

USG Perspectives on Life Sciences Research Oversight

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Extraordinary Benefits of Life Sciences Research

Life sciences research underpins:

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

However, certain kinds of life science research can be inherently risky given the possibility for biosafety lapses or deliberate misuse.

DURC and ePPP

Dual Use Research of Concern (DURC)

A subset of life sciences research that has the greatest potential for generating information that could be readily misused to threaten public health and national security

Pandemic Potential Pathogens (PPP)

- A PPP is a pathogen that both: 1) is likely highly transmissible and likely capable of wide and uncontrollable spread among humans, and 2) likely highly virulent and likely to cause significant morbidity and/or mortality in humans.
- An enhanced PPP (ePPP) is a PPP resulting from the enhancement of the transmissibility and/or virulence of a pathogen.

Oversight of DURC & P3CO

- Dual Use Research Of Concern (DURC)
 - USG Policy for Oversight of Life Sciences DURC (March 2012) requires federal funding agencies to identify DURC in their research portfolios and work to mitigate risks as needed
 - USG Policy for Institutional Oversight of Life Sciences DURC (effective 2015) requires federally-funded research institutions to establish a system to identify DURC and work with funding agencies to mitigate risks as needed
- Potential Pandemic Pathogen Care and Oversight (P3CO)
 - OSTP P3CO Policy Guidance (2017) directs Federal departments and agencies to adopt a department-level, multidisciplinary, pre-funding review mechanism
 - HHS P3CO Framework (2017) ensures HHS department-level pre-funding review and evaluation of proposed ePPP research

Opportunities and Challenges

- Have the DURC policies been effective, including related to: pathogen list and experimentation type; publication, public communication, and dissemination of dual use research methodologies and results; and, impact on research institutions.
- Reevaluate the DURC definition, considering the COVID-19 pandemic, life science advances, and convergence with other disciplines.
- What is the relative value of different types of experiments and are there some types of experiments that may be too risky and/or not need to be done?