September 1, 2023

Office of Science and Data Policy
Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
Submitted via email: scientificintegrity@hhs.gov

Re: Request for Comments on the Draft HHS Scientific Integrity Policy (88 FR 46802)

As organizations whose work involves federal scientific integrity issues, we appreciate the opportunity to comment on the draft scientific integrity policy from the US Department of Health and Human Services (HHS). The policy represents an important step toward ensuring that agency scientists and decisionmakers can generate and use the best available evidence to advance the agency's mission to "enhance the health and well-being of all Americans." We recommend several revisions to make the HHS scientific integrity policy an even stronger tool for protecting science and science-based decision-making from political interference. Specifically, we urge that that the HHS scientific integrity policy contain:

1) Protections and accountability for grantees;
2) More explicit procedures for investigating allegations;
3) Specifics that delineate scientists' ability to communicate with the media and public about their areas of expertise, without leaving scientists vulnerable to bad-faith attacks;
4) Clarification of the scope and duration of scientific clearance procedures;
5) Penalties sufficient to deter wrongdoing and hold accountable all scientific integrity violators, including political appointees;
6) Language from the model scientific integrity policy regarding conflicts of interest on federal advisory committees and the importance of equity;
7) Specific protections from retaliation for those engaged in scientific activities that may put them at risk for reprisal;
8) A mechanism for addressing allegations that involve multiple OpDivs/StaffDivs, multiple agencies, and/or high-level officials; and
9) Incorporation of the HHS Policy for the Common Data Use Agreement (DUA) Structure and Repository.

In reviewing the draft HHS scientific integrity policy, we also examined the model policy released by the White House Office of Science and Technology Policy as part of *A Framework for Federal Scientific Integrity Policy and Practice*.[1] We note areas where the HHS draft policy

[1] Scientific Integrity Framework Interagency Working Group of the National Science and Technology Council. (2023). *A Framework for Federal Scientific Integrity Policy and Practice*. https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf

improves upon the model policy as well as areas where using more of the model policy's language would enhance the HHS policy.

Scientific integrity is essential to ensure that all people have access to information and programs that can help them lead healthy lives. When individuals with political motivations meddle in research or undermine decisions that should be based on science, the health of communities across the nation, particularly BIPOC (Black, Indigenous, and people of color) communities, can suffer. Scientific integrity problems at HHS have ranged from unwarranted age restrictions on emergency contraception during the Obama administration to halting important research and interfering with COVID-19 guidance during the Trump administration. HHS should design its scientific integrity policy to provide protections against such meddling and effective avenues for correction when interference occurs. HHS should also consider the possibility of individuals acting in bad faith using the policy to harass scientists who are doing their jobs, and HHS should erect barriers to such bad-faith attempts.

1. Protections and accountability for grantees

The draft policy mentions HHS's role as a funder of research in a few places; most notably, I.13 requires disclosure of participation in foreign talent recruitment programs as a condition of "receipt of Federal extramural research funding"; II.6 requires accurate representation of "the work and conclusions of scientists funded or supported by the federal government"; and the responsibilities of the Secretary of Health and Human Services include cooperating with the SIO to oversee implementation and improvement of "policies and processes affecting the integrity of scientific activities funded, conducted, or overseen by HHS." We recommend additional protections specific to research funding and service grants, as well as making grantees accountable for upholding scientific integrity:

A. **Prohibition against terminating grants for political reasons:** Given that the abrupt early cancelation of Teen Pregnancy Prevention grants[2] and cessation of federally funded research involving fetal tissue[3] are two prominent examples of scientific integrity problems that occurred at HHS in recent years, we recommend that the revised policy include specific protections against early termination of both research and service grants for political reasons. For instance, the "Protecting Scientific Processes" section could include a prohibition against terminating intramural or extramural research funding for reasons other than breach of contract, abusive behavior, or gross mismanagement.

B. **Prohibition against requiring non-evidence-based practices by grantees:** Additional protections for service grants are also warranted given the disastrous consequences that

[2] Kay J. (2017). Trump administration suddenly pulls plug on teen pregnancy programs. *Reveal.* https://revealnews.org/article/trump-administration-suddenly-pulls-plug-on-teen-pregnancy-programs/

[3] Wadman M. (2019). Trump administration restricts fetal tissue research. *Science*. https://www.science.org/content/article/trump-administration-restricts-fetal-tissue-research

clients of the Title X family planning program faced after the Trump administration adopted a rule requiring that grantees provide care contrary to evidence-based standards and medical ethics as a condition of receiving Title X funding, including by requiring that providers refer pregnant patients for prenatal care and not for abortions regardless of what the patient wanted. When the administration first proposed this "domestic gag rule," critics warned that it would result in qualified providers leaving the program and sharply reduce access to family planning care for people with low incomes, [4] and that is what occurred.[5] As HHS noted when it proposed revising the rule, the Title X system served more than half a million fewer low-income clients in 2019, after the gag rule took effect, than in 2018.[6] To prevent such problems in the future, HHS's revised scientific integrity policy should include a prohibition against requiring grantees to provide services in a manner that is inconsistent with evidence-based consensus guidelines or that is reasonably anticipated to result in a substantial reduction in access to high-quality, guideline-concordant care. This prohibition could also appear in the "Protecting Scientific Processes" section of the policy.

C. **Accountability for grantees:** We appreciate that the draft policy makes clear that grantees "are expected to uphold the principles of scientific integrity described in this policy." We recommend that the policy also include a mechanism for accountability, such as specifying that grantees found to have violated the scientific integrity policy will be barred from receiving new HHS contracts for two years following the determination.

2. More explicit procedures for investigating allegations

We appreciate the draft policy's inclusion of procedures for "Addressing Scientific Integrity Concerns" (pages 15-16) and the fact that the procedures include the possibility of informal consultations, formal complaints and investigations, and appeals from both complainants and respondents. The procedures specify that when investigations are opened, the HHS scientific integrity official (SIO) will form an investigation committee along with at least two other Scientific Integrity Council members or their delegates; Council members are senior career employees from different divisions. We recommend that the revised policy contain the following as well, and that procedures be published in the Federal Register.

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[4] Jacobs Institute of Women's Health. (2018). Re: Family Planning: Compliance With Statutory Program Integrity Requirements. https://www.regulations.gov/document/HHS-OS-2018-0008-155665

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

[6] Office of the Secretary, U.S. Department of Health and Human Services. (2021). Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services (Proposed Rule). Federal Register, 86 FR 19812. https://www.federalregister.gov/documents/2021/04/15/2021-07762/ensuring-access-to-equitable-affordable-client-centered-quality-family-planning-services

A. **Independent appeal mechanisms on findings and decisions:** Agency personnel will be reassured that investigations and findings are handled appropriately if an independent appeal process exists. The revised policy should give more specifics about the appeals process(es) that will be available to all affected personnel, including those found to have violated scientific integrity policies and those whose allegations were not investigated or remedied. The policy should establish an independent mechanism for appeals, such as the ability to appeal to the National Science and Technology Council (NSTC) Subcommittee on Scientific Integrity, and affirm that procedures will protect employees' due process rights.

B. **Additional mechanisms to safeguard the independence of investigators:** We appreciate that section V.6 of the draft policy specifies "Consistent with applicable law, an SIO or other scientific integrity staff may not be terminated or reassigned without good cause or legitimate organizational reason." This kind of protection is essential for allowing SIOs and Council members to avoid undue pressure from their supervisors or political appointees. To further bolster such protection, we recommend that the revised policy specify avenues for safeguarding independence when allegations involve high-level officials, such as by allowing investigators to coordinate with their inspector general's office and/or the NSTC Subcommittee on Scientific Integrity.

C. **Timeliness provisions:** Scientific integrity policies should include provisions to assure the timely resolution of an allegation of a loss of scientific integrity. For instance, a decision to investigate an allegation could be required within 10 working days and a determination within another 45 working days, and the appeal process could be limited to 30 working days. Exceptions to the timeline should be allowed at the request of employees for reasons such as needing more time to hire counsel or build their case.

3. Specifics that delineate scientists' ability to communicate with the media and public about their areas of expertise, without leaving scientists vulnerable to bad-faith attacks

Ensuring that scientists are able to communicate efficiently with members of the media and publish findings promptly can help improve public awareness of and trust in agency activities. Scientists are most likely to make use of opportunities to speak with members of the media and the public when the policies related to these activities are explicit and unambiguous. Some text in the draft policy is too ambiguous, and one provision could be weaponized by bad-faith actors who disapprove of a particular area of research, such as one related to reproductive health. We recommend the following changes:

A. **Eliminate problematic language that could be weaponized by bad-faith actors.** Section II.4 contains the extremely broad statement that HHS scientists "shall refrain from making or publishing statements that could be construed as being judgments of, or recommendations on, HHS or any other Federal Government policy." A bad-faith actor seeking to harass a scientist whose work they find distasteful could claim to have

"construed" virtually any statement as a judgment of government policy. For instance, a scientist who makes a factual statement about the effect of a policy — for instance, explaining how a Trump administration directive to stop procuring fetal tissue halted work on an HIV study — could be accused of criticizing that policy decision. We recommend that HHS remove this text from its scientific integrity policy to avoid creating a weapon for bad-faith actors.

B. **Specifics regarding ethics rules:** In item II.3, "Encourage, but not require, HHS scientists to participate in their official capacities in communications with the media regarding their scientific activities and areas of expertise, subject to limitations of government ethics rules," and Item II.4, "Allow, subject to limitations of government ethics rules, HHS scientists to express their personal views and opinions with appropriate written or oral disclaimers, including on social media," we recommend the revised policy specify what kinds of ethics rules apply to communications with media and the public – e.g., "the limitations of government ethics rules regarding compensation for speaking engagements."

C. **Explicit language reinforcing federal anti-gag rules:** To comply with the Whistleblower Protection Enhancement Act and guard against any potential chilling effect on employees concerned about communicating with the media or the public, HHS should ensure that any communication policy, and any directives or instructions distributed to employees explaining such policies, contains the explicit language the Whistleblower Protection Enhancement Act mandates must be included under the "anti-gag" provisions of § 115 and 5 U.S.C. § 2302(b)(13) in any nondisclosure policy, form, or agreement:

   "These provisions are consistent with and do not supersede, conflict with, or otherwise alter the employee obligations, rights, or liabilities created by existing statute or Executive order relating to (1) classified information, (2) communications to Congress, (3) the reporting to an Inspector General of a violation of any law, rule, or regulation, or mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, or (4) any other whistleblower protection. The definitions, requirements, obligations, rights, sanctions, and liabilities created by controlling Executive orders and statutory provisions are incorporated into this agreement and are controlling."

   We recommend the addition of this language at the end of Section II., Ensuring the Free Flow of Scientific Information.

4. Clarification of the scope and duration of scientific clearance procedures

We applaud the HHS draft policy for requiring that "technical review and clearance processes include provisions for timely clearance and expressly forbid censorship, unreasonable delay,

and suppression of objective communication of data and results without scientific, legal, or security justification" (II.10) and specifying in II.13 that "Violations of clearance policies that result in suppression, delay, or alteration of scientific and technological information without scientific, legal, or security justification constitute violations of the HHS Scientific Integrity Policy and may be reported under the Procedures for Addressing Scientific Integrity Concerns." To augment the policy's ability to encourage timely and appropriate clearance, we recommend the following additions:

A. **Clarification of the scope of scientific clearance procedures:** Scientific clearance procedures typically relate to quality control of scientific materials intended for publication or presentation rather than to interview or public speaking requests, and we recommend making this distinction explicit. One option for doing so would be to add a sentence stating "Scientific clearance procedures are only applicable to scientific materials intended for publication or presentation and do not apply to interview and speaking requests" at the end of item II.10. Another option would be to assure that communications officers and political appointees are prohibited from conducting scientific clearance review.

B. **Specifics regarding timely clearance:** We recommend the addition of the following provision regarding clearance procedures:

   "Each OpDiv/StaffDiv must have a written clearance policy that specifies who must review work products and gives deadlines by which comments must be given or the product can move to the next stage (e.g., if a supervisor does not clear or provide comments on a product five days after receiving it, it moves to the next-level approver; if there is no next-level approver, the author may submit the paper to a journal, deliver the presentation, etc.). The policy must also provide an appeal mechanism for those who are denied clearance and a method for obtaining a second opinion if an author disagrees with a requested revision."

5. Penalties sufficient to deter wrongdoing and hold accountable all scientific integrity violators, including political appointees

The draft policy makes appropriate references to corrective actions to be taken after a loss of scientific integrity is determined to have occurred. In order to deter wrongdoing and promote accountability, we urge that it also specify penalties for those found to have caused a loss of scientific integrity (which will only be enforced after those found in violation of the policy have declined or exhausted appeal opportunities). We recommend:

A. **Specific penalties for violations:** Penalties for violating scientific integrity policies should appear in HHS's official table of penalties, and the scientific integrity policy should reference them and task the SIO and Secretary with ensuring they are enforced. Penalties should be sufficiently meaningful to discourage violations — e.g., warnings,

suspension, demotion, or removal.

B. **Consequences comparable to those for ethics violations.** We recommend that HHS include in its policy the following responsibility — which OSTP included in its own agency scientific integrity policy[7]— for the Secretary of Health and Human Services: "Ensures that violations of scientific integrity policies be considered comparable to violations of government ethics rules, with comparable consequences. There must be appropriate consequences for scientific integrity violations."

C. **Publicly identify appointees found to have violated policies:** When an investigation determines that a political appointee has caused the loss of scientific integrity, the identity of that official should be made public and reported through their chain of command and to the NSTC Subcommittee on Scientific Integrity and the relevant Cabinet Officer.

6. Language from the model scientific integrity policy regarding equity in the scientific workforce and conflicts of interest in federal advisory committees

Given the importance of equity and transparency in scientific integrity, we recommend that the revised HHS policy include statements related to equity in the scientific workforce and conflicts of interest (COI) in federal advisory committees (FACs) that appear in the model policy.

A. **Equity in the scientific workforce:** In V.2., we recommend that the sentence "Promote diversity, equity, inclusion, and accessibility in the scientific workforce and to create safe workspaces that are free from harassment and discrimination" be followed by the sentence that follows it in the model policy: "Support scientists and researchers including, but not limited to, Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQI+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality; and advance the equitable delivery of Federal programs."

B. **Conflicts of interest in FACs:** To improve transparency, we recommend that Section VII include the following item, which appears in the model policy: "Except when prohibited by law, HHS should make all COI waivers granted to committee members publicly available."

[7] White House Office of Science and Technology Policy. (2023). White House Office of Scientific Integrity Policy (OSTP) Scientific Integrity Policy. https://www.whitehouse.gov/wp-content/uploads/2023/06/OSTP-SCIENTIFIC-INTEGRITY-POLICY.pdf

7. Specific protections from retaliation for those engaged in scientific activities that may put them at risk for reprisal

We applaud the HHS draft policy for going beyond the model policy to protect SIOs and others involved with scientific integrity policy implementation from reprisal (in V.3 and V.6), rather than relying on existing whistleblower protections alone. Although current laws and policies to protect whistleblowers are important and beneficial, their protections are not sufficient. We recommend that HHS add to its policy additional protections for those who could face reprisal when scientific integrity is compromised or when a bad-faith actor tries to misuse the scientific integrity policy to target an individual or area of research for inappropriate reasons. We recommend the following:

A. **Include the model policy's language regarding conducting work free from reprisal or concern for reprisal:** It is important that HHS not only take corrective action and assess penalties when reprisal is found to have occurred; preventing retaliation and ensuring employees can work free from concern for reprisal is also essential to avoid the chilling effect that occurs when employees see a colleague face reprisal or the threat of reprisal. We appreciate the value of HHS stating that it is HHS policy for leadership and management to ensure covered individuals can conduct their work "objectively and free from political interference and other inappropriate influence" (I.3); however, we urge that the HHS policy also include the model policy's requirement that covered individuals be able to conduct their work "free from reprisal or concern for reprisal."

B. **Offer additional protections against specific forms of retaliation.** We urge that HHS's policy not only make general statements about protecting covered individuals from "retribution, retaliation, or reprisal" (Section V), but specifically provide protections against blocklisting/blacklisting and retaliatory investigations and offer an affirmative defense to whistleblowers who are subjected to civil or criminal lawsuits.

C. **Acknowledge the possibility of reprisal and retaliation for scientific activities that do not meet the definition of whistleblowing.** We recommend adding a statement that reprisal or retaliation based on the topic or implications of an area of research is considered a violation of this scientific integrity policy.

8. A mechanism for addressing allegations that involve multiple OpDivs/StaffDivs, multiple agencies, and/or high-level officials

The "Addressing Scientific Integrity Concerns" procedures should establish one or more mechanisms for addressing situations when SIOs from multiple OpDivs/StaffDivs or agencies are involved or when the person accused of violating the scientific integrity policy is a high-level official. For instance, those with concerns might be instructed to contact the NSTC Subcommittee on Scientific Integrity. The framework explains that this Subcommittee's roles include "provid[ing] advisory responses to agency requests for another agency to review their

internal scientific integrity policies and processes, such as inquiries related to senior-level officials, political appointees, or scientific integrity officials" and "sharing of analysis or commentary on public allegations of scientific integrity violations that cannot be suitably handled at an individual agency-, department-, or Executive Office of the President component-level, such as allegations involving senior-level officials, political appointees, or SIOs or allegations involving multiple agencies."

9. Incorporation of the HHS Policy for the Common Data Use Agreement (DUA) Structure and Repository

We appreciate the recognition in Section II., Ensuring the Free Flow of Scientific Information, that the free flow of scientific and technological information supports scientific integrity. HHS has a strong data sharing policy, and we recommend that its scientific integrity policy incorporate it. Specifically, we recommend that Section II include the following:

"Ensure that all OpDivs/StaffDivs adhere to the HHS Policy for the Common Data Use Agreement (DUA) Structure and Repository (HHS-OCIO-CDO-2023-01-001). This should apply to all data that are collected with direct or indirect financial support from HHS agencies, including research grants and contracts, medical registries, and other sources of data intended to benefit the health and well-being of the public."

This could be added to item II.1 or follow it as a separate item.

The changes described above will make the HHS scientific integrity policy an even stronger tool for protecting science and science-based decision-making from political interference.

Thank you for the opportunity to comment on HHS's draft scientific integrity policy. If you have any questions, please contact Liz Borkowski of the Jacobs Institute of Women's Health at borkowsk@gwu.edu.

Center for Reproductive Rights
Climate Science Legal Defense Fund (CSLDF)
Equity Forward
Government Accountability Project
Government Information Watch
Ibis Reproductive Health
Jacobs Institute of Women's Health
National Center for Health Research
Project On Government Oversight
Public Employees for Environmental Responsibility (PEER)
Union of Concerned Scientists