period to an amount less than 0.5. See 66 FR 12940.

CMS GME Final Regulation Change

In August 2022, CMS finalized a new methodology for applying the direct GME FTE resident cap when a hospital's weighted allopathic and osteopathic FTE resident count is greater than its direct GME FTE resident cap, in a way that does not reduce the weighting factor of residents that are beyond their initial residency period to an amount less than 0.5. Under the new method, if a hospital's unweighted allopathic and osteopathic FTE resident count exceeds its direct GME FTE resident cap, then the weighted allopathic and osteopathic FTE resident count is equal to the hospital's direct GME FTE resident cap or its actual weighted allopathic and osteopathic FTE resident count, whichever is lesser. The direct GME FTE resident cap reflects the maximum number of allopathic and osteopathic residents that a hospital may count for purposes of direct GME payment in a cost reporting period.

Alignment of CHGME and Medicare GME Policy

For more than two decades, HRSA has followed CMS's approach to calculating the FTE resident count. [See March 1, 2001, **Federal Register** *Notice* (66 FRN 12940), ''*The Department follows Medicare rules regarding the use of the initial residency period. The Medicare rules reduce counts for all hospitals that train residents beyond their initial residency period (i.e., fellows) with regard to the [direct medical education] DME and [indirect Medical Education] IME portions of the GME reimbursement.*''] Therefore, HRSA proposes to adopt CMS's modified direct GME payment methodology with respect to determining the weighted number of allopathic and osteopathic FTE residents (*i.e.,* fellows) for all eligible children's hospitals participating in the CHGME Payment Program beginning in FY 2026.

In this notice, we refer to the FTE adjusted cap (or 2013 CHGME Reauthorization cap pursuant to Pub. L. 113–98) reported on Line 4.06, 5.06, and 6.06 of the HRSA 99–1 Form as the ''direct GME FTE resident cap'' to correspond with CMS terminology.

HRSA proposes to modify its methodology to adopt the CMS methodology described in the amended 42 CFR 413.79 in whole. HRSA anticipates implementing the updated methodology for determining the weighted allopathic and osteopathic FTE resident count starting in the FY 2026 application cycle (project period October 1, 2025, through September 30, 2026).

Direct GME Methodology in FY 2026—Proposal for Public Comment

Starting in FY 2026, where a CHGME participating hospital's unweighted allopathic and osteopathic FTE resident count exceeds the hospital's FTE resident cap, and the weighted allopathic and osteopathic FTE resident count also exceeds that FTE resident cap, the respective weighted allopathic and osteopathic FTE resident count is adjusted to make the total weighted allopathic and osteopathic FTE resident count equal the FTE resident cap. If the weighted allopathic and osteopathic FTE resident count does not exceed that FTE resident cap, then the allowable weighted allopathic and osteopathic FTE resident count for direct GME payment is the actual weighted allopathic and osteopathic FTE resident count.

This proposed update to the methodology for determining the weighted allopathic and osteopathic FTE resident count for the CHGME Program is intended to reconcile weighted FTE resident counts reported in Lines 4.13 (both Hospital Data columns), 5.13, and 6.13 of the HRSA Form 99–1 with Lines 9 and 22 of the CMS Form 2552–10, Worksheet E–4, respectively. Entries in Lines 4.13 (both Hospital Data columns), 5.13, and 6.13 report the weighted resident FTE count for allopathic and osteopathic programs following application of the direct GME FTE resident cap.

This updated methodology for determining weighted allopathic and osteopathic FTE resident count may result in adjustments to the weighted FTE resident 3-year rolling average used to determine direct medical education (DME) payment amounts for the eligible children's hospitals participating in the CHGME Payment Program.

The DME payment amounts for CHGME are impacted by many factors including the number of residents the hospital trained during the year, the hospital's wage index, as well as the overall appropriation. The updated methodology for determining the weighted FTE resident count will impact awardees that add more residents and fellows above their hospital's direct GME FTE resident cap. The updated methodology may also impact the DME payments for awardees overall as a hospital may receive a different relative share of the CHGME appropriation due to these shifts in the weighted FTE resident counts experienced by some hospitals.

The CHGME Payment Program proposes to implement this updated methodology beginning in FY 2026 to reduce burden on hospitals participating in CHGME and Medicare GME and to reduce the risk of potential audit discrepancies that may impact payments.

Diana Espinosa,

Principal Deputy Administrator.

[FR Doc. 2024–31240 Filed 12–27–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Final Scientific Integrity Policy of the U.S. Department of Health and Human Services

AGENCY: Office of the Assistant Secretary for Planning and Evaluation, Office of the Secretary, HHS.

ACTION: Notice of final policy.

SUMMARY: The Department of Health and Human Services (HHS) is publishing its Scientific Integrity Policy to increase access to and raise awareness of the Policy.

DATES: The effective date of the Policy is October 16, 2024.

FOR FURTHER INFORMATION CONTACT: Karen Wehner, Ph.D., Scientific Integrity Officer, Office of Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation, Office of the Secretary, HHS at 240–453–8435 or *scientificintegrity@hhs.gov.*

SUPPLEMENTARY INFORMATION: Scientific integrity plays a vital role in the mission of HHS. Ensuring integrity in science throughout the Department allows HHS to foster and produce high-quality science, communicate effectively with the public, and base critical policy decisions on trustworthy and rigorous scientific findings. HHS has adopted a Department-wide scientific integrity policy to further strengthen scientific integrity and evidence-based policymaking throughout the Department.

The Scientific Integrity Policy of the U.S. Department of Health and Human Services (Policy) was approved on September 16, 2024. The finalized Policy was announced to the HHS community and posted on the HHS scientific integrity website, at *https://www.hhs.gov/programs/research/scientificintegrity/index.html,* on September 30, 2024. The effective date of the Policy is October 16, 2024.

The content of the finalized Policy, reformatted to conform to the requirements of the **Federal Register**, is

provided below. This content is also available in its original format on the HHS website, at *https://www.hhs.gov/sites/default/files/hhs-scientific-integrity-policy.pdf.*

The Scientific Integrity Policy of the U.S. Department of Health and Human Services

Purpose

The purpose of this policy is to promote a continuing culture of scientific integrity at the U.S. Department of Health and Human Services (HHS). This policy aims to ensure the integrity of all aspects of HHS scientific activities, including proposing, conducting, reviewing, managing, and communicating about science and scientific activities, and using the results of science to inform policy and program decision-making.

Core Values That Support Scientific Integrity at HHS

The success of HHS's mission to enhance the health and well-being of all Americans depends on the development and use of accurate, complete, and timely scientific and technical information. Scientific integrity requires that such information be developed under and subjected to well-established scientific processes, free from inappropriate interference that undermines impartiality, nonpartisanship, or professional judgment. HHS agencies work to maximize the quality, accuracy, objectivity, utility, and timeliness of the scientific and technological information they produce, use, and disseminate. In turn, this information enables HHS to employ innovative approaches to effectively address the many public health and human services challenges that our work targets. These efforts allow accurate, complete, and timely scientific and technical information to improve the design, delivery, and impact of HHS policies and programs, and support equity, justice, and trust. Responsibility for upholding scientific integrity lies with the entire scientific ecosystem, including all HHS employees, its contractors and grantees, and those engaged in science and scientific activities outside HHS.

Definition of Scientific Integrity and Scientific Integrity Official

HHS adopts the following Official Federal Definition of Scientific Integrity:

> Scientific integrity is the adherence to professional practices, ethical behavior, and the principles of honesty and objectivity when conducting, managing, using the results of, and communicating about science and scientific activities. Inclusivity, transparency, and protection from inappropriate influence are hallmarks of scientific integrity.[1]

HHS designates a senior career employee as the HHS Scientific Integrity Official (HHS SIO) [2] to oversee implementation and iterative improvement of the HHS Scientific Integrity Policy and related processes. The roles and responsibilities of the HHS SIO are described in more detail on pages 17–18.

This policy empowers the HHS SIO with the independence necessary to gather and protect information to support the review and assessment of scientific integrity concerns and ensure implementation of corrective scientific actions such as policy changes or correction or retraction of published materials. The HHS SIO also advocates for appropriate engagement of scientific leadership in decision making.

Effective Date and Policy Amendments

This policy is effective 30 days after the date of finalization. This policy will be reviewed by HHS one year after its effective date and every two years thereafter. Proposals to amend this policy will be overseen by the HHS SIO, in collaboration with the HHS Scientific Integrity Council described below and communicated to the Director of the White House Office of Science and Technology Policy (OSTP) no later than 30 days after adoption.

Applicability & Scope

Scientific integrity is the responsibility of the entire HHS workforce. Covered individuals who are required to adhere to this policy include all HHS employees, including all Operating and Staff Division (OpDiv/StaffDiv) employees; Public Health Service Commissioned Corps officers; political appointees; HHS fellows, trainees, and interns; and advisory committee members in their capacity as special government employees, when in the course of their official duties they propose, conduct, review, or communicate about science and scientific activities, and all levels of employees who manage or supervise scientific activities and use scientific information in decision making.

HHS is composed of OpDivs/StaffDivs (hereinafter ''Division''), some of which have division-specific scientific integrity policies and procedures. The HHS Scientific Integrity Policy applies to all covered individuals, as listed above; Division-specific Scientific Integrity policies apply to covered individuals within that division. Division-specific policies align with and support the HHS-wide policy at a minimum but may institute additional requirements and responsibilities as appropriate for the mission of the division. In addition to Division-specific policies, Divisions may develop their own scientific integrity procedures (*e.g.,* procedures for resolving differences of scientific opinion) at their discretion.

HHS contractors; partners; permittees; lessees; grantees; extramural trainees and fellows (*i.e.,* those supported by HHS grants to non-HHS organizations); and volunteers who engage or assist in HHS scientific activities are not considered covered individuals but are strongly encouraged to uphold the principles of scientific integrity described in this policy, particularly those described in the Protecting Scientific Processes, Ensuring the Free Flow of Scientific Information, Protections, and Professional Development sections. Specific requirements may be incorporated into the terms of their engagement with HHS. In addition, each institution that applies for or receives Public Health Service (PHS) support for biomedical or behavioral research, research training, or activities related to that research or research training must comply with 42 CFR part 93, PHS Policies on Research Misconduct, overseen by the HHS Office of Research Integrity (ORI), and may need to comply with other applicable laws, regulations, and policies. Research misconduct, which includes fabrication, falsification, and plagiarism, is one way in which scientific integrity can be compromised.

Authorities

Pursuant to the 2021 Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking,[3] and consistent with the 2009 Presidential Memorandum on Scientific Integrity [4] and the 2010 Memorandum from the White House Office of Science and Technology Policy on Scientific Integrity,[5] all Federal agencies must establish a scientific integrity policy. The requirements of this policy are derived from the 2022 National Science and Technology Council (NSTC) Report of the Scientific Integrity Fast Track Action Committee (SI–FTAC), Protecting the Integrity of Government Science [6] (SI–FTAC Report), and align with the 2021 NSTC Framework for Federal Scientific Integrity Policy and Practice.[7]

This policy is established in accordance with:

1. Public Law No 111–358—The America COMPETES Reauthorization Act of 2010, Section 103, as amended.
2. Public Law No 115–435—The Foundations

for Evidence-based Policymaking Act of 2018.
3. Public Law No 106–554—The Information Quality Act of 2000.
4. 67 FR 8451—OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies.
5. 70 FR 2664—OMB Final Information Quality Bulletin for Peer Review.
6. 65 FR 76260–76264—Federal Policy on Research Misconduct.
7. Pub. L. 101–12—The Whistleblower Protection Act (WPA) of 1989, as amended.
8. 41 U.S.C. 4712—The National Defense Authorization Act, Enhancement of contractor protection from reprisal for disclosure of certain information.
9. 5 U.S.C. 13103 *et seq.*—The Ethics in Government Act of 1978, as amended, and 5 CFR part 2635, Standards of Ethical Conduct for Employees of the Executive Branch.
10. 18 U.S.C. 201–209—Statutes regarding Bribery, Graft and Conflicts of Interest.
11. 5 CFR parts 5501 and 5502—Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services.
12. 5 U.S.C. Ch. 10—The Federal Advisory Committee Act of 1972.
13. 45 CFR part 73—Standards of Conduct.
14. 5 CFR part 735—Employee Responsibilities and Conduct.
15. 45 CFR part 46—HHS Protection of Human Subjects Regulation.
16. PPD 19—Protecting Whistleblowers with Access to Classified Information, 2012.
17. M–20–12—OMB Phase 4 Implementation of the Foundations for Evidence-Based Policymaking Act of 2018: Program Evaluation Standards and Practices.
18. 42 CFR part 93—Public Health Service Policies on Research Misconduct.
19. 10 U.S.C. 1034, made applicable to the Public Health Service Commissioned Corps through 42 U.S.C. 213a(a)(18), and implemented by Commissioned Corps Directive (CCD) 121.06.
20. Pub. L. No 117–328—Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, Division FF, Title II, Section 2321.
21. Pub. L. No 117–167—CHIPS and Science Act of 2022, Title VI, Subtitle D, Section 10631.

Exceptions

This policy will be implemented consistent with applicable federal law and Executive Orders.

Definitions

For the purposes of this policy, HHS adopts the following definitions:

Allegation refers to a disclosure of a suspected loss of scientific integrity.

Corrective scientific action refers to actions taken to restore the accuracy of the scientific record after a loss of scientific integrity has been determined, consistent with this policy, such as correction or retraction of published materials.

Covered individuals who are required to adhere to this policy include all HHS employees; Public Health Service Commissioned Corps officers; political appointees; HHS fellows, trainees, and interns; and advisory committee members in their capacity as special government employees, when in the course of their official duties they propose, conduct, review, or communicate about science and scientific activities, and all levels of employees who manage or supervise scientific activities and use scientific information in decision making.

Decision making refers to the (1) development of policies or making determinations about policy or management; (2) making determinations about expenditures of Federal agency funds; (3) implementing or managing activities that involve, or rely on, scientific activities.

Ethical behavior refers to activities that reflect norms for conduct that distinguish between acceptable and unacceptable behavior, such as honesty, lawfulness, equity, and professionalism, and adherence to statutes, regulations, policies, and guidelines governing employee conduct.

Federal agency refers to an Executive department, a Government corporation, or an independent establishment.

Inclusivity refers to the practice of providing equal access to opportunities for full participation of all people and all groups, including marginalized, underserved, and underrepresented contributors, without bias or prejudice. Full participation is enabled through implementation of strategies that promote equitable access and fair treatment in the organization.

Inappropriate influence refers to the attempt to shape or interfere in scientific activities or the communication about or use of scientific activities, against well-accepted scientific methods and theories and without scientific, legal, or security justification.[8 9]

Interference refers to inappropriate, scientifically unjustified intervention in the conduct, management, communication, or use of science. It includes censorship, suppression, or distortion of scientific or technological findings, data, information, or conclusions; inhibiting scientific independence during clearance and review; scientifically unjustified intervention in research and data collection; and inappropriate engagement or participation in peer review processes or on Federal advisory committees.

Loss of scientific integrity refers to the failure to comply with this Scientific Integrity Policy or to adhere to objectivity, transparency, and ethical behavior when conducting, managing, using the results of, and communicating about science and scientific activities. This loss may include research misconduct or inappropriate influence in the conduct, communication, management, and use of science.

Policy refers to laws, regulations, procedures, administrative requirements or actions, incentives, or voluntary practices of governments and other institutions.

Political interference is inappropriately shaping or interfering in the conduct, management, communication, or use of science for political advantage or such that it undermines impartiality, nonpartisanship, or professional judgment.

Research integrity refers to the use of honest and verifiable methods in proposing, performing, and evaluating research; reporting research results with particular attention to adherence to rules, regulations, and guidelines; and following commonly accepted professional codes or norms.

Research misconduct refers to fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.[10]

Research security refers to safeguarding the research enterprise against the misappropriation of research and development to the detriment of national or economic security, related violations of research integrity, and foreign government interference.

Retaliation refers to taking or failing to take or threatening to take or fail to take a personnel action with respect to any employee or applicant for employment because of any disclosure of information that the employee or applicant reasonably believes evidences any violation of any law, rule, or regulation or gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety if such disclosure is not specifically prohibited by law and if such information is not specifically required by Executive Order to be kept secret in the interest of national defense or the conduct of foreign affairs. An employee or applicant is protected from retaliation for the disclosure of information the employee or applicant reasonably believes is evidence of censorship

related to research, analysis, or technical information.[11] [12]

Science refers to the full spectrum of scientific endeavors, including basic science, applied science, evaluation, engineering, technology, economics, social sciences, and statistics, as well as the scientific and technical information derived from these endeavors.

Scientific activities refer to activities that involve the application of well-accepted scientific methods and theories in a systematic manner, and includes, but is not limited to, data collection, inventorying, monitoring, evaluation, statistical analysis, surveying, observations, experimentation, study, research, integration, economic analysis, forecasting, predictive analytics, modeling, technology development, and scientific assessment, as well as any findings derived from these activities.

Scientific integrity is the adherence to professional practices, ethical behavior, and the principles of honesty and objectivity when conducting, managing, using the results of, and communicating about science and scientific activities. Inclusivity, transparency, and protection from inappropriate influence are hallmarks of scientific integrity.

Scientific record refers to published information resulting from scientific activities. HHS is responsible for ensuring the accuracy of elements of the scientific record that are published by HHS.

Scientist refers to an individual whose responsibilities include collection, generation, use, or evaluation of scientific and technical data, analyses, or products. HHS scientists are HHS employees and other covered individuals who conduct these activities. It does not refer to individuals with scientific and technical training whose primary job functions are in non-scientific roles (*e.g.,* policymakers, communicators).

Policy Requirements

Promoting a Culture of Scientific Integrity

HHS leadership at all levels recognizes, supports, and promotes this policy and its underlying principles, and models behavior consistent with a strong culture of scientific integrity.

HHS works to promote a culture of scientific integrity by creating an empowering environment for innovation and protecting scientists and the process of science from inappropriate interference. Scientific findings and products must not be suppressed, delayed, or altered for political purposes and must not be subjected to political interference or inappropriate influence.

A strong culture of scientific integrity begins with ensuring a professional environment that is safe, equitable, and inclusive. Issues of diversity, equity, inclusion, and accessibility are an integral component of the entire scientific process. Attention to these issues can improve the representativeness and eminence of the scientific workforce, foster innovation in the conduct and use of science, and provide for more equitable participation in science by diverse communities. The responsible and ethical conduct of research and other scientific activities requires an environment that is equitable, inclusive, safe, and free from harassment, and discrimination.

To instill and enhance a culture of scientific integrity, HHS has posted this policy prominently on its website, at *https://www.hhs.gov/programs/research/scientificintegrity/index.html*, and educates all covered individuals, as well as contractors who perform scientific activities for HHS, on their rights and responsibilities related to scientific integrity. Training will be made available to all covered individuals to make them aware of their responsibilities under the HHS Scientific Integrity Policy upon hiring, and some covered individuals may be required to complete role-specific training or refresher training as appropriate. Training will be tracked to ensure covered entities have received appropriate training.

HHS also works to apply scientific integrity practices in ways that are inclusive of non-traditional modes of science, such as citizen science, community-engaged research, participatory science, and crowdsourcing. This may include expanded scientific integrity practices and expectations, such as granting communities more autonomy over research questions and research design, recognition of data and knowledge sovereignty, and inclusion of multiple forms of evidence, such as Indigenous Knowledge, as applicable.

To promote a culture of scientific integrity at HHS, this policy outlines seven specific areas:

I. Protecting Scientific Processes
II. Ensuring the Free Flow of Scientific Information
III. Supporting Decision Making Processes
IV. Ensuring Accountability
V. Protections
VI. Professional Development for Government Scientists, and
VII. Federal Advisory Committees

I. Protecting Scientific Processes

Scientific integrity fosters ''honest scientific investigation, open discussion, refined understanding, and a firm commitment to evidence'' (OSTP 2010). It also enables consideration and documentation of differing scientific opinions. Practices that support scientific integrity may include peer review and open science. Science, and public trust in science, thrives in an environment that prevents political interference and inappropriate influence from impacting scientific data and analyses and their use in decision making.

It is the policy of HHS to:

1. Prohibit political interference or other inappropriate influence in the design, proposal, conduct, review, management, evaluation, communication about, and use of scientific activities and scientific information.

2. Prohibit inappropriate restrictions on resources and capacity that limit and reduce the availability of science and scientific products (*e.g.,* manuscripts for scientific journals, presentations for workshops, conferences, and symposia) outside of normal budgetary or priority-setting processes or without scientific, legal, or security justification.

3. Require that leadership and management ensure that covered individuals engaged in scientific activities can conduct their work objectively, free from political interference or other inappropriate influence, and free from retaliation.

4. Require reasonable efforts by covered individuals to ensure the fidelity of the scientific record and to correct identified inaccuracies that pertain to their contribution to any scientific records.

5. Require that covered individuals represent their contributions to scientific work fairly and accurately and neither accept nor assume unauthorized and/or unwarranted credit for another's accomplishments. To be named as an author, contributors should, at a minimum, have (1) made a substantial contribution to the scientific product or provided editorial revisions that include critical intellectual content, (2) approved the final version, and (3) agreed to be accountable for all aspects of the work to which they contributed. Prior consent should be obtained from each author to be represented on a particular work. Obtaining prior consent for acknowledgements is also a good practice. This policy sets a minimum requirement for authorship attribution, and HHS OpDivs/StaffDivs may have additional authorship criteria. Different

scientific disciplines use a range of strategies to attribute scientific work to individuals, and documents may be published without authorship attributions.

6. Ensure independent review of scientific facilities, methodologies, and other scientific activities as appropriate to ensure scientific integrity.

7. Require that covered individuals comply with HHS policies and procedures for planning and conducting scientific activities and show appropriate diligence toward protecting and conserving Federal research resources, such as equipment and other property, and records of data and results that are entrusted to them.

8. Prohibit research misconduct, the deliberate or reckless use of improper or inappropriate research methods or processes, and noncompliance with practices that safeguard the quality of research and other scientific activities or enhance research security.

9. Require that covered individuals design, conduct, manage, evaluate, and communicate about scientific research and other scientific activities honestly and thoroughly, and disclose any conflicts of interest to their supervisor or other appropriate HHS official(s) for their determination as to whether a recusal, disclaimer, or other action is appropriate, consistent with HHS ethics policies and procedures.

10. Require that research involving the participation of human subjects and the use of non-human animals is conducted in accordance with applicable, established laws, regulations, policies, and ethical considerations.

11. Support and enhance scientific integrity with the understanding that violations of scientific integrity can have a disproportional impact on underrepresented groups or weaken the equitable delivery of Federal Government programs.

12. Consistent with OSTP guidance and relevant HHS policy, prohibit HHS personnel engaged in intramural research from participating in foreign talent recruitment programs, unless participation is in an international conference or other international exchange, partnership, or program for which such participation has been approved by the appropriate authority in HHS.[13]

13. Consistent with OSTP guidance and relevant HHS policy, require disclosure of participation in foreign talent recruitment programs, including the provision of copies of all grants, contracts, or other agreements related to such programs, and other supporting documentation related to such programs, as a condition of receipt of Federal extramural research funding awarded through HHS.[10]

14. Prohibit the suspension or early termination of a grant except as consistent with applicable law and grants policies.[14] [15] [16]

II. Ensuring the Free Flow of Scientific Information

Open and timely communication of HHS science plays a valuable role in building public trust and understanding of HHS work. HHS facilitates the free flow of scientific and technological information and supports scientific integrity in the communication of scientific activities, findings, and products.

It is the policy of HHS to:

1. Facilitate the free flow of scientific and technological information, to the extent permissible by federal laws and regulations. Consistent with open government requirements, HHS will expand and promote access to scientific and technological information by making it available freely and without embargo to the public in an online digital format.[17] [18]

2. Ensure that scientific findings and products are not unduly suppressed, delayed, or altered for political purposes and are not subjected to inappropriate influence.

3. Require 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 valid scientific, legal, or security justification. Deviations from clearance policies or procedures that result in suppression, delay, or alteration of scientific and technological information without scientific, legal, or security justification may constitute violations of the HHS Scientific Integrity Policy and may be reported under the Procedures: Addressing Scientific Integrity Concerns section in this document.

4. Prohibit HHS officials, including communications officers, from altering, or directing HHS scientists and technology experts to alter, scientific and technological research findings or presentation of research findings in a manner that may compromise the objectivity or accurate representation of those findings.

5. Ensure that scientific information is accurately represented in responses provided by HHS to Congressional inquiries, testimony, and other requests.

6. Ensure that the work and conclusions of HHS scientists and the work and conclusions of scientists funded or supported by the federal government are accurately represented in HHS communications. If communication documents significantly rely on a scientist's research, identify them as an author, or represent their scientific opinion, the scientist will be given the option to review the scientific content of proposed communication documents prior to publication or public release.

7. Accurately represent the work and conclusions of scientists in HHS social media communications and provide appropriate guidance to HHS scientists on the use of HHS social media. If scientists whose work is represented in HHS social media identify any errors in those representations, HHS social media managers are responsible for making appropriate corrections expeditiously.

8. Require HHS or its OpDivs/StaffDivs, when offering spokespersons in response to media requests, to offer knowledgeable spokespersons who can, in an objective and nonpartisan manner, describe the relevant scientific or technological aspects of their work.

9. Ensure that HHS scientists may communicate their scientific activities objectively without political interference or other inappropriate influence, consistent with HHS and OpDivs/StaffDivs communication and media policies. Scientific products must adhere to relevant HHS technical review procedures.

10. Encourage, but not require, HHS scientists to communicate with the media in their official capacities regarding their scientific activities and areas of expertise, subject to limitations of government ethics rules.[19] In communicating with the media, HHS scientists are encouraged to seek advice from career HHS communications experts.

11. Allow covered individuals to communicate their personal or individual views to the media or the public in their personal capacities, including on social media, subject to the limitations of government ethics rules, HHS supplemental ethics regulations, social media regulations, and obligation to protect nonpublic information.[20] HHS scientists and other covered individuals presenting their personal views may name HHS as their employer as one biographical fact among several; however, their title and position cannot receive more prominence than any other biographical fact and they must make clear that they are presenting their personal and/or individual views—not the views of HHS—and they should not be sourced by the media as an HHS representative.

III. Supporting Decision Making Processes

It is the policy of HHS to:

1. Ensure the quality, accuracy, and transparency of scientific information used to support policy and decision making, including by:

a. Using scientific information that is subject to well-established scientific processes.

b. Ensuring that scientific data and research used to support policy decisions undergo review by qualified experts, where feasible and appropriate, and consistent with law.

c. Adhering to the Office of Management and Budget Final Information Quality Bulletin for Peer Review.[21] For example, as described in the Bulletin, when independent peer reviews of scientific information products are conducted by contractors, a conflict-of-interest review will be conducted.

d. Reflecting scientific information appropriately and accurately and making scientific findings or conclusions considered or relied on in policy decisions publicly available online and in open formats, to the extent practicable.

2. Where legally permissible and appropriate, directly consult with scientists whose work is being used in policy and management decisions to ensure that the science is accurately represented and interpreted.

3. Ensure, to the extent possible, the accuracy of HHS communication of the science upon which a policy decision is based.

4. Ensure that the HHS SIO, with input from the HHS Scientific Integrity Council, develops a transparent mechanism for covered individuals to express differing scientific opinions free from political interference or inappropriate influence.

IV. Ensuring Accountability

It is the policy of HHS to:

1. Ensure correction of the scientific record and implementation of corrective scientific actions when allegations of a loss of scientific integrity are substantiated. Corrective scientific actions may include correction or retraction of published scientific work or related media releases, release of inappropriately suppressed scientific materials, monitoring or supervision of future scientific activities, or required validation of data sources.

2. Encourage and facilitate early informal or formal consultation between employees and scientific integrity officials to advise on preventing loss of scientific integrity, to determine whether a loss of scientific integrity has potentially occurred, and to ascertain whether an allegation should be referred elsewhere for resolution.

3. Provide clear guidance on how to formally and confidentially report concerns and allegations of loss of scientific integrity. Those who report concerns and allegations need not be directly involved or witness a violation.

4. Ensure that the HHS SIO, together with other Scientific Integrity Council members, as applicable, draft procedures to respond to allegations of loss of scientific integrity at HHS in a timely, objective, and thorough manner. These procedures will include an initial assessment and review, a fact-finding process, an adjudication or determination including description of remedies and preventative measures to safeguard the science, an appeals process, follow-up to track implementation of remedies, and reporting. OpDivs/StaffDivs may develop and implement division-specific procedures for handling allegations within their Divisions.

5. These procedures will document the necessary aspects for each step of the process including burden of proof, any necessary determination of intentionality, and reporting, as well as the roles of the HHS SIO and HHS staff in the process.

6. Ensure that relevant HHS OpDivs/StaffDivs have scientific integrity policies that are consistent and in alignment with this policy.

V. Protections

HHS assures the protection of covered individuals as appropriate from retaliation in implementation of this policy.

It is the policy of HHS to:

1. Select and retain candidates for scientific and technical positions based on the candidate's scientific and technical knowledge, credentials, experience, and integrity, and hold them and their supervisors to the highest standards of professional and scientific ethics.

2. Promote diversity, equity, inclusion, and accessibility in the scientific workforce and create safe workspaces that are free from harassment and discrimination. 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, queer, intersex, and asexual (LGBTQIA+) 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.

3. Protect from retaliation those individuals who report in good faith allegations of loss of scientific integrity. Efforts will be made to protect the privacy of individuals involved in allegations.

4. Prevent HHS employees from intimidating or coercing scientists to alter scientific data, findings, or professional opinions or from inappropriately influencing scientific advisory boards.

5. Comply with whistleblower protections, specifically:

a. The requirements of the Whistleblower Protection Act of 1989, and its expanded protections enacted by Public Law 103–424 and the Whistleblower Protection Enhancement Act of 2012. 5 U.S.C. part 2302(b)(8)–(9).

b. The National Defense Authorization Act's expansion of certain whistleblower protections to employees of federal government contractors, subcontractors, and grant recipients. 41 U.S.C. part 4712.

c. Presidential Policy Directive 19, which prohibits supervisors from taking, failing to take, or threatening to take or fail to take any action affecting an employee's eligibility for access to classified information in retaliation for making a protected disclosure.

d. The Military Whistleblower Protection Act (codified at 10 U.S.C. 1034), which is made applicable to the Public Health Service Commissioned Corps (PHSCC) officers through 42 U.S.C. 213a(a)(18), and implemented by Commissioned Corps Directive (CCD) 121.06.

6. The HHS SIO and OpDiv/StaffDiv SIOs are protected by all applicable employee rights as required by law. An SIO or other scientific integrity staff may only be terminated or reassigned for reasons consistent with applicable law.[22] [23]

VI. Professional Development for Government Scientists

HHS encourages its scientists and other covered individuals involved in HHS scientific activities to interact with the broader scientific community, in a manner that is consistent with Federal rules of ethics, employment responsibilities, and to the extent that is practical, given the availability of funding to support such interactions.[24]

It is the policy of HHS to:

1. Encourage timely publication of research such as in peer-reviewed, professional, scholarly journals, HHS

technical reports and publications or other appropriate outlets.

2. Encourage the sharing of scientific activities, findings, and materials through appropriate avenues including digital repositories.

3. Encourage participation in and presentation of research at professional meetings including workshops, conferences, and symposia.

4. When appropriate, permit service on editorial boards, as peer reviewers, or as editors of professional or scholarly journals.

5. When appropriate, permit participation in professional societies, committees, task forces, and other specialized bodies of professional societies, including removing barriers to serving as officers or on governing boards of such societies, to the extent allowed by law.

6. Permit government scientists to receive honors and awards for contributions to scientific activities and discoveries to the extent allowed by law, and to accrue the professional recognition of such honors or awards.

7. Permit HHS scientists to perform outreach and engagement activities, such as speaking to community and student groups, as part of their official duties, as appropriate.

VII. Federal Advisory Committees (FACs)

Federal Advisory Committees (FACs), as defined by the Federal Advisory Committee Act, at *https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/legislation-and-regulations/the-federal-advisory-committee-act,* are an important tool within HHS for ensuring the credibility, quality, and transparency of HHS science. HHS will adhere to the Federal Advisory Committee Act and develop policies in coordination with the General Services Administration and consistent with the guidance on lobbyists serving on FACs when convening FACs tasked with giving scientific advice.

Consistent with all applicable laws and guidance regarding FACs, it is the policy of HHS to:

1. Promote transparency in the recruitment of new FAC members, including, when practical and appropriate, announcing vacancies with a notification in the **Federal Register**.

2. Select members to serve on a scientific or technical FAC based on expertise, knowledge, and contribution to the relevant subject area. Additional factors that may be considered are availability of the member to serve, alignment with relevant Federal Advisory Committee Membership Balance Plan, and the ability to work effectively on advisory committees. Ensure committee membership is fairly balanced in terms of points of view represented with respect to the functions to be performed by the FAC.[25]

3. Comply with current standards governing conflict of interest as defined in statutes and implementing regulations.

4. Except when prohibited by law and to the extent practical, agencies should appoint members of scientific and technical FACs as Special Government Employees.

5. Treat all reports, recommendations, and products produced by FACs solely as the reports, recommendations, and products of such committees rather than of the U.S. Government, and thus not subject to intra- or inter-agency revision. The role of the FACs is to provide advice or recommendations to the agency. The agency may then craft policy based on the FACs' advice or recommendations if it chooses to adopt those recommendations.

Scientific Integrity Council

HHS will establish a Scientific Integrity Council (Council) comprising one senior career employee from each relevant HHS OpDiv/StaffDiv. Relevant HHS divisions include those that conduct, manage, use, and communicate about scientific activities, as defined by the HHS Scientific Integrity Policy. The Council may engage with other HHS divisions as needed to support its responsibilities. The Council will be chaired by the HHS SIO. Where an OpDiv/StaffDiv has established a division SIO, that person will represent the division; where an OpDiv/StaffDiv has not established a division SIO, a similarly high-ranking career official with the appropriate scientific expertise, stature, and authority will represent the division.

Council members will ensure consistent implementation of the Scientific Integrity Policy at HHS, act as liaisons for their respective OpDivs/StaffDivs, assist with training and policy assessment, updates, and amendments, and be available to address any questions or concerns regarding this policy. The HHS SIO, together with the Council, will draft a Scientific Integrity Council Charter outlining criteria for selection as a member, other duties of members, and the frequency of meetings. The primary responsibilities of the Council are to:

1. Ensure that a well-informed and high-level group of experts supports scientific integrity at HHS.

2. Ensure that the HHS Scientific Integrity Policy is implemented consistently across the Department.

3. Review, assess, and revise the HHS Scientific Integrity Policy every two years, or more frequently as needed.

4. Serve on scientific integrity review panels and adjudicate allegations of losses of scientific integrity originating at HHS divisions that do not have their own scientific integrity policy, originating from more than one HHS division, or originating within the Office of the Secretary.

5. Determine handling of investigation and adjudication proceedings from which the HHS SIO is recused.

6. Engage HHS and division leadership in upholding the principles of scientific integrity, and maintain leadership awareness of scientific integrity issues as necessary and appropriate.

7. Support the education of all Department employees on their rights and responsibilities related to scientific integrity.

Procedures

The HHS SIO, in conjunction with the Scientific Integrity Council, has developed the following procedures for addressing scientific integrity concerns, handling differing scientific opinions, and clearance of scientific products and communications.

Addressing Scientific Integrity Concerns

The HHS SIO has primary responsibility for addressing scientific integrity concerns raised to the Department. The Scientific Integrity Council will support and assist the HHS SIO as needed. Full policies and procedures for handling scientific integrity concerns will be made available on the HHS website, at https://www.hhs.gov/programs/research/scientificintegrity/index.html. HHS OpDivs/StaffDivs may have their own procedures for addressing scientific integrity concerns that arise in their own divisions. For information about rights and remedies against retaliation, employees may contact the HHS OIG Whistleblower Protection Coordinator.[26] In general:

1. Concerns about a potential loss of scientific integrity at HHS may be reported to the HHS SIO by any individual who has knowledge of the situation. Reporting may be done anonymously.

2. Employees of HHS or its OpDivs/StaffDivs are encouraged to seek an informal consultation with the HHS SIO or the relevant division SIO to discuss whether a concern constitutes a potential loss of scientific integrity

before submitting a formal complaint. Employees ultimately have the discretion to submit a formal complaint as they see fit without reprisal.

3. If an OpDiv/StaffDiv has its own procedures in place for handling scientific integrity concerns, formal complaints submitted to HHS that involve actions and outcomes specific to that division will be directed to that division for follow up. For divisions without their own procedures, formal complaints will be handled by the HHS Scientific Integrity Council.

4. The HHS SIO, with the help of the Scientific Integrity Council as needed, will complete an initial assessment of each reported concern and determine whether to request additional information from the complainant or others and to determine whether a formal investigation is warranted.

5. Should an investigation be opened, an investigation committee consisting of the HHS SIO and at least two other Scientific Integrity Council members, or their delegates, will be convened. The committee will develop a factual record by exploring the allegation(s) in detail and consulting with subject matter experts, interviewing witnesses, and reviewing documentation as needed. This record will be documented in a report from the committee to the HHS SIO.

6. Once the investigation is complete and a report has been submitted to the HHS SIO, the HHS SIO will determine whether scientific integrity was lost, and if so, what corrective scientific actions are recommended.

7. The complainant and respondent will be given the opportunity to appeal a finding or any corrective scientific actions taken.

Handling Differing Scientific Opinions

Science and decisions based on science are strengthened by vigorous discussion and debate and by considering all available evidence. The process of challenging and improving ideas helps to guard against inadequate science and flawed analysis. Scientists can hold differing opinions without violating scientific integrity, and HHS encourages its scientists to respectfully express and engage with differing views as an integral part of the scientific process. Differing scientific opinions are diverging views held by researchers who are substantively engaged in the science subject area. In some cases, such as when a scientific dispute has a significant impact on public health or policy, a formal scientific dispute resolution process may be necessary. The goal of scientific dispute resolution should be to ensure that all perspectives are heard and documented in an unbiased way. A satisfactory resolution may involve adopting one opinion over another, deciding to conduct additional studies, formulating an alternate theory reconciling the differing opinions, or documenting the disagreement for the benefit of policymakers and fellow scientists. HHS OpDivs/StaffDivs may have dispute resolution policies in place; employees of these divisions must follow any such policies and guidelines. If a division does not have a dispute resolution process already in place, the following steps may be used as a guide. These steps may be completed in any order and are not necessarily an exhaustive list of dispute resolution measures. In general:

- A team member or group of team members with a differing opinion may engage with their colleagues to resolve the issue as soon as the difference of opinion is known. HHS recommends this type of internal discussion as a first step in most dispute resolution proceedings.
- A team may choose to consult a manager. First-level managers may defer to an appropriate higher-level manager if the first-level manager has a conflict of interest or cannot offer an impartial opinion for any reason.
- If the matter cannot be satisfactorily resolved by other means, a team may request assistance from their division's SIO. The HHS SIO may be consulted if the division SIO requests their assistance, if there is no division SIO, or if there is a conflict of interest or perceived conflict of interest with the division SIO. The HHS SIO will review the dispute history and may recommend additional internal discussion, peer review, or involvement of subject matter experts. The HHS SIO may also serve as a mediator or engage the services of a professional mediator to help end the dispute. The HHS SIO acting in this capacity serves to uphold scientific integrity and will not advocate for a particular scientific position.

Roles and Responsibilities

Scientific Integrity is everyone's responsibility. The following individuals have specific scientific integrity roles and responsibilities under this policy:

I. The Secretary of Health and Human Services

1. Provides leadership for HHS on scientific integrity, by leading through example, upholding scientific integrity principles, and regularly communicating the importance of scientific integrity.

2. Ensures that all HHS activities associated with scientific and technological processes are conducted in accordance with this policy.

3. Ensures that all supervisors and managers comply with this policy and ensures accountability for those who do not.

4. Ensures that violations of this policy are investigated to the full extent that is described herein, and that appropriate corrective scientific and/or administrative actions are taken as a result of such investigations.

5. Ensures that HHS scientific integrity efforts support HHS plans for making evidence-based policies, including the evidence-building plans required by 5 U.S.C. 312(a) and the annual evaluation plans required by 5 U.S.C. 312(b).

6. Provides adequate resources and funding to implement this policy including staffing, monitoring, evaluation, reporting, and training.

7. Ensures that SIOs are afforded all applicable career employee rights and appeals and are protected against retaliation of any kind.

8. Supports and respects the HHS SIO's independence, recommendations, and designation of and HHS compliance with corrective scientific actions when violations of this policy are substantiated. Assistance may be sought from the National Science and Technology Council (NSTC) Subcommittee on Scientific Integrity (SOSI) in cases of disagreement.

9. In cooperation with the HHS SIO, oversees the implementation and iterative improvement of policies and processes affecting the integrity of scientific activities funded, conducted, or overseen by HHS, as well as policies affecting the Federal and non-Federal scientists who support the scientific activities of HHS, including scientific-integrity policies.

10. Ensures that HHS establishes as necessary clear administrative actions for substantiated violations of this policy, designating responsibility for each aspect of accountability.

II. HHS Scientific Integrity Official

1. Is a designated, full-time equivalent, career employee who holds a permanent appointment and has appropriate scientific credentials and is designated at a senior level.

2. Oversees implementation and iterative improvement of scientific-integrity policies and processes, provides leadership on matters of scientific integrity, and serves as the primary HHS-level contact for questions regarding scientific integrity.

3. Leads training and outreach initiatives to facilitate employee awareness and understanding of this policy.

4. Serves as a neutral point of contact for receiving allegations of loss of scientific integrity, provides informal consultation for employees who have scientific integrity concerns, and adheres to privacy and confidentiality policies, as applicable.

5. Conducts an initial assessment of all formal complaints and submitted materials, following established procedures, to determine whether the allegations pertain to loss of scientific integrity and the appropriate handling of said allegations. Provides independent oversight of HHS responses to allegations of loss of scientific integrity referred for an inquiry or investigation, including:

a. Reviewing HHS-submitted reports of allegations and their disposition.

b. Maintaining a status report of responses to allegations as a means of monitoring the progress toward resolution.

6. Leads efforts to update this policy and any accompanying guidance, as appropriate.

7. Reports to the HHS Deputy Assistant Secretary for Science and Data Policy on matters involving scientific integrity.

8. Coordinates as necessary with the HHS Offices of Research Integrity (ORI), Human Research Protections (OHRP), Inspector General (OIG), the General Counsel (OGC), Human Resources, Civil Rights, the Assistant Secretary for Public Affairs, and the Chief Information Officer, among others.

9. Reports any potentially criminal behavior related to waste, fraud, abuse, or potential employee misconduct to OIG that is uncovered while responding to an allegation of loss of scientific integrity and coordinates as appropriate related to the referral provided to OIG.

10. Keeps the HHS Secretary informed on the status of the implementation of this policy and any compliance concerns, as warranted.

11. Publishes an annual scientific integrity report as described below.

12. Leads efforts for the iterative improvement of this policy and scientific integrity initiatives overall including development and implementation of an evaluation plan to regularly monitor and evaluate ongoing scientific integrity activities and outcomes.

13. To the extent possible, is involved in high level discussions and strategic planning on the recruitment, retention, development, and advancement of scientists—including scientists from underrepresented communities—to help ensure that scientific integrity is appropriately and carefully considered.

III. HHS Scientific Integrity Council Members

1. As delegated by the HHS SIO, oversees implementation and iterative improvement of scientific integrity policies and processes.

2. Coordinates with the HHS SIO in implementing scientific-integrity policies and processes.

3. Provides oversight for the implementation of the Scientific Integrity Policy at HHS.

4. Acts as liaisons for their respective HHS OpDivs/StaffDivs.

5. Assists with training and policy assessment, updates, and amendments.

6. Is available to address any questions or concerns regarding this policy.

7. Other duties as delegated.

IV. HHS Managers and Supervisors

1. Comply with and ensure HHS and employee compliance with the scientific integrity policy, including reporting or advising others on reporting allegations of loss of scientific integrity.

2. Make themselves aware of and uphold the principles contained in this policy. Lead through example by upholding scientific integrity principles and communicating the importance of doing so.

3. Report any knowledge of potential loss of scientific integrity to the HHS SIO or OpDiv/StaffDiv scientific integrity officials without reprisal.

4. Consult, as appropriate, with the HHS SIO or relevant OpDiv/StaffDiv SIOs, human resources officers, contracting and grant personnel, ethics officers, ORI, OIG, OGC, and the Office for Civil Rights.

V. HHS Employees and Other Covered Individuals

1. Make themselves aware of the principles contained in this policy and how the policy applies to their duties.

2. Comply with this policy.

3. Adhere to accepted professional values and practices of the relevant research/scientific communities to which they belong.

4. Are encouraged to report to the HHS SIO or OpDiv/StaffDiv SIO any concern of loss of scientific integrity and are encouraged to report retaliation or potential criminal activity to the HHS OIG Hotline.[27]

Monitoring and Evaluating Scientific Integrity Activities and Outcomes

HHS will develop and implement an evaluation plan to regularly measure, monitor, and evaluate ongoing scientific integrity activities and outcomes. The plan will include a roadmap of activities, evaluation metrics, and methods of measurement for the purpose of ongoing improvement of SI processes, procedures, and policies. The plan will include expected metrics and measurement methods for evaluating the HHS Scientific Integrity Policy; workforce training; scientific integrity leadership, staffing, and communication; and reporting mechanisms. As part of the monitoring and evaluation plan, HHS will publish an annual report on the number and outcomes of investigations and appeals involving allegations of loss of scientific integrity. To the extent possible, all descriptions of investigations and appeals will be anonymized.

The plan shall also include a timeline for implementation and frequency of data collection, analysis, review, recommendations, and implementing recommendations. Monitoring and evaluation results, recommendations, and policy/procedure changes based on results will be reported to HHS leadership and will be made available to HHS staff and the public in a timely manner.

Reporting

The HHS SIO, with input from the Scientific Integrity Council, is responsible for developing and making prominently available on HHS's public facing website, at *https://www.hhs.gov/programs/research/scientificintegrity/index.html,* an annual report to HHS leadership on the status of scientific integrity within HHS. The report shall highlight scientific integrity successes, accomplishments, or progress across HHS and identify areas for improvement and plans for addressing critical weaknesses, if any. The report shall describe progress toward achieving key metrics, including comparisons to the same metrics from prior years to show trends over time, whenever feasible. It will also include the number of investigations and appeals involving alleged or actual violations of this scientific integrity policy, including pending investigations and appeals. For investigations that have been resolved, the report will include an aggregate summary of the types of corrective actions recommended by the investigation panel to restore scientific integrity, and a summary of the types of actions ultimately taken.

Related Policies and Statutes

Involving SIOs at HHS and its OpDivs/StaffDivs in the writing and updating of related policies can help

provide needed perspectives before such policies are issued and better ensure they support scientific integrity. Officials should consider the scientific integrity-related components of other policies (*e.g.,* professional development of scientists, science-related communications, etc.) and determine where those other policies should be referenced, or perhaps reinforced, within the agency scientific integrity policy to help ensure their longevity. Violations of related and supporting policies may result in a loss of scientific integrity and it is appropriate for SIOs to coordinate with their agency counterparts in these matters.

SIOs should have an awareness of policies and programs that intersect with the development of the culture of scientific integrity within the agency. SIOs, where possible, shall be involved in the development or revision of the broader set of policies and practices that affect the culture and applicability of scientific integrity within HHS.

Research Misconduct

Federal Research Misconduct Policy: *https://www.federalregister.gov/documents/2000/12/06/00-30852/executive-office-of-the-president-federal-policy-on-research-misconduct-preamble-for-research*

Public Health Service Policies on Research Misconduct: *https://www.federalregister.gov/d/05-9643*

Diversity, Equity, Inclusion, and Accessibility (DEIA) in Addressing and Strengthening Scientific Integrity and the Disproportional Impact of Scientific Integrity Policy Violations on Underrepresented Groups

HHS Equal Employment Opportunity and Anti-Harassment Policy: *https://www.hhs.gov/about/agencies/asa/eeo/policy/index.html*

Government-Wide Strategic Plan to Advance Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce: https://www.whitehouse.gov/wp-content/uploads/2021/11/Strategic-Plan-to-Advance-Diversity-Equity-Inclusion-and-Accessibility-in-the-Federal-Workforce-11.23.21.pdf

HHS Diversity, Equity, Inclusion, and Accessibility Strategic Plan 2022: *https://www.hhs.gov/sites/default/files/2022-hhs-deia-strategic-plan.pdf*

Public Access

NIH Public Access Policy: *https://publicaccess.nih.gov/policy.htm*

OSTP Memorandum on Increasing Access to the Results of Federally Funded Research (2013): *https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf*

OSTP Memorandum on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research (2022): *https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf*

5 U.S.C. Part 552—Freedom of Information Act: *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-5*

Human and Animal Subject Protections

Federal Policy for Protection of Human Research Subjects (the Common Rule): *https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html#:~:text=Consent%20Posting%20Guidance-,Federal%20Policy%20for%20the%20Protection%20of%20Human%20Subjects%20*(‘*Common,of%20Biomedical%20and%20Behavioral%20Research*

FDA Policy for the Protection of Human Subjects: *https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fda-policy-protection-human-subjects*

Animal Welfare Act and Regulations: *https://www.aphis.usda.gov/animal_welfare/downloads/bluebook-ac-awa.pdf*

Public Health Service Policy on Humane Care and Use of Laboratory Animals: *https://olaw.nih.gov/policies-laws/phs-policy.htm*

Guide for the Care and Use of Laboratory Animals: *https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf*

Research Security

National Security Presidential Memorandum 33 (NSPM 33): *https://trumpwhitehouse.archives.gov/presidential-actions/presidential-memorandum-united-states-government-supported-research-development-national-security-policy/*

Guidance for Implementing NSPM 33: *https://www.whitehouse.gov/wp-content/uploads/2022/01/010422-NSPM-33-Implementation-Guidance.pdf*

Whistleblower Protections

5 U.S.C. Part 2302—Prohibited personnel practices: *https://uscode.house.gov/view.xhtml?req=29&f=treesort&num=125*

Whistleblower Protection Act of 1989: *https://www.govinfo.gov/content/pkg/STATUTE-103/pdf/STATUTE-103-Pg16.pdf*

Public Law 103—424–Expansion of Whistleblower Protection Act of 1989: *https://www.govinfo.gov/content/pkg/STATUTE-108/pdf/STATUTE-108-Pg4361.pdf#page=3*

Whistleblower Protection Enhancement Act of 2012: *https://www.congress.gov/112/statute/STATUTE-126/STATUTE-126-Pg1465.pdf*

41 U.S.C. Part 4712—Enhancement of contractor protection from reprisal for disclosure of certain information: *https://uscode.house.gov/view.xhtml?req=(title:41%20section:4712%20edition:prelim)*

Presidential Policy Directive 19—Protecting Whistleblowers with Access to Classified Information: *https://www.usda.gov/sites/default/files/documents/ppd.pdf*

US Office of Special Counsel: *https://osc.gov/*

10 U.S.C. Part 1034, made applicable to the Public Health Service Commissioned Corps through 42 U.S.C. 213a(a)(18), and implemented by Commissioned Corps Directive (CCD) 121.06: *https://dcp.psc.gov/ccmis/ccis/documents/CCD121_06.pdf#:~:text=CCD%20121.06%20EFFECTIVE%20DATE%3A%2010%20February%202022%20By,and%20Human%20Services%3A%20Xavier%20Becerra%20SUBJECT%3A%20Protected%20Communications*

Foundations for Evidence-Based Policymaking Act (‘‘Evidence Act’’): *https://www.congress.gov/bill/115th-congress/house-bill/4174/text*

Notification and Federal Employee Antidiscrimination and Retaliation Act (‘‘No FEAR Act’’): *https://www.govinfo.gov/content/pkg/PLAW-107publ174/html/PLAW-107publ174.htm*

Dual Use Research of Concern: *https://www.phe.gov/s3/dualuse/documents/durc-policy.pdf*

The Federal Advisory Committee Act: *https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/legislation-and-regulations/the-federal-advisory-committee-act*

Paperwork Reduction Act: *https://www.govinfo.gov/content/pkg/PLAW-104publ13/html/PLAW-104publ13.htm*

HHS Grants Policy Statement: *https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf*

ASPA’s Guidelines on the Provision of Information to the News Media: *https://www.hhs.gov/sites/default/files/media_policy.pdf*

Endnotes

[1] Guidance by the Scientific Integrity Framework Interagency Working Group of the National Science and Technology Council ''A Framework for Federal Scientific Integrity Policy and Practice.'' January 12, 2023. Available at: *https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf.*

[2] Some HHS Operating and Staff Divisions have or may designate their own Scientific Integrity Officials. This document uses ''HHS SIO'' to refer to the official designated by HHS to coordinate department-wide implementation of this Policy and ''SIO'' to refer to all Scientific Integrity Officials, including those at Operating and Staff Divisions.

[3] Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policy Making, January 27, 2021. Available at: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/.*

[4] Presidential Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity. March 9, 2009. The White House. Available at: *https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09.*

[5] Presidential Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity. December 17, 2010. Office of Science and Technology Policy. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf.*

[6] A report by the Scientific Integrity Fast-Track Action Committee of the National Science and Technology Council. ''Protecting the Integrity of Government Science.'' January 11, 2022. Available at: *https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting_the_Integrity_of_Government_Science.pdf.*

[7] Guidance by the Scientific Integrity Framework Interagency Working Group of the National Science and Technology Council ''A Framework for Federal Scientific Integrity Policy and Practice.'' January 12, 2023. Available at: *https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf.*

[8] Examples may include (1) suppressing a decisionmaker's ability to offer the best judgment based on scientific information; (2) preventing the use of best available science; (3) insisting on preclearance of a scientific product for purposes other than providing advance notification or opportunity to review for technical merit; (4) suppressing, altering or delaying the release of a scientific product for any reason other than technical merit or providing advance notification; (5) removing or reassigning scientific personnel for any reason other than performance, conduct or budgetary constraints; (6) using scientific products that are not representative of the current state of scientific knowledge and research (for example because of a lack of appropriate peer review, poor methodology, or flawed analyses) to inform decision making and policy formulation; or (7) misrepresenting the underlying assumptions, uncertainties, or probabilities of scientific products. This is not intended to be an exhaustive list.

[9] Differences of scientific opinion are not necessarily inappropriate influence.

[10] See Federal Research Misconduct Policy, 65 FR 76260, 76262 (Dec. 6, 2000); see also *https://ori.hhs.gov/definition-research-misconduct.*

[11] Public Law 112–199 § 110.

[12] 5 U.S.C. 2302(b)(8).

[13] See Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, Public Law 117–328, Division FF, Title II, Section 2321 (Jan 3, 2023) *and* Chips and Science Act, Public Law 117–167, Title VI, Subtitle D, Section 10631 (Aug 9, 2022). OSTP guidance and relevant HHS policies to implement this legislation are forthcoming at the time of publication of this policy.

[14] HHS Grants Policy Statement, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Resources and Technology, Office of Grants. January 1, 2007. Available at: *https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.*

[15] HHS Grants Policy Administration Manual Version 1.02. November 13, 2023.

[16] 45 CFR 75.372.

[17] Presidential Memorandum for the Heads of Executive Departments and Agencies on Increasing Access to the Results of Federally Funded Scientific Research. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf.*

[18] Presidential Memorandum for the Heads of Executive Departments and Agencies on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research. Available at: *https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf.*

[19] This provision is further outlined in the United States Office of Government Ethics Standards of Conduct and 18 U.S.C. 208 as Applied to Official Social Media Use. Available at: *https://oge.gov/web/oge.nsf/News Releases/EAE37A7DA3C38BF38525894700775339/$FILE/LA-23-03%20The%20Standards%20of%20Conduct%20and%2018%20U.S.C.%20%C2%A7%20208%20as%20Applied%20to%20Official%20Social%20Media%20Use.pdf.*

[20] Memorandum to Designated Agency Ethics Officials on The Standards of Conduct as Applied to Personal Social Media Use. Available at: *https://www.oge.gov/web/oge.nsf/0/195DAE83D38EF6A9852585BA005BEC69/$FILE/LA-15-03-2.pdf.*

[21] Office of Management and Budget. ''Final Information Quality Bulletin for Peer Review.'' **Federal Register**. Doc. 05–769. Available at: *https://www.federalregister.gov/documents/2005/01/14/05-769/final-information-quality-bulletin-for-peer-review.*

[22] 5 U.S.C. 7513, 4303.

[23] Commissioned Corps Directive 111.02.

[24] Subject to the limitations and requirements as to participation in foreign talent programs outlined in I.12–13 of this policy.

[25] 2010 Memorandum from the White House Office of Science and Technology Policy on Scientific Integrity. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf.*

[26] See *https://oig.hhs.gov/fraud/whistleblower/.* Employees can also contact their OpDiv/StaffDiv's office of Equal Employment Opportunity (''EEO'') for information regarding retaliation based on protected EEO activity or discrimination, or the Office of Special Counsel for information regarding retaliation based on whistleblowing. Additionally, although encouraged to use the process detailed herein, employees may also disclose wrongdoing to their supervisor or another individual higher up in management, the HHS OIG, the Office of Special Counsel, or to Congress. PHSCC officers should also refer to CCD 121.06, ''Protected Communications,'' CCD 111.01, ''Equal Opportunity,'' and CCI 211.03, ''Equal Opportunity.''

[27] *https://oig.hhs.gov/fraud/report-fraud/before-you-submit/.*

Dated: December 16, 2024.

Katherine N. Bent,

Associate Deputy Assistant Secretary, Office of Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Information Technology Advisory Committee Schedule of Meetings

AGENCY: Assistant Secretary for Technology Policy (ASTP), HHS.

ACTION: Notice of meetings.

SUMMARY: The Health Information Technology Advisory Committee (HITAC) was established in accordance with the 21st Century Cures Act and the Federal Advisory Committee Act. The HITAC, among other things, identifies priorities for standards adoption and makes recommendations to the Assistant Secretary for Technology Policy/National Coordinator for Health Information Technology. The HITAC will hold public meetings throughout 2025. See list of public meetings below.

FOR FURTHER INFORMATION CONTACT: Seth Pazinski, Designated Federal Officer, at *Seth.Pazinski@hhs.gov,* (202) 384–2246.

SUPPLEMENTARY INFORMATION: Section 4003(e) of the 21st Century Cures Act (Pub. L. 114–255) establishes the Health Information Technology Advisory