EMORY UNIVERSITY | Research Administration

Dual Use Research of Concern

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Critical Challenges of DURC

- As Dr. Wolinetz, the current Director of the NIH Office of Science Policy, wrote in her 2012 article in Science, “there is still no consensus on how to practically define DURC; whether it is feasible to identify and regulate DURC experiments; how to address risks associated with DURC; and how to balance this risk with the necessity of fostering life sciences research for public health and biodefense.”

NSDD 189

- (NSDD) 189 is a federal policy expressing the principle that openness is essential to scientific progress and should be preserved whenever possible

- *"No restrictions may be placed upon the conduct or reporting of federally-funded fundamental research that has not received national security classification."*

- DURC Policy examples of mitigation plans, e.g., redaction, modification of protocols, are often not consistent with NSDD-189.

Basic Research & Export Control Regulations

- If a federal agency makes a determination that part of a research study should not be published or communicated (i.e., it becomes “classified research”) this would trigger export control requirements.

- Such a determination in advance of the work could impact the work of foreign national members of the research team even if they do not have a direct role in the laboratory due to ”deemed export” rules.

The Challenge of Institutional Uniformity

- A single process or procedure for all universities to review and oversee dual use research is not feasible or appropriate.
- Universities differ by size, sector, funding sources, and scientific expertise and interests.
- These differences influence the types of review and oversight processes implemented at public and private institutions.

Are Universities Equipped to make DURC decisions?

- Use IBC?
- Constitute separate IRE?
- DURC criteria are not clearly defined.
  - Is it possible to do so?
- Role of Journals?

IBCs Often Serve as IREs

Challenges:

IBCs are constituted to evaluate the safety of research protocols involving rDNA. This is very different from evaluating the risk/benefit associated with potential dual use concerns.

IBC minutes are required to be made available to the public upon request. Is this wise for DURC deliberations?

Are colleagues from the same institution best positioned to evaluate DURC and develop mitigation plans if they may impact the PI's academic standing and that of his/her team?

PI/Lab Decisions

- How do you evaluate the risk of performing research that runs the risk of DURC?

- Publication restrictions can lead to:
  - Funding
  - Students
  - Trainees
  - Career Advancement (Tenure and Promotion)

Research Outside the DURC Policy Scope

- Research institutions are encouraged to be mindful that research outside of the scope articulated in this Policy (Section 6.2) may also constitute DURC. Institutions have the discretion to consider other categories of research for DURC potential and may expand their internal oversight to other types of life sciences research as they deem appropriate, but such expansion would not be subject to oversight as articulated in this Policy.

Application of DURC Regulations

- Many leading schools do not have select agent programs.
  - Emory
  - Stanford
  - Yale
- However, faculty frequently consult biosafety professionals and IBC members with concerns that studies not involving the 15 agents and 7 techniques may still lead to DURC outcomes.
- The potential for dual use research to emerge from non-Select Agent and non-microbiological research has been demonstrated several times.

Opportunities Lost?

- It is impossible to measure the value of research not conducted because investigators avoid experiments which may be deemed DURC (regulated or not) leading to the constraints and outcomes referenced above.

Summary

- We share the US Government's interest in mitigating the real risks of DURC, however, we are equally concerned with the potential for impeding important research that may lead to the prevention or treatment of diseases caused by these infectious agents.