

DGOF Research elements of EO 14292: Improving the Safety and Security of Biological Research

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The Engineering Biology Research Consortium (EBRC)¹ applauds the Trump Administration’s commitment to ensuring that the United States continues to “[drive] global leadership in biotechnology, biological countermeasures, biosecurity, and health research” while recognizing the need for robust biosafety and biosecurity measures. EBRC is a non-profit, public-private partnership that works with/across government, academia, and industry to advance engineering biology research and the bioeconomy across our four focus areas, one of which is security. We stand ready to support OSTP and interagency implementers as Executive Order 14292: Improving the Safety and Security of Biological Research is translated into actionable policy. Here, we provide recommendations for dangerous gain-of-function research (dGOFR) policy replacing dual-use research of concern and research with pathogens with enhanced pandemic potential (DURC / PEPP).

A transparent, implementable policy

Policymakers, biosafety officers and other biosafety experts, biosecurity and biodefense experts, and researchers have worked together for decades to make progress toward an understanding of the types of research that need higher oversight and scrutiny. **New policy should be built upon shared understanding of hazard, risk, risk-mitigation, and global health needs.** Policy should seek to be transparent, both with the general public but also with the research community; institutions, biosafety officers, biosecurity experts, and researchers need to understand how—and by which criteria—decisions about “dangerous gain-of-function research” dGOFR will be made, and who will make them.

Defining scope of covered research

The forthcoming revised Framework must define “dangerous gain-of-function research” (dGOFR) with precision and clarity. The definition in Section 8 of EO 14292 is challenging to interpret and thus will lead to inconsistent implementation if unchanged in a new/revised framework. Inconsistent implementation would undermine safety and security. The definition of dGOFR in Section 8 of EO 14292 includes the following three components:

1. “dangerous gain-of-function research means scientific research on an infectious agent or toxin with the potential to cause disease by enhancing its pathogenicity or increasing its transmissibility.”
2. Research activities “that could result in significant societal consequences”
3. Research activities that “seek or achieve” the 7 listed outcomes.

¹ The Engineering Biology Research Consortium brings engineering biology researchers and other stakeholders from industry and academia together with policymakers to advance engineering biology to address national and global needs. EBRC White Papers are developed with significant, substantive direction, guidance, and input from EBRC members through an interactive process. EBRC products do not necessarily reflect the direct views of all EBRC members.

Key comments:

- It is unclear if all three conditions have to be met for research to qualify as dGOFR. New or revised policy should make clear that all three conditions must be met. **The definition should be clear, precise, and narrow.**
 - The outcomes listed in EO 14292 cover a broad swath of research.
 - Currently, “significant societal consequences” provides some limitation as to the research covered. However, this phrase is imprecise and could cover basic BSL-1 research that would yield, for example, at-home diagnostics for endemic viruses or advance crop security. If this phrase is used in the final policy, it should be clearly and narrowly defined.
 - The phrase “could result in significant societal consequences” could instead be replaced by a list of agents or organisms that are of particular concern, and/or could cover pathogens that must be handled at certain biosafety levels.
- **In silico experiments** should be explicitly excluded (for the time being). Stakeholder conversation is on-going as to the actual associated hazards and alternative approaches to mitigation.
- Exemptions should be made explicit for certain types of work such as biosurveillance, diagnostics, and vaccine development.
- Research sometimes yields unanticipated outcomes. Researchers and their institutions should be held responsible for implementing biosafety and biosecurity measures consistent with their understanding of a hazard at a given moment in time.
- DGOFR policy should provide appropriate steps for researchers and institutions to take if research is determined to fall within the policy after experimentation has begun.

Review and oversight of covered research

EO 14292 Section 4.a.i. requires the new/revised Framework to “strengthen top-down independent oversight” for DGOF research. Responsibilities and mechanisms for top-down *review* (after funding recommendations have been made, but before funding is awarded) and top-down *oversight* (after funding has been awarded) of covered research should both be described.

Both *research review* and *oversight* should be conducted by review panels or oversight entities:

- Whose members have sufficient subject matter expertise. Experts in virology, epidemiology, engineering biology, policy, public health, biosafety, and biosecurity should be included;
- Whose processes and assessment criteria are made clear to the research community;
- Whose decisions/conclusions are articulated to the PIs and institutions affected;
- Whose decisions can be appealed by PIs/institutions;
- That is free from political influence; and
- That is adequately staffed.

Furthermore,

- *Research review* entities must be technically able to consider and balance anticipated benefits and risks of research.
- *Oversight* entities should be imbued with adequate enforcement authority, which may involve periodic review of safety and security practices and, if necessary, adjustment of award terms, termination of grant awards, etc. This authority should be used judiciously.

Non-federally funded research

We applaud the Administration’s recognition that no mechanism currently exists to ensure that privately- and industry-funded research are held to the same safety and security standards as publicly-funded research. Any proposed mechanism should seek to **work with the safety and security oversight processes already in place across industry and enhance consistency while safeguarding the intellectual property that makes America a fierce global competitor.**

Transparency

EBRC supports transparency. We encourage the Administration to ensure that **review processes and criteria for dGOFR are communicated clearly and transparently to the research community**. We also encourage the Administration to consider very carefully which information about specific project reviews is made publicly available, recognizing that i) if too much information were shared, adversarial nations could use it to their advantage and our detriment; and ii) over-sharing of certain personal information of researchers and reviewers could make involved parties and laboratories the targets of personal threats, and/or point a malicious actor seeking to do harm to institutions where they might steal/obtain materials that would hasten the development of biological weapons.

Clarity on international funding and partnerships

The language of EO 14292 Section 3.a.ii. importantly recognizes that biosafety and biosecurity practices are not uniform around the world. However, some nations with underdeveloped biosafety and biosecurity practices and oversight are also nations where diseases that could seriously jeopardize public health in the US are endemic or are most likely to spill over from animal populations. It is in our nation's interests to work in partnership with such countries to understand and develop countermeasures and biosurveillance capabilities for associated diseases. **Cutting off US collaboration in key regions could backfire. It risks weakening global early-warning systems, undermines our response capabilities, and opens the door to influence from adversarial nations.** Instead, the US can support these international partners in further developing biosafety and biosecurity practices and oversight. The US can support the implementation of practices consistent with U.S. technical safety and security standards. As appropriate, facilities within or overseen by the U.S. could undertake any necessary high risk research, thereby ensuring adequate oversight.

Further, OSTP policy should provide greater clarity as to the scope of life-sciences research that is covered by EO 14292 3.a.ii. in addition to mechanisms by which compliance with US standards and policies can be demonstrated.

Clarify current vs future policy

Forthcoming policy will need to give implementers time to modify existing research review and oversight systems, but should also provide interim guidance. Careful consideration should be given to the security gaps and waste of federal funding incurred by rapid and unexpected changes to policy, uncertainty about policy, and stays on funded research.

Enforcement

Mechanisms for enforcement should encourage appropriate research review and oversight without being overly punitive. Minor misunderstanding or misinterpretation of policy should be met with **correction and penalty consistent with the magnitude of deviation from policy**. Revocation of all institutional Federal funding would weaken America's research base and undermine our global competitiveness and should instead be reserved for instances of significant negligence.

Alignment with NSCEB Recommendations

The recent report from the bipartisan National Security Commission on Emerging Biotechnology recommends the development of a new, centralized entity for biosafety and biosecurity oversight within the Federal government. With a Congressional Commission and the Executive Branch focused on these issues, OSTP should seek to align new policy with NSCEB proposals to support an independent, uniform, holistic approach to biorisk management that includes regular assessment and updating of policies.

EBRC is ready and willing to be a resource to the Administration at any point as it works to update policy around these critical issues. We look forward to maintaining the strong connection between the technical research community and policymakers that ensure that the US remains the global leader in responsible, secure life sciences research and innovation.