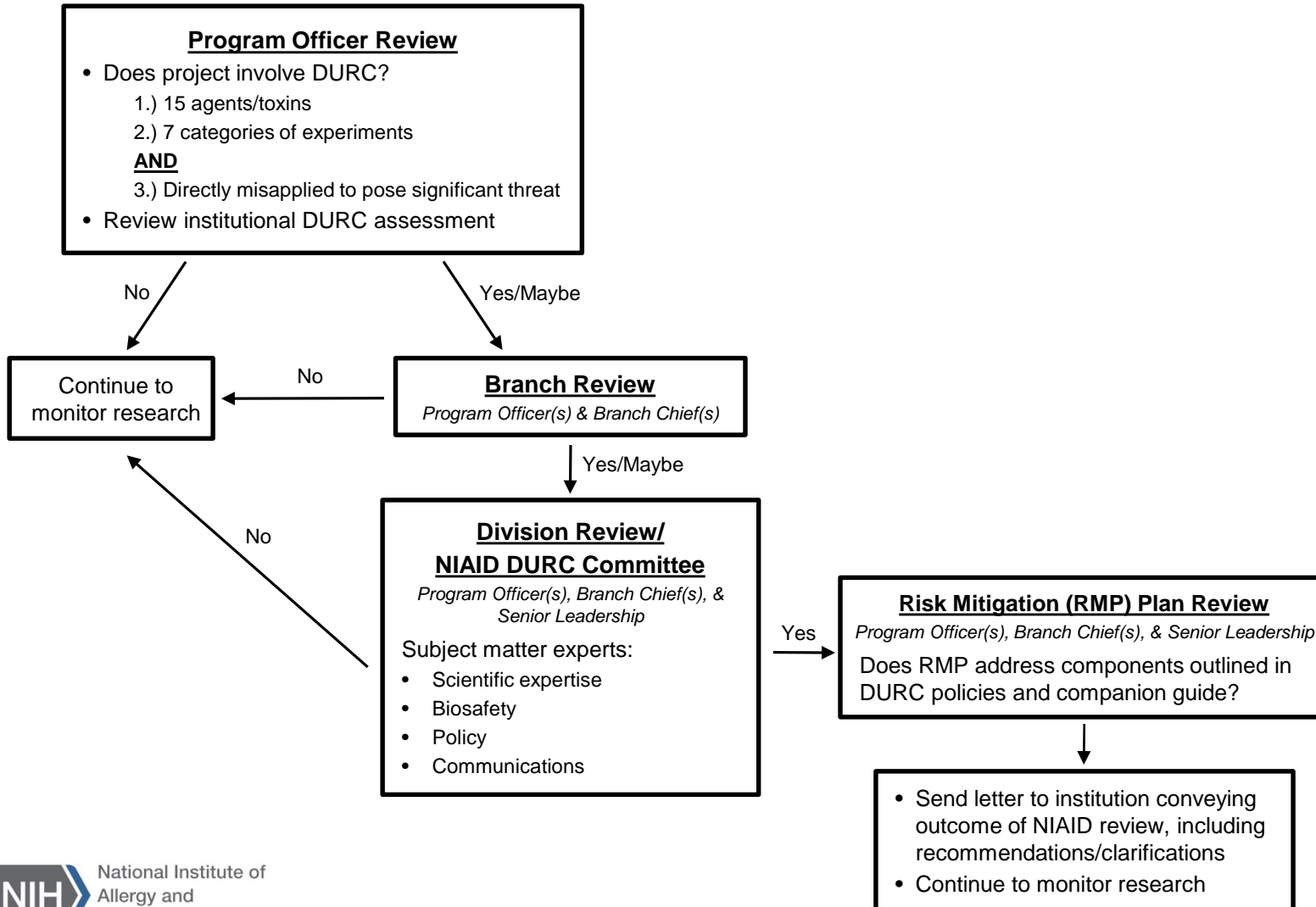
NIAID Extramural Award Review Processes: 2011



NIAID Extramural Award Review Processes: Current



NIAID DURC Review Process



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DURC Communications: Areas For Input

- Funding mechanism
- Risk mitigation plan review
- Draft manuscript evaluation

Funding Mechanism: NIH Grants

- Financial assistance to carry out public purpose (e.g., biomedical research)
- Primarily investigator-initiated
- Limited programmatic direction
- Awardees have primary rights to data
 - NIH has rights of access to records
- Subject to the NIH grants policy
 - Section 8.2: Availability of Research Results
 - *“It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PD/PIs and recipient organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large.”*

Funding Mechanism: NIH Contracts

- Procurement of goods/services for direct benefit/use of U.S. Government
- Substantial programmatic input (e.g., deliverables, reporting requirements)
- Failure to perform can result in legal action or financial consequences
- U.S. Government generally has rights to data
- Subject to the Federal Acquisition Regulation (FAR)
 - FAR 27.404-4: Contractor's release, publication, and use of data
 - *"In contracts for basic or applied research with universities or colleges, agencies shall not place any restrictions on the conduct of or reporting on the results of unclassified basic or applied research, except as provided in applicable U.S. statutes."*

DURC Risk Mitigation Plans: Background

- Guides **both conduct and communication** of DURC
- Institutional Review Entity (IRE) is responsible for developing plans for responsible communication of DURC
- Institutions may consult the federal funding agency in certain circumstances
 - Complex case
 - Unique expertise needed
 - Risks of communication perceived as high
 - IRE considers only viable risk mitigation strategy to be not conducting research
- Draft risk mitigation plans are submitted to federal funding agency for review and final approval

DURC Risk Mitigation Plans: What We Look For

- Does the DURC responsible communication plan:
 - Assess risks and benefits of communicating results?
 - Specify risk mitigation measures?
 - Consider range of communication options?
 - Content, timing, and extent of distribution
- Is responsible communication considered throughout the research process, not only at point of publication?
- Will research staff receive DURC training and education?

“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.”

DURC Manuscripts

- DURC terms of award request sharing of manuscripts prior to journal submission
- NIAID no longer conducts formal DURC assessments of manuscripts
- Recommend sharing with IBC and relevant stakeholders for evaluation
- Encourage review of DURC educational materials on responsible communication
 - DURC policies
 - DURC companion guide
 - DURC code of conduct toolkit

DURC Manuscripts: What We Look For

- Are benefits to public health and reasons for conducting experiments clearly articulated?
- Are descriptions of pathogen phenotypes clear?
 - Comparator strains
 - Address all DURC properties
- Are biosafety and biosecurity measures adequately described?
- Does it align with communication plan in risk mitigation plan?
- Are the cited funding sources accurate?
- Is it clear when the experiments were conducted, if relevant (e.g., prior to a moratorium or funding pause)?

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DURC Communication Lessons Learned

- Requires close interaction between investigators, institutions, and funding agency
- No “one size fits all”
- Scientific details are important
- Look for balance between findings and interpretations
- Communication practices evolve over time
 - Informed by ongoing discussions and new policies
- Education and outreach is critical

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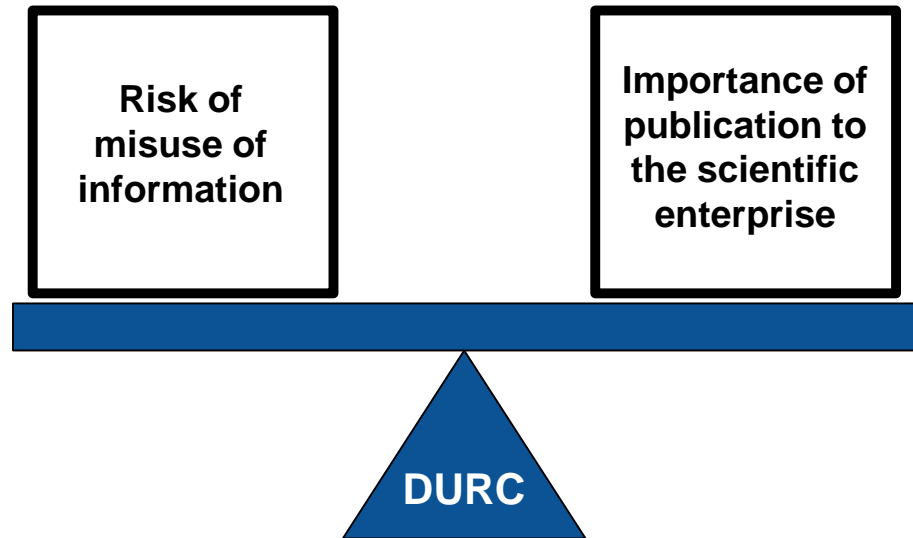
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Challenges In Limiting Communication Of Research Results

- Limited toolkit
- Freedom of Information Act (FOIA)
- Rarely 1:1 relationship between grant/contract and publication
- Unexpected outcomes

Challenges In Limiting Communication Of Research Results

- Communication of DURC is a delicate balance



Effects on public trust and the perceived value of science

Acknowledgements

- NIAID DURC & GoF Team
 - Intramural and extramural staff
 - Subject matter experts
 - Scientific expertise
 - Biosafety
 - Policy
 - Communications
 - Senior Leadership