Comment Form: Draft NIH Scientific Integrity Policy Preview

September 22, 2023 – November 9, 2023

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Submit date: 9/25/2023

I am responding to this RFI: On behalf of myself

Name: JEAN PUBLIE

Type of Organization: Other

Type of Organization-Other: american citizen

Role: Member of the public

Comment:

THIS AGENCY IS NOT OPEN AND TRANSPARENT. NOT WHEN IT TRIES TO HOLD DOCUMENTS FOR 76 YEARS. CERTAINLY YEARS AND YEARS 36 ON ANOTHER OPRA REQUEST IS WHEN YOU WANT TO GIVE DOCUMENTS TO THE PUBLIC. 99% OF YOUR MEETINGS ARE CLOSED SO THAT THEPUBLIC CANT FIND OUT WHAT YOU ARE UP TO. THE ENTIRE AGENCY IS SNEAKY, SUBSTANDARD, AND HARMS THE US CITIZENRY. THEre is no scientificintegrity shown ever. to say you do that is a bold faced lie. criminality goes on at this agency.entire agency is a big pharma puppet. health of americans has gone down down down under dicta of this agency for last 3-5 years. using 8 mice to deamand vaccine is shot into the worlds arms shows the corruption of this agency. the mice were sick from the vaccine. this agency is the opposite of science. it is a propaganda agency.this agency has never been fair, just, impartial honest or accessible - never. the free flow of science does not exist into your agency but you spend taxpayer dollars to flow crap out to the usa citizenry. and your outflow is dishonest and corrupt. this proplsa shoudl prohibit the hiring of attack journalists. the conflict of interest in every employee in this agency is suspect so that we dont get truthful research - we get proosals that will benefit their own pockets and big pharma solely.

Description: this agency lies with its current proposal. this agency has been guilty of criminal corruption for the last 3 years.

Submit date: 9/26/2023

I am responding to this RFI: On behalf of myself

Name: Jacoby Davis

Name of Organization: Instrumentality LLC

Type of Organization: Other

Type of Organization-Other: Cybersecurity Compliance Consulting

Role: Member of the public

Comment:

In-document Comments added by Ghost_000(Jacoby Davis): Examples of changes that could be made that would draw attention to the seriousness with which NIH takes integrity. The additional responsibilities reflect a subjective “well-rounding” of these leadership positions.

Sections that were adjusted:

Page 2

1. Purpose

2. Scientific Integrity at NIH - 1st Paragraph Only.

Page 10

1. CS Role (Added more responsibilities + 10)

2. SIO Role (Added more responsibilities + 6)

Page 11

1. Intro paragraph for the council.

2. NIH Council Responsibilities (Added more responsibilities + 5)

If outside of NIH document scope or outside of this review scope, please disregard. Otherwise, the last item I would recommend is a change log at the top of the document. Name | Department | Date | Purpose.

I would be happy to draft SOPs for each as well. :)

Bon chance, fellow humans.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/Draft_SI_Policy.pdf

Description: Draft_SI_Policy_edited_by_Jacoby_Davis

Submit date: 10/17/2023

I am responding to this RFI: On behalf of myself

Name: Jean

Name of Organization: Public

Type of Organization: Other

Role: Member of the public

Comment:

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/SI-Jean-Public-508.pdf

Submit date: 10/17/2023

I am responding to this RFI: On behalf of myself

Name: Robert Charrow

Name of Organization: Self

Type of Organization: Other

Role: Member of the public

Comment:

See Attached. Comment relates to all of the above 1-5.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/10-17-23-Comment-to-NIH-Policy-on-Scientific-Integrity.docx

Description: Comment

Submit date: 10/17/2023

I am responding to this RFI: On behalf of myself

Name: Payson Sheets

Name of Organization: University of Colorado

Type of Organization: University

Role: Scientific researcher

Comment:

#4.I strongly support this section. We really need it. The future integrity of research requires it.

Submit date: 10/19/2023

I am responding to this RFI: On behalf of myself

Name: Ruqaiijah Yearby

Name of Organization: The Ohio State University

Type of Organization: University

Role: Scientific researcher

Comment:

I am writing about the prohibitions against political interference. Particularly, I suggest adding the word objectivity to the definition of political interference as a way to show how it connects to the problem of scientific integrity.

Below is my revised definition for political interference:

¡ Political interference is inappropriately shaping or interfering in the conduct, management, communication, or use of science for inappropriate partisan advantage or such that it undermines objectivity, impartiality, nonpartisanship, or professional judgement.

Submit date: 10/23/2023

I am responding to this RFI: On behalf of myself

Name: William Bauza

Type of Organization: Professional org association

Role: Member of the public

Comment:

I'm a retired NY State retired 7th grade Middle Level Life Science teacher with both BS and MS in Sec Ed Bio from Buffalo State University. Raised, educated and

retired from NY State Public schools I'm grateful for the well-rounded, professional teachings I received. In today's world Science is less revered, respected or chosen as

a reference, a career, or positive influence. I was very disappointed when so many people avoided and belittled the COVID-19 pandemic: I spoke to clear misconceptions and

outright lies that continue today. I blame the prevalence and lack of policing by the social media, and the blind neglect of the undereducated. Therefore I am speaking positively for a leadership committee which reflects on recognized professional development and proven leadership in conversation and publication as you consider persons for the positions within and representing the NIH.

Scientific integrity is earned via rigorous education resulting in advanced degrees and evidence of continued study and involvement. The average layperson has no clue as to the challenging courses, lab experiences and self-control Science demands. There are great television programs available on PBS and cloud media, but those are selected by individual choice. To reach the masses we need more general exposure to combat ignorance/intolerance, to present and certify newly appointed leaders, to instill trust and the need for compliance. To protect the masses we need to monitor and eliminate the doomsday negativity of anti-establishment provocateurs, be it a president or the kid down the block on his tablet! I am an active member of the AAAS and the Union of Concerned Scientists, and retired member of the National Science Teachers' Association, the National Middle Level Science Teacher's Association, the NEA, AFT and New York State Teacher's Association.

Submit date: 10/30/2023

I am responding to this RFI: On behalf of an organization

Name: Stuart Buck

Name of Organization: Good Science Project

Type of Organization: Nonprofit research organization

Type of Organization-Other:

Role: Institutional official

Comment:

See attachment.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/Comments-on-NIH-Integrity-Policy.docx

Submit date: 11/1/2023

I am responding to this RFI: On behalf of myself

Name: jean publie

Name of Organization: american citizen

Type of Organization: Other

Type of Organization-Other: american citizen

Role: Member of the public

Comment:

rereearch papers that have no scientifi.c integrity. we have a real problem here. american taxpayers already pay for several agenciesin the nih/cdc niahd to check on the work of researchers and see that it is accurate but apparntly they arent catching anything at all .we have a private org called retraction watch that needs to catch these cheats. why are taxpayers paying for non effective work. at the federal level

it appear to me that every single alleged research accomplishment needs to have an agency that is mandatorily required to check it out and verify that it has merit.

oviiously the taxpayers are gettign rotten work from the nih, cdc for the huge massive amounts of tax dollars we pay these cheats who put out rotten research.

it evidently takes 7years sometimes to catch these cheats and meanwhile ther is alot of bad rotten medicine that is going on based on not ctching research cheaters.

and we shoudl not re emplt=oy them when they are caught doing substandard work. they should be fired. go somewhere else than the federal govt to doyour work.taxpayes do not want to pay salaries to research cheats.the entire operation at the cdc nih is rotten tot he core and needs a criminal invstigqtion. criminal investition. none of them should get further grants when they have been caught cheating on research. research wacth cites several examples what are disgusting.

Submit date: 11/2/2023

I am responding to this RFI: On behalf of myself

Name: Guido Frosina

Type of Organization: Nonprofit research organization

Role: Scientific researcher

Comment:

As for any human activity, behaviours deviating from the usual rules of ethics have always been present in Scientific Research. The current economic crisis with dropped resources for Science has led to an increase in these phenomena, periodically reported by the most important scientific journals. Why this happens is largely a matter of culture and education and once again school, university and family may exert a major role in educating young researchers to refrain from looking for shortcuts. However, many research institutions face this problem fearfully, in the concern that openly addressing cases of scientific malpractice may demotivate the public from donations. But in Scientific Research, the lack of transparency often creates more problems than it solves and hiding, or downsizing altered scientific practices may facilitate their spreading. An open discussion may witness the ability of Research institutions to honestly deal with these problems and warrant donors more transparent, fair and reliable Scientific Research. Eventually, the scientific community may only take advantage of openly opposing altered practices, without waiting for someone else to do it. It's excellence, not flaw.

This field is completely devoid of legislative instruments. There are no shared rules about what can or cannot be done from an ethical point of view in Scientific Research and this certainly fosters confusion.

This bill (which is in English because the problem is not limited to Italy) is based on a few simple principles aimed at increasing the transparency, fairness and reliability of Scientific Research:

Prevention of conflict of interest: those sitting on the evaluation board cannot participate in the competition [neither in person nor through their collaborators (who can be precisely defined)]. Peer evaluating is a mandatory task of any Research job and is subject to rotation.

Transparency and freedom of information: any administrative act of the Research institution (subject to the exceptions of the Law: e.g. sensitive data) must be readily and easily accessible to anyone.

Quality control: quality control of data, especially concerning ethical aspects, is to be performed by the affiliated Research institution besides Journal Editorial Boards. It might be wise for everybody to take care of a bit more of quality and a bit less of quantity.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/021123-Proposed-law_Rules-on-the-integrity-of-Scientific-Research.pdf

Submit date: 11/3/2023

I am responding to this RFI: On behalf of an organization

Name: Jeff Ruch

Name of Organization: Public Employees for Environmental Responsibility (PEER)

Type of Organization: Other

Type of Organization-Other: Public interest advocacy organization assisting government scientists

Role: Member of the public

Comment:

November 6, 2023

Tara A. Schwetz,

Acting Principal Deputy Director

National Institutes of Health

Attn: Scientific Integrity Comments

9000 Rockville Pike

Bethesda, Maryland 20892

Submitted electronically at https://osp.od.nih.gov/comment-form-draft-scientific-integrity-policy-for-the-national-institutes-of-health/.

RE: PEER Comments on draft Scientific Integrity Policy of the National Institutes of Health

Public Employees for Environmental Responsibility (PEER) wishes to express its profound disappointment with the provisions of the draft Scientific Integrity Policy of the National Institutes of Health (NIH) now available for public comment.

PEER has provided legal representation to federal scientist struggling with scientific integrity issues for more than 30 years. Our work help lay the foundation for the 2009 Obama Directive on Scientific Integrity. During the Obama presidency, PEER filed more complaints on behalf of scientists for violations of agency scientific integrity policies than any other organization.

Based upon this experience, PEER has provided the White House Office of Science &Technology Policy (OSTP) extensive feedback in its development of its Model Policy Framework. However, both the OSTP Model Policy and NIH draft policy continue exhibit the same fundamental weaknesses that led President Biden to issue his January 2021 Memorandum on Restoring Trust in Government through Scientific Integrity and Evidence Based Policymaking in the first place.

as President Biden pledged in his government-wide memorandum to public trust in the integrity of federal science. Unfortunately, based upon our analysis as detailed below, the proposed NIH policy will do almost nothing to accomplish this. Notably, the policy lacks fundamental safeguards against the suppression or political manipulation of science. It leaves key functions blank, such as how investigations of alleged scientific misconduct will be conducted, to be filled in later. Further, it lacks any protections for scientists who express dissenting scientific opinions or face reprisal due to the controversial implications of their research.

Significantly, the NIH draft policy uses the word "integrity" 152 times in its 33 pages of text but contains scant concrete provisions that would work to secure or promote scientific integrity.

PEER's comments address five gaps in NIH's draft policy:

I. Inappropriate, Inconsistent and Illegal Restrictions on Scientist Communications

II. No Process for Independent Investigation of Misconduct Allegations

III. Opaque Transparency Provisions Allow Suppression of Research

IV. No Meaningful Protections for Scientists Against Retaliation

V. Complete Lack of Accountability for Violators

Turning to each of these concerns in order:

I. Inappropriate, Inconsistent and Illegal Restrictions on Scientist Communications

A. Contradictory Language

The NIH draft declares that scientists may "express their personal views and opinions with appropriate written or oral disclaimers, including on social media" but then states that scientists "shall refrain from making or publishing statements that could be construed as being judgments of, or recommendations on, NIH or any other Federal Government policy…" (Emphasis added)

The draft policy makes no attempt to reconcile these two seemingly conflicting statements. Nor does, NIH identify what public policy is served by this poorly written sweeping restriction on scientist speech.

The fundamental sentiment behind this restriction seems to be that federal scientific research is fine if it does not ruffle any political feathers. NIH apparently fails to recognize that scientific research that carries policy implications is at the greatest risk of suppression or political manipulation – for precisely that reason – and, therefore, is in greater need for protection.

NIH should resolve this apparent contradiction. Optimally, NIH should completely discard this misguided prohibition against statements that "could be construed' as comments or recommendations on federal policies. In PEER's view, this language (underlined above) has no place in any agency scientific policy.

B. Conflicted Role

The NIH draft describes itself as a "Policy Development Agency" using the following language:

"NIH promotes progress in the biomedical research enterprise through the development of sound and comprehensive policies. To achieve this, NIH engages partners within and outside of NIH to develop policies on a wide range of issues including biosafety, biosecurity, genetic testing, genomic data sharing, human subjects protections, the organization and management of the NIH, and the outputs and value of NIH-funded research. This is accomplished through a wide range of analyses and reports, commentary on emerging policy proposals, and the development of policy proposals for consideration by NIH, the Federal Government, and the public."

It is unclear how NIH scientists can play a role in policy development across this broad range of topics without being able to make statements that "could be construed" as judgments on or recommendations about how policies should evolve.

C. Similar Provision Abused by U.S. Department of Agriculture

This provision is apparently based upon a similar provision in the U.S. Department of Agriculture's scientific integrity policy. On July 14, 2021, PEER wrote to OSTP specifically warning about this provision in the USDA policy. Unfortunately, our warning to OSTP was not heeded as it included this language in its "Model Scientific Integrity Policy" released this past January. Further, OSTP did not respond to a letter sent in April 2023 by PEER and more than a dozen public interest groups urging the removal of this language from the OSTP Model.

Among the reasons for these warnings was that USDA had used this provision as the basis for ordering a staff entomologist represented by PEER to remove his name from a peer-reviewed journal article on how monoculture farming reduces diversity in insect populations, limiting beneficial pollinators. This same provision of the USDA policy was also cited as the basis for barring this scientist from speaking at a conference about effects on pollinators from genetically modified crops and the insecticides used to treat them. He later resigned in frustration, convinced that he could no longer conduct meaningful research while employed at USDA.

In addition tp our entomologist client, PEER received reports from other USDA scientists that managers had initiated –

- Directives not to publish data on certain topics of particular sensitivity to industrial agricultural interests, such as pesticide manufacturers;

- Orders to rewrite scientific articles already accepted for publication in a peer-reviewed journal to remove sections which could provoke industry objections; and

- Inordinate, sometimes indefinite, delays in approving submission for publication of scientific papers that may be controversial with agricultural interests.

In short, this provision that NIH proposes to adopt was used, and is still being used, to pressure USDA scientists working on topics with direct relevance to industry interests not to do anything to upset important “stakeholders.”

NIH should be aware that its adoption of such a far-reaching restriction is bound to create a chilling effect among scientists, just as it did at USDA. Rather than encouraging sharing of information by federal scientists it has – and continues to have – the opposite effect of constraining it.

D. Broad Chilling Effect – Dickey Amendment Amplified

In the 1997 federal omnibus spending bill, Congress inserted a rider, called The Dickey Amendment (named after its author Rep. Jay Dickey [R-AR] that provided “none of the funds made available for injury prevention and control at the Centers for Disease Control and Prevention & Prevention (CDC) may be used to advocate or promote gun control.”

Although the Dickey Amendment did not explicitly prohibit research on gun violence, for nearly two decades the CDC avoided all research on gun violence for fear it would be financially penalized. Such research finally resumed after Congress narrowed the language and earmarked funding for gun violence research in the federal omnibus spending bill for FY2020.

The Dickey Amendment language was not nearly as broad as the language NIH proposes to insert in its Scientific Integrity Policy. The former language banned activity "to advocate or promote…" By contrast, the NIH draft language outlaws any statement "that may be construed as a judgment of, or recommendation on" any policy by any federal agency (not just NIH agencies) – a far more nebulous and potentially wide-ranging prohibition.

If the Dickey bar against blatant advocacy and promotion worked to effectively stifle research, our concern is that this more far-reaching NIH language could have a far more extensive chilling effect on research across an array of controversial subjects studied by NIH scientists. Under the broad draft language, it is not difficult to imagine many scenarios in which this provision could be used to threaten public scientists or stifle controversial research across a wide range of topics. For example, publicizing medical breakthroughs achieved in National Institutes of Health funded research using fetal tissues could be construed as a recommendation for HHS Secretary Becerra's recent actions to resume federal funding for research using fetal tissues.

Further, it is also quite possible the NIH language could spur self-imposed restrictions on gun violence research to avoid statements that could be construed as judgments on weak federal gun control policies.

E. Restriction Subject to Abuse – Especially with Change of Administration

While current NIH leadership may have no intention of applying this language in ways suggested above, it has no control over how a succeeding administration may use this prohibition. In other words, NIH should have had second thoughts about adopting language that a differently constituted administration could use to stifle research – all while claiming with a straight face that they are simply enforcing a Biden scientific integrity protection.

Consider the case of Dr. George Luber, an epidemiologist, who served as Chief of the Climate and Health Program at CDC. He had been the very public face of climate science at CDC, frequently appearing on TV news and speaking at professional conferences. He is the lead author of the Fourth National Climate Assessment's Chapter on Human Health, released in 2018 and was the lead author for a report the U.S. Supreme Court cited in its seminal 2007 ruling that greenhouse gases should be regulated under the Clean Air Act.

In February 2017, shortly after the Trump inauguration, CDC cancelled, over his objections, a symposium Dr. Luber was slated to host featuring Al Gore. He was then directed to stop using the phrase "climate change" and forbidden from responding to any further media or congressional inquiries.

In March 2018, CDC revoked his badge, phone, and credentials, placing him on a BOLO (be on the lookout) list as a security risk, barring him from entering the facility except under armed guard and with prior approval, and then only to retrieve materials. Every time he went to his office, Dr. Luber and his car were thoroughly searched in front of his colleagues.

In a letter dated October 22, 2018, CDC Environmental Health Center Director Patrick Breysse (the same official who ordered Dr. Luber to stop using the term "climate change") proposed his removal based upon an alleged failure to obtain permission to author a 2015 book, give lectures at Emory University, and more than 30 other charges. Had the NIH policy been in place at CDC, Dr. Luber could also have been charged with lectures and writing that could easily be construed as judgments on the effects of several federal policies, including those related to the release of greenhouse gases.

This proposed action was withdrawn after a reporter for the New York Times called to inquire about it. PEER later successfully negotiated an outplacement for Dr. Luber so that he is able to continue his research free from the constraints CDC wished to impose. The point of this episode is to underline how quickly political strictures can be placed upon scientists, even those within agencies such as CDC.

The many other attempts to stifle science during the Trump tenure need not be recounted here , except to note that they were the basis for President Biden declaring that the Obama-era scientific integrity policies obviously did not work to prevent these abuses and must be strengthened. Above all, NIH must act to strengthen its Scientific Integrity Policy, not weaken it.

F. Unconstitutional As Applied to Scientists' Personal Statements

This provision could be used to violate a government scientist's First Amendment right to speak freely in their capacity as citizens on matters of public concern. In addition, this provision can be used to prevent agency scientists, as well as private scientists collaborating with or contracting with a federal agency, from even discussing the policy implications of vital research.

The First Amendment is not absolute, however, and courts apply a balancing test that weighs the public importance of the speech versus any potential disruption of efficient government operations. Such a calculus should weigh heavily in favor of the public interest value of research conducted by a federal government scientist against potential embarrassment to a government agency.

Significantly, one of the stated aims of the NIH draft policy is to promote a free and open exchange of scientific information. Yet, this poorly worded, overly broad provision clearly does the opposite.

II. No Process for Independent Investigation of Misconduct Allegations

Under the NIH draft policy, the key official reviewing allegations of scientific misconduct or lack of integrity will be an official known as the Scientific Integrity Officer or SIO. Among the key responsibilities of this position are to "Lead the review and adjudication of allegations of loss of NIH scientific integrity (particularly related to political interference) in cases where such allegations fall outside of existing processes…"

A. No Independence

The draft policy designates the Associate Director of Science Policy to serve as the NIH SIO. The draft policy further declares:

"This policy empowers the NIH SIO with the independence necessary to gather and protect information to support the review and assessment of scientific integrity concerns."

The NIH SIO reports directly to the NIH Chief Scientist. The only provision in the draft policy addressing SIO independence reads –

"Consistent with applicable law, an SIO or other scientific integrity staff may not be terminated or reassigned without good cause or legitimate organizational reason. Possible good cause reasons include, but are not limited to, consistent poor performance, inefficiency, neglect of duty, malfeasance, conviction of a felony, conduct involving moral turpitude, knowing violation of a law, rule, or regulation, gross mismanagement, gross waste of funds, and abuse of authority…"

While it is of scant comfort that NIH will accord its designated SIOs "all applicable employee rights as required by law," that is hardly an assurance that they are independent or will exercise judgment independent of their superiors, particularly on matters of political sensitivity. Further, the notion that an SIO may be removed for an unspecified "legitimate organizational reason" apart from good cause underlines the political vulnerability of the occupants of this pivotal post.

More importantly, this supposed safeguard overlooks the greater likelihood that SIOs will act to do anything possible to avoid situations that could trigger official reprisal. In PEER's experience, we have seen several examples of SIOs dismissing valid complaints, declining to investigate complaints restricting the scope of investigations when they occur, or shielding political appointees.

In PEER's experience, senior civil servants occupying positions such as Associate Director are often unwilling to take actions that will hinder their later career ascension or success. Acting to confirm a scandal within agency ranks or leadership, especially by political appointees, is usually not a path for career advancement.

An example of the type of political interference that can hinder an SIO's work can be found in PEER's representation of an SIO who was removed after pursuing a complaint against the staff of the Secretary of Interior.

In short, it is simply not credible for a system designed to ensure integrity to depend almost entirely on an official designated by the top officials he is supposed to investigate. It is certainly not an arrangement that would restore public trust in the credibility of NIH science. Rather than relying solely on one senior official to make all of these decisions, NIH should consider using panels of outside experts to make or confirm sensitive judgments about the loss of scientific integrity.

B. No Procedures for Investigation and Adjudication

It is somewhat surprising that neither current NIH policies or this draft policy specify how allegations of misconduct in its intramural program are to be investigated and adjudicated. Instead, the NIH policy declares an intention to develop such policies:

"NIH is firmly committed to establishing and formalizing procedures to identify and adjudicate allegations regarding compromised scientific processes or technological information."

Further, NIH is proposing no process for how these policies will be developed but instead the policy provides it will "Ensure that the NIH SIO or other NIH entities draft procedures, as needed, to respond to allegations of loss of scientific integrity in a timely, objective, and thorough manner." This language suggests that the SIO is free to make up rules in an ad hoc fashion "as needed."

The complete absence of these procedures is particularly surprising for an intramural program that the draft describes as "the largest biomedical research program on earth."

Further, the SIO is confined to matters that fall outside the "existing processes managed by the Office 11 of Extramural Research (OER), the Office of Intramural Research (OIR), the Office of Management

Analysis (OMA), and the HHS Office of the Inspector General (OIG)." By law, the OIG jurisdiction is not limited, thus it is unclear what matters the SIO can address that are outside the purview of the OIG.

C. Murky Path to Appeal

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

The draft does not specify to whom an aggrieved party may appeal or what procedures govern this appeal. Nor is there a firm timetable for the promulgation of these procedures. Further, it appears that these procedures will be developed without any further input or review from the public, employee unions, or anyone else.

Under current scientific integrity policies, when an SIO arbitrarily dismisses or derails a complaint, there is little recourse provided. Similarly, it is not clear whether NIH SIO findings that no investigation is warranted will be appealable.

Despite claiming that these eventual procedures to ensure the redress of deviations from scientific integrity will occur "in a timely, objective, and thorough manner" the genesis of this draft policy does not bode well for the timeliness or thoroughness of the promised final rule. Since the final NIH rules are a largely unfinished work in progress, their own ultimate objectivity and integrity remain to be seen.

D. No Transparency

The closest the NIH policy comes to specificity about investigations is the following passage:

"Should an investigation be opened, an investigation committee consisting of the NIH SIO and other agency integrity officials from the NIH Scientific Integrity Council will be convened to develop a factual record by exploring the allegation(s) in detail and consulting with subject matter experts, interviewing witnesses, and reviewing documentation as needed. Once the investigation is complete, the NIH SIO will determine whether scientific integrity was lost and report findings to the appropriate management entity."

The draft policy charges the Council with overseeing investigations, while providing little detail on how these investigations will function. The pertinent provision of the draft policy reads –

"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 SIO."

There is no provision that this report of investigation be made publicly available. To the contrary, the draft policy suggests that NIH will take steps to cloak the specifics of cases from public view:

"As part of the monitoring and evaluation plan, an annual report on the number and outcomes of investigations involving allegations of loss of scientific integrity will be published. To the extent possible, all descriptions of investigations will be anonymized." (Emphasis added)

It is not clear on what basis such a report could be withheld from release under the Freedom of Information Act. In the past, PEER has successfully used to FOIA to force release of such reports over agency objections.

More significantly, President Biden's directive that started this process had the words "Restoring Trust in Government Through Scientific Integrity" in its title. It is hard to argue that releasing only after-the-fact summaries that have been "anonymized" to be devoid of any detail will restore public trust in the integrity of federal science. Public credibility in the integrity of federal science requires a degree of transparency that this draft policy sorely lacks.

III. Opaque Transparency Provisions Allow Suppression of Research

The NIH draft defines "Interference" to include "suppression" of "scientific or technological findings, data, information, or conclusions." Yet the draft policy does not specify how it will prevent such suppression.

The draft makes reference to the "NIH-wide Policy for Manuscript and Abstract Clearance Procedures" but these procedures contain no timeline for clearance, not criteria for denying clearance, and no appeal where clearance is denied. Rather it merely specifies the form to use when applying for publication clearance.

Instead, as with investigations of alleged misconduct, NIH's draft only pledges to develop "technical review and clearance processes include provisions for timely clearance and expressly forbid censorship, unreasonable delay, and suppression of objective communication of data and results without scientific, legal, or security justification."

Again, there is no timeline for the promulgation of these processes or any indication as to who develops these clearance provisions. Nor does the draft policy –

- Define what is meant by “timely clearance” or what constitutes impermissible delay:

- Specify what is a legitimate basis for “technical review”; or

- Indicate if there is any avenue of appeal to speed up an untimely clearance process.

As outlined above, the NIH draft policy appears to invite managers to screen potential publications to ensure that they contain no statements that can be construed as judgements on or recommendations about any federal policy. Depending on the topic, such a review may take weeks and involve considerable internal debate.

The draft policy further indicates that “Violations of clearance policies that result in suppression, delay, or alteration of scientific and technological information produced by NIH scientists without scientific, legal, or security justification constitute violations of the NIH Scientific Integrity Policy and may be reported under the procedures for Addressing Scientific Integrity Concerns.”

However, since clearance policies are not specified, it is unclear what constitutes a “Violation of clearance policies.” Moreover, this remedy requires a formal complaint that may ultimately be referred for resolution back to the very officials who are obstructing its clearance for publication in the first place.

Thus, despite all the rhetoric in the NIH draft about promoting “timely publication” and “sharing” of scientific data, there is nothing the policy that ensures those goals are met or that victimized scientists have any realistic recourse.

IV. No Meaningful Protections for Scientists Against Retaliation

The NIH draft contains some language suggesting that scientists should not be subject to retaliation, but the language merely restates current law. For example, the draft states:

“[I]t is unlawful for NIH to take or threaten to take a personnel action against an employee because he or she made a protected disclosure of wrongdoing. A protected disclosure is defined as a disclosure of information that the individual reasonably believes is evidence of a violation of law, rule, or regulation; gross mismanagement; gross waste of funds; and abuse of authority; or a substantial and specific danger to public health or safety.”

That is merely a restatement of the Whistleblower Protection Act (WPA) – a statute that NIH has no power to modify. As such, the draft offers no additional safeguards beyond what NIH is statutorily required to do anyway.

Similarly, the draft declares a policy of protecting those who are involved with scientific integrity allegations, with this language –

"Protect from reprisal those individuals who report allegations of loss of scientific integrity in good faith. Efforts will also be made to protect from inappropriate actions those covered individuals alleged to have compromised scientific integrity."

First, it is curious that the NIH drafters are express equal concern about protecting those accused of scientific misconduct as about protecting those who disclose the misconduct. Nor are the promised protections for the accused delineated.

Second, the purported protection from reprisal is limited to those "who report allegations of loss of scientific integrity in good faith." However, those who file these reports already have legal protection through the WPA which already covers employee disclosures of any violation of agency rules, and a scientific integrity policy would be such a rule. Thus, scientists who file scientific misconduct/integrity complaints are disclosing an alleged violation of a rule and, for that reason, already have whistleblower status. In this regard, PEER has successfully represented scientists who suffered reprisal after filing these complaints before the Office of Special Counsel (OSC) on the basis that filing that complaint entitled that person whistleblower protection.

However, the 2009 Obama Scientific Integrity Directive called for "additional" expanded whistleblower protections or procedures to prevent retaliation against or suppression of scientific work due to its policy, economic, or political implications. This part of Obama's directive was largely ignored or given lip service by both the OSTP and federal agencies during the intervening years -- and is not addressed at all in the NIH draft.

The WPA does not protect scientists who are not whistleblowers yet who are suffering retaliation or obstruction for pursuing research on controversial matters or publishing research that does not support an agency position.

Nor does the WPA shield scientists who face blowback after expressing a differing professional opinion – an option explicitly endorsed by the NIH draft policy. Notably the NIH draft posits a goal to "Ensure that covered individuals are free to express differing scientific opinions free from political interference or inappropriate influence." It further declares a policy to "Prevent NIH employees from intimidating or coercing NIH scientists to alter scientific data, findings, or professional opinions."

However, the draft does not specify through what mechanism those goals will be achieved. In discussing differing scientific opinions, the draft states –

"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."

Yet, it does not indicate what that formal dispute resolution process is or who administers it other than noting that the "NIH SIO may be consulted if their assistance is requested…"

In short, President Obama's promise of "additional" protections for scientists who face reprisals due to the substance or content of their research findings will remain unfulfilled by the proposed NIH policy.

Protection of whistleblowers required the enactment of a law. The ideal solution would be for Congress to enact a Scientist Protection Act which would provide protections that are enforceable against the Executive Branch in court, in the same manner that, for example, the WPA is enforced.

In the absence of a new statute, there is an administrative path to address enforcement of scientific integrity policies. Apart from protecting whistleblowers, OSC has very broad but little used jurisdiction under 5 USC § 1216:

"(a) In addition to the authority otherwise provided in this chapter, the Special Counsel shall, except as provided in subsection (b), conduct an investigation of any allegation concerning . . . (4) activities prohibited by any civil service law, rule, or regulation, including any activity relating to political intrusion in personnel decision making." (Emphasis added.)

For example, OSC uses this authority to take action to remedy and prevent discrimination on the basis of sexual orientation in the federal workplace by enforcing an executive order to that effect. Similarly, OSC could extend protection to scientists if they were covered by an executive directive to that effect, or a directive from a Cabinet Secretary, such as the HHS Secretary.

PEER urges that NIH policy be amended to fill this scientist protection vacuum so that its scientists have some legal protection from official reprisal due to the content of their research or the unwelcome implications flowing from it. Safeguarding these emerging inconvenient truths should be central to any scientific integrity policy.

V. Complete Lack of Accountability for Violators

The NIH draft provides that the cure to the loss of scientific integrity would be a "corrective action" which it defines as follows:

"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. In addition to scientific actions, administrative actions may also be taken in response to substantiated violations of this policy."

Administrative action appears to be synonymous with disciplinary action, such as demotion, suspension, involuntary transfer, up to termination.

In a significant gap, the draft does not specify whose role it is to ensure that appropriate corrective scientific and/or administrative actions are taken as a result of investigative findings. PEER has seen cases where a presidential appointee has failed to take any action despite review panels who have found a favored manager guilty of serious and deliberate misconduct.

A. No Assurance of Consistency in Penalties

Nor does the draft specify what penalty applies to what type of violation or a repeat violation. Thus, there is no guardrail to assure consistent application of sanctions.

B. No Punishment for Political Appointees

A major anomaly in these policies supposedly aimed at curbing political manipulation of government science is the lack of clear application to political appointees. It is political appointees, after all, who presumably are a major source for politically motivated misconduct.

Political appointees, however, are beyond the reach of the civil service disciplinary process. They are only answerable to the political official who appointed them. To the extent that the official is acting to further the agency's political agenda, it is unlikely that person will face any punishment and, in fact, may even be promoted.

In 2021, when a member of the White House staff was reported to have engaged in threatening behavior, President Biden immediately had that official removed. The White House also issued a statement indicating zero tolerance for acts of incivility by its staff.

The NIH draft purports to cover political appointees but lacks a similar zero tolerance policy that any political appointee found guilty of scientific misconduct (or the loss of scientific integrity) should be removed from federal service.

Further, when an SIO or review panel determines that a political appointee has engaged in scientific misconduct or caused the loss of scientific integrity, the policy should provide the identity of that official should be reported by the Secretary to the White House and that report should be publicly displayed on the agency website.

Conclusion

For the reasons articulated above, PEER believes that the draft NIH scientific integrity policy fails to meet the standards that President Biden laid out in his Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking of January 27, 2021. We urge that NIH withdraw this draft and rework it to include –

- A guarantee that scientists may freely discuss and write about the possible implications of their research;

- Transparent procedures for independent investigation of allegations, as well as public review of investigatory results and corrective action decisions;

- Clear written policies delineating any clearance procedures for scientists to publish, lecture, or communicate with the media and public about their areas of expertise, including practical and timely enforcement of those guarantees;

- Protections for scientists from retaliation for the content or implications of their research and for scientists who express scientific dissent; and

- Rule providing for consistent penalties for those who violate scientific integrity prohibitions, including provisions for holding political appointees accountable.

We believe that these elements should be the bedrock of any federal scientific integrity policy, but unfortunately, they are largely absent from this NIH draft.

Sincerely,

Jeff Ruch

Pacific Director

Public Employees for Environmental Responsibility (PEER)

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/PEER-comments-on-NIH-Draft-Scientific-Integrity-Policy-11-6-23.pdf

Submit date: 11/5/2023

I am responding to this RFI: On behalf of an organization

Name: AAMC

Name of Organization: Association of American Medical Colleges

Type of Organization: Professional org association

Role: Institutional official

Comment:

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/AAMC-Comments-on-NIH-draft-scientific-integrity-policy.pdf

Description: AAMC Comments on NIH Draft Scientific Integrity Policy

Submit date: 11/6/2023

I am responding to this RFI: On behalf of myself

Name: Nick Felker

Type of Organization: Other

Role: Member of the public

Comment:

Dear NIH,

I am writing to express my strong support for the draft Scientific Integrity Policy and to encourage the inclusion of specific provisions that promote the use of open-source software (OSS) in biomedical research. OSS has emerged as a powerful tool for ensuring the reproducibility and integrity of scientific research. By making research code openly accessible, OSS allows for independent scrutiny, replication, and extension of research findings. This transparency is essential for building trust in scientific results and fostering a culture of open collaboration.

In the context of biomedical research, OSS can play a critical role in addressing the growing concerns about p-hacking, a questionable research practice that involves manipulating data or statistical analyses to produce statistically significant results. OSS can help to mitigate p-hacking by making it easier for researchers to share and validate their code, allowing others to assess the robustness of their findings.

Furthermore, OSS can encourage a more exploratory and data-driven approach to research by facilitating the development and sharing of novel analytical methods and tools. By providing access to a vast repository of open-source code, researchers can easily experiment with different data analysis techniques, including randomization and simulation, to gain a deeper understanding of their data and generate more robust conclusions.

In addition to its benefits for scientific integrity, OSS also promotes efficiency and innovation in biomedical research. By eliminating the need to repeatedly reinvent the wheel, OSS allows researchers to focus on the core scientific questions rather than spending time and resources developing custom software tools. This can accelerate the pace of research and lead to new breakthroughs.

Therefore, I strongly urge the NIH to explicitly endorse the use of OSS in biomedical research and to provide incentives for researchers to adopt open-source practices. This can be achieved by requiring researchers to share their code as a condition of funding, providing training and support for OSS development, and recognizing the value of OSS contributions in promotion and tenure decisions.

By embracing OSS, the NIH can play a leading role in fostering a more transparent, reproducible, and innovative biomedical research ecosystem. This will ultimately benefit the scientific community and the public at large.

Thank you for your consideration.

Submit date: 11/7/2023

I am responding to this RFI: On behalf of myself

Name: Madison Carolyn Feehan

Name of Organization: Space Copy / Moon Trades / NASA

Type of Organization: Other

Type of Organization-Other: Small Business / Private Organization

Role: Member of the public

Comment:

Good Day:

I am responding to this request for comment for the Draft NIH Scientific Integrity Policy on behalf of topic area 2: Role and Responsibilities of the NIH Chief Scientist (CS).

All comments are my own personal opinion based on the merit of the Draft Policy in which I have reviewed. Please find my attached PDF. Thank you for your time and consideration.

Sincerely,

Madison C. Feehan

madisonfeehan@shaw.ca

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/Feedback-Comments-For-The-2023-Updated-Scientific-Integrity-Policy-of-the-National-Institutes-of-Health-NIH-Topic-Area-2_-Role-and-Responsibilities-of-the-NIH-Chief-Scientist-CS-.pdf

Description: Feedback Comments For The 2023 Updated Scientific Integrity Policy of the National Institutes of Health (NIH) - Topic Area #2 Role and Responsibilities of the NIH Chief Scientist (CS)

Submit date: 11/7/2023

I am responding to this RFI: On behalf of an organization

Name: Roi Turalde

Name of Organization: American Association of Colleges of Osteopathic Medicine (AACOM)

Type of Organization: Professional org association

Role: Member of the public

Comment:

On behalf of the American Association of Colleges of Osteopathic Medicine (AACOM), please find attached our comments regarding aspect #5, specifically on Federal Advisory Committees (FACs).

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/AACOM-Response-to-Draft-Scientific-Integrity-Policy-of-the-NIH-RFI.pdf

Description: AACOM Response to Draft Scientific Integrity Policy of the NIH RFI

Submit date: 11/7/2023

I am responding to this RFI: On behalf of an organization

Name: Mary-Ann Bjornsti, PhD

Name of Organization: Federation of American Societies for Experimental Biology

Type of Organization: Professional org association

Role: Scientific researcher

Comment:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on proposed updates to the NIH Scientific Integrity Policy. As indicated in the Federal Register announcing availability of the draft policy for comment, NIH has a long-standing commitment to ensuring that scientific findings are objective, credible, and readily available to the public. The intent of the proposed updates is to bolster existing policies by defining individuals and parties responsible for developing, evaluating, and upholding scientific integrity policies. The proposed updates also align NIH's existing scientific integrity policy with that of the Framework for Federal Scientific Integrity Policy and Practice issued by the White House Office of Science and Technology Policy earlier this year, the goal of which is to establish uniform framework for fostering and enforcing scientific integrity across federal science agencies.

1. Role and Responsibilities of the NIH Scientific Integrity Officer - Per the draft policy, the Scientific Integrity Officer (SIO) is the primary official responsible for directing scientific integrity matters within the agency. The designation of the Associate Director of Science Policy as the SIO for NIH is appropriate and aligned with the existing responsibilities for this role as well as the reporting line to the Principal Deputy Director, who is defined within the policy as the Chief Scientist. Specifically, the Associate Director of Science Policy is already responsible for coordinating policy development and implementation across divisions within the NIH Office of the Director (e.g., Office of Extramural Research, Office of Intramural Research, Office of Management Analysis), within the Department of Health and Human Services, the White House Office of Science and Technology Policy, and interagency committees. Designation of the Associate Director for Science Policy as the SIO also reinforces existing practice within NIH.

2. Role and Responsibilities of the Chief Scientist - The draft policy defines the Chief Scientist (CS) as providing oversight of all NIH scientific integrity policies and procedures and designates the NIH Principal Deputy for this role. As noted in our comments regarding the SIO role, this designation is appropriate and aligned with existing responsibilities and reporting lines.

3. Responsibilities of the NIH Scientific Integrity Council - As outlined in the draft policy, the role of the Scientific Integrity Council is to assist the SIO in ensuring that the agency's scientific integrity policies are rigorous, responsive to scientific integrity concerns, and uniformly applied. Although the responsibilities of the NIH Scientific Integrity Council are well outlined in the draft policy (pages 11 - 12 of the comment draft), FASEB recommends incorporating more context regarding the desired attributes of the individuals recruited to serve on the Council, including topical expertise, role(s) within an Institute/Center, and career stage. This would complement the justifications for designation of the SIO

and CS and reiterate the agency's commitment to fostering a culture of integrity across all scientific activities.

Since the intent of the proposed policy updates is to provide a scientific framework that restores trust in government science, FASEB recommends consideration of including a small number of external scientists to serve as ad hoc members of the NIH Scientific Integrity Council. This strategy could help reduce potential concerns about the stringency of Council actions while also expanding the collective expertise of Council members. For instance, Research Integrity Officers serving at research institutions could offer important external perspective to scientific integrity policy development and implementation.

4. Prohibitions Against Political Interference - The draft policy outlines seven specific areas through which NIH aims to cultivate a culture of scientific integrity, with several including explicit callouts prohibiting political interference. For example, the first item within Section I, Protecting Scientific Processes, "prohibits political interference or other inappropriate influence on the design, proposal, conduct, management, evaluation, communication of, and use of scientific activities conducted by covered individuals." FASEB also appreciated the explicit linkage of timely and accurate release of research findings to furthering public trust in science.

5. Other Comments - FASEB commends NIH on these proposed updates to align its existing Scientific Integrity Policy with the January 2023 guidance from the Scientific Integrity Framework Interagency Working Group of the National Science and Technology Council. As NIH finalizes this policy, FASEB encourages incorporation of feedback received on related Requests for Information and/or Notices of Proposed Rulemaking open for comment at the same time (e.g., the Request for Information seeking input on proposed updates to the NIH mission statement open August 25 - November 24, 2023 and the Notice of Proposed Rulemaking on Public Health Service Policies on Research Misconduct open October 6 - December 6, 2023).

FASEB also recommends updating the definition of "covered individuals" to ensure readers understand for whom the policy applies. For instance, the policy includes, ""¦clinical, research, and postdoctoral fellows; doctoral trainees; interns;"¦" (page 5). While it is implied that this is referring to individuals holding those roles within the NIH intramural program, an explicit statement could minimize confusion. We also suggest clarifying whether "all levels of employees who manage or supervise scientific activities and use scientific information in policymaking" includes employees engaged in program administration roles. FASEB also recommends explicitly denoting peer reviewers as a role not defined as "covered individuals," but for whom their efforts on behalf of NIH require upholding the principles of scientific integrity as described in the policy as part of the terms of their engagement with NIH.

Finally, FASEB appreciates the expansion the subsection on "Promoting a Culture of Scientific Integrity" within "Policy Requirements" (pages 13 - 14 of the comment draft) to acknowledge the interdependence between work environments that are equitable, inclusive, safe, and free from harassment, discrimination, and exploitation in fostering a strong culture of scientific integrity. Ongoing efforts from the Office of Scientific Workforce Diversity and the UNITE initiative have resulted in measurable progress, and FASEB looks forward to future NIH initiatives to achieve this goal more fully.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/FASEB-Comments-on-Draft-NIH-Scientific-Integrity-Policy_FINAL_20231107.pdf

Description: PDF file are FASEB's comments on formal letterhead and signed.

Submit date: 11/8/2023

I am responding to this RFI: On behalf of an organization

Name: Matthew Rizzo, MD

Name of Organization: American Brain Coallition

Type of Organization: Professional org association

Role: Medical provider

Comment:

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/NIH-Scientific-Integrity-Comments-from-ABC_final-submission.pdf

Submit date: 11/8/2023

I am responding to this RFI: On behalf of an organization

Name: Carter Alleman

Name of Organization: American Society for Pharmacology and Experimental Therapeutics (ASPET)

Type of Organization: Professional org association

Role: Member of the public

Comment:

The American Society for Pharmacology and Experimental Therapeutics (ASPET) appreciates the opportunity to provide comments on the Request for Information regarding the DRAFT Scientific Integrity Policy of the National Institutes of Health. ASPET is a 4,000-member scientific society whose members conduct basic and clinical pharmacological research and work in academia, government, industry, and non-profit organizations. ASPET members conduct research leading to the development of new medicines and therapeutic agents to fight existing and emerging diseases. ASPET is a global pharmacology community that advances the science of drugs and therapeutics to accelerate the discovery of cures for disease. We are in constant pursuit of our Mission through research, education, innovation, and advocacy.

ASPET appreciates the opportunity to provide comments on proposed updates to the NIH Scientific Integrity Policy. ASPET agrees that defining individuals and parties responsible for developing, evaluating, and upholding scientific integrity policies is important and believes that that the proposed roles and responsibilities of the NIH Scientific Integrity Officer and Chief Scientist as well as the proposed designated individuals to take on those roles fitting and align with existing responsibilities of the designated individuals. ASPET also agrees with the proposed roles of the NIH Scientific Integrity Council in supporting the role of the SIO.

In regard to the prohibitions Against Political Interference, ASPET appreciates the effort NIH has put in the draft to call out various ways in which it prohibits political interference and inappropriate influence. ASPET also encourages NIH to incorporate language in the draft on how the newly proposed NIH scientific integrity infrastructure will interface with the Office of Research Integrity at the Department of Health and Human Services.

Thank you for the opportunity to offer comments on the update for the Scientific Integrity Policy of the National Institutes of Health and we look forward to its implementation.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/NIH-RFI-on-Scientific-Integrity-Policy-of-the-National-Institutes-of-Health-ASPET-Comment.pdf

Description: ASPET Comment Letter

Submit date: 11/8/2023

I am responding to this RFI: On behalf of an organization

Name: Mary Jo Hoeksema

Name of Organization: Population Association of America/Association of Population Centers

Type of Organization: Professional org association

Role: Institutional official

Comment:

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/PAA-APC-comments-to-NIH-re-scientific-integrity-policy-FINAL-11-23.docx

Submit date: 11/8/2023

I am responding to this RFI: On behalf of myself

Name: Nanwei Cao

Name of Organization: NIAAA

Type of Organization: Government agency

Role: Government official

Comment:

The section "Roles and responsibilities" doesn’t list Role and Responsibilities of the NIH top leader, managers and supervisors, employees, and other covered entities, such as principal investigators of extramural grants, especially principal investigators of grants to foreign organizations.

Submit date: 11/8/2023

I am responding to this RFI: On behalf of myself

Name: Dr. Anon

Type of Organization: University

Role: Scientific researcher

Comment:

1) Cap the # of R01s to 2/PI. I've been in and around labs with 2, 3 and 4+ concurrent R01s and they are all fraud factories. Nothing is real out of those labs. Those PIs are experts in psychology and not areas of their "research field". They hire desparate people and manipulate them into quick and fraudulent data. The PI gets $200-800k base salary (e.g., UCSD) and fame all built on bullsh1t. In my opinion, 80% of published research is completely fraudulent (no experiments actually performed). Cap the concurrent R01s to 2. This simple act will remove these mega fraud labs from the research enterprise.

2. Unrelated, the NIH needs to train and perform oversight of their staff. Incompetence and corruption at the NIH are the most common traits that I've identified after a couple of decades of dealing with them. I've personally experienced professional threats from a CSR for adding a researcher to a request not to review my grant app. I witnessed this same CSR getting wasted at The Society for Neuroscience conference social while he was bad mouthing a couple of smaller institutions. I've also been appalled to have a grant rejected at the door of an NIH institute (not even reviewed) after discussing the grant app with a PO at that institute that said it was a "good fit". The PO didn't apologize and even recommended that I submit it as an R21 at NIGMS which doesn't even have an R21. I have dozens of these personal anecdotes. The early career reviewer program is a sham. It's a program designed to allow powerful PIs to rotate off of a study section and the CSR to appoint the PI's postdoc in their place as an "early career reviewer". This allows the powerful PI to maintain control via their NIH-sanctioned proxy. I applied for this program twice as a pre-tenure faculty member. I was never contacted during that time despite following up with emails to CSRs and POs. However, I did receive an email requesting my participation in this program AFTER I was tenured and thus no longer eligible. I'm sure that it is a just a coincidence that the program application form has the expected date of tenure.

No matter how badly broken that the NIH is, there are some great and honest researchers out there fighting for a better future. I encourage everyone to contact their Congressman/Congresswoman a and media to expedite change.

Submit date: 11/9/2023

I am responding to this RFI: On behalf of an organization

Name: Liz Borkowski

Name of Organization: Eleven organizations: APA Justice Task Force, AAFEN, CRR, Equity Forward, GAP, GIW, JIWH, NCHR, POGO, PEER, UCS

Type of Organization: Other

Type of Organization-Other: Organizations whose work involves federal scientific integrity issues

Role: Member of the public

Comment:

Please see the attached comment from eleven organizations whose work involves federal scientific integrity issues.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/11-Organizations-Comment-to-NIH-on-Draft-Scientific-Integrity-Policy.pdf

Description: Comment from eleven organizations whose work involves federal scientific integrity issues regarding the NIH draft scientific integrity policy

Submit date: 11/9/2023

I am responding to this RFI: On behalf of an organization

Name: Janine McCarthy

Name of Organization: Physicians Committee for Responsible Medicine

Type of Organization: Nonprofit research organization

Role: Scientific researcher

Comment:

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/PCRM-Comment_NIH-draft-scientific-integrity-policy.pdf

Submit date: 11/9/2023

I am responding to this RFI: On behalf of an organization

Name: Abigail Echo-Hawk

Name of Organization: Urban Indian Health Institute

Type of Organization: Nonprofit research organization

Role: Scientific researcher

Comment:

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/UIHI-Comments-on-NIH-Draft-Scientific-Integrity-Policy.pdf

Submit date: 11/9/2023

I am responding to this RFI: On behalf of an organization

Name: Makyba Charles-Ayinde

Name of Organization: American Association for Dental, Oral, and Craniofacial Research

Type of Organization: Professional org association

Role: Institutional official

Comment:

November 9, 2023

Tara A. Schwetz, PhD

Acting Principal Deputy Director, National Institute of Health

9000 Rockville Pike,

Bethesda, MD 20892 USA

Re: Request for Information on the DRAFT Scientific Integrity Policy of the National Institute of Health.

via website: https://www.federalregister.gov/documents/2023/09/25/2023-20733/request-for-information-on-the-draft-scientific-integrity-policy-of-the-national-institutes-of

The American Association for Dental, Oral, and Craniofacial Research (AADOCR) is the leading professional community for multidisciplinary scientists who advance dental, oral, and craniofacial research. We appreciate the opportunity to share our thoughts on the National Institute of Health's (NIH) draft scientific integrity policy. AADOCR recognizes and applauds NIH's effort to preserve scientific integrity throughout all NIH activities, establish key roles and responsibilities for those who will lead the agency's scientific integrity program, and establish relevant reporting and evaluation mechanisms. To respond to this request for comments, AADOCR engaged its Science Information Committee and its Board of Directors.

Scientific integrity is an essential tenet of every scientific study and discovery1. It provides certification that the data can be verified, repeated, and reproduced1. It is especially critical in the biomedical research space where scientific innovation and research discoveries contribute to life saving and quality of life improving measures. Therefore, AADOCR would like to congratulate NIH on a very detailed and comprehensive draft policy that aims to foster scientific integrity so as to ensure that scientific findings are objective, credible, and readily available to the public, and that the development and implementation of policies and programs is transparent, accountable, and evidence based. The additions to the policy on the roles and responsibilities of the Scientific Integrity Officer and the responsibilities of the Scientific Integrity Council are clear, logical, and necessary. Additionally, the inclusion of prohibitions against political interference is a socially responsible addition in all areas where it was introduced.

AADOCR would like to provide considerations for two specific areas of the policy:

- Page two of the policy document defines the NIH Mission as "to seek fundamental knowledge about the nature and behavior of living systems and apply that knowledge to enhance health, lengthen life, and reduce illness and disability". However, as the mission is currently under review to be potentially revised to "to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to optimize health and prevent or reduce illness for all people" AADOCR supports considering finalizing the scientific integrity policy only upon the confirmation of the new NIH Mission.
- The roles and responsibilities of the Chief Scientist was introduced on page 10 of the policy document. However, the definition of the term Chief Scientist provided on page 5, describes the Chief Scientist as the Principal Deputy Director. This indicates that the roles and responsibilities of the Chief Scientist will be carried out by the Principal Deputy Director. The introduction of a new title (Chief Scientist) to an existing position where that position is retained may be confusing to the public and policy makers. Some may make the incorrect assumption that Presidentially-appointed, Senate-confirmed NIH Director is the NIH Chief Scientist. Therefore, AADOCR supports considering, in lieu of a new title, providing clarification that the role of the Principal Deputy Director also includes the responsibilities listed under Chief Scientist within the policy document - oversight of all NIH scientific integrity policies and procedures. In the event that the Chief Scientist role would eventually evolve to an individual that is separate and apart from the Principal Deputy Director, AADOCR supports the consideration of "Deputy Director for Scientific Integrity" as a potential title for this employee. This is bolstered by the need to be sensitive to appropriation of and lack of respect for the Native American culture with the title "Chief" in creating a new position. [AADOCR recognizes the need to examine our own titles in this regard.]

AADOCR appreciates the opportunity to provide comments on NIH's draft scientific integrity policy and stands ready to work with NIH through an inclusive process to safeguard scientific integrity.

If you have any further questions, please contact Dr. Makyba Charles-Ayinde, Director of Science Policy, at mcayinde@iadr.org.

Sincerely,

Christopher H. Fox, DMD, DMSc
Chief Executive Officer

Alexandre Vieira, DDS, MS, PhD
President

1Diaba-Nuhoho P et al. (2021). Reproducibility and Research Integrity: The Role of Scientists and Institutions. BMC Research Notes. 14(451).

2Bohanon M. (2022). DEI Expert Lee Bitsóí Explains Why 'Chief' Should Be Eliminated from Diversity Titles. Retrieved from: https://www.insightintodiversity.com/words-matter-dei-expert-lee-bitsoi-explains-why-chief-should-be-eliminated-from-diversity-titles/. Accessed on November 1, 2023.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/10/AADOCR-Response-to-Draft-Scientific-Integrity-Policy.pdf

Submit date: 11/9/2023

I am responding to this RFI: On behalf of an organization

Name: Michael Streeter

Name of Organization: Wiley

Type of Organization: Other

Type of Organization-Other: Role: Scholarly Publisher

Comment:

In response to #1, the Role and Responsibilities of the NIH Scientific Integrity Officer We thank the National Institutes of Health for the opportunity to comment on the Institute's Draft Scientific Integrity policy. As a publisher of peer-reviewed research, Wiley is committed to research integrity, and we recognize that that commitment ensures public trust in the research output published across our portfolio. We have a responsibility to maintain and uphold the integrity of the scholarly record. For Wiley, that includes the work that we do to ensure, to the extent possible, that manuscripts submitted to our journals comply with industry-wide research integrity best practices and standards, with the editorial policies established in our peer-reviewed journals, and the community standards in the various disciplines represented in our portfolio. After publication, Wiley is accountable for the accuracy of the scholarly record, memorialized as the Version of Record (VoR), particularly if a concern is raised about the accuracy or conclusions represented in a published article. When those concerns are raised, Wiley undertakes a process of investigation to review those concerns and establish whether or not a post-publication amendment is required. A post-publication correction may include, a correction, a retraction, or potentially an Expression of Concern. We include a brief overview of the post-publication actions that we may take following a review and investigation of a research integrity concern here: https://authorservices.wiley.com/ethics-guidelines/retractions-and-expressions-of-concern.html. Wiley is a member of the Committee on Publication Ethics (COPE); we follow their guidance and industry best practices in investigating concerns and taking any action required after publication. Additional information regarding COPE can be found here: https://publicationethics.org/. Along with researchers, academic institutions, indexers, and others, Wiley and the NIH are key stakeholders in the execution and publication of research, its dissemination, and quality control practices. We recognize that a culture of collaboration across the research ecosystem is essential to upholding trust in the scholarly record. Wiley and NIH both recognize a responsibility for the accountability of the research record. Point 1, in Section IV of the draft states: "Ensure correction of the scientific record and implementation of corrective scientific actions when allegations of a loss of scientific integrity are substantiated." In response to that point, we recommend that the NIH clarify in this statement that any necessary correction be applied to the VoR for the research article in question and that the suitable publisher or host of that VoR be contacted with the request to take the NIH-recommended post-publication action. A request by NIH to the relevant publisher or host would need to be accompanied by the rationale for the requested post-publication action to enable the publisher or host to transparently describe, or investigate themselves, the reason behind the post-publication correction. Anonymity required in any such request should be preserved as well. The VoR of any published article is the version that has been accepted following peer