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January 28, 2020

Chloe Kontos
Executive Director
National Science and Technology Council
Office of Science and Technology Policy
JCORE@ostp.eop.gov

RE: Docket ID OSTP-2019-0006 and OSTP-2019-0007 Request for Information on the American Research Environment (RFI Response: JCORE)

Dear Ms. Kontos:

I write on behalf of the University of California (UC) system with regard to the Notice of Request for Information (RFI) on the American Research Environment originally issued on November 26, 2019 with a notice on December 17, 2019 extending the comment period.

The UC system is comprised of ten research-intensive campuses, six medical schools, and three affiliated U.S. Department of Energy national laboratories. As a system, UC receives approximately $6 billion annually of extramural awards to support research conducted throughout all UC locations.

We wish to emphasize that UC understands the risks and challenges presented by undue foreign influence on research integrity in open academic environments. We welcome partnerships with federal agencies and are grateful for the opportunity to collaboratively address these issues.

While we recognize that the Office of Science and Technology Policy (OSTP) is seeking comments on 17 specific questions that have multiple components, UC respectfully submits comments generally pertaining to JCORE's four main areas. Our comments largely request that the federal government harmonize across agencies and departments, and provide, clear, consistent and regular communication.

In addition to the specific comments provided below, UC supports the sentiments captured in the comment letters submitted by the Association of American Medical Colleges (AAMC), Association of American Universities (AAU), and Council on Governmental Relations (COGR).

I. Improving Research Rigor and Integrity

It is longstanding UC policy that all persons engaged in research at the University are responsible for adhering to the highest standards of intellectual honesty and integrity in research.[1] We strongly value open science, which includes open publication, data sharing, full reporting of methods, maintenance of accurate and detailed research procedures and results, and suitable assignment of credit and responsibility for research and publications. Government and academia have made considerable efforts to invest in strong science, identifying and reducing biases, and increasing transparency and reproducibility. **UC supports continuing these investments and urges OSTP to focus on supporting existing efforts to improve research transparency. In addition, UC believes it is critical for the federal funding agencies to make investments in infrastructure for use throughout the scientific community as well as broadly promoting scientific ethics and integrity.**

Specifically, a 2013 OSTP Memo discusses policy principles and federal agency plans to increase public access to federally-funded research. This 2013 Memo directed federal agencies with more than $100M in R&D expenditures to develop plans to make the published results of federally-funded research freely available to the public within one year of publication and requiring researchers to better account for and manage the digital data resulting from federally-funded scientific research. A 2016 summary of progress by federal agencies in relation to the 2013 Memo shows that while federal agencies need to engage in further efforts to increase access to federally funded research, public access has increased. UC recommends that OSTP promote improvements to this already established model and invest in infrastructure that supports open science across a broad range of scientific disciplines.

In addition, the National Academies of Sciences, Engineering, and Medicine report on *Reproducibility and Replicability in Science* (2019), referenced in the RFI, puts forth recommendations to increase access to publicly funded science. UC strongly supports recommendation 6-3, which urges funding agencies to invest in open-source, usable tools and infrastructure that support reproducibility for a broad range of studies across different domains, and recommendation 6-5 that calls on the NSF to harmonize with other funding agencies repository criteria and data management plans for scholarly objects.

Furthermore, consortia efforts among academia, medical scientists, industry and publishers have developed several protocols and guidelines specifically designed to improve reporting and evaluation of studies that will improve the quality and transparency of the interpretation of findings. These protocols and guidelines, such as CONSORT, ARRIVE, and STROBE, offer existing tools to evaluate study quality and may be worth adopting rather than reinventing the wheel. The support and use of Registered Reports as a publication framework can also provide a way to ensure that all research is published, regardless of outcome. Incentivizing this type of publication could be a way to facilitate the reporting of null or negative results. Additionally, federal funding could encourage reproducibility of data by increasing funding for studies that provide confirmatory results or secondary findings that build upon existing research.

UC believes that reproducibility and replicability are not the only metrics for research rigor but rather are a piece of the broader research integrity landscape that includes objectivity, honesty, openness, accountability, fairness, good stewardship, and clear tracking of data. Moreover, there are limits to

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[1] University Policy On Integrity In Research: https://policy.ucop.edu/doc/2500496/IntegrityInResearch

reproducibility and replicability. Certain situations are impossible to recreate or should not be, due to the severity of health outcomes or the circumstances surrounding the exposures. For instance, emergency responses to the 2010 Deepwater Horizon explosion and oil spill or a decade-long prospective cohort study on lead exposure in drinking water and adverse effects on childhood IQ would be difficult to replicate or reproduce.

In order to facilitate a research environment that fosters integrity, UC supports relying on the knowledge of professionals who have long supported researchers in achieving this goal. Researchers will need training and support in implementing effective practices that ensure the highest standards of research integrity. Among others, library staff have long played a key role in educating researchers and advocating for effective data management practices and open science. For this reason, UC strongly supports the continued role that library staff play in supporting the open science ecosystem.

Overall, UC believes that the federal government stands in a unique position to promote the many aspects of scientific ethics and integrity, including by working with universities, professional societies, and publishers to ensure that the responsibilities of all stakeholders in maintaining research integrity are clearly stated, acknowledged, and adopted. Harmonization of these responsibilities across federal funding agencies and with international scientific organizations is highly encouraged.

II.   **Identifying and Reducing Administrative Burdens for Research**

Financial Conflict of Interest

In 2011, the Department of Health and Human Services amended the Public Health Services (PHS) regulations designed to promote objectivity in PHS-funded research.[2] Among other changes, the revised PHS Financial Conflict of Interest (FCOI) rule, which took effect in August 2012, lowered the de minimis reporting threshold for disclosing financial interests from $10,000 to $5,000, required disclosure of travel, and required retrospective reviews designed to identify possible bias in situations where financial interests had not been reported or reviewed in a timely manner. 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 research.[3] There were, however, significant costs associated with these regulatory changes. The AAMC found that "Participating institutions incurred significant costs beyond their ongoing program administration costs to fully implement the regulations. The total investment by 71 institutions was almost $23 million for an average of approximately $318,000 per institution."[4]

Closer alignment of federal FCOI policies would greatly reduce administrative burden and could be achieved by revisiting the reporting thresholds for significant financial interest. **UC strongly believes that a streamlined, harmonized federal-wide policy for FCOI would provide benefits with**

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[2] 42 CFR Part 50 and 45 CFR Part 94
[3] 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
[4] ibid

respect to reducing administrative work. We recommend that such a federal-wide FCOI policy be modeled on the NSF policy, eliminating myriad federal policies with different standards and reporting requirements. At a minimum, we urge federal agencies to consider what constitutes a FCOI, and how actual conflicts are managed and reported. Harmonization is needed in the following key areas:

- Harmonize definitions and terminology across federal agencies. For example, the definition of "Financial Conflict of Interest," and use of the terms "apparent," "perceived," "potential," "actual," "real" and "identified" vary across agencies.
- Harmonize federal agency and departmental disclosure thresholds in conformance with NSF.
- Harmonize the definition of Disclosers. We suggest using the definition of Investigator.
- Harmonize the definition of Immediate Family. We suggest all agencies use, "the Investigator's spouse and dependent children," coupled with the PHS' definition of Investigator.
- Harmonize timing of review and disclosure.
- Harmonize who makes the Conflict of Interest determination. We believe the applicant institution should make that determination.
- Harmonize reporting requirements, including by developing a uniform reporting system for collecting required reports.

UC also recommends the following pertaining to federal agencies' Conflict of Interest policies:

- Federal agencies should develop clear and consistent instructions and communications regarding the full scope of disclosure expectations.
- Some agencies are now issuing research awards as contracts rather than grants and requiring Organizational Conflict of Interest review. We believe that this is a misinterpretation of the Uniform Guidance (§200.112) "Review for Organizational Conflict of Interest." This is addressed by OMB in COFAR FAQ 200.112-1.
- Eliminate PHS's required disclosure of travel consistent with other agency policies.
- Eliminate the retrospective review and mitigation report required under PHS policy in instances where investigator has not disclosed financial interests that are later determined to constitute a financial conflict of interest, where the institution does not conduct a timely review, and/or an investigator does not comply with a conflict of interest management plan put in place after identification of a financial conflict of interest. While these reviews are intended to identify whether there is bias, this is virtually impossible to prove. We recommend that instead, institutions put in place a process to determine what might need to be done to address non-disclosure or non-compliance in terms of the research project (e.g., amending informed consent documents) and consequences for the non-reporting/non-compliant Investigator.

Proposal Submission

Our system of R&D investment, decentralized to 26 different federal funding agencies (plus over 100 DOD awarding components, and 26 funding offices within the NIH), creates unique opportunities for scientific discovery through research programs aligned with the mission of these distinct federal agencies. However, it is not an administratively agile process, particularly as each funding office insists on agency-specific proposal and grants management rules and systems. Despite real progress made through the Paperwork Reduction Act, Grants.gov, and collaborations through venues like the Federal Demonstration Partnership (FDP), UC and other institutions of higher education face continued administrative burdens because of on-going agency insistence on supporting agency-specific solutions for grant proposal system and award management.

The federal government should implement one system (as grants.gov was meant to be) for receiving grant proposals with uniform standard requirements, forms, and instructions (e.g. standard Conflict of Interest and Other Support forms), and for 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. We urge the federal science agencies to embrace a streamlined submission process.

In any case, a helpful 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. The more competitive funding environment has resulted in larger volumes of applications, triggering compliance reviews and straining limited research administration resources to support the proposal submission process.

Under this approach, if applications are selected for funding, the grantee would submit any additional supporting information necessary during the just-in-time phase. Information such as other support, facilities/resources, conflict of interest reviews, human and animal subject approvals, detailed budget, budget justification, and data management plans could be provided at this phase. Such an approach would mitigate administrative burden at universities and allow our researchers to focus on what is essential.

III.   Partnering with Research Institutions to Mitigate Research Security Risks

The UC system has an unparalleled international reputation for research and innovation and performs nearly one-tenth of all the academic research in the U.S.[5] UC's culture of research excellence and innovation stems in large part from our ability to attract scientists and students from around the world. While we must vigilantly work to safeguard research, we must also ensure that the U.S. remains a desirable and welcoming destination for talented researchers from around the world.

The December 2019 JASON report on *Fundamental Research Security* observes the tension between open research environments and legitimate concerns about the security of intellectual property created in these environments:

> Open science relies on the free exchange of information between scientists around the world. Since the start of the Second World War, open science has come into tension with the need for secrecy for technology surrounding the military uses of technology.[6]

Achieving the appropriate balance between our nation's security and an open, collaborative scientific environment requires better communication from and among the federal regulating agencies, law enforcement agencies, and due diligence on the part of research institutions. Overall, we believe that there could be great benefit in partnerships to further these efforts, and stand ready to collaborate with the federal government, other research institutions and higher education associations.

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[5] University of California Accountability Report 2019. Accessed online:
https://accountability.universityofcalifornia.edu/2019/chapters/chapter-9.html
[6] "Fundamental Research Security." JASON. December 2019.

Disclosures

We understand the need and are supportive of strengthening controls around disclosure of outside activities. We believe institutions bear the primary responsibility for developing and maintaining policies and procedures for disclosure that meet the federal standards, and for making their investigators aware of those policies and procedures and providing assistance to increase investigator' compliance. While risk can never be entirely eliminated, federal agencies should be able to rely on the grantee institution's conflict management policies and procedures for oversight of outside activities in accordance with the federal requirements.

In order for research institutions to commit an appropriate level of institutional resources, we recommend that OSTP work with all federal agencies to disseminate information research institutions may need to assess high-risk outside activities, and harmonize requirements around those high-risk areas. One strategy could be to set a de minimis threshold (in dollars or days) above which outside research activities would be reportable. Such a structure would help reduce the burden associated with monitoring outside activities that present minimal risk, shifting the focus towards more consequential activities that carry greater risk.

Furthermore, we do not believe that the lack of full or accurate disclosures should necessarily be considered research misconduct. Sometimes in these situations, there is no direct impact on the conduct of research by an omitted required disclosure. The consequences for the researcher may be equally grave, but intentional incomplete disclosure would be better categorized as "professional misconduct" rather than "research misconduct."

Vetting International Research Partners

Increased scrutiny of foreign government interference by federal science agencies has put in focus the need for new approaches in vetting international research partnerships. UC is strongly committed to international research cooperation and global engagement. We believe, however, that the higher education community can better balance the benefits and risks with timelier, clearer and more transparent guidance and information from the government as discussed below.

Federal law enforcement agencies have access to information that, if shared with the university community, would be helpful in assessing and addressing risks. For example, individuals at institutions that have cleared facilities may receive such information on a need-to-know basis, but other institutions who may face similar risks do not receive the same information. This results in a disparity of information among the entities engaged in research. We urge federal law enforcement agencies to work with federal funding agencies and regulatory agencies to identify and communicate important information publicly to universities and through multiple channels so that our institutions may better manage risk.

In order to help assess risks related to research security and integrity, UC urges the federal government to:

- Provide 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.
- Provide current and timely information on strategies used by certain foreign governments, including strategies to procure sensitive technologies (e.g. through changes in talent program recruitment strategies).
- Foster better intergovernmental coordination, including law enforcement, funding and regulatory agencies (involved in export controls) for identification and communication of important information which may currently be shared by on a very limited basis.
- Foster partnerships between universities and the federal government and provide opportunities to better inform each other of the challenges and nature of our respective environments. This could create a culture of awareness that will help put risks into context for those engaged in the academic research enterprise.

As outlined in the December 2019 JASON report on *Fundamental Research Security* in section 7.3, UC strongly supports the recommendation to promulgate assessment tools "in the form of a series of questions, tailored to the level of the stakeholder in question". This is similar to the Heilmeier Catechism used by DARPA. These questions can be developed through collaboration of university associations, university community members and the National Academies of Science, Engineering and Medicine Science, Technology and Security Roundtable and address "know your collaborator" and end-use/end-user assessment questions important to research integrity, security and export control considerations.

Greater Support and Clarity on When and How to Secure Research

In order to better partner with the research enterprise in enhancing research security where appropriate, UC urges the federal government to:

- Support the principles of NSDD-189, recognizing that the "strength of American science requires a research environment conducive to creativity, an environment in which the free exchange of ideas is a vital component."[7] NSDD-189 makes clear that fundamental research should remain unrestricted to the fullest extent possible, and that "where the national security requires control, the mechanism for control of information generated during federally-funded fundamental research in science, technology and engineering at colleges, universities and laboratories is classification."[8] Government agencies should clearly outlay in solicitations which research is classified, with a need to be protected from public disclosure, and which is fundamental research, free from publication and participation restrictions. Further, the government should discourage the use of new Controlled Unclassified (CUI) definitions as a mechanism to erect intermediate-level boundaries around fundamental research areas, a strategy inconsistent with NSDD-189, and which causes implementation confusion, leaving both the research and the universities vulnerable to non-compliance. These recommendations are supported in the JASON report.

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[7] Background on National Security Decision Directive (NSDD) 189, September 21, 1985,
https://www.reaganlibrary.gov/sites/default/files/archives/reference/scanned-nsdds/nsdd189.pdf
[8] Ibid.

- Provide clear and consistent communication on identified risks. Consistent messaging from the government is crucial for keeping stakeholders apprised of new or ongoing developments.
- Target communication to various stakeholders including institutional leadership, researchers, and staff supporting travel, sponsored programs, and export compliance as well as global activities. Consider reestablishing regular high-level communication mechanisms between the academic and security communities, perhaps through the ODNI task force to be established pursuant to Section 5722 of the FY 20 NDAA.
- Strengthen the relationships between research organizations, intelligence agencies, and law enforcement to help keep all organizations updated on the most pertinent security issues. This includes promoting communication among these entities of an evidence-based description of the scale and scope of problems posed by foreign influence in research, as well as to communicating to other government agencies the critical importance of foreign researchers and collaborations to U.S. fundamental research.
- Engage with the community of foreign researchers in the United States to enlist them in the effort to foster openness and transparency in research, nationally and globally, as well as to benefit from their connections to identify, recruit and retain the best scientific talent to the United States.

IV. Fostering Safe and Inclusive Research Environments

UC shares the federal government's commitment to eliminating harassment in the workplace and seeks to create and maintain a community dedicated to the creation, application, and transmission of knowledge and creative endeavors through academic excellence. All individuals who participate in university programs and activities should be able to work and learn together in a safe and secure environment, free of harassment and discrimination. These values are reflected both in our policies and practices.

<u>Consistency among Federal Grant-Making Agencies</u>

Ensuring a safe and inclusive research environment requires both federal agency and institution of higher education efforts. UC commends the leadership of the NSF for their efforts to directly address harassment among its grantees. The updated term of award requiring institutions to disclose, in a timely manner, any findings or determinations of violation of a code of conduct, statute, regulation, or executive order relating to sexual harassment, sexual assault, and other forms of harassment, and if a PI or any co-PI is placed on administration leave or if any administrative action has been taken is a clear statement that such behaviors will not be tolerated. UC supports these heightened efforts to eradicate harassment in the academic research environment.

While UC fully supports the goals of the NSF and other major federal grant-making agencies, each agency, such as the NIH and NASA, has created its own policy and requirements related to harassment. The lack of consistency across federal agencies creates challenges in UC's ability to respond in a compliant manner when we need to either conduct an investigation or report findings to an agency. For example, NSF and NASA have similar reporting requirements with regards to sexual harassment findings, but they have different requirements as to when and how findings should be reported. It would be prudent to have a common set of rules that apply to all agencies.

UC recommends consistency across federal grant-making agencies to avoid confusion about different harassment reporting requirements. Competing agency requirements, whether they involve managing sexual harassment and violence or more routine contract and grant administrative issues, create complexity and greater likelihood of inconsistent compliance. While UC supports federal recommitment to creating safe research environments, we believe that greater inter-agency coordination would yield stronger administrative practices to successfully ensure such environments.

In parallel with federal agency action, universities have already put forth efforts to 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 re-visited on a regular basis. The federal government could assist by developing suggested checklists for conducting fair, objective, and unbiased investigations, including steps to determine, in good faith, the facts of an allegation, identification of witnesses, and maintenance of proper records.

Creating a Safer Research Enterprise Supporting Re-Entry Path for Survivors of Sexual Harassment

The actions by the major science agencies to reaffirm the importance of a safe research environment in the past few years have been important reminders of the critical work that still must be done.

The NIH Advisory Committee to the Director (ACD) Working Group on Changing the Culture to End Sexual Harassment included in its final report specific recommendations that ALL federal science agencies could embrace to foster a safer research enterprise and support a re-entry path for survivors of sexual harassment. These recommendations include making it easier for targets of harassment to confidentially change mentors under NIH fellow and career development awards and creating new incentives and funding opportunities to restore the careers of those targeted by harassment and other affected individuals. UC supports these recommendations.

The final report also highlights a pilot program initiated by UC Davis that has since been adopted by UC San Diego to stop the practice of "passing the harasser," where "faculty members found guilty of bullying or sexual harassment move to a new job without telling their new employer about their past conduct." [9] Under this pilot program, an institution conducts reference checks on final candidates for academic appointments with tenure or security of employment and obtains and review information about candidates' personal conduct involving gender discrimination, sexual harassment, and sexual violence. Since UC Davis implemented its pilot program, neither faculty applicants nor institutions contacted for reference checks have protested this requirement. UC Davis believes that this reference check requirement decreases the likelihood of applications from candidates whose behavior is inconsistent with the UC Faculty Code of Conduct and Principles of Community, thereby reducing the incidence and negative consequences of harassment. [10]

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[9] Mervis, Jeffrey. "Universities move to stop passing the harasser." (2019): 1057-1057. Accessed online: https://science.sciencemag.org/content/366/6469/1057

[10] Testimony of Philip H. Kass, DVM, MPVM, MS, PhD, Vice Provost for Academic Affairs Professor of Analytic Epidemiology University of California, Davis Before the U.S. House of Representatives Committee on Science, Space, and Technology On Combating Sexual Harassment in Science. June 12, 2019: https://science.house.gov/imo/media/doc/Kass%20Testimony.pdf

The University of California applauds OSTP's efforts to reach out to the research community and thanks you for the opportunity to provide our input. We would be happy to further engage with you in finding workable solutions.

Sincerely,

Lourdes G. DeMattos
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Research Policy Analysis & Coordination