

United States Senate

WASHINGTON, DC 20510
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<http://www.senate.gov>

September 9, 2021

The Honorable Gene Dodaro
Comptroller General
U.S. Government Accountability Office
441 G St., N.W.
Washington, DC 20548

Dear Comptroller General Dodaro:

We write to request that the Government Accountability Office (GAO) produce a report on the following matters:

- 1) An audit of U.S. government authorities, policies, and processes governing cooperation with other nations as it relates to life sciences research that could be weaponized or pose dual-use concerns, such as pathogens or toxins, synthetic biology, and related emerging technologies, and the degree to which these authorities, policies, and processes account for national security, proliferation, and country-specific considerations in decisions on whether to pursue such collaboration.
- 2) An assessment of the degree of coordination between Federal departments and agencies responsible for public health preparedness and the governance of biomedical research and Federal departments and agencies responsible for national security, especially the U.S. Department of State, to assess and account for security implications of cooperation with other nations on life sciences research.

International cooperation in the life sciences provides opportunities to advance global health security and bring forward new treatments, therapies, and medical countermeasures. However, certain categories of research – for example biological research that could be weaponized – also present significant risks to the health and national and economic security of the United States. Such risks grow if conducted with foreign governments that do not share U.S. policy goals, where concerns exist about the country’s compliance with the Biological Weapons Convention or its pursuit of dual-use research, and/or in countries that have inadequate biosecurity standards and practices. The rapid development of the life sciences also requires government oversight to keep pace. As a 2018 National Academies of Sciences, Engineering, and Medicine report pointed out, “Biotechnology in the age of synthetic biology expands the landscape of potential defense concerns.”

These challenges require attention of the public health preparedness and biomedical research agencies like the U.S. Department of Health and Human Services and national security agencies like the U.S. Department of State, and require appropriate oversight related to national security, proliferation, and other concerns.

There are a number of questions we would like the GAO to address in its investigation:

1. Which Federal department or agencies or other governmental entities provide funding or other material support for life sciences research, especially biological research, with other nations?
2. What authorities, policies, and processes currently exist for reviewing and approving grant funding or other material support for biological research with other nations? Which Federal departments and agencies, including specific bureaus and offices, are involved? What are the steps within these review, approval, and monitoring processes?
3. Under what circumstances is enhanced review, monitoring, and coordination among federal departments and agencies applied to proposed collaboration? To what extent and how are national security, proliferation, or country-specific considerations, such as a nation's adherence to the Biological Weapons Convention, among the circumstances that trigger enhanced scrutiny of whether the U.S. government should fund a particular research program? How are these considerations accounted for throughout a process of deciding whether the U.S. government should fund such research?
4. To what extent and how do federal departments and agencies that support biomedical research coordinate with federal departments and agencies responsible for national security on U.S. government funding or other material support for life sciences research collaboration with other countries? Similarly, to what extent and how do federal departments and agencies responsible for national security proactively coordinate with federal departments and agencies that support biomedical research to appropriately share information and help inform decisions on U.S. government funding or other material support? In instances where coordination by statute or regulation is required, is such coordination actually occurring, and what does it look like?
5. What information is required to be included in an application for U.S. government funding of life sciences research to address potential national security, proliferation, or country-specific concerns? How does this vary across departments? To what extent do federal departments and agencies with national security responsibilities have visibility into such information, even if grantees are applying to funding from another federal department or agency?
6. Once a grant or other funding for international research involving pathogens, toxins, or related technologies that could be weaponized or pose dual-use concerns is approved, what are the processes and timeline by which funds are issued to the awardee or awardees, and to what extent are these funds monitored for national security implications thereafter? How, if at all, are federal departments and agencies with national security responsibilities involved in such research after funds are awarded?

Thank you for your prompt attention to this request. We view this effort as critical to the committees' future oversight of the appropriate roles and responsibilities for the Department of

Mr. Gene Dodaro
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State and the Department of Health and Human Services to uphold and improve biosecurity and prevent the misuse of the life sciences by our adversaries.

Sincerely,

A handwritten signature in blue ink, appearing to read "J. Risch".

James E. Risch
Ranking Member
Senate Foreign Relations Committee

A handwritten signature in blue ink, appearing to read "R. Burr".

Richard Burr
Ranking Member
Senate Health, Education, Labor and
Pensions Committee