Jacobs Institute
of Women's Health
THE GEORGE WASHINGTON UNIVERSITY

July 28, 2021

White House Office of Science and Technology Policy
Via email: ScientificIntegrityRFI@ostp.eop.gov

Re: Request for Information To Improve Federal Scientific Integrity Policies (86 FR 34064)

The Jacobs Institute of Women's Health appreciates the opportunity to comment in response to the "Request for Information to Improve Federal Scientific Integrity Policies" (86 FR 34064). The Jacobs Institute of Women's Health strongly supports the work of the White House Office of Science and Technology Policy (OSTP) to improve the effectiveness of federal scientific integrity policies and practices to enhance public trust in science.

The Jacobs Institute of Women's Health's mission is to identify and study aspects of healthcare and public health, including legal and policy issues, that affect women's health at different life stages; to foster awareness of and facilitate dialogue around issues that affect women's health; and to promote interdisciplinary research, coordination, and information dissemination, including publishing the peer-reviewed journal *Women's Health Issues*.

Below we provide brief examples of problems that existing scientific integrity policies did not prevent and offer recommendations for strengthening scientific integrity policies and practices. The identified issues and recommendations below focus on three areas: Strong scientific integrity policies, Evidence-based distribution of grant funds, Transparency of federal advisory committees, and Enforcement of scientific integrity policies.

I. Strong scientific integrity policies

The Jacobs Institute of Women's Health is one of a wide range of organizations that contributed to the 2020 publication *Restoring Science, Protecting the Public: 43 Steps for the Next Administration*.[i] That document describes numerous examples of recent scientific integrity abuses (some of which we mention below) and offers suggestions for improvements. Consistent with that document, we recommend that OSTP require scientific integrity policies to:

- Protect the right of scientists to share scientific data and analysis with the public and lawmakers free from political interference and filters, and to review content that will be released publicly

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in their names or that significantly relies on their work.

- Explicitly prohibit retaliation against government employees who raise concerns about scientific integrity or offer scientific opinions that differ from those of the administration or their agency.

- Specify that media policies allow scientists to share their expertise without political vetting, and advance other initiatives to improve scientific communication.

- Provide a clear, detailed policy and procedure for addressing allegations of scientific integrity violations, including appeal rights, and for publicly reporting their resolution.

Because the last of these items is so important, we address it separately in Section IV.

II. Evidence-based distribution of grant funding

In the reproductive health area, several of the scientific integrity problems during the Trump administration occurred in the area of grant distribution. Three examples—which are presented in greater detail in the Department of Health and Human Services (HHS) memo[ii] of a set of agency-specific memos to which the Jacobs Institute contributed (*Restoring Science, Protecting the Public: Recommendations for Federal Agencies in the Next Presidential Term*[iii])—illustrate problems that scientific integrity policies and practices should guard against:

- **Teen Pregnancy Prevention grants:** The abrupt cessation of Teen Pregnancy Prevention (TPP) program grants while grantees were in the midst of data collection halted promising research and the delivery of services to adolescents across the country; although courts eventually required HHS to restore grantees' funding, the damage to their staff capacity and research processes could not be repaired with that reversal. The Trump administration also weakened evidence standards in grant announcements for new funding, and selected unqualified or lesser-qualified external reviewers for the proposal reviews.

- **Title X family planning program:** The regulation known as the "domestic gag rule" effectively prohibits providers that receive federal Title X family planning grants from providing evidence-based and ethical care to pregnant patients; it resulted in the Title X network losing roughly half its capacity to serve female clients in the year following its implementation.[iv] Commenters on the proposed rule warned, based on evidence from a similar move in Texas, that it would cause such a drop in capacity. HHS brushed these concerns aside and asserted, without compelling evidence, that new providers who could meet clients' needs would enter the program.

- **NIH grants for research involving human fetal tissue:** The Trump administration ended longstanding NIH grant funding for research relying on fetal tissue, and then discontinued funding of future research requiring newly acquired fetal tissue. For advice on continued funding for some existing grants, it formed a Human Fetal Tissue Ethics Advisory Board. The majority of the board's members had expressed outright opposition to fetal tissue and stem cell research, and their names were not released until the day of their first meeting. The board recommended against funding for 13 of 14 NIH grants using fetal tissue that they reviewed; the only study that was recommended for funding investigates alternatives to fetal tissue research.

Although courts have reversed many of the TPP program changes and the Biden administration has lifted the fetal-tissue research prohibition and begun the process of reversing the domestic gag rule, they cannot undo the damage that communities across the country have suffered as TPP programs, Title X clinics, and research studies shut down.

Agencies must do more to ensure that grant funding decisions are based on evaluations by experts with relevant qualifications, and they must guard against political interference with funding programs' criteria and awards. We recommend that OSTP take the following steps:

- Scientific integrity policies should require that agencies make publicly available both the criteria for selecting evaluators and the criteria they will apply when scoring funding applications. When stakeholders raise concerns about either of these—as our organization and others did in response to the domestic gag rule and the TPP program's weakening of standards—agencies must be ready to either provide a sound explanation for keeping them or make modifications.

- Agencies must better guard against politically motivated interference with grant programs. The firewalls between political leadership (whether from the administration, Congress, or other political entities) and program managers, evaluators, and grantees must be strengthened through specific policies and protocols.

III. Transparency for federal advisory committees

Federal advisory committees (FACs) are essential to the effective functioning of agencies that protect the public's health. Examples of FACs of particular interest to the Jacobs Institute include the CDC Advisory Committee on Immunization Practices, the HHS/DOJ National Advisory Committee on Violence Against Women, and the many advisory committees that advise FDA on approval of drugs and devices. Consistent with the FAC memo[v] of the *43 steps* document[i], we recommend that OSTP require agencies to take the following steps:

- Publish clear criteria for nominating and selecting qualified committee members, while prohibiting current members from having veto power over candidates.

- After selecting candidates for membership, make that roster public and request comments.

- Identify and make public the process used for committee formation, including how agencies screen members and assess committees for balance.

- Publish background information on each committee member on a public online portal (e.g., integrity.gov), including information on qualifications, employers, and funding sources for the previous five years, along with any conflict-of-interest waivers granted.

- When allowing FACs to expire, archive their websites and all related documents so agencies and the public can still access the information.

- Instruct agencies to identify outstanding complaints made against existing FACs, investigate those complaints, and take corrective action where warranted.

In addition, OSTP should ask the Office of Government Ethics to provide clear guidelines that:

- Explicitly define what constitutes a conflict of interest and transparently outline the degree to which a conflict of interest would disqualify a nominee from participating on a committee.

- Direct agencies to clarify their criteria for appointing advisory committee members as individuals or as organization representatives, and take steps to ensure that conflicts of interest are properly scrutinized.

- For committees with a mission solely dedicated to providing objective scientific advice (as opposed to committees designed to gather input from diverse stakeholders), ensure members are appointed as special government employees and vetted for financial conflicts of interest. They should recuse themselves from scientific discussions with which they have a direct conflict of interest, and those recusals should be announced to the public at the start of meetings and be included on meeting notes, reports, and other documents.

- Ensure that scientists who have taken public positions on issues or received government funding for scientific work are not excluded from advisory committees because of unfounded concerns about bias.

Scientific FACs play a key role in providing scientific advice to policy makers, regulators, and the public. Although agencies are not bound to follow FACs' advice, acting against it risks compromising public trust. We therefore recommend:

- When recommendations and/or advice are given, particularly in the regulatory setting, the response by the relevant agency (e.g., FDA, EPA) should be transparent and scientifically valid. Agencies should establish a process that gives the public access to information about the agency's rationale for actions that are not in line with FAC advice.

IV. Enforcement of scientific integrity policies

Abuses of scientific integrity were rampant during the Trump administration despite the existence of strong scientific integrity policies at several agencies. President Biden has publicly committed to scientific integrity, but recent problematic decisions regarding guidance for vaccinated individuals from the Centers for Disease Control and Prevention (CDC)[vi] and the Food and Drug Administration (FDA) approval of Alzheimer's drug Aduhelm[vii] raise the possibility that decisionmakers might feel pressure to inappropriately emphasize certain evidence while sidelining other data, even if that pressure is not coming from the White House.

Although many employees reported violations of scientific integrity policies during the Trump administration, such reports rarely (if ever) resulted in reversals or prevented future interference. To ensure that scientific integrity policies are effective, they must encourage reporting of violations. People who witness wrongdoing are more likely to report it if they trust that agencies will guard them against retaliation, investigate the allegation, and, when they find evidence of wrongdoing, act to correct the situation. Current policies leave agencies with too few options for taking corrective action when investigations determine that wrongdoing occurred, and inadequate responses risk deterring future reporting.

We recommend that each agency's scientific integrity policy contain the following:

- **Authority for punishing wrongdoers.** For policies to deter wrongdoing effectively, agencies must have the authority to punish individuals who are found to have violated them. Agencies

can determine the appropriate route for establishing this authority—e.g., granting it to the scientific integrity official, using Human Resources processes, or establishing a mechanism for quickly involving the Office of the Inspector General—but it is an essential step.

- **Timelines for investigating allegations.** When investigations move slowly, the policy violator has more time to continue misconduct, and the person who reported the violation can lose faith in the system. In setting timelines, agencies must balance the imperative for fair and thorough investigations with the need to deter wrongdoing. Timelines should include options for interim actions that limit the damage alleged perpetrators can continue to cause in cases where there is strong evidence of wrongdoing but the investigation is still ongoing.

- **Consequences for those found to have violated scientific integrity policies.** Consequences for those found to have violated policies must be sufficiently strong to deter future wrongdoing. All violations should become part of the wrongdoer's file, and sanctions should be in line with those for personnel policy violations such as theft and unexcused absences. The severity should not depend on whether the attempt at interference was successful or not; punishment of all violations is essential to create a culture of respect for scientific integrity.

- **Safeguards against retaliation.** To encourage individuals to report wrongdoing, policies must offer credible assurances that reporters will not face retaliation. Policies should limit the potential for the accuser's identity to be disclosed to the accused, and they should allow for individuals to report outside of their supervisory chains. Reporters should have recourse for meaningful corrective action in cases when they experience retaliation.

- **Reporting mechanisms for multiple stakeholders.** Contractors as well as employees should be able to report wrongdoing that they witness, and policies should specify mechanisms by which members of the public can report violations.

Thank you for this opportunity to comment in response to "Request for Information to Improve Federal Scientific Integrity Policies." If you have any questions, please contact Jacobs Institute managing director Liz Borkowski at 202-994-0034 or borkowsk@gwu.edu.

[i] Multiple organizations. *Restoring Science, Protecting the Public: 43 Steps for the Next Presidential Term*. June 2020. Available: http://www.thepumphandle.org/wp-content/uploads/2020/06/Restoring-Science-Protecting-the-Public.pdf

[ii] Multiple organizations. Department of Health and Human Services: Sexual and Reproductive Health, Education, and Services. In: *Restoring Science, Protecting the Public: Recommendations for Federal Agencies in the Next Presidential Term*. October 2020. Available: http://www.thepumphandle.org/wp-content/uploads/2020/10/Restoring-Science-HHS-SRH.pdf

[iii] Multiple organizations. *Restoring Science, Protecting the Public: Recommendations for Federal Agencies in the Next Presidential Term*. October 2020. Available: http://www.thepumphandle.org/wp-content/uploads/2020/10/restoring-science-protecting-the-public-oct2020.pdf

[iv] Dawson, R. Trump Administration's Domestic Gag Rule Has Slashed the Title X Network's Capacity by Half. Guttmacher Institute Policy Analysis. February 5, 2020. Available: https://www.guttmacher.org/article/2020/02/trump-administrations-domestic-gag-rule-has-slashed-title-x-networks-capacity-half

[v] Multiple organizations. Federal Advisory Committees: Restoring the role of independent expert advice in government. In: *Restoring Science, Protecting the Public: 43 Steps for the Next Presidential Term*. June 2020. Available: http://www.thepumphandle.org/wp-content/uploads/2020/06/Restoring-Science-Protecting-the-Public_Federal-Advisory-Committees.pdf

[vi] Borkowski, L. With COVID-19 Policies and Alzheimer's Drug Approval, Biden Administration Lets Us Down. June 20, 2021. Available: http://www.thepumphandle.org/2021/06/20/with-covid-19-policies-and-alzheimers-drug-approval-biden-administration-lets-us-down/#.YP1Zly1h3UZ

[vii] National Center for Health Research. Scientific Coalition Letter on Aduhelm to HHS Inspector General, CMS, and Congress. July 7, 2021. Available: https://www.center4research.org/scientific-coalition-letter-on-aduhelm-to-hhs-inspector-general/