Representing Over 130,000 Researchers



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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 Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to share its feedback on the recently released <u>Request for Information</u> (RFI) seeking input on the American Research Environment. As a coalition of 29 biological and biomedical scientific societies collectively representing over 130,000 individual scientists and engineers, FASEB recognizes the importance of maximizing the quality and effectiveness of the American research environment to ensure continued leadership and competitiveness in science and technology.

Our comments in response to the questions posed by the Office of Science and Technology Policy (OSTP) in this RFI reiterate FASEB positions on core issues of interest to our members: enhancing rigorous and reproducible research; reducing duplicative or unnecessary regulatory oversight of research initiatives; preserving U.S. investments while maintaining international collaborations; and fostering a diverse and representative research workforce working in safe and inclusive environments.

Research Rigor and Integrity

In 2015, FASEB organized a series of roundtable discussions to explore various factors contributing to the inability to reproduce research results. Participants included representatives from our member societies, federal agency staff, and invited experts on topics including mouse model research, development and use of antibodies, and publication policies. These deliberations identified three factors as impediments to the inability to reproduce experimental results: lack of uniform definitions, both for the issue of reproducibility and for reagents; insufficient reporting of experimental details; and gaps in scientific training. In 2016, FASEB issued <u>consensus</u> recommendations highlighting strategies that institutions/research organizations, individual investigators, and professional societies and organizations could each take to address these deficiencies.

The American Physiological Society • American Society for Biochemistry and Molecular Biology • American Society for Pharmacology and Experimental Therapeutics American Society for Investigative Pathology • American Society for Nutrition • The American Association of Immunologists • American Association for Anatomy Society for Developmental Biology • American Peptide Society • Association of Biomolecular Resource Facilities • The American Society for Bone and Mineral Research American Society for Clinical Investigation • Society for the Study of Reproduction • The Society for Birth Defects Research & Prevention • The Endocrine Society The American Society of Human Genetics • American College of Sports Medicine • Biomedical Engineering Society • Genetics Society of America The Histochemical Society • Society for Pediatric Research • Society for Glycobiology • Association for Molecular Pathology • Society for Redox Biology and Medicine Society For Experimental Biology and Medicine • American Aging Association • U. S. Human Proteome Organization • Society of Toxicology • Society for Leukocyte Biology Recognizing the time- and space-limitations of conference presentations and posters, FASEB also launched a pilot among its Scientific Research Conferences to assess the effectiveness of communicating experimental methods and/or reagents using icons. The voluntary pilot was offered for three years, with uptake varying by discipline and investigator age. In 2017, FASEB and the National Institute of General Medical Sciences co-hosted a workshop, "Responsible Communication of Basic Biomedical Research: Enhancing Awareness and Avoiding Hype," that examined the role of science communication on the public's perception of science. A diverse group of experts discussed the problems associated with overselling or misrepresenting research findings as well as the difficulties of communicating science in today's media landscape.

Coordinating Administrative Requirements for Research

FASEB appreciates the subcommittee's efforts to identify and assess opportunities to coordinate agency policies pertaining to financial conflict of interest (FCOI) disclosures, federal grant processes, and research administrative burden. The Federation has demonstrated its long-standing commitment to streamlining regulations for biological research by engaging with member societies and the broader scientific community on numerous occasions. In response to our 2013 <u>survey</u> regarding a National Science Board RFI, participants cited conflict of interest reporting as a significant burden. Proposed recommendations included standardizing reporting, implementing a requirement to report only when grant funding exceeds a specific threshold, and providing pre-populated forms with relevant grant information. These recommendations remain pertinent to the scientific community's present concerns on this issue.

While we recognize the questions in the current RFI are primarily related to FCOI, this complex issue is more closely aligned with the mission of our colleagues that represent institutions such as the Association of American Medical Colleges (AAMC), Council on Government Relations (COGR), and Association of American Universities, among others. We respectfully defer to their expertise and institutional perspective for guidance on mechanisms to reduce administrative burden native to FCOI.

Another area of significant importance to FASEB and its member societies is administrative burden associated with animal research. There is a clear role for OSTP to serve as a leader on this issue, one that requires a delicate balance between streamlined regulations and animal welfare assurance. In a recent <u>report</u>, FASEB, AAMC, COGR, and the National Association for Biomedical Research highlighted inconsistencies of animal research policies across federal agencies. More importantly, the report outlined ways in which the U.S. National Institutes of Health (NIH) and U.S. Department of Agriculture (USDA) could streamline federal regulations, policies, and guidelines governing the use of animals in research while ensuring that humane treatment and care of animal subjects remains a top priority.

Earlier this year, FASEB and COGR co-hosted <u>webinars</u> in partnership with representatives from NIH Office of Laboratory Animal Welfare (OLAW) and USDA to clarify understanding of various animal research regulations among institutions, Institutional Animal Care and Use Committee administrators, and investigators. Key points of burden – and confusion - included: alternatives to annual renewals for post-approval monitoring, use of estimates to statistically justify group size in accordance with the *Guide*, and protocol rewrite for triennial review. These concerns and other FASEB recommendations were reiterated in our recent <u>comments</u> to NIH

OLAW, USDA, and the Food and Drug Administration regarding their final <u>report</u>, "*Reducing Administrative Burden for Researchers: Animal Care and Use in Research.*"

In keeping with JCORE's mission to strengthen the scientific research enterprise, FASEB urges OSTP to include animal research regulations in conversations related to coordination of administrative requirements. Although many of these policies will have to be addressed at the institutional level, federal agencies can and should play a role in facilitating stakeholder efforts to address ongoing challenges.

Research Security

Earlier this year, FASEB <u>reaffirmed</u> the importance of and its support for international scholars to furthering discovery and innovation in the life sciences. Nearly 20 percent of the 130,000 individual scientists represented by the Federation's 29 member societies are of non-U.S. origin. Continued federal investments in science and technology has resulted in the U.S. being recognized as the leading nation in these fields, attracting scientists from around the world to train and work in a broad range of research environments. International collaborations have played critical roles in numerous biological research endeavors, ranging from deciphering the human genome to stemming the spread of infectious diseases such as Ebola and Zika virus.

FASEB also recognizes the delicate balance between fostering an environment of open scientific collaboration and protecting U.S. investments and discoveries. Therefore, we welcome the opportunity to work with OSTP and federal research agencies as well as interested stakeholders in the research community to develop and communicate policies that confirm appropriate utilization of critical resources and outputs and discoveries gained from those resources.

Safe and Inclusive Research Environments

U.S. research environments should foster a culture of inclusivity and reflect the diversity of the Nation and are at the heart of FASEB's goal to ensure a diverse and fully trained workforce in the biological and biomedical sciences. This commitment was reaffirmed by the adoption of an <u>organizational statement</u> on diversity, equity, and inclusion (DEI) and the development of a <u>strategic plan</u> to guide the Federation's efforts in fostering a diverse, equitable, and inclusive organization and research environment across the biological and biomedical sciences.

Since the release of the 2018 NASEM study, <u>Sexual Harassment of Women: Climate, Culture,</u> <u>and Consequences in Academic Sciences, Engineering, and Medicine</u>, we've gained insight into how professional misconduct, particularly harassment of any form, can be pernicious and damaging to careers. Similarly, microaggressions and unconscious biases can lead to research environments that are less inclusive and thus less representative of the public they serve. Changing the workplace climate is a challenging task with no straight forward solution, but FASEB remains actively engaged in discussions to work towards ensuring non-hostile, diverse, and inclusive research environments.

FASEB <u>commends</u> the leadership of the National Science Foundation (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. The information collection does not add significant administrative burden, but crucially does aid in proper enforcement of the award.

The Federation is also closely monitoring the efforts of the NIH's Advisory Committee to the Director's Working Group on Changing the Culture to End Sexual Harassment. Earlier this year, the Working Group issued four interim recommendations. FASEB reviewed and submitted feedback on these interim recommendations, specifically highlighting the need for the agency to treat professional misconduct, including gender and sexual harassment, with the same severity of research misconduct. FASEB also recommended implementation of a mechanism requiring PIs to attest that they have not violated and will not violate their institutional code of conduct as part of grant application and progress report submissions. While FASEB agreed with the Working Group's interim assessment that strategies to support and encourage the return of survivors to pursue research activities are necessary and important, we also urged careful consideration of eligibility for and review of such requests. Similarly, we urged NIH to continue developing mechanisms to reduce co-dependency of students and postdoctoral trainees on PIs for financial support, noting this relationship can be particularly tenuous for foreign scholars who may be dependent on their mentors for both research support and visa status.

FASEB recognizes the role of scientific societies as standard bearers for advancing professional and ethical conduct, climate, and culture. FASEB has a broad <u>anti-harassment policy</u> that covers all aspects of the organization, and the Federation and its member societies have implemented Codes of Conduct to promote transparency in and awareness of organizational processes for reporting harassment at <u>conferences</u> and <u>meetings</u>. Our dedication to furthering scientific excellence while also improving the climate and culture of research is strengthened through our membership and active engagement in the <u>Societies Consortium on Sexual Harassment in</u> <u>STEMM</u>. Engagement in the Consortium provides a forum to share experiences and promising practices to address harassment and disparities across STEMM disciplines. It also allows scientific societies to have a unified voice when recommending policies and procedures to foster culture change.

FASEB appreciates the opportunity to provide feedback on this RFI and looks forward to future engagement with OSTP regarding ways to maximize federal investments in biological and biomedical research.

Sincerely,

Janrah V. Carey

Hannah V. Carey, PhD FASEB President