COGR

Council On Governmental Relations

An Association of Research Institutions

January 27, 2020

Chloe Kontos
Executive Director
National Science and Technology Council
White House Office of Science and Technology Policy

RE: Request for Information on the American Research Environment [FR Doc. 2019-25604]

Transmitted Electronically via email: JCORE@ostp.eop.gov

Dear Ms. Kontos,

The Council on Governmental Relations (COGR) is an association of 188 research universities and affiliated academic medical centers and independent research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.

We are pleased to provide you with our response, attached, to the November 26, 2019, OSTP Request for Information on the American Research Environment. We very much appreciate the extension of the deadline, which allowed us to provide much more thoughtful input.

Please feel free to contact me at (202) 289-6655, or by email at wstreitz@cogr.edu if you have any questions.

Sincerely,

Wendy D. Streitz
President

COGR's Response to the RFI on the American Research Environment [FR Doc. 2019-25604]

The Council on Governmental Relations (COGR) is an association of 188 research-intensive universities and affiliated academic medical centers and independent research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. We very much appreciate the important work that the Office of Science and Technology Policy (OSTP) has undertaken through its Joint Committee on the research Environment in convening representatives from across federal agencies to address important issues affecting research and to make the most efficient use of federal research dollars. These cross-agency efforts are critical to solving many of the long-standing problems that have grown over the last few decades, with the significant growth of research funding, accompanied by significant increases in administrative requirements. At the same time, the U.S. dominance in research is being challenged by other nations, most notably China[1]. Our researchers spend a significant portion of time trying to meet myriad and often conflicting requirements from federal agencies. If we are to maintain our competitive position, agencies must work together and in dialog with research institutions and associations to address key issues. COGR is pleased to be able to provide input on actions that could be taken to maximize the effectiveness of the American research environment.

As an overarching observation, agency requirements are promulgated by a variety of means, including rulemaking, policy statements, guidance, frequently asked questions (FAQs), and even proposed information collection notices. In some cases, there is an opportunity for the grantee community to comment and provide input, but in many cases, there is not. When there is no advance opportunity for input, the resulting requirements can lack clarity, introduce confusion, and be difficult to implement, ultimately placing an unnecessary burden on grantees, while at the same time failing to meet the underlying objectives of the agency. A better outcome is almost always achieved through consultation, especially when, as now, there are many moving parts. If there is anything OSTP can do to drive such consultation and dialog as a standard part of issuing new or revised agency requirements, we believe the grantee and grantor communities would both be better served.

The following are our more specific comments on the issues presented in the RFI.

Research Rigor and Integrity

In 2018, COGR issued a survey report of several excellent suggestions and examples of resources for institutions to promote research quality and foster rigor and reproducibility[2]. Resources include computing, biostatistical/statistical support, data analysis, data management, mentoring, training, and other tools and information.

Meanwhile, the National Institutes of Health (NIH) and the National Science Foundation (NSF) have both

[1] https://ncses.nsf.gov/pubs/nsb20201/global-r-d

[2] https://www.cogr.edu/sites/default/files/COGR%20Report%20on%20Institutional%20Resources%20for%20Promoting%20Research%20Quality.pdf

engaged in significant efforts to strengthen rigor and reproducibility in science. We recommend an assessment of the progress that federal agencies have observed or documented over the last several years to help determine next steps. For example, are applicants incorporating the principles of research rigor and reproducibility into proposals? Are there differences across disciplines? Are there success stories around holding reviewers and investigators accountable for research rigor and reproducibility?

In addition, federal funding agencies could consider:

- recognizing and giving investigators "credit" for negative studies even if they do not get published, for example, reporting these results in progress reports or highlighting this in other ways
- publishing models of rigorous experimental design for several disciplines
- consistently encouraging researchers to list data sets and code as a product of research to be included in progress reports, which would allow high-quality research outputs (other than published papers) to be rewarded and recognized
- supporting scientific societies in the development of research rigor and reproducibility standards of their discipline
- partnering with international scientific organizations to help incorporate standards to advance and help change the culture beyond the U.S.
- providing funding to support rigor and reproducibility

Coordinating Administrative Requirements for Research

As noted at the beginning of this document, inconsistent, duplicative, or unclear regulations may place an additional burden on research institutions and their investigators, thereby diminishing the effectiveness of the national investment in research, and creating an unreimbursable expense, since the administrative portion of indirect costs are capped[3]. As an example, recent reminders and new guidance issued by NIH caused a great deal of confusion regarding what information about other support to disclose and where to disclose it, mainly since forms were not updated to reflect the new/clarified requirements. Federal agencies should be required to issue revised relevant forms and instructions simultaneously to match new policies and guidance (or significant reinterpretation of former policies and guidance).

Conflict of Interest

Closer alignment of federal conflict of interest policies would be a significant improvement to administrative burden and could be achieved by revisiting the reporting thresholds for significant financial interest. In 1995, both the NIH and NSF issued financial conflicts of interest policies that set a reporting threshold of $10,000 for disclosing financial relationships. This threshold has not been increased since then, and, indeed, the 2011 Public Health Services (PHS) regulation reduced that reporting threshold by half. The American Association of Medical Colleges (AAMC) issued a report in April 2015 that demonstrated a substantial increase in disclosures due to the lower reporting threshold under the 2011 regulations, with no corresponding increase in risk to the objectivity in

[3] NAS report on Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century, p. 6

research[4].

In addition to raising the reporting threshold, we recommend that the PHS regulation be revised to eliminate the requirement to report routine sponsored travel, which is not required by any other federal sponsor. The high burden, which translates to unreimbursed expense related to reporting sponsored travel, does not justify the marginal benefits in identifying risks to objectivity in research[5]. Reporting of sponsored travel could be implemented on a case-by-case basis, for example, as part of a management plan, without creating burdens for tens of thousands of other researchers.

Retrospective reviews should also be eliminated from the PHS regulations, which provide little benefit, but which add significantly to the administrative burden and expense.

A move that would have an even more significant impact would be for the federal government to implement a single, streamlined federal-wide conflict of interest policy. The policy could address the needs of federal agencies, hold institutions and investigators accountable, reduce distractions and waste associated with maintaining multiple systems and procedures, enable individuals and institutions to focus on objectivity in research, and could significantly improve efficiency and compliance[6]. We recommend that such a federal-wide conflict of interest policy be modeled on the NSF policy, eliminating myriad federal requirements with different standards and reporting requirements[7]. The NSF policy is well-understood and efficient, and requires that:

- research institutions have a policy that addresses objectivity in research;
- investigators disclose significant financial interests before the expenditure of federal funds and at least annually after that; and
- institutions inform the sponsor when a conflict of interest exists that cannot be appropriately managed.

While we support a harmonized policy, COGR would oppose any move to use the 2011 PHS FCOI rules as the basis for such a federal-wide policy since we have already demonstrated that this policy is unnecessarily costly and burdensome. Any new harmonization effort would need to be done thoughtfully in collaboration with experts at research institutions who effectively manage research conflicts of interest.

Proposal Submission and Awards

The current system of proposal submission and issuance of research funding through 26 different federal funding agencies (including over 100 Department of Defense (DOD) awarding components, numerous Department of Energy (DOE) awarding components, and 26 funding offices within the NIH) is an inefficient use of federal

[4] Proposed Collection; Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought 42 CFR Part 50 Subpart F and Responsible Prospective Contractors 45 CFR Part 94 (OD) https://www.cogr.edu/sites/default/files/NIH_Request_for_3-year_Extension_of_Reporting_Requirements_Associated_with_Revised_FCOI_Requirements.pdf

[5] AAMC COI Metrics Project: Measuring the Cost and Outcomes of the NIH Rule on Financial Conflicts of Interest in PHS-Funded Research https://www.aamc.org/what-we-do/mission-areas/medical-research/conflicts-of-interest/metrics-project

[6] NAS report on Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century, p. 7

[7] https://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510

research dollars and creates high administrative burdens at recipient institutions. As a bold move, the federal government could implement *one* system for receiving grant proposals and issuing research and education awards, using standard formats and Research Terms and Conditions for all research assistance awards, eliminating one-offs and requirements that are not essential to the process. High level science policy leadership and agency/program-specific expertise is still key to the process, for example, setting the research agenda, peer review, selection of the most meritorious projects, and portfolio management. Note that many, though not all agency-specific requirements are due to Congressional mandates. Legislative action may be required to fully effect this change.

An essential overarching principle for grant submissions would be to limit research proposals to the minimal information necessary to permit peer evaluation of the merit of the scientific questions being asked, the feasibility of answering those questions, and the ability of the researcher or research team to carry out that research. Any supplementary information should, if required, be provided only for proposals selected for funding, i.e., just-in-time [8]. We recommend a three-phase system for as many projects as possible, including:

- Phase 1 - increase the use of pre-proposals to enable federal sponsors to determine the most promising projects with a minimal amount of information to help both applicants and reviewers;
- Phase 2 - for those proposals that are selected to move forward, require only the information necessary to support peer review or merit review of the project being proposed, e.g., the proposal abstract, project description, references, biosketch, and high-level non-detailed budget; and
- Phase 3 - for proposals selected for funding, request any additional supporting information necessary during the just-in-time phase, e.g., other support, facilities/resources, conflict of interest reviews, human and animal subject approvals, detailed budget; budget justification, and training and data management plans.

In addition:

- Consider the minimal amount of information for resubmission of an unsuccessful application, for example, only what has changed since the previous submission.
- Promote consistency across agencies when data are mined in government systems to reduce burden and redundancy.
- Use consistent templates for data management and sharing whenever possible.

Research Security

Disclosure

We understand the need and are supportive of strengthening controls around the disclosure of outside activities. As an overarching suggestion, in order to commit an appropriate level of institutional resources and provide assurance to federal agencies that outside activities are monitored, we encourage OSTP to take a lead role across

[8] NAS report on Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century, Recommendation 4.2, p. 11

all federal agencies in implementing a risk-assessment model focused on the most high-risk outside activities. For example, agencies could set a de-minimis threshold (in dollars or days) above which outside research activities would be reportable. This type of risk-based model would allow institutions and agencies to focus resources on the highest risk activities, rather than those activities that are low risk.

Disclosed information should be used to gain clarification of the nature of any potentially overlapping research support, if any, and plans to address the overlap. The information should not be used to identify "well-funded" investigators that, in the view of the agency, may not require additional public support.

Current instructions, policies, and forms regarding the disclosure of an investigator's current and pending and other support were not designed for the disclosure of every single resource, including, for example, non-financial support that potentially might be relevant to the research. One result is that investigators may not be consistently reporting this information. Federal agencies should directly and unambiguously define activities subject to disclosure requirements as research activities that require a time commitment. If the primary concern is participation in "talent programs" then the investigator should be explicitly asked if they are participating or plan to participate in a "talents program" (e.g., lead or participate in a research program at another institution or mentor students or post docs at another institution). Ideally, reporting of "talent programs" and research activities that take place outside the purview of the applicant institution would be completed using forms separate from those used to report support at the applicant institution and certified by the researcher(s). Disclosures of non-research activities (e.g., non-research consulting) should not be required.

Further, reporting of facilities, personnel, and other resources should only be required if they directly benefit the application. Duplication of reporting should be eliminated wherever possible.

Importantly, we do not believe that the lack of full or accurate disclosures should be considered to be a form of research misconduct. "Scientific or research misconduct" is a well-defined and well-understood term, and it would be entirely inappropriate to expand it to include a failure to disclose other support fully. Rather, intentional incomplete disclosure could be considered something along the lines of "professional misconduct."

As for timing, disclosures of other support, current and pending support, and facilities and other resources should only be required for grant applications that will be awarded. A federal-wide policy to request this information only for grant applications selected for funding will harmonize regulations and reduce unnecessary administrative burden since only about 20% of federal proposals are ultimately funded. Information earlier than this is not helpful or relevant to reviewers of the grant applications; federal agencies should not rely on the peer review process to identify potential undue foreign influence.

Finally, we note that institutions are responsible for developing and maintaining policies and procedures for disclosure that meet the federal standards. Institutions are also responsible for making their investigators aware of those policies and procedures and providing assistance to help investigators comply. To the extent possible, federal agencies should rely on the grantee institution's conflict management policies and procedures for oversight of outside activities and assurance that activities are within the bounds of the institution's requirements, with the realization that risk can never be entirely eliminated. We also note that the institution must necessarily rely on

the investigators for details of any outside activities (e.g., exact dates, funding levels, effort commitment). As such, the primary consequences when investigators fail to disclose significant outside activities should fall on the investigators themselves and not the entire grantee institution. This might include sanctions on an investigator's ability to receive future federal funding but should not go so far as to impact the federal funding of all investigators at the institution.

Partnering

Institutions need timely information on entities and individuals who have been identified by government security agencies to be high risk (in advance of placement on the entity list), including identification of U.S. based associated companies/subsidiaries. If research organizations were made aware of threats or entities that pose risks on a timelier schedule, they would be better able to plan, prepare, and prevent possible security breaches. In addition, the entities list itself does not seem to be kept up to date, as well as it could be. For example, Huawei was not listed until after data breaches and potential espionage had already occurred. If the entities list is kept current and quickly updated when new threats emerge, it will increase the time research organizations have to plan and take actions to protect data and their interests.

Current and timely information on strategies foreign governments are using to procure talent and sensitive technologies (e.g., changes in talent program recruitment strategies) is also needed. Better intergovernmental coordination to create a standard risk assessment process would increase efficiencies and give research organizations a clearer picture of how to handle likely threats. One positive outcome could be a clear, consistent definition of a foreign talent recruitment program for interagency use. A list of organizations that may present concerns because of linkages is not particularly helpful without more information as to the nature of the ties and the concerns raised. Clear communication of the actual degree of risk posed by involvement with a particular foreign entity is necessary so each institution can properly respond based on their risk tolerance and research portfolios.

Guidance on how to communicate potential issues to the government and who in the government to communicate with also would be helpful. Consistent messaging from the government is crucial for keeping stakeholders apprised of new or ongoing developments. The government should target communication to a variety of stakeholders, including institutional leadership, researchers, and staff supporting travel, sponsored programs, export compliance, and global activities. Reestablishing regular high-level communication mechanisms between the academic and security communities could also be quite helpful. One such mechanism could be under the auspices of the Office of the Director of National Intelligence (ODNI) task force to be established pursuant to Section 5722 of the FY 20 NDAA. Strengthening the relationships between research organizations and local FBI field offices to help keep all organizations updated on the most pertinent security issues also would be beneficial. Clear guidance should be provided on expectations and requirements for research security in funding announcements, grants policy documents, notices of award, and contract language. Grant application form sets should clearly call out what information should be provided where, with standardized application and reporting templates across agencies, wherever possible.

The government needs to complete the effort begun a year ago to clearly identify critical early stage technologies.

In doing so, it should adopt a "high fences around narrow areas" approach. The recent Commerce rule imposing controls on software specially designed to automate the analysis of geospatial imagery is a good example. If the result is promulgation of additional export controls covering emerging technologies, fundamental research generally should continue to be exempted in accordance with NSDD 189 and the current fundamental research exclusion (FRE) under export control regulations. If not covered by the FRE, the research should be protected by Technology Control Plans and other requirements set forth in export control regulations.

Other Practices

Institutions should review and revise institutional policies as needed to ensure compliance with expectations of review and transparency. They should also integrate business processes to support central review and oversight of researcher activities. Also, it would be helpful to expand the responsible conduct of research (RCR) training to include more information on the culture and ethics of U.S. research institutions.

The Effective Practices to Address Science and Security Concerns developed by AAU/APLU serves as an excellent mechanism for research organizations to benchmark their efforts to assure the security of research and protect against intellectual property theft and academic espionage by foreign entities (or others). One size does not fit all, and each institution needs to consider its research portfolio, international collaborations, and activities. Institutions differ in their degree of risk tolerance, and these differences must be reflected in the practices they adopt.

Safe and Inclusive Research Environments

Climate surveys conducted by associations, universities, and federal agencies alike have demonstrated that more needs to be done to foster a culture of safe and inclusive research environments. Institution leadership may take many steps to create an inclusive culture, including but not limited to ensuring that there are confidential, anonymous and "safe" places for victims to share their experiences; ensuring follow up and providing mechanisms for victims to return to their research environment; ensuring that the entire campus is responsible for reducing and preventing sexual harassment; and measuring progress through campus-wide reporting.

Preventing harassment in an academic setting from the beginning isn't easy, but a concerted effort by all members of the academic community to embrace the assurance of a harassment-free environment will likely lessen the number of incidents. Proper tones should be set by leadership to instill a culture of respect and a willingness to change power structures within an organization, integrate values, improve transparency, and hold violators accountable for their actions.

Institutions can develop and implement mentoring programs and strategies to reduce sexual harassment in the workplace and ensure that policies, procedures, and codes of conduct are thorough and revisited on a regular basis. In addition, institutions should review and perhaps strengthen anti-retaliation policies protecting those who report harassment.

Another action that could be helpful is to develop checklists regarding the process of an investigation, with respect to both victims and the accused. For example, victims and the accused may each want to consider asking the employer to identify steps to be taken by the employer for purposes of determining, in good faith, the facts of an allegation. Identifying witnesses and maintaining proper records to support allegations will be essential in conducting a fair, objective, and unbiased investigation.

Thank you again for the opportunity to comment on these important issues. COGR is prepared to work with OSTP on improving the effectiveness of the research environment and would be more than happy to provide additional information or answer any questions you may have as you consider actions that may be taken by JCORE.