Response to Request for Information To Support The Development of a Federal Scientific Integrity Policy Framework [Document Number 2022-04466]

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These comments respond to the Office of Science Technology Policy Request for Information regarding the Development of a Federal Scientific Integrity Policy Framework.[1] My comments are based on my 35-year experience as an epidemiologist serving in the Federal government at the Centers for Disease Control /Agency for Toxic Substances and Disease Registry (CDC/ATSDR 1985-2015) and the Environmental Protection Agency (EPA 2015-2020). I was the principal author of CDC's 1st Scientific Misconduct Policy, co-author of its scientific clearance guidelines, principal author of EPA's Plan To Increase Access to Results of EPA-Funded Scientific Research[2], and assisted in the completion of Best Practices for the Clearance of Scientific Products at EPA.[3] I held several scientific positions conducting, reviewing and approving agency intramural research at CDC/ATSDR. At EPA, I was the Director of the Office of the Science Advisor, Human Subjects Research Review Official, and Acting Scientific Integrity Official. In 2020, I responded to the EPA Administrator's effort to finalize Strengthening Transparency in Regulatory Science (STRS) rule by writing a differing scientific opinion (DFO)[4] and publishing a related Opinion in the Hill.[5]

Introduction

Several actions should be taken to secure scientific integrity across the Federal government. These include formalizing scientific integrity into new or existing rules, implementing institutional policies, creating firewalls between political appointees and the scientific process, and extending scientific integrity policies to Federal Advisory Committees, state governments, and academic institutions. All institutions awarded Federal funding for scientific activities as well as those submitting scientific data to the Federal government should be required to develop and implement scientific integrity policies.

Scientific integrity may be guided by the Executive Office of the President (EOP), but it is best practiced using a peer-to-peer and agency-by-agency approach. The culture of scientific integrity is built from the ground up. Few scientists work in isolation. You can be taught scientific integrity in a classroom, but you practice scientific integrity shoulder-to-shoulder with your research partners, your team, and your collaborators.

Applying scientific integrity principles across the Federal government is not a one-size-fits-all situation. Institutions have different expectations of scientists and supervisors. Scientists conducting laboratory studies have different responsibilities from those who work within a

[1] These comments are mine alone. I received no funding from any organization. These comments have not been reviewed by any potentially affected parties. I have no financial relationship with any entity having a financial interest in Federal scientific integrity. I currently hold adjunct professor positions at both the University of Maryland School of Public Health and the Emory University Rollins School of Public Health. My detailed curriculum vitae is available upon request.

[2] https://www.epa.gov/sites/default/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

[3] https://www.epa.gov/sites/default/files/2018-05/documents/best_practices_for_clearance_of_scientific_products_at_epa_final_21may2018.pdf

[4] https://int.nyt.com/data/documenttools/dissenting-scientific-opinion/8fdd7838c67f4c21/full.pdf

[5] https://thehill.com/opinion/energy-environment/527872-epas-scientific-integrity-in-question-over-science-rule

national security organization or help to establish science-based programs in the field. Each Federal department or agency that conducts or uses science should establish scientific guidelines that facilitate the work done by that department or agency. Investigations of a loss of scientific integrity should be conducted within the department or agency involved. Afterall, the scientists familiar with the technical expertise at question and the culture of scientific integrity that exists in the department or agency are those most qualified to evaluate the situation. Oversight for these investigations should be given to the department or agency scientific integrity official or program and/or its inspector general. A firewall is needed to shield scientists, research data and analysis, and scientific integrity programs from inappropriate political interference. The EOP can help establish how to create an effective firewall, but it should not oversee scientific integrity practices within departments and agencies. In addition, congress has an oversight role when a loss of scientific integrity is filed by a whistle blower.

1. *Information is requested on how scientific integrity policies … address …*

   (3) Emerging modes of science, such as citizen science and community-engaged research;

   Federally funded citizen science and community-engaged research and training should be covered by department and agency science integrity policies. Extramural grants, contracts, and cooperative agreements should address scientific integrity and awarded institutions should have policies equivalent to Federal policies. Research data submitted to the Federal government in response to a regulation or for Federal action should also comply with Federal scientific integrity policies. An example of a best practice is the quality assurance guidelines for citizen scientists developed by EPA.[6]

   (4) Coordination with related policy domains, such as open science and data; quality guidelines for data and information that agencies release; promotion of safe, equitable workplaces free from harassment and discrimination; and protection of research security and responding to research misconduct.

   Several science policy domains are related to scientific integrity. Each department and agency should examine these relationships and determine how best to encourage collaboration or separation as appropriate given their organization. Definitions and flowcharts should help each agency identify how to approach collaboration or separation. Prohibited personnel practices and personnel grievances should be excluded from scientific integrity actions. Each agency should clearly document how scientific integrity and scientific misconduct are addressed. For example, the Office of Research Integrity (ORI) within Health and Human Services deals exclusively with scientific misconduct, not scientific integrity.

2. *Information is requested on the criteria that should be used to evaluate scientific integrity policies: Content, implementation, outcomes, and impacts in Federal agencies and other*

[6] https://www.epa.gov/citizen-science/quality-assurance-handbook-and-guidance-documents-citizen-science-projects

> *components of the Executive Branch. Consider methods and metrics for evaluating elements such as, but not limited to: Policy provisions, practices, capacity, and actions so that determinations can be made on their efficacy to achieve desired outcomes and impacts.*

Evaluation of scientific integrity programs and practice should at first be based on metrics documenting their establishment and implementation. As programs mature, new metrics focused on program progress and impact can be used. While evaluation can help effective programs build upon strengths and fix weaknesses, too much evaluation can become burdensome and expensive, redirecting resources away from needed program implementation. Useful indicators of impact will be a challenge. Scientific success can be measured, but those metrics will not be specific for scientific integrity. Specific indicators of scientific integrity impact will likely focus on the frequency and degree of harmful practices and broken systems.

A reasonable first set of metrics could be drawn from those used by the Government Accountability Office's (GAO) review of scientific integrity policies in ten Federal agencies.[7] GAO stated that two core principles of scientific integrity was to: 1) Ensure the open exchange of information, and 2) Prevent the distortion of research findings for political or other reasons. Metrics focused on educating staff, providing oversight, and monitoring and evaluating policy-related activities.

While the GAO audit was a good start, it was expensive, time consuming, and did not evaluate the two core principles of scientific integrity it identified. It did identify strengths and weaknesses across the ten agencies it evaluated. It did not include contractors or grantees, Federal extramural research programs, or scientific integrity within national security activities. The cost of the GAO report likely exceeded the annual budget of most scientific integrity programs. GAO costs included compensation for 9 analysts and possibly contract support. Data collection included multiple teleconferences, requests for documents, and surveys. In-kind costs covering the salaries of dozens of government employees who responded to the GAO requests are unknown. The process took 13 months. GAO did not measure open exchange of information or distortion of research findings. GAO stated … *we reviewed agencies' scientific integrity policies and did not assess the extent to which agency officials may try to influence scientific research, nor did we examine how scientific and technological information is used in agencies' development of public policy (*pg 29*).*

Evaluation of program implementation, progress, and impact will be more difficult and will take some time to perfect. Because these evaluations can become tedious and expensive, most metrics should take advantage of routinely collected, and validated, data and avoid special data collection efforts. For example, training metrics could focus on certification of e-training modules. Percent of scientists, administrators, students, contractors, grantees, and political appointees certified would be easy once registration and personnel information are linked. Production, clearance, and public access to scientific products is another area for evaluation. An agency that establishes and implements clearance guidance into an agency-wide e-clearance system could track submitted products, approvals, timelines, and public accessibility to manuscripts and datasets. Political appointees should not be included in the clearance approval process but should be able to review and comment on the scientific products. A third set of

[7] https://www.gao.gov/assets/gao-19-265.pdf

indicators could examine investigations of the loss of scientific integrity and the time to resolve them. This requires clear guidelines that identify scientific integrity failures, protections for those making allegations as well as those being accused, and a clear set of investigation procedures. Creating an electronic tracking system of allegations could be used to generate data, however this system must be secured. It is not only important to identify issues that are not scientific integrity, but also scientific integrity concerns that will not be resolved by investigation. For example, the Office of Research Integrity recognizes plagiarism as scientific misconduct but considers most plagiarism claims to be authorship disputes.[8] While ORI has included authorship guidelines on its website, it does not investigate them. It is also important to distinguish between loss of scientific integrity or scientific misconduct from personnel misconduct and the grievance process and to direct each issue accordingly to not overwhelm scientific integrity investigations.

3. *Information is requested on how to ensure that scientific integrity evaluation findings, and other findings that evolve over time, such as findings on the emergent issues identified above, lead to iterative improvement of Federal scientific integrity policy and practices.*

   [no response]

4. *Information is requested on how to ensure the long-term viability and implementation of Federal scientific integrity policies, practices, and culture through future Administrations. Consider information on, but not limited to: Ways to ensure Federal scientific integrity is robust through changes in government leadership, funding, and cultural shifts; how to institutionalize policies and practices that ensure the integrity of science, build and sustain a culture of scientific integrity, and encourage transparency; and how to provide accountability, such as through procedures to identify, address, and provide appropriate and meaningful consequences for instances when scientific integrity policies have been violated*.

The best way to ensure long-term viability of scientific integrity policies and practices would be to establish a Federal Rule that could be adopted within the authorities of each Department or agency that conducts science. Such a rule could institutionalize policies and practices, build and sustain a culture of scientific integrity, promote transparency, and assure accountability. The authority for establishing such a rule may be available to OSTP through the 2007America COMPETES Act which ... *required the* Office of Science and Technology Policy (OSTP) to take actions to enhance the integrity of federal scientific research[9]. Should OSTP not have the authority, another Federal Department authorized to conduct science may have it. To develop a comprehensive Scientific Integrity Rule, the Common Rule might be used as a template. The Common Rule regulates human subjects research across 15 Federal departments and agencies.[10] One feature of the Common Rule worth considering is the creation of Institutional Review Boards at the institutional level that assure uniform standards are established protecting human subjects used in research across the country.

[8] https://ori.hhs.gov/ori-policy-plagiarism

[9] https://www.congress.gov/110/plaws/publ69/PLAW-110publ69.pdf

[10] https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

Establishing Scientific Integrity Boards could similarly formalize scientific integrity practices at institutions across the county. Another feature that has grown out of the Common Rule is the systematic training and credentialing of researchers who conduct human subjects research through the CITI program[11]. A similar program of training and credentialing for scientists to establish a culture of scientific integrity could be developed.

Should a Federal-wide rule not be established, an alternative approach to assuring long-term viability of scientific integrity would be to introduce language into existing and new science-based regulations or rules. This would be less likely to protect the entire Federal science landscape but could provide protection on a department-by-department or agency-by-agency basis. OSTP could work with the departments to identify model language to be inserted.

Regardless of rules and regulations, department and agency guidelines are necessary to implement scientific integrity practices across departments and agencies. However, these are unprotected from any administration that decides to ignore or rewrite them. Whether or not scientific rules or regulations can be established, additional work on existing guidelines and policies will strengthen current scientific integrity policies and guidance. These include the following:

- Establish agency-wide enforceable guidelines for clearance and approval of scientific manuscripts and products. Clearance guidelines should establish and enforce timelines so that scientific products are not discarded due to inattention.
- Establish agency wide electronic clearance systems to track progress and link scientific products to its public access portals.
- Prevent political interferences impacting scientific products by expanding the firewalls between political appointees and scientific products.
- Political appointees should not be included as an approver of scientific products. Political appointees should be allowed to review and comment on scientific products.
- Assure that all political appointees receive scientific integrity training and acknowledge that they are included under scientific integrity policies.
- Financial and institutional conflicts-of-interest of special government employees on Federal advisory committees should be avoided or balanced. Obtaining a research grant from the Federal government is not a financial conflict-of-interest.
- Definitions for key concepts such as *best available science* and *transparency* are needed. The quality of a scientific product and the scientific transparency of an agency is not based upon data availability.
    - Unbiased definitions of research transparency have been provided by social scientists. One such definition states research transparency is … *the obligation to make data, analysis, methods, and interpretive choices underlying their claims visible in a way that allows others to evaluate them*.[12] Social scientists include three dimensions

[11] https://about.citiprogram.org/?gclid=EAIaIQobChMIjsORleD49gIV821vBB1JHwS9EAAYAiAAEgI_2PD_BwE

[12] https://www.princeton.edu › ~amoravcs › library

in their definition: 1) data access, 2) production transparency, and 3) analytic transparency.[13] The data access dimension includes the statement …*If you generated or collected those data yourself, sharing those data or explaining why you cannot do so*. Any definition of research transparency that includes data access should emphasize that data access is the responsibility of the data owner and existing laws and regulations prevent release of protected data including personal identifying information.

- A definition for *best available science* requires flexibility and context. Several examples of definitions for best available science are available to consider.[14],[15] The *best* research is judged on type, quality, and relevance.

I appreciate the opportunity to provide these comments to OSTP. Feel free to contact me for follow-up should you have any questions.

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[13] From the Social Science Research Council https://managing-qualitative-data.org/modules/4/b/

[14] From https://www.epa.gov/sites/default/files/2017-09/documents/swinomish-wqs-title19-chapter6.pdf (see definitions page 13)

[15] From https://www.epa.gov/sites/default/files/2017-06/documents/tsca_ra_guidance_final.pdf [see page 7 definitions]