U.S. Government Policy Regarding Oversight of Life Sciences Dual Use Research : The Evolving Policy Landscape

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Overview

- Dual Use Research (DUR) in the Life Sciences
- Federal Dual Use Research of Concern (DURC) Policies
- Gain-of-Function (GOF) Deliberative Process and Research Funding Pause

Importance of Life Sciences Research

Life sciences research underpins:

- **Biomedical and public health advances**
- **Improvements in agriculture**
- **Safety and quality of food supply**
- **Environmental quality**
- **Strong national security and economy**

But, good science can be put to bad uses

DUR vs DURC

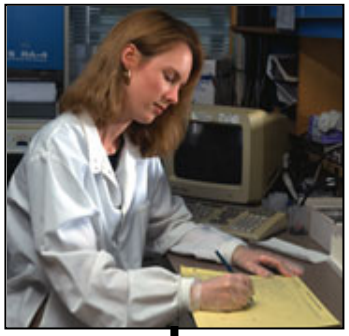
DUR

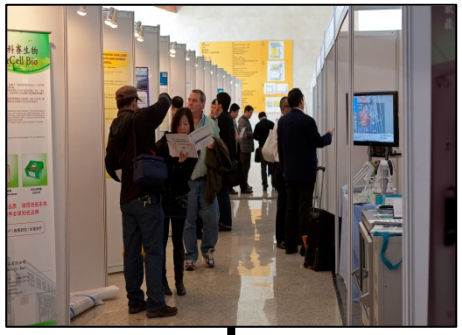
- **Research conducted for legitimate purposes**
- **That generates information, technologies, and/or products that can be utilized for both benevolent and harmful purposes**

DURC

- **Most life sciences research could be considered DUR in that it has *some* potential to generate information that could be misused**
- **A subset of research that has the greatest potential for generating information that could be readily misused to threaten public health and national security has been termed "*dual use research of concern*" or DURC**

Oversight of Research Process





Conceptualize project

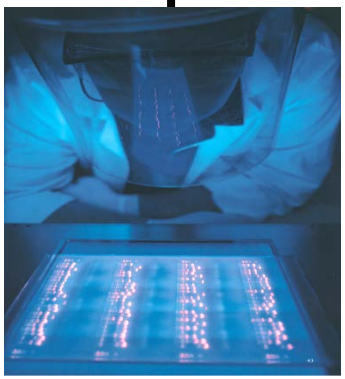
Funding review

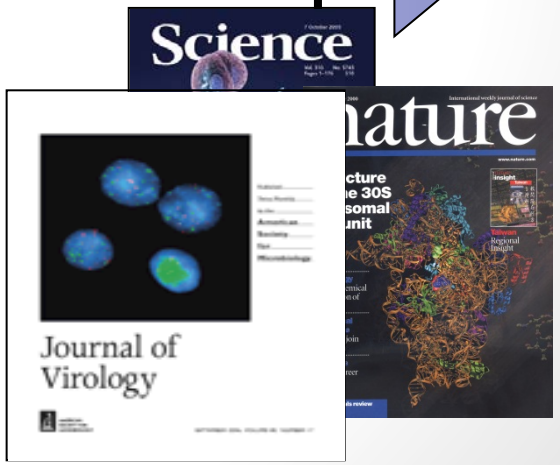
Institutional review

Conduct research

Present research: Seminars, posters abstracts

Publish or post online





NSABB Proposes Federal Framework for Oversight of Dual Use Research

- **The NSABB was charged with proposing an oversight framework for the identification, review, conduct, and communication of life sciences research with dual use potential.**

- **The document articulates a criterion for identifying DURC, and delineates seven categories of information, products, or technologies that might be especially likely to meet the threshold for DURC.**

USG Policy for Oversight of Life Sciences DURC – *March 29, 2012*

- **Aims to preserve the benefits of life sciences research while minimizing the risk of misuse of the information, products, or technologies generated by such research**
- **Promulgated to establish regular Federal review of USG-funded or -conducted research with certain high-consequence pathogens and toxins for its potential to be DURC**
- **Involves the following:**
  - **Identifying projects (ongoing and new) that may raise significant dual use concerns**
  - **Implementing risk mitigation strategies for these projects**

March 2012 DURC Policy Scope

Research involving any of the following 15 listed agents or toxins:

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin (in any quantity)
4. *Burkholderia mallei*
5. *Burkholderia pseudomallei*
6. Ebola virus
7. Foot-and-mouth disease virus
8. *Francisella tularensis*
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of *Clostridium botulinum*
13. Variola major virus
14. Variola minor virus
15. *Yersinia pestis*

March 2012 DURC Scope

Research that produces, aims to produce, or is reasonably anticipated to produce any of the listed effects:

1. **Enhances the harmful consequences of the agent or toxin**
2. **Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification**
3. **Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies**
4. **Increases the stability, transmissibility, or the ability to disseminate the agent or toxin**
5. **Alters the host range or tropism of the agent or toxin**
6. **Enhances the susceptibility of a host population to the agent or toxin**
7. **Generates or reconstitutes an eradicated or extinct listed agent or toxin**

Overview of Policy

Step 1:
Does research involve one or more of the 15 agents and toxins listed in the policy?

Step 2:
Does research aim to produce one of the 7 listed experimental effects?

Step 3:
Does research meet definition of DURC?

Requires additional Federal and local oversight and risk mitigation strategies to address dual use concerns

Federally Funded Life Sciences Research

USG Policy for Institutional Oversight of Life Sciences DURC – September 24, 2014

United States Government Policy for
Institutional Oversight of Life Sciences Dual Use Research of Concern

Key Dates
Release date: September 24, 2014
Effective date: September 24, 2015

Relevant Notices
See the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse.

Issued By
The United States Government

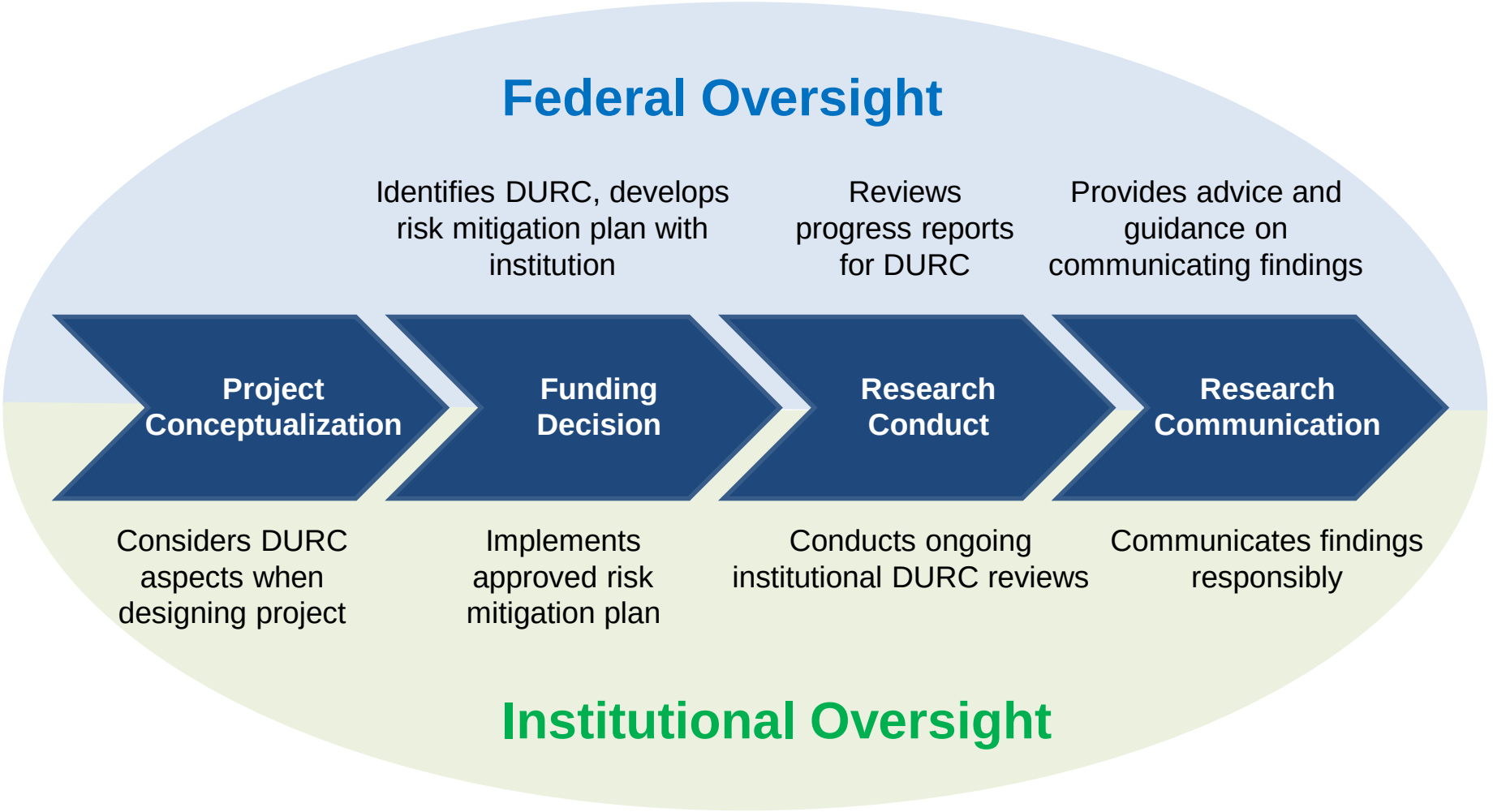
Overview
Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called "dual use research." Dual use research *of concern* is a subset of dual use research defined as: "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security." *The United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* articulates the practices and procedures required to ensure that dual use research of concern is identified at the institutional level and risk mitigation measures are implemented as necessary.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse.

All provisions in this Policy supersede those contained in the previous draft policy published on February 22, 2013 (Federal Register 78 (36): 12369-12372). This Policy and the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern, which was released on March 29, 2012 (http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf) are complementary and emphasize a culture of responsibility by reminding all involved parties of the shared duty to uphold the integrity of science and prevent its misuse.

- **Addresses roles and responsibilities of USG-funded research institutions and investigators**
- **Issued for public comment in the spring 2013, and policy revised to reflect comments**
- **Final policy issued and is available at www.phe.gov/s3/dualuse**
- **Extensive rollout campaign accomplished; educational campaign underway**
- **One-year implementation time is being given before full compliance is required**

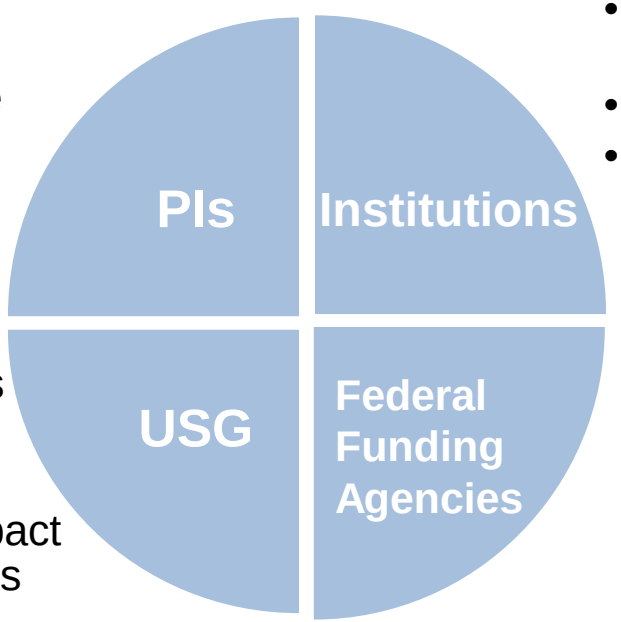
DURC Oversight: A Shared Responsibility Throughout the Research Continuum



USG Policy for Institutional DURC Oversight - Roles and Responsibilities

- Identify projects that should be reviewed
- Train and educate lab personnel
- Conduct and communicate DURC responsibly

- Establish policies and practices for identification and oversight of DURC
- Ensure appropriate review of research
- Educate and train employees
- Report to funding agencies as required (including noncompliance)

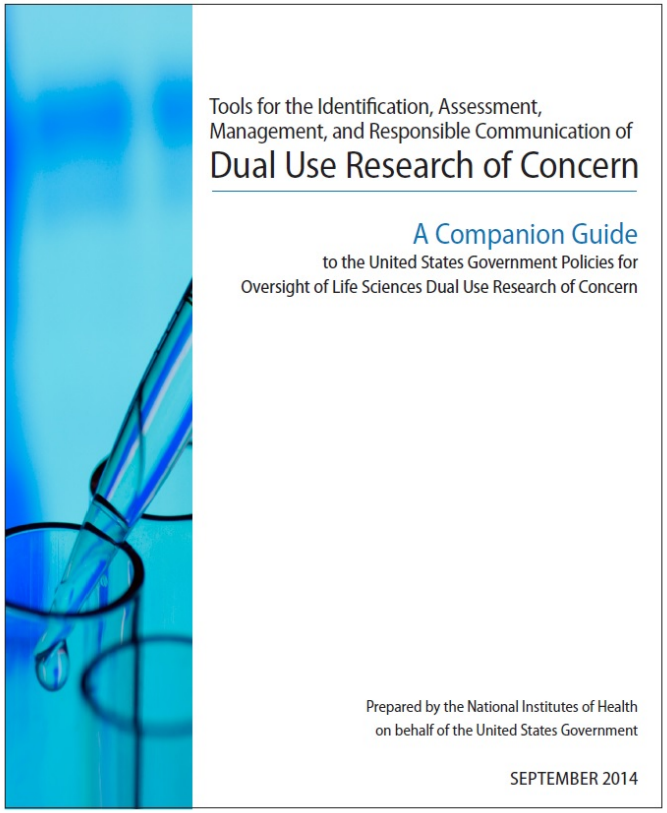


- Develop and disseminate training tools and materials
- Education and outreach to stakeholders
- Periodically assess the impact of the policy on life sciences research programs
- Update policies as appropriate

- Review funded research
- Work with institutions to develop risk mitigation plans
- Assist institution in complying with policy

Resources for PIs and Institutions

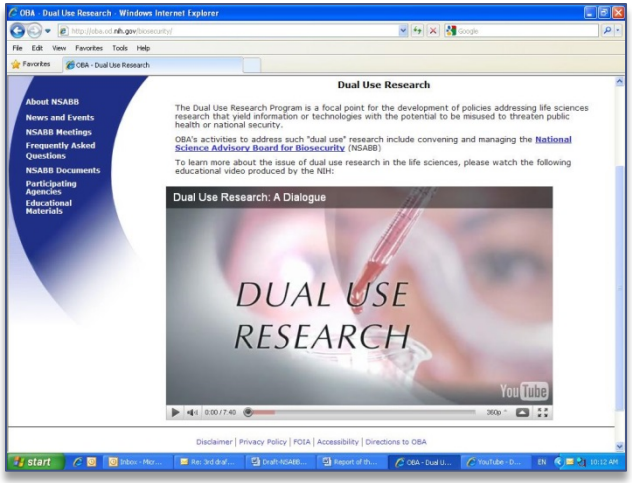
The Companion Guide: *Tools for the Identification, Assessment, Management, and Responsible Communication of DURC*



- **Qs & As on the USG Policies for the Oversight of DURC**
- **Framework for Risk-Benefit Assessment and Risk Mitigation**
- **Guidance for the Responsible Communication of Research with DURC Potential**
- **Resources for outreach and education on dual use research**

Educational Tools on DURC

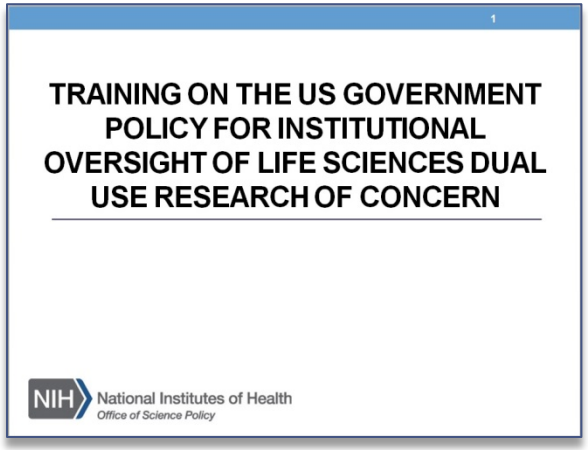
Educational DVD



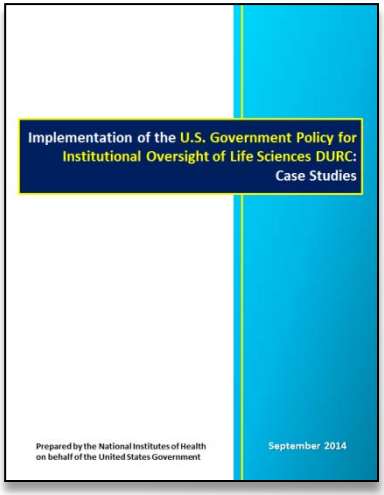
Online video

Brochure for PIs

Awareness-raising poster



Training slides



Case studies

www.phe.gov/s3/dualuse

Future Education and Outreach on Policy for Institutional DURC Oversight

- During the 1-year implementation period, the USG will engage with the research community
- Stakeholder meeting
  - Educate institutions on key responsibilities under the oversight policy
  - Learn about the experiences of institutions
  - Identify challenges in implementing the policy

GOF Studies

- The USG supports research aimed at understanding pathogens toward the goal of preventing and treating their infections.

- Some researchers have used a GOF approach to better understand the genetic determinants of pathogenicity, transmissibility, and host range in certain pathogens.

- The recent series of laboratory incidents at U.S. facilities has caused the federal government to reassess the risk-benefit calculus that underpins funding for certain types of GOF studies.

GOF Studies Have Raised Concerns

- **Dual Use:** Do the studies generate information that could be utilized to create a potentially human-transmissible form of a pathogen that, in the wrong hands, could be intentionally released to threaten public health and security?
- **Biosafety:** Could the engineered pathogens accidentally infect a lab worker or be released into the environment?

Should such research findings be communicated? If so, how can they be responsibly communicated?

Under what conditions can these studies be safely conducted?

Should this type of research be conducted at all?

Guiding HHS Funding Decisions for HPAI H5N1 Gain-of-Function Research: A Framework

- Requires **additional in-depth and multi-disciplinary review and approval, prior to being funded,** for a subset of proposals for research of greatest concern:
  - Research that is reasonably anticipated to generate HPAI H5N1 viruses that are transmissible in mammals via the respiratory route
- Has been expanded to include review of similar proposals involving H7N9 virus

GOF Deliberative Process and Research Funding Pause

- On October 17, the White House Office of Science and Technology Policy and Department of Health and Human Services announced that USG was launching a deliberative process to assess the potential risks and benefits associated with GOF studies.
- During the period of deliberation, the USG instituted a pause on funding for any new studies that include certain GOF experiments involving influenza, SARS, and MERS viruses.
- Specifically, the funding pause will apply to research that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.

Deliberative Process Will Involve Two Complementary Entities

NSABB

- Draft a set of recommendations for GOF research that will be reviewed by the broader life sciences community
- Serve as the official Federal advisory body for providing advice on oversight of this area of dual use research

National Academies

- Convene scientific conferences to facilitate broad discussion of the issues associated with GOF research, to include discussion of the NSABB draft recommendations

Estimated Timeline*

Oct-Nov 2014
NSABB deliberates key features of study design

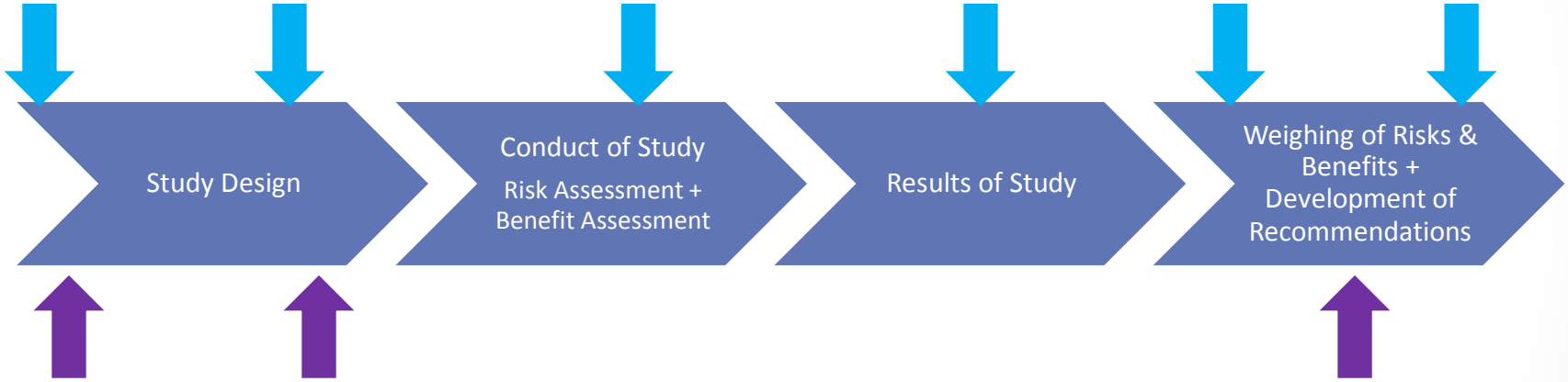
Nov 2014-Jan 2015
NSABB considers National Academies input & advises on draft study design

Early 2015
NSABB periodically assesses progress & reviews preliminary results

June 2015
NSABB reviews final results

June 2015
NSABB analyzes & discusses results → Develops draft recommendations

August 2015
NSABB delivers final recommendations to USG



Dec 2014
National Academies host Public Symposium to discuss assessment of GOF research

Jan 2015
National Academies provide Symposium Summary

July 2015
National Academies host Public Symposium to discuss NSABB draft recommendations & provide Symposium Summary

*The USG intends for these efforts to occur as expeditiously as possible, and dates are subjects to change based on the deliberative process.

Additional Information

Information about dual use research in the life sciences, the DURC policies, and the GOF deliberative process and research funding pause, please see the following:

www.phe.gov/s3/dualuse