



8120 Woodmont Avenue, #750,
Bethesda, MD 20814-2762
(301) 347-9309; (301) 347-9310 (fax)
www.coalitionforlifesciences.org

RE: RFI on the American Research Environment

Transmitted electronically to JCORE@ostp.eop.gov

The Coalition for the Life Sciences (CLS) appreciates the opportunity to provide comments on the Request for Information (RFI) on the American Research Environment. The CLS is an alliance of professional organizations working together to foster public policies that advance basic biological research and its applications in medicine and other fields.¹

We focus our comments on research security – an area of utmost concern for the CLS and a subject core to sustaining a global research enterprise.

First and foremost, we must avoid the unintended consequences of harming the very enterprise we hope to protect. Any response should consider the more than 300,000 international students and 75,000 foreign-born faculty members working in American universities and research institutes, where they have contributed profoundly to the research endeavor.² One of the great strengths of the US research enterprise is that its excellence motivates top researchers from around the world to participate in the US rather than drawing solely from our national pool of talent. To highlight this point, please note that 25% of American Nobel Prize winners in Chemistry, 25% of American Nobel Prize winners in Physics, and 29% of American Nobel Prize winners in Medicine or Physiology were born outside the US. We must continue to cultivate an environment that attracts outstanding scientists from all corners of the world. While we agree that we must be vigilant to safeguard research against unethical actors by addressing weaknesses and loopholes in our system, we reaffirm our support for thousands of law-abiding international researchers and want to ensure preservation of the global scientific community.

¹ More information about the CLS can be found at its website:

<https://www.coalitionforlifesciences.org/about-us>.

² National Science Board, National Science Foundation, 2018, *Foreign-Born Students and Workers in the US Science and Engineering Enterprise* [Fact Sheet], Retrieved from

<https://nsf.gov/nsb/publications/2018/foreign-born-one-pager.pdf>

1. How can the US government work with organizations that perform research to manage and mitigate the risk of misappropriation of taxpayer or other funds through unethical behaviors in the research enterprise?

While universities and research institutions should have wide discretion to recruit the most talented researchers, it is incumbent upon these employers to require financial and affiliation disclosures. Indeed, this is standard practice, applied at least to faculty, to avoid conflicts of interest and conflicts of commitment. These disclosure agreements should extend to anyone involved in the research, supported financially for doing the research, and with access to proprietary information. For those in these positions, full disclosure should be mandatory. In alignment with standard practice at most institutions, disclosed information should include, but not be limited to, foreign financial support and associations.

The National Institutes of Health (NIH) has worked with research institutions to address non-disclosure issues as appropriate. To date, they have uncovered problems at > 70 awardee institutions (<3% of the total number of NIH-funded institutions) related to this issue. Their efforts have directly or indirectly led to a range of actions³:

- Termination or suspension of scientists who have engaged in egregious violations of NIH grant terms and conditions and institutional policies;
- Interventions to address previously un-reported affiliations with foreign institutions;
- Relinquishment or refund of NIH funds;
- Prohibition of certain individuals from serving as investigators on NIH grants;
- Outreach to FBI for assistance;
- Discovery (through acquisition of certain foreign grants and contracts) of overlapping or duplicative work, or conflicts in stating committed effort to research projects. This discovery has led to NIH suspensions of active grants as appropriate.

CLS generally supports NIH's efforts to address issues relating to security breaches, and the CLS understands that actions must be swift. At the same time, we urge the agency to uphold the imperative for open science and to avoid the appearance of bias against the participation of foreign born scientists in this endeavor. Standard procedures to address research misconduct should be used, including institutional notification to NIH,

³ Securing the US Research Enterprise from China's Talent Recruitment Plans: Hearing before the Senate Homeland Security and Governmental Affairs Permanent Subcommittee on Investigations, Senate, 116 Cong. (Testimony of Michael S. Lauer, M.D.)

institutional investigation, review and reporting to NIH, and NIH posting validated cases of misconduct on the Office of Research Integrity public website.

2. **How can the U.S. government best partner across the research enterprise to enhance research security?**

In the past year, government agencies with large science portfolios have made policy and practice changes to better manage and secure research programs against improper influence or appropriation of US intellectual property by foreign governments. They have reached out to universities and research institutions across the country to raise awareness of the problem and determine best practices to address and minimize theft of proprietary information. Many steps are highlighted in a report issued by the Senate Homeland Security and Government Affairs Committee (HSGAC) that recommends ways the federal government can partner with the research enterprise to protect and enhance research security.

The CLS supports and encourages JCORE/OSTP to adopt the following from the HSGAC Report⁴:

- Support for agency compliance programs and inspectors general;
- Research institutions should establish best practices in monitoring scientific and research collaboration with foreign nationals;
- Federal agencies must develop a comprehensive strategy to combat both illegal and extralegal transfers of US intellectual capital;
- While taking steps to better protect research and intellectual property, Congress and the Executive Branch should reaffirm the critical importance of foreign students and researchers in the United States and the importance of international research collaboration;
- US grant-making agencies should standardize reporting requirements for disclosing all foreign conflicts of interest, conflicts of commitment, and all outside and foreign support;
- US grant-making agencies should work with research institutions to ensure they have the necessary cybersecurity practices in place to reduce the risk of research data misappropriation.

While we support those ideas, CLS reiterates that policies to enhance security not harm open science and the global research ecosystem. Visas for attendance at scientific conferences should not be unnecessarily

⁴ US Senate, Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs: *Threats to the U.S. Research Enterprise: China's Talent Recruitment Plans*. <https://www.hsgac.senate.gov/imo/media/doc/2019-11-18%20PSI%20Staff%20Report%20-%20China's%20Talent%20Recruitment%20Plans%20Updated2.pdf>

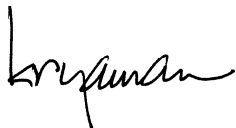
restricted or delayed. Security practices should not discriminate selectively against particular nations or ethnic groups.

3. What other practices should organizations that perform research adopt and follow to protect the security and integrity of the research enterprise?

NIH and other funding agencies must protect the integrity of peer review of grant applications as part of monitoring scientific misconduct. Notably, however, current policies are sound: NIH staff is trained to identify and report suspicious activity and peer reviewers twice sign a clearly stated confidentiality agreement during the review process. In addition, an oral and written definition of what constitutes breaking confidentiality is revisited at the start and end of peer review meetings.

Depending on the severity of the misconduct, violators could be barred from future participation in peer review, and from applying for or receiving NIH funds for research.

Sincerely,

A handwritten signature in black ink, appearing to read "K. Yamamoto".

Keith R. Yamamoto, Ph.D.
Chair, Coalition for the Life Sciences
Vice Chancellor for Science Policy and Strategy, UCSF
Director, UCSF Precision Medicine
Vice Dean for Research, School of Medicine
Professor, Cellular & Molecular Pharmacology