From: [redacted]
To: OASH ORI Public Comments; [redacted]
Subject: Fwd: immigrant who do research misconduct should be deported from this country
Date: Saturday, September 3, 2022 10:09:47 AM

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public comment on federal register americans who do it should never get another govt job.

this includes getting paid to do a job and lying on that job and wasting american tax dollars. i see no defense to that at all. such a person who does that should lose his govt job forever. if someone in private industry want to hire them anyway, that isfine. but if he is an immigrant, he shuold be deported for that criminality. weneed to have honesty in research. and certainly with the limimted manpower there is alot more research misconduct than is ever caught, so we are geting low quality of reserch. and if you make it so little punishjment they will do misconduct more. this is erious. fire them and never let them work for govt ever again. no second hacds. no morfe misconduct coming. this commetn is for thepublic record. please receipt. [redacted]

[Federal Register Volume 87, Number 169 (Thursday, September 1, 2022)]
[Notices]
[Pages 53750-53751]
From the Federal Register Online via the Government Publishing Office
[www.gpo.gov]
[FR Doc No: 2022-18884]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Request for Information (RFI).

SUMMARY: The Department of Health and Human Services (HHS), Office of Research Integrity (ORI) seeks the perspectives of individuals, research funding agencies, institutional officials, organizations, institutions, and other members of the general public on the 2005 Public Health Service Policies on Research Misconduct to help structure ORI's future plans to revise the regulation. To this end, ORI issues this RFI to collect input on the current regulation (see details in SUPPLEMENTARY INFORMATION section).

DATES: Responses to the RFI must be received electronically no later than 5:00 p.m. ET on October 31, 2022. Mailed paper submissions and submissions received after the deadline will not be reviewed.

ADDRESSES: Comments must be submitted electronically to OASH-ORI-Public-Comments@hhs.gov. Include ``Regulations RFI'' in the subject line of the email.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Dr., P.H., MT (ASCP), Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453-8200.

SUPPLEMENTARY INFORMATION: ORI oversees and directs Public Health Service (PHS) research integrity activities on behalf of the Secretary

of HHS, with the exception of the regulatory research integrity activities of the Food and Drug Administration (FDA). ORI's mission is to protect science and public health and to conserve public funds by ensuring the integrity of all PHS-supported biomedical and behavioral research.

The Public Health Service Policies on Research Misconduct, 42 CFR parts 50 and 93, established several requirements regarding the handling of allegations of possible research misconduct and

[[Page 53751]]

fostering of an environment that promotes research integrity and discourages research misconduct. Institutions receiving funding for research from any of the PHS funding components \1\ must adhere to these requirements to receive PHS funding.

\1\ PHS funding components are ``any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity that involves the conduct of biomedical or behavioral research, research training or activities related to that research or research training, e.g., agencies, bureaus, centers, institutes, divisions, or offices and other awarding units within the PHS.'' 42 CFR 93.209. This includes the: National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), FDA, Substance Abuse and Mental Health Services Administration (SAMHSA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Office of the Assistant Secretary for Health (OASH), and Administration for Strategic Preparedness and Response (ASPR).

ORI conducts oversight of institutional research misconduct proceedings (inquiries and investigations) as well as institutional compliance with the PHS Policies on Research Misconduct at 42 CFR part 93. ORI also conducts outreach and develops educational resources that aid institutional efforts ``to teach the responsible conduct of research, promote research integrity, prevent research misconduct, and . . . respond effectively to allegations of research misconduct. . . .'' 65 FR 30600, 30601 (May 12, 2000).

The Public Health Service Policies on Research Misconduct (42 CFR part 93) \2\ became effective in June 2005, replacing the Responsibilities of Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science (42 CFR part 50), which was promulgated in August 1989. ORI contemplates beginning a regulatory revision process for the 2005 ORI regulation at 42 CFR part 93 in the near future, using conventional rulemaking processes and channels for public notification and comment.

\2\ Hereafter referred to as the ``2005 ORI regulation at 42 CFR part 93.''

Input on the 2005 Public Health Service Policies on Research Misconduct

ORI seeks the perspectives of individuals, research funding agencies, institutional officials, organizations, institutions, and other members of the general public to help structure ORI's future work toward an updated regulation. To this end, ORI issues this RFI to collect input on the current regulation at 42 CFR part 93.

ORI is not seeking specific regulatory language at this time, only the identification of potential topic(s), issue(s), or area(s) that stakeholders and other members of the general public see as being important to consider when revising the 2005 ORI regulation at 42 CFR part 93. Responders may find it helpful to consider the following questions when preparing responses (the order of the questions below should not be taken to imply importance, priority, or precedence):

(1) Which section(s) should be changed or augmented when revising 42 CFR part 93? Why? How should the section(s) be changed or augmented?

(2) Which section(s) should be retained as it currently is in 42 CFR part 93? Why?

(3) Which section(s) should be considered for removal when revising 42 CFR part 93? Why?

ORI views this RFI as a brainstorming process. Short responses, limited to just a few words on a given topic, issue, or area will facilitate the organization and categorization of responses. If an idea specifically relates to a part of the current regulation, citing that section (e.g., Sec. 314.3) would be helpful.

Collection of Information Requirements

Please note: This RFI is issued solely for information and planning purposes. It does not constitute a solicitation for: Request for Proposals (RFPs), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or to make a grant award. Further, ORI is not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in responding to this RFI; all costs associated with responding to this RFI will be solely at the expense of the responding parties. ORI notes that not responding to this RFI does not preclude participation in future conventional rulemaking concerning 42 CFR part 93. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request.

ORI will actively consider all input received as our office initiates the rule making process in the near future. ORI may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or to issue a grant. Information obtained from this RFI may be used by the U.S. Government on a non-attribution basis. Responders should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned.

Dated: August 29, 2022.
Wanda K. Jones,
Acting Director, Office of Research Integrity, Office of the Assistant Secretary for Health.
[FR Doc. 2022-18884 Filed 8-31-22; 8:45 am]
BILLING CODE 4150-31-P

From: [redacted]
To: OASH ORI Public Comments
Subject: ORI Announces a Request for Information (RFI) on the 2005 Public Health Service Policies on Research Misconduct
Date: Monday, October 17, 2022 2:27:13 PM
Attachments: Scientic Misconduct ADP.pdf

Dear Sir or Madam

This email is in response to the ORI's request for information about the 2005 Public Health Services Policies on Research Misconduct.

I have been doing biomedical research for [redacted] years and have published over [redacted] peer review papers. I have seen multiple examples of likely scientific misconduct not addressed to protect the institution and examples of investigators who clearly did not engage in misconduct charged with such because of reasons unrelated to the work in the laboratory.

I recently wrote an article [redacted] on scientific misconduct [redacted] I have attached it to this email. As you see, I investigated every claim recorded by the ORI as documented misconduct and found some strong common threads. The citation is:

[redacted]

I would greatly appreciate your opinion on the three recommendations [redacted] which I think should be considered for the revised policy:

1. Require all investigators to get a certificate of training via an on-line course on good research practices before working in a research lab
2. Set up regional academic ORI centers where any research misconduct would only be investigated by a center which does NOT include anyone from the institution where the investigator works
3. Strictly define misconduct as the use of falsification/fabrication/plagiarism in figures/text DIRECTLY related to the main points of the paper.

These 3 recommendations to the current Public Health Service policy would much reduce the incidence of misconduct and stop having it politicized by institutions who are either trying to protect someone guilty of misconduct or to incorrectly accuse someone who did not commit misconduct

Thank you

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Subject: Regulations RFI
Date: Monday, October 24, 2022 1:22:42 PM

To whom it may be concerned,

I think it would be beneficial for ORI to provide the public more rationale for how cases are settled and determinations are made. For instance, two recent cases have very similar settlements, but the extent of misconduct appeared to be vastly different (plagiarism vs. falsification and fabrication):

1) plagiarism: Case Summary: Magnuson, Terry | ORI - The Office of Research Integrity (hhs.gov)
2) falsification and fabrication: Case Summary: Kaushal, Deepak | ORI - The Office of Research Integrity (hhs.gov)

Moreover, I think grant reviewers need to be made aware of ongoing investigations. It is troubling to me that a researcher was awarded a grant after having being found guilty of falsification in a previous version of the same grant application: Case Summary: Chen, Shuo | ORI - The Office of Research Integrity (hhs.gov)

Because it is so difficult to prove data fabrication and falsification, I worry that when someone is found guilty, we are just scratching the surface, and thus, I think supervisory periods are insufficient. There need to be much harsher penalties to better deter researchers from engaging in these types of activities.

Finally, I think that ORI needs to respond to inquiries made on PubPeer and other venues.

Thank you for your consideration,
[redacted]

From: [redacted]
To: OASH ORI Public Comments
Subject: Public comment on revising the 2005 ORI regulation at 42 CFR part 93
Date: Monday, October 24, 2022 5:43:49 PM

Here are some ideas for revising the ORI regulation:

1. More clear-cut guidance is needed from the Office of Research Integrity about ethics in publishing. Perhaps adopt a "code of ethics" derived from this: https://www.nature.com/nature-portfolio/editorial-policies. While this code may only be enforceable on NIH-funded papers, having this as US policy might nudge US institutions (at least) to follow suit.
2. Require research to be published in open-access journals; public pays for it, public should get access (something like this may already be in the works per White House announcement)
3. Require data retention for 10 years with a data custodian (can be institution or for-profit data warehouse) pre-identified in grant requests and published paper and extend ORI investigation window to 10 years
4. Require data to be publicly available – with anonymization for patient data and PII
5. Require funded researchers to agree to submit to independent audit or ORI examination upon request, with automatic grant money claw-back if they do not agree when being investigated (like if they lawyer-up).
6. Require that institutional whistleblower protections are in place before grants awarded
7. Require funded institutions to have a publicly identified "research integrity officer"
8. Require institutions (instead of authors) to correct published research when research misconduct investigations are concluded.

From: [redacted]
To: OASH ORI Public Comments
Subject: Regulations RFI
Date: Monday, October 24, 2022 6:49:23 PM

Hello,

I would like to suggest the addition of a section to subpart C, to implement publishing requirements. Specifically, if journal article authors were required to append all raw analytical data at the time of publication – many of the delayed misconduct findings could be avoided. This type of requirement would allow both peer reviewers and journal subscribers to easily assess data quality and would deter authors from using or inferring results from questionable datasets. Such a requirement is easily accomplished considering the no-cost option to include supplementary data with online article submissions.

VR,

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Subject: Regulations RFI
Date: Tuesday, October 25, 2022 7:48:11 AM

Thank you for the opportunity to offer input on Research Misconduct regulations.

a) The definition of research misconduct should be extended to include federal staff who are fail to report knowledge of misconduct to ORI or attempt to obstruct investigations. In the event that such activities come to light, concerned staff should be formally sanctioned.
b) Research misconduct should include breaches of confidentiality in pre-decisional activities such as grant reviews.
c) Investigation of research misconduct should be handled by ORI and not by the concerned agencies since many agency staff develop long term professional relationships with researchers that impeded their judgment.
d) The mere 'slap on the wrist' sanctions in vogue today should be replaced by more appropriate deterrents and research institutions should be held accountable along with the individual investigator.
e) The budget of ORI should be increased very substantially

Sincerely

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Subject: Regulations RFI
Date: Tuesday, October 25, 2022 12:22:03 PM

I have served on several committees during my tenure and have interacted with ORI previously. I have two comments relating to trainees and mentors that ORI should strongly consider in updating their guidelines.

(1) Supervision rulings by ORI should not be published publicly if the misconduct was done as a trainee.

Trainees are vulnerable and subject to poor mentorship and stress of publishing and/or defending. I have witnessed over my career countless students fall victim to pressure from mentors that can end in poor decisions and misconduct. In cases that result in supervision rulings I believe trainee names should not be published publicly to allow them a second chance for rehabilitation. Taxpayers in most cases have already invested tens, if not hundreds, of thousands of dollars into their education and training and ORI public rulings for relatively minor cases (i.e. supervision) almost always permanently prevent subsequent work in research, wasting time and money in what could still be a successful career. This is what NSF does. There is no benefit to publicly shaming a trainee. Debarment, on the other hand for serious offensives should be published publicly.

(2) Mentors should be held accountable for their trainees.

Mentors are the guardians of the public trust and resources and need to be held accountable for the mistakes of their lab and trainees. Too often investigators share none of the blame and their role in a trainee's misconduct should not be ignored. What drives a trainee to commit misconduct often results from poor mentorship and pressure. ORI should not turn a blind eye to this as it perpetuates the problem.

From: [redacted]
To: OASH ORI Public Comments
Subject: Regulations RFI
Date: Tuesday, October 25, 2022 12:49:01 PM

-Institute better training for RIOs

-Statue of limitations for ORI should be lowered to 5 years to comply with the length of federal non-capital offensives. Lowering the time will also allow you to further investigate and limit the backlog of cases

-Make universities more responsible financially for research misconduct

From: [redacted]
To: OASH ORI Public Comments
Subject: RFI for the PHS 2005 Policies on Research Misconduct
Date: Tuesday, October 25, 2022 1:59:39 PM

Good afternoon,

I'm responding to question 1: Which section(s) should be changed or augmented when revising 42 CFR part 93? Why? How should the section(s) be changed or augmented? I have no opinions on questions 2 and 3.

93.300(c): Instead of "fostering a research environment that promotes..." strengthen the language to "creates a mechanism for investigators to engage in..."

Clarify 93.307(d) to further distinguish the inquiry from the assessment phase. When an allegation is received, it is assessed for whether or not it is substantive, made in good faith, and falls under the definition of research misconduct, which are the exact same review criteria for an inquiry. In certain situations, it can become unclear how conducting an inquiry differs from conducting the assessment (except, perhaps, for involving more people).

Best,

[redacted]

*Thank you for your consideration.***

From: [redacted]
To: OASH ORI Public Comments
Cc: [redacted]
Subject: Regulations RFI
Date: Wednesday, October 26, 2022 2:27:07 PM

My suggestions are:

1. NIH must reduce the indirect cost on their approved grants, and the savings to be used to hire more ORI investigators to help tackle this cancer issue of research misconduct and fraud.
2. Many times, institutions opted to protect fraudsters and punish the whistleblowers (literally firing them!), ORI must proactive when such cases occur, esp. when the whistleblower contacts them. It has been almost impossible to obtain responses in timely fashion from ORI.
3. Regardless of the institutional decision, ORI must conduct an independent investigation with its investigators on site to corroborate the institution claims.
4. The funding ban must be for life and not a slap on the wrist with 2-3 yrs ban, esp for repeat offenders who feel like the untouchables.

From: [redacted]
To: OASH ORI Public Comments
Subject: My Public Comment on OASH Request for Information on the 2005 Public Health Service Policies on Research Misconduct
Date: Wednesday, October 26, 2022 8:38:49 PM

Need for increased fairness in regulation by **limiting §93.105(b)(1)** as follows:

Subsequent use exception. The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of **the specific research data or words** that were alleged to have been fabricated, falsified, or plagiarized.

. . . . . .

In cases that I have considered in the past 15 years, it is clear to me that it was **unfair**, under the HHS/ORI subsequent use regulation "research" clause, **for one just have to cite**, in a paper, presentation, or grant application, an earlier abstract, publication, or presentation, **even in a biographical sketch or curriculum vitae**, that had been found previously by ORI to have contained some limited falsified, fabricated, or plagiarized material – **without that new citation referring to the actual results or words (the falsified, fabricated, or plagiarized material itself) as the "subsequent use."**

Sincerely,

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Subject: Regulations RFI
Date: Thursday, October 27, 2022 8:28:36 AM

Regarding the Office of Research Integrity RFI

I believe that SELF-PLAGIARISM needs to be added to the list of offenses that constitutes misconduct. Under the current regulations (42 CFR part 93) self-plagiarism is not considered misconduct. This situation allows individuals to publish the same data in multiple venues, thus *gaming* the system of metrics by which scientists are judged for promotions, grants, awards, etc. Self-plagiarism is double-dipping, and is not a practice that should be encouraged by being beyond the reach of ORI.

Thank-you,

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Subject: Regulations RFI
Date: Thursday, October 27, 2022 1:09:48 PM
Attachments: 2022-10-27-orip-rfi.pdf

To whom it may concern:

As the Office of Research Integrity (ORI) is aware, a number of high-profile cases involving misconduct by federally funded investigators have been recently publicized, including the devastating possibility that a 2006 study of Alzheimer's disease in rats may have misled the scientific and patient communities for more than a decade, resulting in millions of wasted research dollars.

ORI recently published the results of several investigations into National Institutes of Health (NIH)-funded researchers at the University of California–Los Angeles, University of California–Berkeley, University of Wisconsin–Madison, and Albert Einstein College of Medicine who were determined to have "intentionally, knowingly, and/or recklessly falsified" data in scientific publications and/or federal grant applications that involved the use of animals. The recent ORI reports also included documented misconduct from Deepak Kaushal, director of one of the nation's seven multimillion-dollar national primate research centers and the current recipient of more than $7.5 million in NIH grant funds. Currently, the penalties for misconduct do not prohibit the investigators from continuing to receive federal research funds, and many of these investigators continue to conduct their work with taxpayer money.

Presently, there is no mechanism that ensures that individuals charged with reviewing grant applications are aware of misconduct or Public Health Service (PHS) Policy violations committed by applicants or their home institutions. This lack of transparency impacts reviewers' ability to make informed judgments based on a comprehensive set of facts pertaining to the application. The current grant review system enables individuals who have engaged in research misconduct to continue receiving federal funds, potentially producing additional compromised and misleading results. This practice not only rewards investigators for problematic work but also erodes the public's trust in science.

Additionally, misconduct involving vulnerable human subjects and non-human animals should garner additional scrutiny from ORI. Research with non-consenting animals or human participants who are unable to provide full consent, or who have been otherwise identified vulnerable (pregnant women and fetuses, minors, prisoners, persons with diminished mental capacity, and those who are educationally or economically disadvantaged) deserve the highest level of protections. Any respondents found guilty of misconduct while conducting research with these populations should be barred from research using these populations in the future.

Government funding for research is an honor that should be preserved for scientists who have demonstrated integrity; it should be denied to those who disregard PHS requirements and federal laws and regulations, particularly when that disregard exploits vulnerable individuals.

Therefore, when revising 42 CFR part 93, the following sections should be changed:

§ 93.105(b) Exceptions to the six-year limitation.

A subpart (4) should be added to this section:

> (4) *Vulnerable subjects exception*. If the alleged misconduct involved research undertaken using vulnerable human participants (pregnant people, fetuses and neonates, minors, incarcerated persons, individuals with mental disabilities, and educationally or economically disadvantaged persons) or non-human animals.

§ 93.108 Confidentiality.

A subpart (a)(3) should be added to this section:

> (3) If misconduct is established, the identity of the respondents must be revealed in federal grant applications as well as to institutional human subjects and animal use

review boards, where applicable.

§ 93.318 Notifying ORI of special circumstances.

A subpart (h) should be added to this section:

> (h) The alleged misconduct involved research undertaken using vulnerable human participants (as defined above) or non-human animals.

§ 93.401 Interaction with other offices and interim actions.

Subpart (c) should be changed to read:

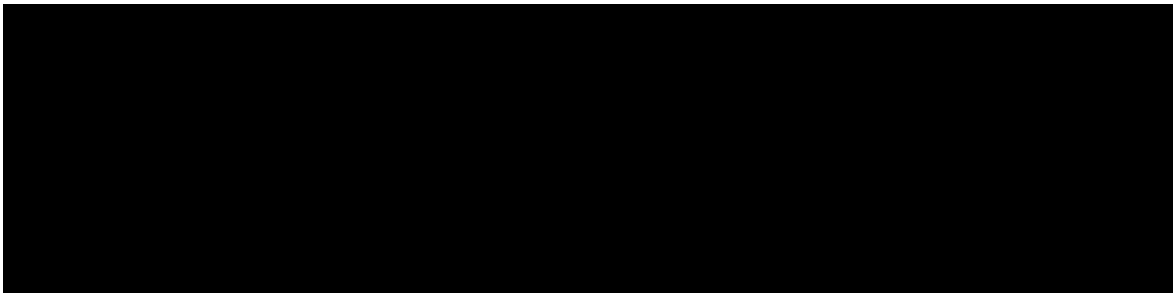
> (c) The information provided will be disclosed as part of the peer review and advisory committee review processes and may be used by the Secretary in making decisions about the award or continuation of funding.

§ 93.407 HHS administrative actions.

An additional subpart (d) should be added to this section:

> In connection with findings of research misconduct that involved studies using vulnerable human participants (as defined above) or non-human animals, respondents will be barred from using vulnerable human subjects or non-human animals under PHS-supported research.

Sincerely,



October 27, 2022

Office of the Secretary
Department of Health and Human Services
Via e-mail: OASH-ORI-Public-Comments@hhs.gov
Re: Regulations RFI

To whom it may concern:

As the Office of Research Integrity (ORI) is aware, a number of high-profile cases involving misconduct by federally funded investigators have been recently publicized, including the devastating possibility that a 2006 study of Alzheimer's disease in rats may have misled the scientific and patient communities for more than a decade, resulting in millions of wasted research dollars.

ORI recently published the results of several investigations into National Institutes of Health (NIH)-funded researchers at the University of California–Los Angeles, University of California–Berkeley, University of Wisconsin–Madison, and Albert Einstein College of Medicine who were determined to have "intentionally, knowingly, and/or recklessly falsified" data in scientific publications and/or federal grant applications that involved the use of animals. The recent ORI reports also included documented misconduct from Deepak Kaushal, director of one of the nation's seven multimillion-dollar national primate research centers and the current recipient of more than $7.5 million in NIH grant funds. Currently, the penalties for misconduct do not prohibit the investigators from continuing to receive federal research funds, and many of these investigators continue to conduct their work with taxpayer money.

Presently, there is no mechanism that ensures that individuals charged with reviewing grant applications are aware of misconduct or Public Health Service (PHS) Policy violations committed by applicants or their home institutions. This lack of transparency impacts reviewers' ability to make informed judgments based on a comprehensive set of facts pertaining to the application. The current grant review system enables individuals who have engaged in research misconduct to continue receiving federal funds, potentially producing additional compromised and misleading results. This practice not only rewards investigators for problematic work but also erodes the public's trust in science.

Additionally, misconduct involving vulnerable human subjects and non-human animals should garner additional scrutiny from ORI. Research with non-consenting animals or human participants who are unable to provide full consent, or who have been otherwise identified vulnerable (pregnant women and fetuses, minors, prisoners, persons with diminished mental capacity, and those who are educationally or economically disadvantaged) deserve the highest level of protections. Any respondents found guilty of misconduct while conducting research with these populations should be barred from research using these populations in the future.

Government funding for research is an honor that should be preserved for scientists who have demonstrated integrity; it should be denied to those who disregard PHS requirements and federal laws and regulations, particularly when that disregard exploits vulnerable individuals.

Therefore, when revising 42 CFR part 93, the following sections should be changed:

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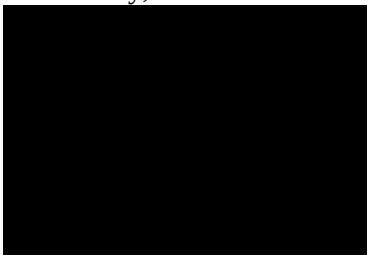
An additional subpart (d) should be added to this section:

> In connection with findings of research misconduct that involved studies using vulnerable human participants (as defined above) or non-human animals, respondents will be barred from using vulnerable human subjects or non-human animals under PHS-supported research.

Sincerely,



From: [redacted]
To: OASH ORI Public Comments
Cc: Jones, Wanda K. (DHHS/OS/OASH); [redacted]
Subject: Regulations RFI - (Tighten Jurisdiction)
Date: Thursday, October 27, 2022 2:40:47 PM

Refers to:

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Sec.  93.103  Research misconduct.

    Research misconduct means fabrication, falsification, or plagiarism
in proposing, performing, or reviewing research, or in reporting
research results.
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The "jurisdiction" for research misconduct was expanded in 2005 (??to comport with the White House's broader OSTP need??) to include "Reviewing Research." (i.e., P, P, **R**, and P)

But here interpretation of the jurisdiction gets very fuzzy.

The blog 'Retraction Watch" generated much comment after someone submitted material to the American Heart Association (AHA) which they had plagiarized from a nonrelated scientist's NIH grant application.

One interpretation of "PPRP" then was that regardless of jurisdiction, you cannot 'steal' (plagiarize) from an NIH grant application (since you were getting paid by the NIH during the review). But what would happen if their postdoc -paid from another source- submitted it to the AHA?

Tighten up the jurisdiction for "Reviewing Research."

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Subject: RFI Comment Letter
Date: Friday, October 28, 2022 4:30:43 PM
Attachments: [redacted] ORI RFI Research Misconduct Policies Oct 30 2022 PDF.pdf

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To Whom it May Concern,

Please see attached joint comment letter [redacted] in response to ORI's Request for Information on the 2005 Public Health Service Policies on Research Misconduct.

Sincerely,

[redacted]

[redacted]

[redacted]

October 30, 2022

Submitted electronically to: OASH-ORI-Public-Comments@hhs.gov

Dr. Wanda K. Jones, Acting Director
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Dear Dr. Jones:

[redacted] submit this letter in response to the Office for Research Integrity's Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct published in the September 1, 2022, Federal Register. [87 FR 53750] (the "RFI"). [redacted] is an association of over 200 public and private United States research universities and affiliated academic medical centers and research institutes. [redacted] is an [redacted] that shares best practices and strategies for handling research misconduct allegations and promoting ethical research. Both [redacted] are concerned with the impact of federal regulations, policies, and practices on the performance of research conducted at their member institutions, and research integrity is one area of significant interest and expertise among [redacted]

Ensuring the responsible and ethical conduct of research, free from fabrication, falsification, and plagiarism, is a primary responsibility and focus of every university that conducts research, regardless of funding source. Given the prominence of Public Health Service (PHS) funding for so much of the research that is conducted at many United States universities and the fact that current regulations have been in place since 2005, universities have had ample opportunity to see how the Public Health Service (PHS) Policies on Research Misconduct at 42 CFR Part 93 ("Research Misconduct Policies") work in practice. Accordingly, we appreciate the Office of Research Integrity's (ORI) solicitation of stakeholder input as it contemplates changes to the Research Misconduct Policies, and we hope that this RFI will serve as the beginning of continuing dialog with the research community regarding any such changes.

We also point out that for over 20 years there has been a federal-wide research misconduct policy promulgated by the White House Office of Science and Technology Policy (OSTP).[1] Universities rely upon such federally harmonized approaches to promote compliance and minimize administrative burden, and we urge ORI to use its review process as an opportunity to work with other federal research funding agencies toward harmonization of research misconduct policies. Of course, consistency as a singular goal may produce either consistently bad or consistently good outcomes. Thus, any harmonization efforts should focus on identifying/developing requirements that effectively provide for the review of research misconduct allegations in a manner that is fair to the parties and does not unnecessarily burden the institutions charged with administering the process. In this regard, given that both NIH and the National Science Foundation (NSF) have had long-standing research misconduct regulations,[2] consideration should be given to comparing how each agency's regulatory framework has worked in practice and using this information in developing any new, harmonized regulatory model.

Our specific comments are organized below under each question posed in the RFI, and they are presented in order of the regulations at 42 CFR Part 93 to which they pertain. At the beginning of each response, we have included a bulleted list of the main points addressed. Note, that our comments do not encompass every section or aspect of the regulations at 42 CFR Part 93, but rather focus on our primary concerns.

QUESTION 1: WHICH SECTION(S) SHOULD BE CHANGED OR AUGMENTED WHEN REVISING 42 CFR PART 93? WHY? HOW SHOULD THE SECTION(S) BE CHANGED OR AUGMENTED?

a. ***42 CFR §93.105, Time limitations, including the interplay of this section with §93.310(h), Pursue leads and §93.316, Completing the research misconduct process***

Major Topics Addressed in this Response:

- Provide institutions with more discretion to terminate proceedings at assessment or inquiry
- Retain health or safety of public exception at §93.105(b)(2)
- Delete or substantively revise the subsequent use exception at §93.105(b)(1)
- Set clear limitations on the phrases "pursue diligently all significant issues and leads discovered" in §93.310(h) and "pursue diligently all significant issues" in §93.316(a)

One of the most important recommendations that we offer in this letter is for ORI to rethink the provisions of §93.105, §93.310(h) and §93.316 as they pertain to the scope of inquiries/investigations and the circumstances under which an inquiry or investigation may be

[1] 65 Fed. Reg. 235 (Dec. 6, 2000).
[2] NSF Research Misconduct Policies (45 CFR Part 689).

closed. ORI has interpreted these provisions to greatly expand the scope of investigations beyond what the allegations and evidence suggest. Institutions recognize that they may uncover additional instances of research misconduct during their review of initial allegations, and they take seriously their obligations to conduct a robust review. However, an overly broad scope may require universities to spend countless hours attempting to locate and assess information about rarely cited publications, unfunded proposals, unpublished research activities, and laboratory research records many years after their creation. This problem is compounded, and raises key process fairness concerns, when the respondent and/or key witnesses have left the institution and cannot be located or remain non-responsive to requests for information. Requiring institutions to allocate scarce institutional resources to these frequently fruitless tasks hampers institutional efforts to address new or higher-impact concerns, as well as to conduct preventative and educational activities. For these reasons, and other factors detailed below, we urge ORI to take the following actions to better enable institutions to prioritize their activities in the review of the research misconduct matters to optimize the ultimate goals of fair proceedings and meaningful correction of the scientific record:

(1) Provide institutions with discretion to terminate research misconduct proceedings at assessment or inquiry based on factors including, but not limited to the following items[3]:

- Scope of the allegations
- Respondent's status/non-status as an active researcher in the U.S.
- Institution's inability, after diligent efforts, to establish any factual basis that supports culpability of a respondent
- Impact of the questioned research on federal funding (e.g., was funding awarded based on questioned research) and the public scientific record (e.g., was the questioned research limited to the lab, did it result in a publication, and was that publication highly cited)
- Impact of the questioned research on public health or safety (e.g., does the questioned research impact practices that could influence public health and safety)
- Impact of the questioned research on the research record (e.g., has or will the research record be corrected).

(2) Retain the health or safety of the public exception at §93.105(b)(2), while deleting the subsequent use exception at §93.105(b)(1). If the subsequent use exception is retained, ORI should revise the exception to make clear that it applies only to the citation, republication, or use of the questioned data, or the conclusions or results derived from the questioned data.

(3) Clarify that the phrase "pursue diligently all significant issues and leads discovered" in §93.310(h) and the phrase "pursue diligently all significant issues" used in §93.316(a) are

[3] *See, also,* comments below concerning §93.307(d).

limited to issues and leads the institution discovers from evidence and testimony obtained during the inquiry or investigation, and that any review of a researcher's publications and proposals is limited to those implicated by such allegations/evidence.

Per §93.105(a), the Research Misconduct Policies apply to "research misconduct occurring within six years of the date HHS, or an institution receives an allegation of research misconduct." Sequestering the evidence and identifying witnesses necessary to substantiate allegations becomes more difficult with the passing of each year after the questioned event occurs, and beyond six years, it may become exceedingly difficult, thus raising questions of fair process for the respondent. Further, application of this limitation is complicated by the "subsequent use exception" detailed at §93.105(b)(1). The broad and vague language of this exception states that the "respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized." Given that the definition of "research record" in §93.224 includes research proposals, many, if not all, of which will include citations to a respondent's entire body of research work, the "exception" ends up swallowing the rule. Additionally, the lack of any firm time limitation sends institutions on time-consuming and expensive historical "paper chases," combing through ancient computers, lab instruments, file cabinets, and document storage facilities for data associated with papers that were published decades ago. Frequently, these data are no longer technically accessible (e.g., equipment or software that is no longer supported, damaged computers), or it has been lost or destroyed, and in many cases any information that is obtained through these pursuits does little to contribute to the advancement of a case.

Section §93.310(h) requires institutions to "pursue diligently all significant issues and leads discovered that are determined relevant to the investigation." The Research Misconduct Policies do not define the term "significant issues and leads," but on its face, this term indicates that institutions should follow the evidence they have discovered in the investigation. ORI's guidance on the scope of research misconduct,[4] however, goes beyond the plain language of §93.310(h) and calls for institutions to perform "a cursory review of other papers and grant applications within the six-year time limitation (§93.105(a)) to eliminate the possibility of any additional instances of research misconduct." First, the notion of a "cursory" review to "eliminate" the possibility of additional instances of research misconduct is unrealistic in cases in which images must be analyzed or figures compared from one publication to the next. Second, ORI calls for this review even though there may be no evidence or allegations to suggest that the papers contain fabrication, falsification, or plagiarism. In other words, ORI considers the mere existence of any paper or proposal authored during the six-year period to constitute a "significant issue or lead discovered" that must be pursued. Moreover, when ORI's interpretation of §93.310(h) is considered in connection with the subsequent use exception under §93.105(b)(1), the scope of the investigation

[4] ORI, Scope of Research Misconduct (May 27, 2021).

can quickly become limitless, imposing a tremendous burden on the investigating institution, and causing the respondent to undergo a lengthier investigation that may be completely unwarranted by the actual evidence.

[redacted] strongly support the need to ensure that the scientific record is correct, and we advocate for prioritizing institutional resources to investigating allegations and leads from actual evidence because they present a greater likelihood of producing dispositive conclusions that lead to appropriate retractions and other corrections. For similar reasons, we also encourage limiting the investigation to a reasonable number of years for which data, reliable testimony, and other evidence can be obtained and accurately assessed. Importantly, this approach also supports the rationale behind "statutes of limitations": to refrain from putting a respondent in the position of defending against allegations that are so old the respondent can no longer obtain the evidence or witnesses necessary to refute the allegations. At a minimum, ORI should develop criteria that would enable institutions to limit the review of additional papers or grant applications in research misconduct proceedings, to those that have a significant potential impact on the field, the funding agency, and/or public health and safety. Requiring unlimited review of *all* papers and grant applications in a researcher's body of work (especially those over six-years old) without regard to their scientific impact/value or the nature of the evidence results in institutions diverting scarce time and resources away from more important and productive pursuits such as the review of other, more serious misconduct concerns and/or educational and preventative efforts. Additionally, in many cases, there often are alternative methods to address concerns subsequent to the proceedings through communications with authors and journals concerning correction of the scientific record.

Finally, we also recommend that the "health or safety of the public exception," in §93.105(b)(2) be retained, so that ORI maintains the ability to require an institution to look beyond the six-year limitations period in the most important cases concerning research with major public impacts.

b. ***§93.104, Requirements for findings of research misconduct***

Major Topics Addressed in this Response:

- Define all state-of-mind terms used in the Research Misconduct Policies.

The requirement for a finding of research misconduct set forth in §93.104, includes an intent requirement, i.e., that the misconduct be committed "intentionally, knowingly, or recklessly." The determination of the intent of the respondent in performing activities that may constitute research misconduct is vital, yet, surprisingly, none of these terms are defined under Subpart B, the Research Misconduct Policy's definitions section.

Although the terms "intentionally," "knowingly," and "recklessly," may be commonly used in legal settings, the committees of scientists that review research misconduct cases are generally not

familiar with how these terms are used to frame intent. Additionally, as a matter of fundamental fairness, these terms should be defined in the regulations to ensure the respondent fully understands the allegations against them and to promote their consistent application in proceedings. Accordingly, [redacted] urge ORI to amend the regulations to include a definition of each of these terms and to provide guidance to the community that includes examples illustrating the differences among the terms and discussing common situations in which they apply.

c. ***93.108, Confidentiality***

Major Topics Addressed in this Response:

- Clarify the "need to know principle" in §93.108 to address:
  - Multiple entities involved in research misconduct proceedings;
  - Institution that hires a researcher during the conduct of a proceeding; and
  - Communications with journals.

Section 93.108 states as follows:

> Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, ***to those who need to know*** consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. . . . (***Emphasis added***).

[redacted] recognize the potential damage that unproved allegations of research misconduct may cause to a researcher's reputation, and we fully support strong regulations to ensure that the confidentiality of research misconduct proceedings is maintained. Yet, we are also cognizant of the fact that increasingly research misconduct proceedings, including interviews of witnesses, sequestration of evidence, and inquiry and investigation proceedings, span multiple institutions inside and outside of the United States. In these circumstances, it can be extremely difficult to determine who falls into the scope of "those who need to know." Should ORI proceed with changes to the Research Misconduct Policy, we urge it to consider updating this section on confidentiality to expressly acknowledge that a research misconduct proceeding may involve multiple entities, i.e., "to those who need to know consistent with a thorough, competent, objective and fair research misconduct proceeding, ***that may involve multiple entities and require communications among those entities . . ."***

The "need to know principle" also frequently arises when a respondent departs for employment at another institution during the misconduct proceedings. Institutions have no desire to interfere with a respondent's employment. Yet circumstances often require that the institution that initiated the proceedings communicate with the respondent's new employer to carry out the proceeding (e.g., need for additional testimony or sequestration of additional data). To facilitate such

communications, we recommend that ORI clarify that the phrase "those who need to know" may include the Research Integrity Officer, or other institutional officials, at the institution that employs the respondent, if the respondent ceases employment with the institution conducting the research misconduct proceedings during the process.

Finally, we believe that ORI also should consider providing guidance concerning the applicability of the "need to know" principle in the context of communications with journals. Correction of the scientific record is at the core of research misconduct proceedings, yet the confidentiality provisions do not explicitly address communications between the institution conducting the proceeding and journals that review and publish affected manuscripts. ORI should make clear that during the conduct of research misconduct proceedings, journals may be considered as having a "need to know" if substantive fact-finding has confirmed that data underlying materials provided to the journal are unreliable/inaccurate/false; provided, however, that communications should separate the matters of data reliability/accuracy/veracity from the issue of culpability until the proceedings on that issue have concluded. Being able to take this action when the need arises will allow for speedier correction of the scientific record.

d. ***§93.307(d) Criteria Warranting an Investigation***

Major Topics Addressed in this Response:

- Limit the criteria for proceeding to an investigation in §93.307(d) to circumstances in which there is reasonable basis for:
  - Finding the allegation falls under definition of research misconduct; and
  - Allegation has substance; and
  - Allegation does not stem from honest error or difference of opinion

This section states that an investigation is warranted if there is:

(1) A reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS supported biomedical or behavioral research, research training, or activities related to that research or research training as provided in §93.102; and
(2) Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

The use of the term "may have substance" in subsection (2) is so broad that it prevents the closing at inquiry of many cases that should not proceed to investigation because a realistic evaluation of the evidence demonstrates that it will be insufficient to support a finding of research misconduct after investigation. Although a "reasonable basis" is required for finding that the allegation falls within the definition of research misconduct, there is no similar requirement of reasonableness for

the evidence gathered at the inquiry stage. Yet, a vast amount of evidence is collected and reviewed at the inquiry stage because of rigorous sequestration requirements. Despite this fact, mandating only that an allegation ***may have*** substance often propels an inquiry with even minimal evidence into the investigation stage. It also requires an investigation even when sufficient evidence from preliminary information-gathering and preliminary fact-finding demonstrates that an honest error or mistake occurred. Rather than compel institutions to continue with investigations in virtually all these types of cases, [redacted] urge ORI to revise this provision as follows (changes shown in ***bold italicized text***) to (a) incorporate a "reasonableness" standard in both prongs of the test for moving to investigation; and (b) add a new provision to expressly recognize that an investigation is not warranted if preliminary information and fact-finding demonstrate credible evidence of honest error or a difference of opinion as a defense to the allegations:

(2) Preliminary information-gathering and fact-finding from the inquiry provides a ***reasonable basis*** for concluding that the allegation has substance**; *and***
(3) Preliminary information-gathering and fact-finding from the inquiry provide credible evidence that the allegations do not stem from honest error or a difference of opinion.

e. ***§93.307(g), Inquiry report and §93.311(a) Time limit for completing an investigation***

Major Topics Addressed in this Response:

- Eliminate 60-day deadline for inquiry in §93.307(g)
- Eliminate 120-day deadline for investigation in §93.311(a)
- Acknowledge that the timeline depends on facts and circumstances of each case and replace each deadline with a requirement for the institution and ORI to develop a schedule for completion of the inquiry/investigation
- Acknowledge extensions may be granted per reasonable request and progress reports may be required.

Section 93.307(g) states that the time for completion of the inquiry is 60 days from the date of initiation, and §93.311(a) states that the time for completing an investigation is within 120 days of its initiation. Each of these timelines is an arbitrary number that applies regardless of the nature of the case and neither has proved to be a realistic estimate of the time required to conduct an inquiry or investigation. In fact, many investigations may take a year or more to complete, and ORI has addressed this issue by granting extensions in response to institutional requests.

The time required to conduct either an inquiry or investigation is completely dependent upon the individual circumstances of the case and calculating this time is complex. Accordingly, rather than attempt to determine a specific completion period that applies in all cases, [redacted] suggest that in the case of inquiries, ORI require institutions to diligently pursue their conduct,

while affording the institution the discretion to set its own timetable based on the circumstances of the case. In the case of investigations, we suggest that the current 120-day deadline be deleted, and the institution propose, for ORI's acceptance, a schedule for the completion of the investigation, with full recognition by the institution and ORI that this schedule may require adjustment as circumstances develop. Below, suggested revised provisions are set forth:

> **§93.307(g): Time for completion**: The institution must undertake and diligently conduct the inquiry and complete it within a reasonable time based on the facts and circumstances of the case. In the event ORI reasonably believes that the inquiry is not being conducted diligently, it may require the institution to provide a progress report that describes remaining steps and an estimate of the time by which the inquiry will be completed, with follow-up reports, as necessary.
>
> **§93.311(a), Time limit for completing an investigation:** An institution must diligently conduct the investigation and complete all aspects of the investigation (including conducting the investigation, preparing the report of the findings, providing the draft report for comment in accordance with §93.312, and sending the final report to ORI under §93.315) within a reasonable time based on the facts and circumstances of the case. At the beginning of the investigation, the institution shall provide ORI, for ORI's approval, a tentative schedule indicating when the investigation will be completed. Recognizing that the complexity of research misconduct proceedings makes it difficult to predict a completion date, ORI may grant an institution one or more extension(s) of the investigation period, based on written request(s) of the institution that identifies reasonable facts and circumstances supporting the extension. In the event ORI reasonably believes that the investigation is not being conducted diligently, it may require the institution to provide a progress report that describes remaining steps and an estimate of the time by which the investigation will be completed, with follow-up reports, as necessary.

QUESTION 2: WHICH SECTION(S) SHOULD BE RETAINED AS IT CURRENTLY IS IN 42 CFR PART 93? WHY?

42 CFR §93.103, Research Misconduct

Major Topics Addressed in this Response:

- Do not expand definition of "research misconduct" under §93.103 to address:
  - Behaviors encompassed under scientific or research integrity.
  - Misconduct beyond falsification, fabrication, or plagiarism
- Reconsider the current definition of "plagiarism" under §93.103(c).

A key provision of the current Research Misconduct Policies that should remain unchanged is the definition of the term "Research Misconduct," which is limited to "fabrication, falsification, or

plagiarism [FFP] in proposing, performing, or reviewing research, or in reporting research results." The term research misconduct should not be replaced by or conflated with the terms "research integrity" or "scientific integrity," each of which encompass a more diverse array of behaviors and threats, including bias, reproducibility, and data security.[5] The process set forth in the Research Misconduct Policies for examining and adjudicating allegations of "research misconduct" is tailored to examining allegations of FFP and would be unwieldy when applied to broader terms. Rather, the concepts of "research integrity" or "scientific integrity," should continue to be addressed through separate requirements such as those pertaining to training in the responsible and ethical conduct of research.[6]

Along the same lines, we contend that the definition of research misconduct should not be altered to incorporate behavior beyond FFP. For example, certain individuals and groups recommend that behavior such as failure to disclose "foreign research ties" should be investigated as "research misconduct."[7] Similarly, some individuals/groups believe that sexual harassment should be treated as research misconduct.[8] We strongly disagree. Institutions have developed mature programs to meet the requirement for handling allegations of research misconduct that include elements specifically developed for scientists to effectively review claims of fabrication, falsification, or plagiarism. These programs include elements such as sequestration of evidence and consideration of whether there has been a significant departure from the scientific standards of the relevant research community, and these processes that would be ineffective and inappropriate for the assessment of other types of allegations.

We fully support steps already taken to improve related reporting, investigation, and sanctions for research security concerns, harassment, and bullying. However, we firmly believe that these activities should ***not*** be reviewed under an investigational process that was specifically designed to examine accuracy of the scientific record. Instead, existing pathways designated for the investigation of malign foreign influence or sexual harassment should be utilized, as these processes were developed specifically for, and contain procedural protections that are unique to, these subject areas Similarly, if the review of research misconduct allegations unearths evidence of harassment, undisclosed conflicts of interest, or other prohibited behaviors, referrals are made to the appropriate institutional officials/processes specifically designated for investigating those

[5] *See, e.g.,* National Science and Technology Council (STC), Scientific Integrity Fast-Track Action Committee, Protecting the Integrity of Government Science (Jan. 2022) at p. 1-2 (identifying principles of scientific integrity); U.S. Dept. of Agriculture, Scientific Integrity and Research Misconduct webpage (accessed Oct. 5, 2022) (identifying research misconduct as compromised subset of research integrity).
[6] National Institutes of Health (NIH), *FY 2022 Updated Guidance: Requirement for instruction in the Responsible Conduct of Research* (NOT-22-055) (Feb. 17, 2022).
[7] Mervis, J., *U.S. Scientists who Hide Foreign Ties Should Face Research Misconduct Sanctions, Panel Says*, SCIENCE (Dec. 11, 2019).
[8] Marin-Spiotta, E., *Harassment Should Count as Scientific Misconduct*, NATURE (May 9, 2018); Kuo, M., *Scientific Society Defines Sexual Harassment as Scientific Misconduct*, SCIENCE (Sept. 20, 2017) (American Geophysical Union adopts policy that considers sexual harassment to be a type of scientific misconduct).

allegations. To do otherwise, risks running afoul of laws, regulations, policies, processes, and concerns specific to these areas.

Additionally, we believe that ORI should take this opportunity to reconsider its definition of plagiarism. Section 93.103(c) currently defines plagiarism as the "appropriation of another person's ideas, processes, results, or words without giving appropriate credit," yet the plagiarism of "ideas" is extremely difficult to prove (e.g., the accused may have access to many different public documents that would disprove a complainant's allegation of plagiarism of ideas). Similarly, ORI has recognized in guidance that collaborators' use of joint research without appropriate attribution is an authorship matter, as opposed to plagiarism. ORI should consider these concerns and address them through revisions to the definition.

QUESTION 3: WHICH SECTION(S) SHOULD BE CONSIDERED FOR REMOVAL WHEN REVISING 42 CFR PART 93? WHY?

Major Topics Addressed in this Response:

- Eliminate Subpart E and revise appeals process to call for direct appeal to the Assistant Secretary of Health.

[redacted] advocate for eliminating the current Subpart E and replacing it with an appeals process that is simpler for respondents to navigate. Currently, Subpart E calls for a hearing before an administrative law judge (ALJ), who makes a recommendation to the Assistant Secretary for Health (ASH). The ASH may modify or reject the ALJ's decision if it is found to be arbitrary and capricious or clearly erroneous as detailed in §93.523. If debarment or suspension is part of the recommended administrative actions, the debarring official makes the final Department of Health and Human Services (HHS) decision on those actions.

A much simpler process would be to have a respondent direct their appeal to the ASH, who would review it and make a recommendation to the Secretary of HHS or the Deputy Secretary of HHS (or their designee), who would decide the appeal. This type of process is currently in use at the National Aeronautics and Space Administration,[9] the National Science Foundation,[10] the Veterans Administration,[11] and the Department of Department of Defense,[12] and adopting this recommendation would align the HHS appeals process with that of other federal agencies.

[9] 14 CFR §1275.108.
[10] 45 CFR §689.10.
[11] Veterans Health Administration Directive 1058.02 (Jul. 10, 2020).
[12] Dept. of Defense, Instruction 3.7 (Oct. 15, 2018).

CONCLUSION

It is always good practice to periodically review regulations to determine whether changes need to be made to better achieve regulatory goals. [redacted] support ORI in its efforts to undertake such a review of the Research Misconduct Policies, and we are grateful to ORI for not undertaking this review in a vacuum, but rather reaching out to the stakeholder community for input. We hope that the comments and recommendations set forth herein will assist ORI in its mission, and any questions regarding this transmittal may be directed to [redacted] We look forward to continuing the dialog with ORI on any proposed changes to the regulations at 42 CFR Part 93, and once again thank the agency for this opportunity to submit comments.

Sincerely,

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Subject: Research Misconduct regulations RFI Comment Letter
Date: Friday, October 28, 2022 5:25:30 PM
Attachments: [redacted] Response ORI RFI Research Misconduct Regs October 2022.pdf

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To Whom it May Concern,

Please see attached comment letter from [redacted] in response to ORI's Request for Information on the 2005 Public Health Service Policies on Research Misconduct.

Sincerely,

[redacted]

[redacted]

[redacted]

October 30, 2022

Submitted electronically to: OASH-ORI-Public-Comments@hhs.gov

Dr. Wanda K. Jones, Acting Director
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Dear Dr. Jones:

[redacted] is a [redacted] from many different types of US research institutions. Because [redacted] research misconduct allegations, they are [redacted] to respond to the Office of Research Integrity's (ORI) current Request for Information (RFI) concerning revisions to the Public Health Service Policies on Research Misconduct, 42 C.F.R. Part 93, (the "regulation"). As [redacted] I am writing on behalf of the [redacted] member institutions and appreciate the opportunity to provide input that will directly affect our institutions and institutional processes.

[redacted] has already submitted a [redacted] to this RFI together with the [redacted] institutions. This addendum represents an effort by a wider range of [redacted] to emphasize and expand upon some of the key points raised in that [redacted] especially as intended to help simplify and streamline the research misconduct process.

1. **Keep the definition of research misconduct limited to falsification, fabrication, and plagiarism (FFP).** Broadening of the definition to include issues outside of FFP, *i.e.,* issues of sexual or other forms, of harassment, other detrimental research practices (DRPs), or foreign influence, will require institutions to use the complex and time-consuming research misconduct process to resolve such issues. Since the regulation is written, and is specific for, the purpose of reviewing scientific data, applying the regulation to concerns outside of data review would be unmanageable. Institutions may have, or can develop, other more appropriate processes to handle concerns outside of FFP.

2. **Specifically define the terms "intentionally, knowingly, or recklessly" that is included in the requirements for a finding of research misconduct.** Institutional officials and investigation committees often struggle with the criteria for making a finding of research misconduct at §93.104(b) that states, "The misconduct be committed intentionally, knowingly, or recklessly." Institutions must be able to consistently describe these different

state-of-mind terms and standard definitions must be adopted nationally. This is particularly true for the concept of research misconduct committed recklessly, where no definition or guidance has been provided, to date. We recommend that in addition to including a standard definition for these terms in the regulation, ORI also provide specific guidance that distinguishes between these terms and describe examples of research misconduct committed intentionally, knowingly, or recklessly with the evidence to review in each case.

3. **Revise the criteria to warrant an investigation.** We emphasize the importance of creating a path to terminate research misconduct proceedings at assessment or inquiry under certain circumstances, as determined by institutional RIOs and other officials, while also ensuring the integrity of the research record. Institutions often have a very good idea of the evidence available because of the robust sequestration that must occur prior to notification of or the initiation of an inquiry. During assessment and inquiry, the institution has to also carefully look at the role of the respondent(s) in the research at issue. Currently, institutions are obligated to pursue cases through investigation, even when it is clear earlier in the process that findings of research misconduct will have no consequence to the institution or respondent, or that evidence does not exist to support making research misconduct findings.

   For cases that will be moving forward to an investigation, we recommend that ORI allow institutions to follow §93.307(d) that states that the inquiry is an initial review of the evidence and does not require a full review of all the evidence related to an allegation and ORI should replace the requirement for an inquiry report with a checklist at §93.307(d). Additionally, the regulation should be revised to specifically state that performing an inquiry does not require a full committee. This could streamline the process and permit institutions to more quickly determine if the allegations warrant a full investigation without having to engage in a laborious and time-consuming committee process that is not necessary to make this determination. Additionally, we recommend allowing institutions to have increased discretion to close cases at inquiry when the evidence leads to any combination of the following circumstances: sufficient evidence proves that the data inconsistencies are a result of honest error; the scope of the allegations are limited and correction of the research record has occurred; the allegations involved papers published over the six-year time limit; the respondent is not continuing research at the institution or in the US; a questioned publication is not highly cited; funding was not based on allegedly falsified data; questioned data is not influencing practices that could affect health and safety of the public, or the institutional actions implemented were sufficient. It is our understanding that these are similar circumstances that ORI assesses when it declines to pursue a research misconduct finding. A critical aspect for closing cases under these circumstances are that institutions would still be required to ensure correction/retraction of the research record, as appropriate. Similar to §93.316, where case closure occurs with an admission, an institution would notify ORI of its plans to close a case under such circumstances.

4. **Timelines for completing an inquiry or investigation**. The current timelines for completing an inquiry (60 days) or an investigation (120 days) are arbitrary time periods that do not

account for the complexity and scope of current cases. Institutions must seek multiple extensions for each phase. Respondents often raise procedural challenges that institutions did not adhere to the regulatory requirements for meeting the time deadlines. We suggest that the regulation state that the time periods serve only as a guideline for institutions to complete the process and specifically state that extensions are a normal and usual part of a research misconduct processes, which are dependent on the complexity and scope of individual cases.

5. **Clarify the concept for broadening the scope of research misconduct proceedings**. The phrase "pursue diligently all significant issues" in the context of inquiries, §93.310(h), and investigations, §93.105(b)(2), has led to draining institutional resources and having all involved individuals endure much longer investigations than the initial allegations would require. In connection with the subsequent use exception under §93.105, research misconduct proceedings can quickly become unmanageable. We believe a solution is three-fold: 1) to allow institutions the discretion to determine when significant issues and leads relevant to the investigation require expanding the scope of an ongoing proceeding, 2) omitting the subsequent use exception under §93.105, and 3) requiring correction of the research record for all concerns identified. These revisions would allow a simpler research misconduct proceeding that can focus on the most critical issues and still ensure the integrity of the research record for all concerns identified.

6. **Clarify the concept of need to know**. Although institutions recognize that confidentiality is a hallmark of research misconduct proceedings, a very strict interpretation of who has a need to know can trigger difficult consequences, particularly when allegations are made public, when respondents move from one institution to another, or when an affected publication needs to be corrected or retracted during the course of a research misconduct process. We strongly recommend that the regulation be revised to include broadening the need-to-know principle to include officials at other institutions, when those institutions (a) may possess records relevant to allegations under review, or (b) employ or fund research being conducted by a respondent found to have committed research misconduct. We also suggest that with ongoing investigations, ORI mediate communication between institutions particularly when a respondent seeks to leave an institution to avoid a research misconduct process. Further, we recommend that journal editors and/or publishers be explicitly included as those who need to know when sufficient fact-finding has identified that data are incorrect or unreliable, while remaining silent on the issue of culpability or intent, in ongoing research misconduct proceedings.

7. **Finally, [redacted] supports revision of the hearing process described under Subpart E.** One key recommendation we suggest, limiting the complexity of institutional research misconduct proceedings, is revision of the hearing process under Subpart E. The current hearing process in the Department of Health and Humans Services (HHS) is before an administrative law judge (ALJ), in the Departmental Appeals Board (DAB), who makes a recommendation to the Assistant Secretary for Health (ASH). The ALJ is bound by all Federal statutes and regulations, Secretarial delegations of authority, and applicable HHS

policies. However, research misconduct proceedings are academic reviews of research practice, evaluating behavior in relation to the accepted practices of the relevant research community, and are not legal proceedings. Thus, Subpart E places stringent and demanding legal requirements for ORI to make independent research misconduct findings, which may concur with an institution's findings. ORI often must reach out to institutions, sometimes years after institutional findings are made, to request additional information. The legal burden for ORI, therefore, seeps into the institutional procedures increasing the burden for carrying out institutional misconduct processes. We believe the hearing process should be replaced with a simpler appeal process that would make research misconduct proceedings easier for ORI, institutions, and respondents to navigate. We recommend a respondent appeal ORI research misconduct findings directly to the ASH in HHS. Departmental appeals of research misconduct are currently performed in other federal agencies, including the National Aeronautics and Space Administration, the National Science Foundation, the Veterans Administration and the Department of Defense, and it simplifies the appeals process while still ensuring due process rights. Moreover, the proposed harmonization with other agencies would have the added benefit of returning the process to its roots and avoiding the misunderstandings that arise when legal conventions are applied to an academic review process.

[redacted] appreciates the opportunity offered by ORI to provide input into the revisions of 42 C.F.R Part 93. We hope that the recommendations offered in this letter, based on extensive experience of [redacted], as well as the [redacted] letter, will help ORI make suitable and beneficial changes to simplify research misconduct proceedings. Further, any effort by ORI to harmonize procedures with other federal agencies would benefit institutional reviews, particularly for research funded by multiple federal agencies. [redacted] remains committed to working with ORI with respect to the research misconduct regulations and welcome any opportunity to partner with or assist ORI in related activities.

Sincerely,

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Cc: [redacted]
Subject: Response to RFI on 2005 PHS Policies on Research Miscondcut.
Date: Friday, October 28, 2022 5:29:02 PM
Attachments: 2022 PHS Policies_Research Misconduct_RFI Response - [redacted] 28 Oct 2022.pdf

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Please see the attached letter on behalf of the the [redacted] in response to the above RFI.

Thank you,
[redacted]

[redacted]

[redacted]

28 October 2022

Wanda K. Jones
US Department of Health and Human Services
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, Maryland 20852
OASH-ORI-Public-Comments@hhs.gov

Re: Response to RFI on 2005 Public Health Service Policies on Research Misconduct (42 C.F.R. Part 93)

Dear Director Jones:

Maintaining current and effective policies for research misconduct is essential to ensuring the integrity of the science community. As [redacted] supports ORI in these efforts. The University appreciates this opportunity to share perspectives to help structure ORI's plans to revise the 2005 Public Health Service Policies on Research Misconduct.

The University Recommends Several Revisions or Augmentations

Definition or explanation of "honest error."
The policy does not define honest error. While institutions are free to create their own definitions, defining it within the policy would ensure greater consistency. Honest error is vital in determining if an allegation is research misconduct. An investigation or inquiry may find plagiarism, fabrication, or falsification occurred, but if it was an honest error, it does not constitute research misconduct.[1] Since honest error is a key factor in finding research misconduct, a definition or explanation of the term in 42 C.F.R. Part 93 would ensure greater consistency and fairness.

Definition or guidance for "accepted practices of the relevant research community."
A finding of research misconduct requires a significant departure from "*accepted practices"* of the relevant research community, but the policy does not define accepted practices.[2] For some situations, there is no clear accepted practice within the community, and some practices that are common appear questionable. Providing a definition or guidance on this requirement will help ensure consistency and fairness in the review process.

[1] 42 CFR § 93.103(d) (2022).
[2] *Id.* § 93.104.

Combine the inquiry with the assessment.
Conducting an inquiry separately from the initial review of the allegation/assessment appears to protract the review process without providing any benefit. The purpose of the inquiry is to review the allegation to determine if it "may have substance."[3] Similarly, the assessment determines if an inquiry is warranted by determining if the allegation "falls within the definition of research misconduct and …is sufficiently credible and specific."[4] Neither the assessment nor inquiry conduct a deep or extensive dive into the evidence. Since the assessment and inquiry only conduct preliminary reviews of the allegation and evidence, they may be combined into one step. This would shorten the review process, decrease administrative burden, and lessen the number of people involved, thus reducing the chance for the inadvertent disclosure of confidential information.

Limit the requirement to notify ORI that an investigation will occur.
Institutions are required to notify ORI before or on the date an investigation begins.[5] This requirement seems excessive because not all allegations are material to or potentially undermine the integrity of the research findings. Instead, 42 C.F.R. Part 93 should be revised to only require an impending investigation be reported to ORI if the investigation meets a certain threshold, such as (1) the misconduct appears material to the integrity of the research project's overall findings, (2) the project was funded by specific CFDA numbers, or (3) the allegation involves criminal or civil fraud violations. Section 318 requires institutions immediately report specific special circumstances to ORI; the threshold requirements, such as those suggested above, should not duplicate these requirements. If an allegation does not meet the threshold requirements, ORI would be notified after the investigation according to section 318 This revision would reduce administrative burden for institutions and ORI.

The University Recommends a Section Should be Retained as Currently Written

The definition of "research misconduct."
The current definition of research misconduct is appropriately scoped to issues arising from the integrity of research processes or results. Expanding the definition risks overlapping into other federal compliance areas. For example, failure to comply with an IACUC protocol could undermine the integrity of research processes and results. But other federal regulations already address non-compliance in that area. Adding new issues to the definition of research misconduct would increase administrative burden and create confusion for institutions investigating issues arising from two or more unrelated regulations. Moreover, other issues that do not affect the integrity of the research results or processes, such as authorship disputes, are correctly excluded from the definition of research misconduct.

Thank you for this opportunity to provide information for potential revisions to the research misconduct policies. The University appreciates ORI's efforts to maintain current and effective policies for research misconduct and looks forward to reviewing any future revisions.

Sincerely,

[redacted]

[3] 42 CFR § 93.307(d) (2022).
[4] *Id.* § 93.307.
[5] *Id.* § 93.309, 310(b).

From: IU [redacted]
To: OASH ORI Public Comments
Cc: [redacted]
Subject: RFI on Policies on Research Misconduct - Response
Date: Monday, October 31, 2022 9:08:51 AM
Attachments: ORI RFI - [redacted] Response FINAL.pdf

Good morning:

Please see the attached response to the recent Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct, from [redacted]

Thank you for providing an opportunity to provide feedback on this important process.

[redacted]

[redacted]

October 31, 2022

Wanda K. Jones, Dr., P.H., MT (ASCP)
Acting Director
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

Submitted via email to OASH-ORI-Public-Comments@hhs.gov

RE: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct (published September 1, 2022)

Dr. Jones and colleagues:

Thank you for the opportunity to share feedback regarding the current DHHS regulations on research misconduct (42 CFR part 93). [redacted] and participated in discussions regarding [redacted] response to this RFI. [redacted] generally supports [redacted] comments, and offers the following additional thoughts on the questions posed by the RFI:

(1) Which section(s) should be changed or augmented when revising 42 CFR part 93? Why? How should the section(s) be changed or augmented?

Definition of research misconduct

Regarding the definition of research misconduct at 42 CFR 93.103, [redacted] diverges from [redacted] would support a revision to the definition at 42 CFR 93.103 to include detrimental research practices (DRPs) of an egregious nature that risk the integrity of research, when oversight is not already provided by another federal policy (e.g., the Common Rule). Examples may include abuse of confidentiality involved in the peer review process; stealing, destroying, or damaging the research property of others with the intent to alter the research record; directing, encouraging, or knowingly allowing others to engage in fabrication, falsification, or plagiarism; and/or actively preventing research colleagues from publishing, reporting, or otherwise significantly contributing to research for purposes unrelated to the research.

While DRPs fall outside the limited scope of falsification, fabrication, and plagiarism (FFP) currently defined by §93.103, they pose a similar danger to the research record and scientific community, and appropriate resolution is likely to result in similar consequences (e.g., retraction, suspension). Given the similarities, 42 CFR 93 offers an established and accepted set of procedures that serves the same interests of assuring the integrity of the research record and the conservation of public funds, as described in §93.100. If defined carefully, adding DRPs to the definition of research misconduct would provide institutions with the obligation and authority to address these practices without overly burdening research integrity officers. Adding DRPs to the

definition of research misconduct would be most advantageous when coupled with revisions to the regulatory sections requiring institutional inquiry (§§ 93.307 – 93.308). As noted in [redacted] providing for a streamlined inquiry process would reduce institutional burden, allowing institutions to focus their resources on the most egregious allegations of potential research misconduct and providing additional resources for addressing DRPs.

Timelines for inquiry/investigation

[redacted] comment regarding the time limits for inquiry and investigation currently defined at §§ 93.307 and 93.311. The time limits for 60 and 120 days, respectively, are inappropriate for all but the simplest of allegations and do not reflect the vast disparity in research and resources across institutions. As such, the currently defined time limits are rarely met, creating unreasonable expectations for respondents. Removing the time limits would allow institutions to apply more appropriate deadlines based on the circumstances and available resources, while setting realistic expectations for respondents.

Time limitation

[redacted] comments include a suggestion that the subsequent use exception at § 93.105 be removed to allow institutions more flexibility when determining scope of research misconduct proceedings. If the exception is retained, [redacted] would ask that the language be revised to indicate application if *any* respondent continues or renews the use. Such a revision would avoid disparate application of allegations in proceedings with multiple respondent collaborators. Under the current reading, if there are multiple respondent collaborators but only one cites the disputed research beyond the six-year limitation, any related allegations can only proceed against that respondent. Such a scenario could result in inconsistent findings when multiple individuals may be responsible for the potential research misconduct.

Ensuring no conflicts of interest

Section 93.300(b) requires institutions to "ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses." This requirement has been interpreted by institutions around the country as a requirement to provide respondents with an opportunity to object to committee members' participation prior to their appointments to inquiry and/or investigation committees. While not required by the regulations or the model federal policy, offering this opportunity for objection has become the unwritten standard. Unfortunately, such a standard is inconsistent with similar requirements for objectivity employed by other research compliance committee. For example, institutional review boards are also required to identify and avoid any conflicts of interests between reviewers and the protocols to be reviewed; however, IRB reviewers and staff conduct conflict of interest vetting on their own, without input from the individuals whose protocols are reviewed. [redacted] would encourage clarification from ORI that ensuring fair and objective research misconduct proceedings does not require opportunity for objection as long as institutions are fulfilling the regulatory standard.

(2) Which section(s) should be retained as it currently is in 42 CFR part 93? Why?

Requirement for sequestration

Section 93.305 requires institutions to obtain custody of and retain research records needed to conduct the research misconduct proceedings. It is worth stating that this particular provision is

vital to the success of the research misconduct process. While the need to obtain records may appear obvious to research integrity officers, the existence of a regulatory obligation to that effect provides an absolutely necessary authority that facilitates collecting those materials from respondents and institutional officials. [redacted] encourages maintenance of this provision.

Sincerely,

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Cc: [redacted]
Subject: Regulations RFI
Date: Monday, October 31, 2022 2:27:54 PM

Dear Dr. Jones,

[redacted] would like to submit our response to the Office for Research Integrity's Request for Information (RFI) and Comments on the 2005 Public Health Service Policies on Research Misconduct published in the September 1, 2022, Federal Register. [redacted] participated in the development of the [redacted] responses to the RFI and concurs [redacted]

In addition to the recommendations provided by [redacted] would like to see updates related to confidentiality. Currently, when ORI refers an allegation to an institution, ORI does not share the identity of the complainant who brought forth the allegation to ORI. We recently had two cases referred to us from ORI where the identity of the complainant may have been relevant. As such, we recommend that the section on confidentiality allow ORI, when relevant to the review of the research misconduct allegation, to share the identity of the complainant with the institution.

We also recommend that ORI develop guidance for best practices on data sequestration, particularly in a digital context. ORI's current guidance and training on data sequestration should be modernized, taking into consideration the impact of technology on research practices and data management.

Best Wishes,

[redacted]

[redacted] Please email or call to arrange a Zoom meeting or conference call as needed.

From: [redacted]
To: OASH ORI Public Comments
Cc: [redacted]
Subject: Regulations RFI
Date: Monday, October 31, 2022 2:55:37 PM
Attachments: [redacted] Comments to ORI re 87 FR 53750.pdf

Hello,

Please find attached comments from the [redacted] in response to the HHS Office of Research Integrity's request to review the Public Health Service Policies on Research Misconduct (87 FR 53750).

My colleague [redacted] and I are happy to answer any questions with regard to these comments. Thank you for the opportunity to engage with ORI on this issue.

Best,

[redacted]

[redacted]

October 31, 2022

Department of Health and Human Services
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, Maryland 20852

Re: 87 FR 53750: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Submitted electronically to OASH-ORI-Public-Comments@hhs.gov

[redacted] appreciates the opportunity to provide feedback to the Department of Health and Human Services (HHS), Office of Research Integrity (ORI) on the 2005 Public Health Service Policies on Research Misconduct at 42 CFR Part 93 to help structure any future plans to revise the regulation. [redacted] is a nonprofit association dedicated to improving the health of people everywhere through [redacted] Its members comprise all [redacted] Through these institutions and organizations, the [redacted] leads and serves America's [redacted], including more than [redacted] Following a [redacted] U.S. membership and expanded its reach to international academic health centers.

As ORI contemplates beginning a regulatory revision process for the 2005 ORI regulation, we would like to emphasize the following points, which are described in more detail within this letter:

- We support retaining the current definition of research misconduct at 42 CFR §93.103 as limited to fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- We recommend changing the current language at §93.104 (b) for the requirements for findings of research misconduct to remove the word "recklessly" as part of the criteria for how a misconduct is committed.
- We recommend a thorough review of the required institutional processes through the allegation assessment, inquiry and investigation stages, to allow institutions greater flexibility from the initiation to the close of an investigation.

The Definition of Research Misconduct

[redacted] believes that the current definition of research misconduct at §93.103, which is limited to fabrication, falsification, or plagiarism in research, is the appropriate definition and allows ORI to operate at the most focused approach and within its clear expertise.

Several proposals in recent years have called for an expansion of the definition of research misconduct, and subsequently the scope of ORI's mission, to include many additional behaviors that have no place in the research ecosystem. We recognize that within this environment, scientists, trainees, and research staff may be adversely affected by many other types of inappropriate or unethical behavior, including but not limited to sexual harassment, bullying, discrimination, and bias. [redacted] strongly concurs that these actions and behaviors have no place in research and should be reported and investigated. However, we agree with the conclusions of a 2017 report from the National Academies[1] that "because such actions are not unique to the research process, they do not constitute research misconduct… (and) should, therefore, be addressed in other ways."

ORI should not be tasked with building the expertise and processes to address actions that may impact the research environment but are not specific to the conduct of research itself. A broader, coordinated framework of institutional and agency actions should instead address those harmful actions that do not constitute fabrication, falsification, or plagiarism. Such actions are already subject in many cases to existing laws, regulations, funder reporting requirements, and institutional and employment policies that directly address and seek to protect against and respond to these actions. [redacted] also understands that in some cases, the existing policies and regulations to address these behaviors are insufficient or have been shown to be ineffective at accomplishing their stated goals and supports reform and revision under the appropriate authority to effectively combat and penalize behaviors such as harassment in the research environment.[2]

Criteria for Findings of Research Misconduct

The current language at §93.104 for findings of research misconduct require among other things that the misconduct be committed "intentionally, knowingly, *or recklessly*." Years of institutional attempts to apply the more subjective "recklessness" standard to the concrete requirements of fabrication, falsification, or plagiarism has proven difficult to interpret consistently. We recommend removal of the word "recklessly" from this phrase, to require instead that an institution find that an action constituting research misconduct was committed "intentionally" or "knowingly."

Too often in a research misconduct proceeding, the terms "reckless" and "negligent" are equated, causing internal committees to debate whether someone should be held responsible for the intentional misconduct of those being supervised "negligently." Adding to the confusion, in the factors that ORI

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[1] National Academies of Sciences, Engineering, and Medicine 2017. *Fostering Integrity in Research.* Washington, DC: The National Academies Press. https://doi.org/10.17226/21896.

[2] See, e.g. the work of the Societies Consortium on Sexual Harassment in STEMM (https://societiesconsortium.com/) in which [redacted]

may consider in determining remedial HHS administrative actions, §93.408 asks if "the respondent's actions (were) knowing or intentional or was the conduct reckless?," implying that the three standards should not be considered equivalent and should lead to differential outcomes. Removing "recklessly" from §93.104 would clarify an institution's obligations.

Institutional Inquiry and Investigation

The [redacted] recommends a review of the provisions pertaining to the rules and responsibilities for the institution during the course of an ORI investigation. The current three-part investigational process for institutions is onerous, time-consuming, and difficult to navigate, leaving institutions few opportunities to conclude the process when existing evidence is conflicting or insufficient to warrant continuation. Additionally, the prescriptive nature of the procedures outlined for institutions often prevents the institution from moving forward in the way that is most beneficial to the investigation. We recommend that ORI evaluate the following specific provisions for potential updates:

- We propose that institutions be given greater flexibility over when the process for misconduct is triggered and advances. §93.201 and §93.300 state that an allegation is "a disclosure of possible research misconduct through any means of communication… to an institutional or HHS official" and that institutions must "respond to each allegation of research misconduct for which an institution is responsible." We recommend that there be clearer guidance within the regulation as to what constitutes an allegation, with the institution given wider latitude to determine when an allegation contains enough specificity to warrant follow up.
- §93.307(d) states that an investigation is warranted if there is (1) "a reasonable basis for concluding that the allegation falls within the definition of research misconduct" and (2) that "preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance." We recommend that the standard in the latter be changed to also require that preliminary information indicate a reasonable basis for concluding a substantial allegation, to prevent institutions from having to move forward with investigations with minimal evidence to meet the "may have substance" clause.
- §93.310(h) indicates that institutions should pursue "any evidence of additional instances of possible research misconduct" discovered during the investigation. This provision can extend and expand the scope of the investigation without limits, and we recommend that there be greater flexibility for how to handle these discoveries during an ongoing investigation, including the potential to move them to a new inquiry or determine that the scope of the existing inquiry would cover the substance that the new allegations purport to address and should run to its conclusion before considering additional information.

Finally, [redacted] notes that federal agencies have their own reporting requirements for institutions regarding research misconduct, separate from reporting to ORI. We recommend that ORI, in concert with other federal agencies, clearly communicate the government-wide expectations for when and at what point in the proceeding an institution is required to report the status or findings of an investigation to federal entities other than ORI, in order to standardize and clarify the requirements and expectations across the government.

We look forward to continued engagement with ORI as it continues the review of this regulation and its effectiveness in handling of allegations of possible research misconduct and fostering the

improved conduct of scientific research. Please feel free to contact me or my colleagues [redacted] with any questions about these comments.

Sincerely,

[redacted]

cc: [redacted]

From: [redacted]
To: OASH ORI Public Comments
Cc: [redacted]
Subject: Regulations RFI
Date: Monday, October 31, 2022 3:03:06 PM
Attachments: [redacted] Comments on Federal Research Misconduct Policies.pdf

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Dear Dr. Jones,
Please find attached comments from [redacted] on the request for information and comments on 2005 Public Health Service Research Misconduct Policy.

Thank you for this opportunity. Please feel free to contact me if [redacted] can provide any further information.

Best,
[redacted]

[redacted]

[redacted]

[redacted]

October 31, 2022

Wanda Jones, DrPH
Acting Director
Office of Research Integrity
Department of Health and Human Services
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Submitted via email to OASH-ORI-Public-Comments@hhs.gov

Dear Dr. Jones,

[redacted] appreciates the opportunity to respond to the Office of Research Integrity (ORI) "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct" published in the *Federal Register* on September 1, 2022.

[redacted] is a [redacted] Through educational programming, professional development opportunities, and public policy initiatives, [redacted] seeks to ensure that all stakeholders in the research enterprise appreciate the central importance of ethics to the advancement of science.

[redacted] applauds and strongly supports ORI's intent to update the Public Health Service (PHS) policies for research misconduct. Over the last decade, the scientific research landscape has been radically transformed by the increased use of emerging digital technologies, open science, and team science. Thus, we believe that a revision of these regulations is long overdue.

[redacted] understands the importance and value of regulations that define and clearly describe a process for handling allegations of research misconduct to the research community. To that end, [redacted] endorses the comments submitted by [redacted] **However, we urge ORI to also take this opportunity to undertake a broader and more wholistic assessment of the current research landscape, specifically as it pertains to research integrity.**

[redacted] appreciates that the regulatory definition of research misconduct solely as fabrication, falsification, or plagiarism (FFP), allows for an objective investigation process. **However, it is important to also recognize that research integrity (and integrity of the research record) can be**

[redacted]

compromised by violations of other responsible conduct of research (RCR) domains, beyond FFP. For example, faculty producing piecemeal publications under pressure to meet tenure and promotion requirements can skew the literature, or an overcommitted researcher reneging on their mentoring responsibilities could lead to future scientists not being adequately trained in responsible data stewardship.

To be clear, we are not recommending that any and all detrimental research practices or irresponsible conduct of research be subsumed under the regulatory definition of research misconduct. Rather**, we are suggesting that there is value in acknowledging in the policy the importance of RCR, generally,** especially given that various funding agencies have instituted policies mandating RCR education.[1][2] Furthermore, even though the PHS policy for research misconduct applies only to publicly funded research, the concept of RCR as introduced by ORI has been widely adopted and has impacted the conduct of all research (not only publicly funded research), as well as the training of future generations of scientists.

In light of the fact that the *Federal Register Notice* states that ORI views this RFI as a part of a brainstorming process, [redacted] recommends that, in addition to revising the research misconduct policy based on feedback from entities who have considerable experience in implementing the policy in the field, **ORI consider including in the preamble explicit mention of RCR and a description of how the various domains are interconnected and contribute to scientific integrity**. Providing this as a foundation and framework for the policy will not only be a useful educational tool but will also serve to enhance public understanding and trust in the scientific enterprise.

Thank you again for the opportunity to provide input on the revision of the PHS policy on research misconduct. We hope our comments will be useful to the ORI and we are ready to provide any further assistance or input that might be of use. Please feel free to contact me at [redacted]

Sincerely,

[redacted]

cc: [redacted]

[1] https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html
[2] https://www.nsf.gov/od/recr.jsp

From: [redacted]
To: OASH ORI Public Comments
Cc: [redacted]
Subject: [redacted] Response to Research Misconduct Regulations RFI
Date: Monday, October 31, 2022 3:20:49 PM
Attachments: [redacted]
RFI on Research Misconduct [redacted] Comments 10.31.22.pdf

To Whom It May Concern:

Attached please find [redacted] response to ORI's RFI regarding the 2005 Public Health Service Policies on Research Misconduct.

Thank you, and please confirm receipt.

Best regards,

[redacted]

[redacted]

October 31, 2022

Dr. Wanda K. Jones
Acting Director
Office of Research Integrity
Department of Health and Human Services
1101 Wootton Parkway, Suite 240
Rockville, MD 20582

Re: Request for Information and Comments on the 2005 Public Health Services Policies on Research Misconduct

Dear Dr. Jones:

I am writing on behalf of [redacted] We strongly support of the comments submitted by [redacted] in response to the RFI on the 2005 Public Health Services Policies on Research Misconduct. Both set of comments are attached to this submission.

[redacted] is one of the largest academic medical systems in the [redacted] area, with more than [redacted] employees working across [redacted] hospitals, over [redacted] outpatient practices, a school of nursing, and a [redacted] school of medicine and graduate education. We are directly impacted by the policies of research misconduct and strongly agree with the comments submitted [redacted]

Sincerely,

[redacted]

[redacted]

October 30, 2022

Submitted electronically to: OASH-ORI-Public-Comments@hhs.gov

Dr. Wanda K. Jones, Acting Director
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Dear Dr. Jones:

[redacted] submit this letter in response to the Office for Research Integrity's Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct published in the September 1, 2022, Federal Register. [87 FR 53750] (the "RFI"). [redacted] is an association of over 200 public and private United States research universities and affiliated academic medical centers and research institutes. [redacted] is an [redacted] that shares best practices and strategies for handling research misconduct allegations and promoting ethical research. Both [redacted] are concerned with the impact of federal regulations, policies, and practices on the performance of research conducted at their member institutions, and research integrity is one area of significant interest and expertise among [redacted]

Ensuring the responsible and ethical conduct of research, free from fabrication, falsification, and plagiarism, is a primary responsibility and focus of every university that conducts research, regardless of funding source. Given the prominence of Public Health Service (PHS) funding for so much of the research that is conducted at many United States universities and the fact that current regulations have been in place since 2005, universities have had ample opportunity to see how the Public Health Service (PHS) Policies on Research Misconduct at 42 CFR Part 93 ("Research Misconduct Policies") work in practice. Accordingly, we appreciate the Office of Research Integrity's (ORI) solicitation of stakeholder input as it contemplates changes to the Research Misconduct Policies, and we hope that this RFI will serve as the beginning of continuing dialog with the research community regarding any such changes.

We also point out that for over 20 years there has been a federal-wide research misconduct policy promulgated by the White House Office of Science and Technology Policy (OSTP).[1] Universities rely upon such federally harmonized approaches to promote compliance and minimize administrative burden, and we urge ORI to use its review process as an opportunity to work with other federal research funding agencies toward harmonization of research misconduct policies. Of course, consistency as a singular goal may produce either consistently bad or consistently good outcomes. Thus, any harmonization efforts should focus on identifying/developing requirements that effectively provide for the review of research misconduct allegations in a manner that is fair to the parties and does not unnecessarily burden the institutions charged with administering the process. In this regard, given that both NIH and the National Science Foundation (NSF) have had long-standing research misconduct regulations,[2] consideration should be given to comparing how each agency's regulatory framework has worked in practice and using this information in developing any new, harmonized regulatory model.

Our specific comments are organized below under each question posed in the RFI, and they are presented in order of the regulations at 42 CFR Part 93 to which they pertain. At the beginning of each response, we have included a bulleted list of the main points addressed. Note, that our comments do not encompass every section or aspect of the regulations at 42 CFR Part 93, but rather focus on our primary concerns.

QUESTION 1: WHICH SECTION(S) SHOULD BE CHANGED OR AUGMENTED WHEN REVISING 42 CFR PART 93? WHY? HOW SHOULD THE SECTION(S) BE CHANGED OR AUGMENTED?

a. ***42 CFR §93.105, Time limitations, including the interplay of this section with §93.310(h), Pursue leads and §93.316, Completing the research misconduct process***

Major Topics Addressed in this Response:

- Provide institutions with more discretion to terminate proceedings at assessment or inquiry
- Retain health or safety of public exception at §93.105(b)(2)
- Delete or substantively revise the subsequent use exception at §93.105(b)(1)
- Set clear limitations on the phrases "pursue diligently all significant issues and leads discovered" in §93.310(h) and "pursue diligently all significant issues" in §93.316(a)

One of the most important recommendations that we offer in this letter is for ORI to rethink the provisions of §93.105, §93.310(h) and §93.316 as they pertain to the scope of inquiries/investigations and the circumstances under which an inquiry or investigation may be

[1] 65 Fed. Reg. 235 (Dec. 6, 2000).
[2] NSF Research Misconduct Policies (45 CFR Part 689).

closed. ORI has interpreted these provisions to greatly expand the scope of investigations beyond what the allegations and evidence suggest. Institutions recognize that they may uncover additional instances of research misconduct during their review of initial allegations, and they take seriously their obligations to conduct a robust review. However, an overly broad scope may require universities to spend countless hours attempting to locate and assess information about rarely cited publications, unfunded proposals, unpublished research activities, and laboratory research records many years after their creation. This problem is compounded, and raises key process fairness concerns, when the respondent and/or key witnesses have left the institution and cannot be located or remain non-responsive to requests for information. Requiring institutions to allocate scarce institutional resources to these frequently fruitless tasks hampers institutional efforts to address new or higher-impact concerns, as well as to conduct preventative and educational activities. For these reasons, and other factors detailed below, we urge ORI to take the following actions to better enable institutions to prioritize their activities in the review of the research misconduct matters to optimize the ultimate goals of fair proceedings and meaningful correction of the scientific record:

(1) Provide institutions with discretion to terminate research misconduct proceedings at assessment or inquiry based on factors including, but not limited to the following items[3]:

- Scope of the allegations
- Respondent's status/non-status as an active researcher in the U.S.
- Institution's inability, after diligent efforts, to establish any factual basis that supports culpability of a respondent
- Impact of the questioned research on federal funding (e.g., was funding awarded based on questioned research) and the public scientific record (e.g., was the questioned research limited to the lab, did it result in a publication, and was that publication highly cited)
- Impact of the questioned research on public health or safety (e.g., does the questioned research impact practices that could influence public health and safety)
- Impact of the questioned research on the research record (e.g., has or will the research record be corrected).

(2) Retain the health or safety of the public exception at §93.105(b)(2), while deleting the subsequent use exception at §93.105(b)(1). If the subsequent use exception is retained, ORI should revise the exception to make clear that it applies only to the citation, republication, or use of the questioned data, or the conclusions or results derived from the questioned data.

(3) Clarify that the phrase "pursue diligently all significant issues and leads discovered" in §93.310(h) and the phrase "pursue diligently all significant issues" used in §93.316(a) are

[3] *See, also,* comments below concerning §93.307(d).

limited to issues and leads the institution discovers from evidence and testimony obtained during the inquiry or investigation, and that any review of a researcher's publications and proposals is limited to those implicated by such allegations/evidence.

Per §93.105(a), the Research Misconduct Policies apply to "research misconduct occurring within six years of the date HHS, or an institution receives an allegation of research misconduct." Sequestering the evidence and identifying witnesses necessary to substantiate allegations becomes more difficult with the passing of each year after the questioned event occurs, and beyond six years, it may become exceedingly difficult, thus raising questions of fair process for the respondent. Further, application of this limitation is complicated by the "subsequent use exception" detailed at §93.105(b)(1). The broad and vague language of this exception states that the "respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized." Given that the definition of "research record" in §93.224 includes research proposals, many, if not all, of which will include citations to a respondent's entire body of research work, the "exception" ends up swallowing the rule. Additionally, the lack of any firm time limitation sends institutions on time-consuming and expensive historical "paper chases," combing through ancient computers, lab instruments, file cabinets, and document storage facilities for data associated with papers that were published decades ago. Frequently, these data are no longer technically accessible (e.g., equipment or software that is no longer supported, damaged computers), or it has been lost or destroyed, and in many cases any information that is obtained through these pursuits does little to contribute to the advancement of a case.

Section §93.310(h) requires institutions to "pursue diligently all significant issues and leads discovered that are determined relevant to the investigation." The Research Misconduct Policies do not define the term "significant issues and leads," but on its face, this term indicates that institutions should follow the evidence they have discovered in the investigation. ORI's guidance on the scope of research misconduct,[4] however, goes beyond the plain language of §93.310(h) and calls for institutions to perform "a cursory review of other papers and grant applications within the six-year time limitation (§93.105(a)) to eliminate the possibility of any additional instances of research misconduct." First, the notion of a "cursory" review to "eliminate" the possibility of additional instances of research misconduct is unrealistic in cases in which images must be analyzed or figures compared from one publication to the next. Second, ORI calls for this review even though there may be no evidence or allegations to suggest that the papers contain fabrication, falsification, or plagiarism. In other words, ORI considers the mere existence of any paper or proposal authored during the six-year period to constitute a "significant issue or lead discovered" that must be pursued. Moreover, when ORI's interpretation of §93.310(h) is considered in connection with the subsequent use exception under §93.105(b)(1), the scope of the investigation

[4] ORI, Scope of Research Misconduct (May 27, 2021).

can quickly become limitless, imposing a tremendous burden on the investigating institution, and causing the respondent to undergo a lengthier investigation that may be completely unwarranted by the actual evidence.

[redacted] strongly support the need to ensure that the scientific record is correct, and we advocate for prioritizing institutional resources to investigating allegations and leads from actual evidence because they present a greater likelihood of producing dispositive conclusions that lead to appropriate retractions and other corrections. For similar reasons, we also encourage limiting the investigation to a reasonable number of years for which data, reliable testimony, and other evidence can be obtained and accurately assessed. Importantly, this approach also supports the rationale behind "statutes of limitations": to refrain from putting a respondent in the position of defending against allegations that are so old the respondent can no longer obtain the evidence or witnesses necessary to refute the allegations. At a minimum, ORI should develop criteria that would enable institutions to limit the review of additional papers or grant applications in research misconduct proceedings, to those that have a significant potential impact on the field, the funding agency, and/or public health and safety. Requiring unlimited review of *all* papers and grant applications in a researcher's body of work (especially those over six-years old) without regard to their scientific impact/value or the nature of the evidence results in institutions diverting scarce time and resources away from more important and productive pursuits such as the review of other, more serious misconduct concerns and/or educational and preventative efforts. Additionally, in many cases, there often are alternative methods to address concerns subsequent to the proceedings through communications with authors and journals concerning correction of the scientific record.

Finally, we also recommend that the "health or safety of the public exception," in §93.105(b)(2) be retained, so that ORI maintains the ability to require an institution to look beyond the six-year limitations period in the most important cases concerning research with major public impacts.

b. ***§93.104, Requirements for findings of research misconduct***

Major Topics Addressed in this Response:

- Define all state-of-mind terms used in the Research Misconduct Policies.

The requirement for a finding of research misconduct set forth in §93.104, includes an intent requirement, i.e., that the misconduct be committed "intentionally, knowingly, or recklessly." The determination of the intent of the respondent in performing activities that may constitute research misconduct is vital, yet, surprisingly, none of these terms are defined under Subpart B, the Research Misconduct Policy's definitions section.

Although the terms "intentionally," "knowingly," and "recklessly," may be commonly used in legal settings, the committees of scientists that review research misconduct cases are generally not

familiar with how these terms are used to frame intent. Additionally, as a matter of fundamental fairness, these terms should be defined in the regulations to ensure the respondent fully understands the allegations against them and to promote their consistent application in proceedings. Accordingly, [redacted] urge ORI to amend the regulations to include a definition of each of these terms and to provide guidance to the community that includes examples illustrating the differences among the terms and discussing common situations in which they apply.

c. ***93.108, Confidentiality***

Major Topics Addressed in this Response:

- Clarify the "need to know principle" in §93.108 to address:
  - Multiple entities involved in research misconduct proceedings;
  - Institution that hires a researcher during the conduct of a proceeding; and
  - Communications with journals.

Section 93.108 states as follows:

> Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, ***to those who need to know*** consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. . . . (***Emphasis added***).

[redacted] recognize the potential damage that unproved allegations of research misconduct may cause to a researcher's reputation, and we fully support strong regulations to ensure that the confidentiality of research misconduct proceedings is maintained. Yet, we are also cognizant of the fact that increasingly research misconduct proceedings, including interviews of witnesses, sequestration of evidence, and inquiry and investigation proceedings, span multiple institutions inside and outside of the United States. In these circumstances, it can be extremely difficult to determine who falls into the scope of "those who need to know." Should ORI proceed with changes to the Research Misconduct Policy, we urge it to consider updating this section on confidentiality to expressly acknowledge that a research misconduct proceeding may involve multiple entities, i.e., "to those who need to know consistent with a thorough, competent, objective and fair research misconduct proceeding, ***that may involve multiple entities and require communications among those entities . . ."***

The "need to know principle" also frequently arises when a respondent departs for employment at another institution during the misconduct proceedings. Institutions have no desire to interfere with a respondent's employment. Yet circumstances often require that the institution that initiated the proceedings communicate with the respondent's new employer to carry out the proceeding (e.g., need for additional testimony or sequestration of additional data). To facilitate such

communications, we recommend that ORI clarify that the phrase "those who need to know" may include the Research Integrity Officer, or other institutional officials, at the institution that employs the respondent, if the respondent ceases employment with the institution conducting the research misconduct proceedings during the process.

Finally, we believe that ORI also should consider providing guidance concerning the applicability of the "need to know" principle in the context of communications with journals. Correction of the scientific record is at the core of research misconduct proceedings, yet the confidentiality provisions do not explicitly address communications between the institution conducting the proceeding and journals that review and publish affected manuscripts. ORI should make clear that during the conduct of research misconduct proceedings, journals may be considered as having a "need to know" if substantive fact-finding has confirmed that data underlying materials provided to the journal are unreliable/inaccurate/false; provided, however, that communications should separate the matters of data reliability/accuracy/veracity from the issue of culpability until the proceedings on that issue have concluded. Being able to take this action when the need arises will allow for speedier correction of the scientific record.

d. ***§93.307(d) Criteria Warranting an Investigation***

Major Topics Addressed in this Response:

- Limit the criteria for proceeding to an investigation in §93.307(d) to circumstances in which there is reasonable basis for:
  - Finding the allegation falls under definition of research misconduct; and
  - Allegation has substance; and
  - Allegation does not stem from honest error or difference of opinion

This section states that an investigation is warranted if there is:

(1) A reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS supported biomedical or behavioral research, research training, or activities related to that research or research training as provided in §93.102; and
(2) Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

The use of the term "may have substance" in subsection (2) is so broad that it prevents the closing at inquiry of many cases that should not proceed to investigation because a realistic evaluation of the evidence demonstrates that it will be insufficient to support a finding of research misconduct after investigation. Although a "reasonable basis" is required for finding that the allegation falls within the definition of research misconduct, there is no similar requirement of reasonableness for

the evidence gathered at the inquiry stage. Yet, a vast amount of evidence is collected and reviewed at the inquiry stage because of rigorous sequestration requirements. Despite this fact, mandating only that an allegation ***may have*** substance often propels an inquiry with even minimal evidence into the investigation stage. It also requires an investigation even when sufficient evidence from preliminary information-gathering and preliminary fact-finding demonstrates that an honest error or mistake occurred. Rather than compel institutions to continue with investigations in virtually all these types of cases, [redacted] urge ORI to revise this provision as follows (changes shown in ***bold italicized text***) to (a) incorporate a "reasonableness" standard in both prongs of the test for moving to investigation; and (b) add a new provision to expressly recognize that an investigation is not warranted if preliminary information and fact-finding demonstrate credible evidence of honest error or a difference of opinion as a defense to the allegations:

(2) Preliminary information-gathering and fact-finding from the inquiry provides a ***reasonable basis*** for concluding that the allegation has substance**; *and***
(3) Preliminary information-gathering and fact-finding from the inquiry provide credible evidence that the allegations do not stem from honest error or a difference of opinion.

e. ***§93.307(g), Inquiry report and §93.311(a) Time limit for completing an investigation***

Major Topics Addressed in this Response:

- Eliminate 60-day deadline for inquiry in §93.307(g)
- Eliminate 120-day deadline for investigation in §93.311(a)
- Acknowledge that the timeline depends on facts and circumstances of each case and replace each deadline with a requirement for the institution and ORI to develop a schedule for completion of the inquiry/investigation
- Acknowledge extensions may be granted per reasonable request and progress reports may be required.

Section 93.307(g) states that the time for completion of the inquiry is 60 days from the date of initiation, and §93.311(a) states that the time for completing an investigation is within 120 days of its initiation. Each of these timelines is an arbitrary number that applies regardless of the nature of the case and neither has proved to be a realistic estimate of the time required to conduct an inquiry or investigation. In fact, many investigations may take a year or more to complete, and ORI has addressed this issue by granting extensions in response to institutional requests.

The time required to conduct either an inquiry or investigation is completely dependent upon the individual circumstances of the case and calculating this time is complex. Accordingly, rather than attempt to determine a specific completion period that applies in all cases, [redacted] suggest that in the case of inquiries, ORI require institutions to diligently pursue their conduct,

while affording the institution the discretion to set its own timetable based on the circumstances of the case. In the case of investigations, we suggest that the current 120-day deadline be deleted, and the institution propose, for ORI's acceptance, a schedule for the completion of the investigation, with full recognition by the institution and ORI that this schedule may require adjustment as circumstances develop. Below, suggested revised provisions are set forth:

> **§93.307(g): Time for completion**: The institution must undertake and diligently conduct the inquiry and complete it within a reasonable time based on the facts and circumstances of the case. In the event ORI reasonably believes that the inquiry is not being conducted diligently, it may require the institution to provide a progress report that describes remaining steps and an estimate of the time by which the inquiry will be completed, with follow-up reports, as necessary.
>
> **§93.311(a), Time limit for completing an investigation:** An institution must diligently conduct the investigation and complete all aspects of the investigation (including conducting the investigation, preparing the report of the findings, providing the draft report for comment in accordance with §93.312, and sending the final report to ORI under §93.315) within a reasonable time based on the facts and circumstances of the case. At the beginning of the investigation, the institution shall provide ORI, for ORI's approval, a tentative schedule indicating when the investigation will be completed. Recognizing that the complexity of research misconduct proceedings makes it difficult to predict a completion date, ORI may grant an institution one or more extension(s) of the investigation period, based on written request(s) of the institution that identifies reasonable facts and circumstances supporting the extension. In the event ORI reasonably believes that the investigation is not being conducted diligently, it may require the institution to provide a progress report that describes remaining steps and an estimate of the time by which the investigation will be completed, with follow-up reports, as necessary.

QUESTION 2: WHICH SECTION(S) SHOULD BE RETAINED AS IT CURRENTLY IS IN 42 CFR PART 93? WHY?

42 CFR §93.103, Research Misconduct

Major Topics Addressed in this Response:

- Do not expand definition of "research misconduct" under §93.103 to address:
  - Behaviors encompassed under scientific or research integrity.
  - Misconduct beyond falsification, fabrication, or plagiarism
- Reconsider the current definition of "plagiarism" under §93.103(c).

A key provision of the current Research Misconduct Policies that should remain unchanged is the definition of the term "Research Misconduct," which is limited to "fabrication, falsification, or

plagiarism [FFP] in proposing, performing, or reviewing research, or in reporting research results." The term research misconduct should not be replaced by or conflated with the terms "research integrity" or "scientific integrity," each of which encompass a more diverse array of behaviors and threats, including bias, reproducibility, and data security.[5] The process set forth in the Research Misconduct Policies for examining and adjudicating allegations of "research misconduct" is tailored to examining allegations of FFP and would be unwieldy when applied to broader terms. Rather, the concepts of "research integrity" or "scientific integrity," should continue to be addressed through separate requirements such as those pertaining to training in the responsible and ethical conduct of research.[6]

Along the same lines, we contend that the definition of research misconduct should not be altered to incorporate behavior beyond FFP. For example, certain individuals and groups recommend that behavior such as failure to disclose "foreign research ties" should be investigated as "research misconduct."[7] Similarly, some individuals/groups believe that sexual harassment should be treated as research misconduct.[8] We strongly disagree. Institutions have developed mature programs to meet the requirement for handling allegations of research misconduct that include elements specifically developed for scientists to effectively review claims of fabrication, falsification, or plagiarism. These programs include elements such as sequestration of evidence and consideration of whether there has been a significant departure from the scientific standards of the relevant research community, and these processes that would be ineffective and inappropriate for the assessment of other types of allegations.

We fully support steps already taken to improve related reporting, investigation, and sanctions for research security concerns, harassment, and bullying. However, we firmly believe that these activities should ***not*** be reviewed under an investigational process that was specifically designed to examine accuracy of the scientific record. Instead, existing pathways designated for the investigation of malign foreign influence or sexual harassment should be utilized, as these processes were developed specifically for, and contain procedural protections that are unique to, these subject areas Similarly, if the review of research misconduct allegations unearths evidence of harassment, undisclosed conflicts of interest, or other prohibited behaviors, referrals are made to the appropriate institutional officials/processes specifically designated for investigating those

[5] *See, e.g.,* National Science and Technology Council (STC), Scientific Integrity Fast-Track Action Committee, Protecting the Integrity of Government Science (Jan. 2022) at p. 1-2 (identifying principles of scientific integrity); U.S. Dept. of Agriculture, Scientific Integrity and Research Misconduct webpage (accessed Oct. 5, 2022) (identifying research misconduct as compromised subset of research integrity).
[6] National Institutes of Health (NIH), *FY 2022 Updated Guidance: Requirement for instruction in the Responsible Conduct of Research* (NOT-22-055) (Feb. 17, 2022).
[7] Mervis, J., *U.S. Scientists who Hide Foreign Ties Should Face Research Misconduct Sanctions, Panel Says*, SCIENCE (Dec. 11, 2019).
[8] Marin-Spiotta, E., *Harassment Should Count as Scientific Misconduct*, NATURE (May 9, 2018); Kuo, M., *Scientific Society Defines Sexual Harassment as Scientific Misconduct*, SCIENCE (Sept. 20, 2017) (American Geophysical Union adopts policy that considers sexual harassment to be a type of scientific misconduct).

allegations. To do otherwise, risks running afoul of laws, regulations, policies, processes, and concerns specific to these areas.

Additionally, we believe that ORI should take this opportunity to reconsider its definition of plagiarism. Section 93.103(c) currently defines plagiarism as the "appropriation of another person's ideas, processes, results, or words without giving appropriate credit," yet the plagiarism of "ideas" is extremely difficult to prove (e.g., the accused may have access to many different public documents that would disprove a complainant's allegation of plagiarism of ideas). Similarly, ORI has recognized in guidance that collaborators' use of joint research without appropriate attribution is an authorship matter, as opposed to plagiarism. ORI should consider these concerns and address them through revisions to the definition.

QUESTION 3: WHICH SECTION(S) SHOULD BE CONSIDERED FOR REMOVAL WHEN REVISING 42 CFR PART 93? WHY?

Major Topics Addressed in this Response:

- Eliminate Subpart E and revise appeals process to call for direct appeal to the Assistant Secretary of Health.

[redacted] advocate for eliminating the current Subpart E and replacing it with an appeals process that is simpler for respondents to navigate. Currently, Subpart E calls for a hearing before an administrative law judge (ALJ), who makes a recommendation to the Assistant Secretary for Health (ASH). The ASH may modify or reject the ALJ's decision if it is found to be arbitrary and capricious or clearly erroneous as detailed in §93.523. If debarment or suspension is part of the recommended administrative actions, the debarring official makes the final Department of Health and Human Services (HHS) decision on those actions.

A much simpler process would be to have a respondent direct their appeal to the ASH, who would review it and make a recommendation to the Secretary of HHS or the Deputy Secretary of HHS (or their designee), who would decide the appeal. This type of process is currently in use at the National Aeronautics and Space Administration,[9] the National Science Foundation,[10] the Veterans Administration,[11] and the Department of Department of Defense,[12] and adopting this recommendation would align the HHS appeals process with that of other federal agencies.

[9] 14 CFR §1275.108.
[10] 45 CFR §689.10.
[11] Veterans Health Administration Directive 1058.02 (Jul. 10, 2020).
[12] Dept. of Defense, Instruction 3.7 (Oct. 15, 2018).

CONCLUSION

It is always good practice to periodically review regulations to determine whether changes need to be made to better achieve regulatory goals. [redacted] support ORI in its efforts to undertake such a review of the Research Misconduct Policies, and we are grateful to ORI for not undertaking this review in a vacuum, but rather reaching out to the stakeholder community for input. We hope that the comments and recommendations set forth herein will assist ORI in its mission, and any questions regarding this transmittal may be directed to [redacted] We look forward to continuing the dialog with ORI on any proposed changes to the regulations at 42 CFR Part 93, and once again thank the agency for this opportunity to submit comments.

Sincerely,

[redacted]

[redacted]

October 30, 2022

Submitted electronically to: OASH-ORI-Public-Comments@hhs.gov

Dr. Wanda K. Jones, Acting Director
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Dear Dr. Jones:

[redacted] is a [redacted] from many different types of US research institutions. Because [redacted] research misconduct allegations, they are [redacted] to respond to the Office of Research Integrity's (ORI) current Request for Information (RFI) concerning revisions to the Public Health Service Policies on Research Misconduct, 42 C.F.R. Part 93, (the "regulation"). As [redacted] I am writing on behalf of the [redacted] member institutions and appreciate the opportunity to provide input that will directly affect our institutions and institutional processes.

[redacted] has already submitted a [redacted] to this RFI together with the [redacted] institutions. This addendum represents an effort by a wider range of [redacted] to emphasize and expand upon some of the key points raised in that [redacted] especially as intended to help simplify and streamline the research misconduct process.

1. **Keep the definition of research misconduct limited to falsification, fabrication, and plagiarism (FFP).** Broadening of the definition to include issues outside of FFP, *i.e.,* issues of sexual or other forms, of harassment, other detrimental research practices (DRPs), or foreign influence, will require institutions to use the complex and time-consuming research misconduct process to resolve such issues. Since the regulation is written, and is specific for, the purpose of reviewing scientific data, applying the regulation to concerns outside of data review would be unmanageable. Institutions may have, or can develop, other more appropriate processes to handle concerns outside of FFP.

2. **Specifically define the terms "intentionally, knowingly, or recklessly" that is included in the requirements for a finding of research misconduct.** Institutional officials and investigation committees often struggle with the criteria for making a finding of research misconduct at §93.104(b) that states, "The misconduct be committed intentionally, knowingly, or recklessly." Institutions must be able to consistently describe these different

state-of-mind terms and standard definitions must be adopted nationally. This is particularly true for the concept of research misconduct committed recklessly, where no definition or guidance has been provided, to date. We recommend that in addition to including a standard definition for these terms in the regulation, ORI also provide specific guidance that distinguishes between these terms and describe examples of research misconduct committed intentionally, knowingly, or recklessly with the evidence to review in each case.

3. **Revise the criteria to warrant an investigation.** We emphasize the importance of creating a path to terminate research misconduct proceedings at assessment or inquiry under certain circumstances, as determined by institutional RIOs and other officials, while also ensuring the integrity of the research record. Institutions often have a very good idea of the evidence available because of the robust sequestration that must occur prior to notification of or the initiation of an inquiry. During assessment and inquiry, the institution has to also carefully look at the role of the respondent(s) in the research at issue. Currently, institutions are obligated to pursue cases through investigation, even when it is clear earlier in the process that findings of research misconduct will have no consequence to the institution or respondent, or that evidence does not exist to support making research misconduct findings.

   For cases that will be moving forward to an investigation, we recommend that ORI allow institutions to follow §93.307(d) that states that the inquiry is an initial review of the evidence and does not require a full review of all the evidence related to an allegation and ORI should replace the requirement for an inquiry report with a checklist at §93.307(d). Additionally, the regulation should be revised to specifically state that performing an inquiry does not require a full committee. This could streamline the process and permit institutions to more quickly determine if the allegations warrant a full investigation without having to engage in a laborious and time-consuming committee process that is not necessary to make this determination. Additionally, we recommend allowing institutions to have increased discretion to close cases at inquiry when the evidence leads to any combination of the following circumstances: sufficient evidence proves that the data inconsistencies are a result of honest error; the scope of the allegations are limited and correction of the research record has occurred; the allegations involved papers published over the six-year time limit; the respondent is not continuing research at the institution or in the US; a questioned publication is not highly cited; funding was not based on allegedly falsified data; questioned data is not influencing practices that could affect health and safety of the public, or the institutional actions implemented were sufficient. It is our understanding that these are similar circumstances that ORI assesses when it declines to pursue a research misconduct finding. A critical aspect for closing cases under these circumstances are that institutions would still be required to ensure correction/retraction of the research record, as appropriate. Similar to §93.316, where case closure occurs with an admission, an institution would notify ORI of its plans to close a case under such circumstances.

4. **Timelines for completing an inquiry or investigation**. The current timelines for completing an inquiry (60 days) or an investigation (120 days) are arbitrary time periods that do not

account for the complexity and scope of current cases. Institutions must seek multiple extensions for each phase. Respondents often raise procedural challenges that institutions did not adhere to the regulatory requirements for meeting the time deadlines. We suggest that the regulation state that the time periods serve only as a guideline for institutions to complete the process and specifically state that extensions are a normal and usual part of a research misconduct processes, which are dependent on the complexity and scope of individual cases.

5. **Clarify the concept for broadening the scope of research misconduct proceedings**. The phrase "pursue diligently all significant issues" in the context of inquiries, §93.310(h), and investigations, §93.105(b)(2), has led to draining institutional resources and having all involved individuals endure much longer investigations than the initial allegations would require. In connection with the subsequent use exception under §93.105, research misconduct proceedings can quickly become unmanageable. We believe a solution is three-fold: 1) to allow institutions the discretion to determine when significant issues and leads relevant to the investigation require expanding the scope of an ongoing proceeding, 2) omitting the subsequent use exception under §93.105, and 3) requiring correction of the research record for all concerns identified. These revisions would allow a simpler research misconduct proceeding that can focus on the most critical issues and still ensure the integrity of the research record for all concerns identified.

6. **Clarify the concept of need to know**. Although institutions recognize that confidentiality is a hallmark of research misconduct proceedings, a very strict interpretation of who has a need to know can trigger difficult consequences, particularly when allegations are made public, when respondents move from one institution to another, or when an affected publication needs to be corrected or retracted during the course of a research misconduct process. We strongly recommend that the regulation be revised to include broadening the need-to-know principle to include officials at other institutions, when those institutions (a) may possess records relevant to allegations under review, or (b) employ or fund research being conducted by a respondent found to have committed research misconduct. We also suggest that with ongoing investigations, ORI mediate communication between institutions particularly when a respondent seeks to leave an institution to avoid a research misconduct process. Further, we recommend that journal editors and/or publishers be explicitly included as those who need to know when sufficient fact-finding has identified that data are incorrect or unreliable, while remaining silent on the issue of culpability or intent, in ongoing research misconduct proceedings.

7. **Finally, [redacted] supports revision of the hearing process described under Subpart E.** One key recommendation we suggest, limiting the complexity of institutional research misconduct proceedings, is revision of the hearing process under Subpart E. The current hearing process in the Department of Health and Humans Services (HHS) is before an administrative law judge (ALJ), in the Departmental Appeals Board (DAB), who makes a recommendation to the Assistant Secretary for Health (ASH). The ALJ is bound by all Federal statutes and regulations, Secretarial delegations of authority, and applicable HHS

policies. However, research misconduct proceedings are academic reviews of research practice, evaluating behavior in relation to the accepted practices of the relevant research community, and are not legal proceedings. Thus, Subpart E places stringent and demanding legal requirements for ORI to make independent research misconduct findings, which may concur with an institution's findings. ORI often must reach out to institutions, sometimes years after institutional findings are made, to request additional information. The legal burden for ORI, therefore, seeps into the institutional procedures increasing the burden for carrying out institutional misconduct processes. We believe the hearing process should be replaced with a simpler appeal process that would make research misconduct proceedings easier for ORI, institutions, and respondents to navigate. We recommend a respondent appeal ORI research misconduct findings directly to the ASH in HHS. Departmental appeals of research misconduct are currently performed in other federal agencies, including the National Aeronautics and Space Administration, the National Science Foundation, the Veterans Administration and the Department of Defense, and it simplifies the appeals process while still ensuring due process rights. Moreover, the proposed harmonization with other agencies would have the added benefit of returning the process to its roots and avoiding the misunderstandings that arise when legal conventions are applied to an academic review process.

[redacted] appreciates the opportunity offered by ORI to provide input into the revisions of 42 C.F.R Part 93. We hope that the recommendations offered in this letter, based on extensive experience of [redacted], as well as the [redacted] letter, will help ORI make suitable and beneficial changes to simplify research misconduct proceedings. Further, any effort by ORI to harmonize procedures with other federal agencies would benefit institutional reviews, particularly for research funded by multiple federal agencies. [redacted] remains committed to working with ORI with respect to the research misconduct regulations and welcome any opportunity to partner with or assist ORI in related activities.

Sincerely,

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Subject: Regulations RFI: Comments from [redacted]
Date: Monday, October 31, 2022 3:27:58 PM
Attachments: ORI [redacted].pdf

Dear Office of the Secretary, Department of Health and Human Services (HHS).

We are pleased that your department put out the *Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct.*

Attached, please find our list of recommendations and reasoning behind them.

I am sending this on behalf of our team, [redacted] which includes [redacted]

If you have follow-up questions, feel free to contact [redacted]

Thank you for considering our comments.

Sincerely,

[redacted]

[redacted]

Topic: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct.

Contributor: [redacted]

—

Recommendation 1. We propose that ORI considers focusing on the integrity of scholarly work (e.g., manuscripts) rather than on the integrity or misconduct of an individual (i.e., a focus on the *research* rather than the *researcher*).

Comment 1. This focus can be more impactful for the research community. It would help journals, preprints servers, and others involved in scientific publishing to investigate and retract research not conducted with integrity. This is in alignment with the 2017 National Academy of Sciences, Engineering, and Medicine (NASEM) report, *Fostering Integrity in Research* (https://doi.org/10.17226/21896) which refocuses the question from the researcher to the research itself. For example, the clarity and actionability of **§ 93.106 Evidentiary standards (b1). Burden of proof.** could be improved by shifting the focus from whether the researcher was "*intentionally knowingly, or recklessly"* to whether the research itself was not documented appropriately. A more clear definition of the standard to which research records (e.g., data) should be maintained, which could be based on data management plans set forth in an approved research ethics application, could also improve actionability.

Recommendation 2. § 93.103 Research misconduct (b). We recommend ORI considers expanding the definition of *falsification* to include *selective reporting* of methods, data, analyses, and results, such that the research is substantively misrepresented in a manner leading to misinterpretation or material distortion of the evidential basis for conclusions.

Comment 2. The 2017 NASEM report states that "Publication bias, selective reporting, and poor reporting are serious problems that damage the research record. Authors also need to follow discipline-specific reporting guidelines, such as those covering the registration and reporting of clinical trial results" (https://doi.org/10.17226/21896). Nonetheless, discipline specific guidelines are often not adhered to. In a well-known case of research misconduct by a nutrition scientist at Cornell University (https://www.science.org/content/article/cornell-nutrition-scientist-resigns-after-retractions-and-research-misconduct-finding), the investigation found "misreporting of research data, problematic statistical techniques, failure to properly document and preserve research results, and inappropriate authorship". We suggest expanding the definition of falsification so that such egregious selective reporting of research data is a reason for action on its own. This may have an important signaling effect on the many less egregious (but, in totality, detrimental) cases of

[redacted]

selective reporting in the medical literature: meta-analyses of thousands of clinical trials show that primary outcomes are not reported as registered about one-third of the time and secondary outcomes are not reported as registered about two-thirds of the time (https://doi.org/10.1101/2021.07.07.21259868). Selective reporting is detectable and can be used to misrepresent the research record at various stages, including the methods, data, analyses, and results.

Recommendation 3. § 93.104 Requirements for findings of research misconduct. (a). Remove the following sentence: "There be a significant departure from accepted practices of the relevant research community".

Comment 3. As demonstrated in the example above on selective reporting, there are many instances where "accepted" practices do not align with standards for research integrity. Another study shows that of nearly 2000 publications that had "data available upon request" statements, only 7% of authors could provide the data when asked for it (https://doi.org/10.1016/j.jclinepi.2022.05.019). Thus, the benchmark of "accepted practice" can fall short of expectation for research integrity.

Recommendation 4. § 93.103 Research misconduct (c). Consider expanding the definition of *plagiarism* to include appropriation of *data, code, and figures* without giving appropriate credit.

Comment 4. Data and code are increasingly being recognised as significant contributions to knowledge and transparency of research (https://coara.eu/agreement/the-agreement-full-text/), and image manipulations and plagiarism occur in the published literature (https://journals.asm.org/doi/10.1128/mBio.00809-16) .

Recommendation 5. § 93.103 Research misconduct. Consider expanding the definition of research misconduct to include an additional item: *Authorship manipulation.* The term could be further specified with definitions of guest authorship, ghost authorship, and false contribution statements.

Comment 5. Research has consistently shown that authorship manipulations are the most frequent form of questionable research practices or scientific misconduct across disciplines and can have significant repercussions for the careers of researchers (https://doi.org/10.1371/journal.pone.0023477, https://www.researchsquare.com/article/rs-1296644/v1).

Recommendation 6. § 93.103 Research misconduct. Consider expanding the definition of research misconduct to include an additional item: *Peer Review manipulation.*

Comment 6. Fake peer reviews, intentional stealing of ideas and delaying of publications, or intentional obstruction of competitors during grant reviews occur and have significant impact on the integrity of science. Fake peer review, based on data from Retraction Watch was the most

[redacted]

frequent reason for retractions (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3541886). The current database indicates 3,884 papers retracted due to fake peer reviews, of which, 612 papers were found in the area of Health Sciences.

Recommendation 7. § 93.103 Research misconduct. Consider expanding the definition of research misconduct to include an additional item: *Ad hominem attacks in scholarly works.*

Comment 7. Some scientific journals or publishers list ad hominem attacks as violations of publishing ethics (https://www.elsevier.com/__data/promis_misc/AMEPRE_Guide-to-peer-review.pdf), and in 2021 COPE recommended that: "Journals should have clear policies on what is acceptable and unacceptable in a reviewer report regarding tone, language, and content, and advice on the extent to which a review can be edited to adhere to these policies". Additionally, research has indicated that ad hominem attacks may have the same degree of public perception of science as attacks on the empirical basis of the science claims https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0192025). Note, our group has differences in opinion regarding the definition of this term.

Recommendation 8. § 93.103 Research misconduct. Expand the definition of research misconduct to include an additional item: *Aiding or abetting* any form of research misconduct.

Comment 8. There are cases when Principal Investigators have guided their trainees to perform research misconduct. This definition could be expanded to also include when institutions aid or abet their researchers to perform research misconduct. An example is the 2020 Surgisphere incident which contained a fake database and a retraction that followed. In response, the journal *Lancet* implemented a new authorship requirement: "We require that more than one author directly accessed and verified the underlying data reported in the manuscript." In cases when individuals falsely claim to guarantee integrity of the work, or help misrepresent research or evidence, the ORI policy should be made clear what happens when there is a joint responsibility for the misconduct.

Recommendation 9. § 93.300 General responsibilities for compliance. Add an item that institutions have a responsibility to take actions to ensure the whistleblowers' and complainants' careers are not negatively impacted.

Comment 9. Although **§ 93.300 (d)** states that institutions must "protect the positions and reputations of good faith complainants…from retaliation", it does not go far enough. Complainants should be protected from other negative consequences that do not stem from retaliation. For example, if a PhD student files a complaint against their supervisor and the supervisor is fired, it should be the institution's responsibility that the PhD student is provided with a new supervisor and can graduate on the timeline that was expected. The PhD student should not be left to resolve the issue of losing their supervisor. Additionally, during the case investigation, the Universities should have mechanisms to allow switching to a new supervisor.

From: [redacted]
To: OASH ORI Public Comments
Subject: Regulations RFI-Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct
Date: Monday, October 31, 2022 4:08:06 PM
Attachments: [redacted]
Letter to Dr. Wanda K. Jones Regarding 2005 Public Health Service Policies on Research Misconduct. 10-31-2022.pdf

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Good afternoon,

Attached please find for your consideration our response to the ORI's Request for Information on 42 CFR Part 93. Thank you for considering our comments on these important issues.

Sincerely,

[redacted]

[redacted]

October 31, 2022

Wanda K. Jones, Dr., P.H., MT (ASCP)
Acting Director, Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, Maryland 20852

By Email: OASH-ORI-Public-Comments@hhs.gov

Re: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct ("Regulations RFI")

Dear Dr. Jones:

We are pleased to provide comments on behalf of [redacted] in response to the Department of Health and Human Services (HHS) Request for Information and Comments on the 2005 Public Health Services Policies on Research Misconduct. [redacted] nationwide. Further, [redacted] with more than [redacted] clinical trials and it receives [redacted] of all National Cancer Institute [redacted] institutions. We appreciate the opportunity to offer [redacted] perspective on the 2005 Public Health Service Policies on Research Misconduct (the "Regulation") to help structure the Office of Research Integrity's future plans to revise the Regulation.

Establishment of Absolute Statute of Limitations

We recommend the adoption of an absolute statute of limitations under 42 CFR § 93.105 given that the impact of such misconduct would likely lessen over time. Currently, 42 CFR § 93.105(a) provides that the Regulation "applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation of research misconduct," subject to the subsequent use exception, where "[t]he respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized." Most of the time, we find the subsequent use exception will apply, even if the misconduct occurred many years ago, because

[redacted]

often researchers reference all their publications in their curriculum vitae, such that the publication containing the alleged research misconduct falls within the exception. By having an absolute statute of limitations, such as ten (10) years, that is not subject to this exception, institutions could avoid the significant expenditure of resources, such as costs and time, associated with investigating allegations that took place decades ago, by researchers who often will have left the institution, and related to research that may be obsolete or otherwise not likely to be relied upon in the future.

Streamlining the Three (3) Phase Investigational Process

We suggest the Regulation provide for a more streamlined approach to the multi-phased investigational process. The Regulation requires research misconduct investigations to proceed in three (3) phases – each with distinct timing and reporting requirements. In the first phase, the key question is whether the allegation is "sufficiently credible and specific so that potential evidence of research misconduct may be identified." 42 CFR § 93.307(a)(3). If so, institutions are directed to proceed to the inquiry phase, to determine whether preliminary fact-finding "indicates the allegation may have substance." 42 CFR § 93.307(d). If so, institutions are directed to complete the investigation phase by reviewing all evidence to determine whether it is more likely than not that there was research misconduct. 42 CFR § 93.310. We believe that institutions should be able to combine phases of the process to facilitate a more efficient and timely investigation. This would be particularly beneficial where it is apparent early on to the institution that the allegation does or does not have merit.

Time Interval for Completion of Each Phase

We suggest that ORI revise the Regulation to extend the periods of time given for completion of the inquiry and investigation phases to permit institutions the time needed to complete a comprehensive review. The inquiry phase must take no more than sixty (60) days unless circumstances warrant a longer period. 42 CFR § 93.307(g). The investigation phase must take no more than one hundred twenty (120) days, subject to an extension from ORI. 42 CFR § 93.311(a)-(b). Given that the overall process can be complex, particularly where there are multiple respondents, allegations and/or publications, and where the respondents are no longer affiliated with the institution, we believe it would be beneficial to extend the periods of time allocated for completion of the inquiry and investigation phases to a time period of nine (9) to twelve (12) months.

Clarity of Certain Definitions

We encourage ORI to define the following terms in the Regulation: "intentional," "knowing" and "reckless." A finding of research misconduct made under this part requires that …the misconduct be committed intentionally, knowingly, or recklessly…." 42 CFR § 93.104;

[redacted]

however, "Intentional," "knowing" and reckless" are not defined in the Regulation. Including definitions of those terms within the Regulation, and issuing further formal guidance on the distinction between negligence, reckless and knowing, would assist institutional decision-makers in gathering and evaluating evidence as well as encourage a more consistent application of the process both within and outside of each institution.

Thank you for considering our comments on these important issues. If we can provide any additional information or assistance at this time, please contact me.

Sincerely,

[redacted]

[redacted]

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Subject: Regulations RFI
Date: Monday, October 31, 2022 4:08:48 PM
Attachments: [redacted] response to ORI regulations RFI_103122.pdf

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Please see the attached correspondence, submitted in response to the recent "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct" (87 FR 53750).

Best,

[redacted]

[redacted]

October 31, 2022

Dr. Wanda K. Jones
Acting Director
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

Via electronic mail (OASH-ORI-Public-Comments@hhs.gov)

Re: Regulations RFI

Dear Dr. Jones,

I serve as the Research Integrity Officer ("RIO") for [redacted] I previously served as the RIO for [redacted]

It is in accordance with this experience that I write in support of the attached letters submitted to the Office of Research Integrity ("ORI") [redacted] in response to the "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct" ("the Regulations RFI," 87 FR 53750) issued by ORI and published in the Federal Register on September 1, 2022.

I request that this endorsement of those letters be taken as "comments" responsive to the Regulations RFI. I also wish to express my gratitude for ORI's engagement with the RIO community as the agency contemplates commencing a regulatory revision process for 42 CFR Part 93.

Sincerely,

[redacted]

Enclosures (2)

[redacted]

October 30, 2022

Submitted electronically to: OASH-ORI-Public-Comments@hhs.gov

Dr. Wanda K. Jones, Acting Director
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Dear Dr. Jones:

[redacted] submit this letter in response to the Office for Research Integrity's Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct published in the September 1, 2022, Federal Register. [87 FR 53750] (the "RFI"). [redacted] is an association of over 200 public and private United States research universities and affiliated academic medical centers and research institutes. [redacted] is an association of [redacted] that shares best practices and strategies for handling research misconduct allegations and promoting ethical research. Both [redacted] are concerned with the impact of federal regulations, policies, and practices on the performance of research conducted at their member institutions, and research integrity is one area of significant interest and expertise among [redacted]

Ensuring the responsible and ethical conduct of research, free from fabrication, falsification, and plagiarism, is a primary responsibility and focus of every university that conducts research, regardless of funding source. Given the prominence of Public Health Service (PHS) funding for so much of the research that is conducted at many United States universities and the fact that current regulations have been in place since 2005, universities have had ample opportunity to see how the Public Health Service (PHS) Policies on Research Misconduct at 42 CFR Part 93 ("Research Misconduct Policies") work in practice. Accordingly, we appreciate the Office of Research Integrity's (ORI) solicitation of stakeholder input as it contemplates changes to the Research Misconduct Policies, and we hope that this RFI will serve as the beginning of continuing dialog with the research community regarding any such changes.

We also point out that for over 20 years there has been a federal-wide research misconduct policy promulgated by the White House Office of Science and Technology Policy (OSTP).[1] Universities rely upon such federally harmonized approaches to promote compliance and minimize administrative burden, and we urge ORI to use its review process as an opportunity to work with other federal research funding agencies toward harmonization of research misconduct policies. Of course, consistency as a singular goal may produce either consistently bad or consistently good outcomes. Thus, any harmonization efforts should focus on identifying/developing requirements that effectively provide for the review of research misconduct allegations in a manner that is fair to the parties and does not unnecessarily burden the institutions charged with administering the process. In this regard, given that both NIH and the National Science Foundation (NSF) have had long-standing research misconduct regulations,[2] consideration should be given to comparing how each agency's regulatory framework has worked in practice and using this information in developing any new, harmonized regulatory model.

Our specific comments are organized below under each question posed in the RFI, and they are presented in order of the regulations at 42 CFR Part 93 to which they pertain. At the beginning of each response, we have included a bulleted list of the main points addressed. Note, that our comments do not encompass every section or aspect of the regulations at 42 CFR Part 93, but rather focus on our primary concerns.

QUESTION 1: WHICH SECTION(S) SHOULD BE CHANGED OR AUGMENTED WHEN REVISING 42 CFR PART 93? WHY? HOW SHOULD THE SECTION(S) BE CHANGED OR AUGMENTED?

a. ***42 CFR §93.105, Time limitations, including the interplay of this section with §93.310(h), Pursue leads and §93.316, Completing the research misconduct process***

Major Topics Addressed in this Response:

- Provide institutions with more discretion to terminate proceedings at assessment or inquiry
- Retain health or safety of public exception at §93.105(b)(2)
- Delete or substantively revise the subsequent use exception at §93.105(b)(1)
- Set clear limitations on the phrases "pursue diligently all significant issues and leads discovered" in §93.310(h) and "pursue diligently all significant issues" in §93.316(a)

One of the most important recommendations that we offer in this letter is for ORI to rethink the provisions of §93.105, §93.310(h) and §93.316 as they pertain to the scope of inquiries/investigations and the circumstances under which an inquiry or investigation may be

[1] 65 Fed. Reg. 235 (Dec. 6, 2000).
[2] NSF Research Misconduct Policies (45 CFR Part 689).

closed. ORI has interpreted these provisions to greatly expand the scope of investigations beyond what the allegations and evidence suggest. Institutions recognize that they may uncover additional instances of research misconduct during their review of initial allegations, and they take seriously their obligations to conduct a robust review. However, an overly broad scope may require universities to spend countless hours attempting to locate and assess information about rarely cited publications, unfunded proposals, unpublished research activities, and laboratory research records many years after their creation. This problem is compounded, and raises key process fairness concerns, when the respondent and/or key witnesses have left the institution and cannot be located or remain non-responsive to requests for information. Requiring institutions to allocate scarce institutional resources to these frequently fruitless tasks hampers institutional efforts to address new or higher-impact concerns, as well as to conduct preventative and educational activities. For these reasons, and other factors detailed below, we urge ORI to take the following actions to better enable institutions to prioritize their activities in the review of the research misconduct matters to optimize the ultimate goals of fair proceedings and meaningful correction of the scientific record:

(1) Provide institutions with discretion to terminate research misconduct proceedings at assessment or inquiry based on factors including, but not limited to the following items[3]:

- Scope of the allegations
- Respondent's status/non-status as an active researcher in the U.S.
- Institution's inability, after diligent efforts, to establish any factual basis that supports culpability of a respondent
- Impact of the questioned research on federal funding (e.g., was funding awarded based on questioned research) and the public scientific record (e.g., was the questioned research limited to the lab, did it result in a publication, and was that publication highly cited)
- Impact of the questioned research on public health or safety (e.g., does the questioned research impact practices that could influence public health and safety)
- Impact of the questioned research on the research record (e.g., has or will the research record be corrected).

(2) Retain the health or safety of the public exception at §93.105(b)(2), while deleting the subsequent use exception at §93.105(b)(1). If the subsequent use exception is retained, ORI should revise the exception to make clear that it applies only to the citation, republication, or use of the questioned data, or the conclusions or results derived from the questioned data.

(3) Clarify that the phrase "pursue diligently all significant issues and leads discovered" in §93.310(h) and the phrase "pursue diligently all significant issues" used in §93.316(a) are

[3] *See, also,* comments below concerning §93.307(d).

limited to issues and leads the institution discovers from evidence and testimony obtained during the inquiry or investigation, and that any review of a researcher's publications and proposals is limited to those implicated by such allegations/evidence.

Per §93.105(a), the Research Misconduct Policies apply to "research misconduct occurring within six years of the date HHS, or an institution receives an allegation of research misconduct." Sequestering the evidence and identifying witnesses necessary to substantiate allegations becomes more difficult with the passing of each year after the questioned event occurs, and beyond six years, it may become exceedingly difficult, thus raising questions of fair process for the respondent. Further, application of this limitation is complicated by the "subsequent use exception" detailed at §93.105(b)(1). The broad and vague language of this exception states that the "respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized." Given that the definition of "research record" in §93.224 includes research proposals, many, if not all, of which will include citations to a respondent's entire body of research work, the "exception" ends up swallowing the rule. Additionally, the lack of any firm time limitation sends institutions on time-consuming and expensive historical "paper chases," combing through ancient computers, lab instruments, file cabinets, and document storage facilities for data associated with papers that were published decades ago. Frequently, these data are no longer technically accessible (e.g., equipment or software that is no longer supported, damaged computers), or it has been lost or destroyed, and in many cases any information that is obtained through these pursuits does little to contribute to the advancement of a case.

Section §93.310(h) requires institutions to "pursue diligently all significant issues and leads discovered that are determined relevant to the investigation." The Research Misconduct Policies do not define the term "significant issues and leads," but on its face, this term indicates that institutions should follow the evidence they have discovered in the investigation. ORI's guidance on the scope of research misconduct,[4] however, goes beyond the plain language of §93.310(h) and calls for institutions to perform "a cursory review of other papers and grant applications within the six-year time limitation (§93.105(a)) to eliminate the possibility of any additional instances of research misconduct." First, the notion of a "cursory" review to "eliminate" the possibility of additional instances of research misconduct is unrealistic in cases in which images must be analyzed or figures compared from one publication to the next. Second, ORI calls for this review even though there may be no evidence or allegations to suggest that the papers contain fabrication, falsification, or plagiarism. In other words, ORI considers the mere existence of any paper or proposal authored during the six-year period to constitute a "significant issue or lead discovered" that must be pursued. Moreover, when ORI's interpretation of §93.310(h) is considered in connection with the subsequent use exception under §93.105(b)(1), the scope of the investigation

[4] ORI, Scope of Research Misconduct (May 27, 2021).

can quickly become limitless, imposing a tremendous burden on the investigating institution, and causing the respondent to undergo a lengthier investigation that may be completely unwarranted by the actual evidence.

[redacted] strongly support the need to ensure that the scientific record is correct, and we advocate for prioritizing institutional resources to investigating allegations and leads from actual evidence because they present a greater likelihood of producing dispositive conclusions that lead to appropriate retractions and other corrections. For similar reasons, we also encourage limiting the investigation to a reasonable number of years for which data, reliable testimony, and other evidence can be obtained and accurately assessed. Importantly, this approach also supports the rationale behind "statutes of limitations": to refrain from putting a respondent in the position of defending against allegations that are so old the respondent can no longer obtain the evidence or witnesses necessary to refute the allegations. At a minimum, ORI should develop criteria that would enable institutions to limit the review of additional papers or grant applications in research misconduct proceedings, to those that have a significant potential impact on the field, the funding agency, and/or public health and safety. Requiring unlimited review of *all* papers and grant applications in a researcher's body of work (especially those over six-years old) without regard to their scientific impact/value or the nature of the evidence results in institutions diverting scarce time and resources away from more important and productive pursuits such as the review of other, more serious misconduct concerns and/or educational and preventative efforts. Additionally, in many cases, there often are alternative methods to address concerns subsequent to the proceedings through communications with authors and journals concerning correction of the scientific record.

Finally, we also recommend that the "health or safety of the public exception," in §93.105(b)(2) be retained, so that ORI maintains the ability to require an institution to look beyond the six-year limitations period in the most important cases concerning research with major public impacts.

b. ***§93.104, Requirements for findings of research misconduct***

Major Topics Addressed in this Response:

- Define all state-of-mind terms used in the Research Misconduct Policies.

The requirement for a finding of research misconduct set forth in §93.104, includes an intent requirement, i.e., that the misconduct be committed "intentionally, knowingly, or recklessly." The determination of the intent of the respondent in performing activities that may constitute research misconduct is vital, yet, surprisingly, none of these terms are defined under Subpart B, the Research Misconduct Policy's definitions section.

Although the terms "intentionally," "knowingly," and "recklessly," may be commonly used in legal settings, the committees of scientists that review research misconduct cases are generally not

familiar with how these terms are used to frame intent. Additionally, as a matter of fundamental fairness, these terms should be defined in the regulations to ensure the respondent fully understands the allegations against them and to promote their consistent application in proceedings. Accordingly, [redacted] urge ORI to amend the regulations to include a definition of each of these terms and to provide guidance to the community that includes examples illustrating the differences among the terms and discussing common situations in which they apply.

c. ***93.108, Confidentiality***

Major Topics Addressed in this Response:

- Clarify the "need to know principle" in §93.108 to address:
  - Multiple entities involved in research misconduct proceedings;
  - Institution that hires a researcher during the conduct of a proceeding; and
  - Communications with journals.

Section 93.108 states as follows:

> Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, ***to those who need to know*** consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. . . . (***Emphasis added***).

[redacted] recognize the potential damage that unproved allegations of research misconduct may cause to a researcher's reputation, and we fully support strong regulations to ensure that the confidentiality of research misconduct proceedings is maintained. Yet, we are also cognizant of the fact that increasingly research misconduct proceedings, including interviews of witnesses, sequestration of evidence, and inquiry and investigation proceedings, span multiple institutions inside and outside of the United States. In these circumstances, it can be extremely difficult to determine who falls into the scope of "those who need to know." Should ORI proceed with changes to the Research Misconduct Policy, we urge it to consider updating this section on confidentiality to expressly acknowledge that a research misconduct proceeding may involve multiple entities, i.e., "to those who need to know consistent with a thorough, competent, objective and fair research misconduct proceeding, ***that may involve multiple entities and require communications among those entities . . ."***

The "need to know principle" also frequently arises when a respondent departs for employment at another institution during the misconduct proceedings. Institutions have no desire to interfere with a respondent's employment. Yet circumstances often require that the institution that initiated the proceedings communicate with the respondent's new employer to carry out the proceeding (e.g., need for additional testimony or sequestration of additional data). To facilitate such

communications, we recommend that ORI clarify that the phrase "those who need to know" may include the Research Integrity Officer, or other institutional officials, at the institution that employs the respondent, if the respondent ceases employment with the institution conducting the research misconduct proceedings during the process.

Finally, we believe that ORI also should consider providing guidance concerning the applicability of the "need to know" principle in the context of communications with journals. Correction of the scientific record is at the core of research misconduct proceedings, yet the confidentiality provisions do not explicitly address communications between the institution conducting the proceeding and journals that review and publish affected manuscripts. ORI should make clear that during the conduct of research misconduct proceedings, journals may be considered as having a "need to know" if substantive fact-finding has confirmed that data underlying materials provided to the journal are unreliable/inaccurate/false; provided, however, that communications should separate the matters of data reliability/accuracy/veracity from the issue of culpability until the proceedings on that issue have concluded. Being able to take this action when the need arises will allow for speedier correction of the scientific record.

d. ***§93.307(d) Criteria Warranting an Investigation***

Major Topics Addressed in this Response:

- Limit the criteria for proceeding to an investigation in §93.307(d) to circumstances in which there is reasonable basis for:
  - Finding the allegation falls under definition of research misconduct; and
  - Allegation has substance; and
  - Allegation does not stem from honest error or difference of opinion

This section states that an investigation is warranted if there is:

(1) A reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS supported biomedical or behavioral research, research training, or activities related to that research or research training as provided in §93.102; and
(2) Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

The use of the term "may have substance" in subsection (2) is so broad that it prevents the closing at inquiry of many cases that should not proceed to investigation because a realistic evaluation of the evidence demonstrates that it will be insufficient to support a finding of research misconduct after investigation. Although a "reasonable basis" is required for finding that the allegation falls within the definition of research misconduct, there is no similar requirement of reasonableness for

the evidence gathered at the inquiry stage. Yet, a vast amount of evidence is collected and reviewed at the inquiry stage because of rigorous sequestration requirements. Despite this fact, mandating only that an allegation ***may have*** substance often propels an inquiry with even minimal evidence into the investigation stage. It also requires an investigation even when sufficient evidence from preliminary information-gathering and preliminary fact-finding demonstrates that an honest error or mistake occurred. Rather than compel institutions to continue with investigations in virtually all these types of cases, [redacted] urge ORI to revise this provision as follows (changes shown in ***bold italicized text***) to (a) incorporate a "reasonableness" standard in both prongs of the test for moving to investigation; and (b) add a new provision to expressly recognize that an investigation is not warranted if preliminary information and fact-finding demonstrate credible evidence of honest error or a difference of opinion as a defense to the allegations:

(2) Preliminary information-gathering and fact-finding from the inquiry provides a ***reasonable basis*** for concluding that the allegation has substance**; *and***
(3) Preliminary information-gathering and fact-finding from the inquiry provide credible evidence that the allegations do not stem from honest error or a difference of opinion.

e. ***§93.307(g), Inquiry report and §93.311(a) Time limit for completing an investigation***

Major Topics Addressed in this Response:

- Eliminate 60-day deadline for inquiry in §93.307(g)
- Eliminate 120-day deadline for investigation in §93.311(a)
- Acknowledge that the timeline depends on facts and circumstances of each case and replace each deadline with a requirement for the institution and ORI to develop a schedule for completion of the inquiry/investigation
- Acknowledge extensions may be granted per reasonable request and progress reports may be required.

Section 93.307(g) states that the time for completion of the inquiry is 60 days from the date of initiation, and §93.311(a) states that the time for completing an investigation is within 120 days of its initiation. Each of these timelines is an arbitrary number that applies regardless of the nature of the case and neither has proved to be a realistic estimate of the time required to conduct an inquiry or investigation. In fact, many investigations may take a year or more to complete, and ORI has addressed this issue by granting extensions in response to institutional requests.

The time required to conduct either an inquiry or investigation is completely dependent upon the individual circumstances of the case and calculating this time is complex. Accordingly, rather than attempt to determine a specific completion period that applies in all cases, [redacted] suggest that in the case of inquiries, ORI require institutions to diligently pursue their conduct,

while affording the institution the discretion to set its own timetable based on the circumstances of the case. In the case of investigations, we suggest that the current 120-day deadline be deleted, and the institution propose, for ORI's acceptance, a schedule for the completion of the investigation, with full recognition by the institution and ORI that this schedule may require adjustment as circumstances develop. Below, suggested revised provisions are set forth:

> **§93.307(g): Time for completion**: The institution must undertake and diligently conduct the inquiry and complete it within a reasonable time based on the facts and circumstances of the case. In the event ORI reasonably believes that the inquiry is not being conducted diligently, it may require the institution to provide a progress report that describes remaining steps and an estimate of the time by which the inquiry will be completed, with follow-up reports, as necessary.
>
> **§93.311(a), Time limit for completing an investigation:** An institution must diligently conduct the investigation and complete all aspects of the investigation (including conducting the investigation, preparing the report of the findings, providing the draft report for comment in accordance with §93.312, and sending the final report to ORI under §93.315) within a reasonable time based on the facts and circumstances of the case. At the beginning of the investigation, the institution shall provide ORI, for ORI's approval, a tentative schedule indicating when the investigation will be completed. Recognizing that the complexity of research misconduct proceedings makes it difficult to predict a completion date, ORI may grant an institution one or more extension(s) of the investigation period, based on written request(s) of the institution that identifies reasonable facts and circumstances supporting the extension. In the event ORI reasonably believes that the investigation is not being conducted diligently, it may require the institution to provide a progress report that describes remaining steps and an estimate of the time by which the investigation will be completed, with follow-up reports, as necessary.

QUESTION 2: WHICH SECTION(S) SHOULD BE RETAINED AS IT CURRENTLY IS IN 42 CFR PART 93? WHY?

42 CFR §93.103, Research Misconduct

Major Topics Addressed in this Response:

- Do not expand definition of "research misconduct" under §93.103 to address:
  - Behaviors encompassed under scientific or research integrity.
  - Misconduct beyond falsification, fabrication, or plagiarism
- Reconsider the current definition of "plagiarism" under §93.103(c).

A key provision of the current Research Misconduct Policies that should remain unchanged is the definition of the term "Research Misconduct," which is limited to "fabrication, falsification, or

plagiarism [FFP] in proposing, performing, or reviewing research, or in reporting research results." The term research misconduct should not be replaced by or conflated with the terms "research integrity" or "scientific integrity," each of which encompass a more diverse array of behaviors and threats, including bias, reproducibility, and data security.[5] The process set forth in the Research Misconduct Policies for examining and adjudicating allegations of "research misconduct" is tailored to examining allegations of FFP and would be unwieldy when applied to broader terms. Rather, the concepts of "research integrity" or "scientific integrity," should continue to be addressed through separate requirements such as those pertaining to training in the responsible and ethical conduct of research.[6]

Along the same lines, we contend that the definition of research misconduct should not be altered to incorporate behavior beyond FFP. For example, certain individuals and groups recommend that behavior such as failure to disclose "foreign research ties" should be investigated as "research misconduct."[7] Similarly, some individuals/groups believe that sexual harassment should be treated as research misconduct.[8] We strongly disagree. Institutions have developed mature programs to meet the requirement for handling allegations of research misconduct that include elements specifically developed for scientists to effectively review claims of fabrication, falsification, or plagiarism. These programs include elements such as sequestration of evidence and consideration of whether there has been a significant departure from the scientific standards of the relevant research community, and these processes that would be ineffective and inappropriate for the assessment of other types of allegations.

We fully support steps already taken to improve related reporting, investigation, and sanctions for research security concerns, harassment, and bullying. However, we firmly believe that these activities should ***not*** be reviewed under an investigational process that was specifically designed to examine accuracy of the scientific record. Instead, existing pathways designated for the investigation of malign foreign influence or sexual harassment should be utilized, as these processes were developed specifically for, and contain procedural protections that are unique to, these subject areas Similarly, if the review of research misconduct allegations unearths evidence of harassment, undisclosed conflicts of interest, or other prohibited behaviors, referrals are made to the appropriate institutional officials/processes specifically designated for investigating those

[5] *See, e.g.,* National Science and Technology Council (STC), Scientific Integrity Fast-Track Action Committee, Protecting the Integrity of Government Science (Jan. 2022) at p. 1-2 (identifying principles of scientific integrity); U.S. Dept. of Agriculture, Scientific Integrity and Research Misconduct webpage (accessed Oct. 5, 2022) (identifying research misconduct as compromised subset of research integrity).
[6] National Institutes of Health (NIH), *FY 2022 Updated Guidance: Requirement for instruction in the Responsible Conduct of Research* (NOT-22-055) (Feb. 17, 2022).
[7] Mervis, J., *U.S. Scientists who Hide Foreign Ties Should Face Research Misconduct Sanctions, Panel Says*, SCIENCE (Dec. 11, 2019).
[8] Marin-Spiotta, E., *Harassment Should Count as Scientific Misconduct*, NATURE (May 9, 2018); Kuo, M., *Scientific Society Defines Sexual Harassment as Scientific Misconduct*, SCIENCE (Sept. 20, 2017) (American Geophysical Union adopts policy that considers sexual harassment to be a type of scientific misconduct).

allegations. To do otherwise, risks running afoul of laws, regulations, policies, processes, and concerns specific to these areas.

Additionally, we believe that ORI should take this opportunity to reconsider its definition of plagiarism. Section 93.103(c) currently defines plagiarism as the "appropriation of another person's ideas, processes, results, or words without giving appropriate credit," yet the plagiarism of "ideas" is extremely difficult to prove (e.g., the accused may have access to many different public documents that would disprove a complainant's allegation of plagiarism of ideas). Similarly, ORI has recognized in guidance that collaborators' use of joint research without appropriate attribution is an authorship matter, as opposed to plagiarism. ORI should consider these concerns and address them through revisions to the definition.

QUESTION 3: WHICH SECTION(S) SHOULD BE CONSIDERED FOR REMOVAL WHEN REVISING 42 CFR PART 93? WHY?

Major Topics Addressed in this Response:

- Eliminate Subpart E and revise appeals process to call for direct appeal to the Assistant Secretary of Health.

[redacted] advocate for eliminating the current Subpart E and replacing it with an appeals process that is simpler for respondents to navigate. Currently, Subpart E calls for a hearing before an administrative law judge (ALJ), who makes a recommendation to the Assistant Secretary for Health (ASH). The ASH may modify or reject the ALJ's decision if it is found to be arbitrary and capricious or clearly erroneous as detailed in §93.523. If debarment or suspension is part of the recommended administrative actions, the debarring official makes the final Department of Health and Human Services (HHS) decision on those actions.

A much simpler process would be to have a respondent direct their appeal to the ASH, who would review it and make a recommendation to the Secretary of HHS or the Deputy Secretary of HHS (or their designee), who would decide the appeal. This type of process is currently in use at the National Aeronautics and Space Administration,[9] the National Science Foundation,[10] the Veterans Administration,[11] and the Department of Department of Defense,[12] and adopting this recommendation would align the HHS appeals process with that of other federal agencies.

[9] 14 CFR §1275.108.
[10] 45 CFR §689.10.
[11] Veterans Health Administration Directive 1058.02 (Jul. 10, 2020).
[12] Dept. of Defense, Instruction 3.7 (Oct. 15, 2018).

CONCLUSION

It is always good practice to periodically review regulations to determine whether changes need to be made to better achieve regulatory goals. [redacted] support ORI in its efforts to undertake such a review of the Research Misconduct Policies, and we are grateful to ORI for not undertaking this review in a vacuum, but rather reaching out to the stakeholder community for input. We hope that the comments and recommendations set forth herein will assist ORI in its mission, and any questions regarding this transmittal may be directed to [redacted] We look forward to continuing the dialog with ORI on any proposed changes to the regulations at 42 CFR Part 93, and once again thank the agency for this opportunity to submit comments.

Sincerely,

[redacted]

[redacted]

October 30, 2022

Submitted electronically to: OASH-ORI-Public-Comments@hhs.gov

Dr. Wanda K. Jones, Acting Director
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Dear Dr. Jones:

[redacted] is a [redacted] from many different types of US research institutions. Because [redacted] research misconduct allegations, they are [redacted] to respond to the Office of Research Integrity's (ORI) current Request for Information (RFI) concerning revisions to the Public Health Service Policies on Research Misconduct, 42 C.F.R. Part 93, (the "regulation"). As [redacted] I am writing on behalf of the [redacted] member institutions and appreciate the opportunity to provide input that will directly affect our institutions and institutional processes.

[redacted] has already submitted a [redacted] to this RFI together with the [redacted] institutions. This addendum represents an effort by a wider range of [redacted] to emphasize and expand upon some of the key points raised in that [redacted] especially as intended to help simplify and streamline the research misconduct process.

1. **Keep the definition of research misconduct limited to falsification, fabrication, and plagiarism (FFP).** Broadening of the definition to include issues outside of FFP, *i.e.,* issues of sexual or other forms, of harassment, other detrimental research practices (DRPs), or foreign influence, will require institutions to use the complex and time-consuming research misconduct process to resolve such issues. Since the regulation is written, and is specific for, the purpose of reviewing scientific data, applying the regulation to concerns outside of data review would be unmanageable. Institutions may have, or can develop, other more appropriate processes to handle concerns outside of FFP.

2. **Specifically define the terms "intentionally, knowingly, or recklessly" that is included in the requirements for a finding of research misconduct.** Institutional officials and investigation committees often struggle with the criteria for making a finding of research misconduct at §93.104(b) that states, "The misconduct be committed intentionally, knowingly, or recklessly." Institutions must be able to consistently describe these different

state-of-mind terms and standard definitions must be adopted nationally. This is particularly true for the concept of research misconduct committed recklessly, where no definition or guidance has been provided, to date. We recommend that in addition to including a standard definition for these terms in the regulation, ORI also provide specific guidance that distinguishes between these terms and describe examples of research misconduct committed intentionally, knowingly, or recklessly with the evidence to review in each case.

3. **Revise the criteria to warrant an investigation.** We emphasize the importance of creating a path to terminate research misconduct proceedings at assessment or inquiry under certain circumstances, as determined by institutional RIOs and other officials, while also ensuring the integrity of the research record. Institutions often have a very good idea of the evidence available because of the robust sequestration that must occur prior to notification of or the initiation of an inquiry. During assessment and inquiry, the institution has to also carefully look at the role of the respondent(s) in the research at issue. Currently, institutions are obligated to pursue cases through investigation, even when it is clear earlier in the process that findings of research misconduct will have no consequence to the institution or respondent, or that evidence does not exist to support making research misconduct findings.

   For cases that will be moving forward to an investigation, we recommend that ORI allow institutions to follow §93.307(d) that states that the inquiry is an initial review of the evidence and does not require a full review of all the evidence related to an allegation and ORI should replace the requirement for an inquiry report with a checklist at §93.307(d). Additionally, the regulation should be revised to specifically state that performing an inquiry does not require a full committee. This could streamline the process and permit institutions to more quickly determine if the allegations warrant a full investigation without having to engage in a laborious and time-consuming committee process that is not necessary to make this determination. Additionally, we recommend allowing institutions to have increased discretion to close cases at inquiry when the evidence leads to any combination of the following circumstances: sufficient evidence proves that the data inconsistencies are a result of honest error; the scope of the allegations are limited and correction of the research record has occurred; the allegations involved papers published over the six-year time limit; the respondent is not continuing research at the institution or in the US; a questioned publication is not highly cited; funding was not based on allegedly falsified data; questioned data is not influencing practices that could affect health and safety of the public, or the institutional actions implemented were sufficient. It is our understanding that these are similar circumstances that ORI assesses when it declines to pursue a research misconduct finding. A critical aspect for closing cases under these circumstances are that institutions would still be required to ensure correction/retraction of the research record, as appropriate. Similar to §93.316, where case closure occurs with an admission, an institution would notify ORI of its plans to close a case under such circumstances.

4. **Timelines for completing an inquiry or investigation**. The current timelines for completing an inquiry (60 days) or an investigation (120 days) are arbitrary time periods that do not

account for the complexity and scope of current cases. Institutions must seek multiple extensions for each phase. Respondents often raise procedural challenges that institutions did not adhere to the regulatory requirements for meeting the time deadlines. We suggest that the regulation state that the time periods serve only as a guideline for institutions to complete the process and specifically state that extensions are a normal and usual part of a research misconduct processes, which are dependent on the complexity and scope of individual cases.

5. **Clarify the concept for broadening the scope of research misconduct proceedings**. The phrase "pursue diligently all significant issues" in the context of inquiries, §93.310(h), and investigations, §93.105(b)(2), has led to draining institutional resources and having all involved individuals endure much longer investigations than the initial allegations would require. In connection with the subsequent use exception under §93.105, research misconduct proceedings can quickly become unmanageable. We believe a solution is three-fold: 1) to allow institutions the discretion to determine when significant issues and leads relevant to the investigation require expanding the scope of an ongoing proceeding, 2) omitting the subsequent use exception under §93.105, and 3) requiring correction of the research record for all concerns identified. These revisions would allow a simpler research misconduct proceeding that can focus on the most critical issues and still ensure the integrity of the research record for all concerns identified.

6. **Clarify the concept of need to know**. Although institutions recognize that confidentiality is a hallmark of research misconduct proceedings, a very strict interpretation of who has a need to know can trigger difficult consequences, particularly when allegations are made public, when respondents move from one institution to another, or when an affected publication needs to be corrected or retracted during the course of a research misconduct process. We strongly recommend that the regulation be revised to include broadening the need-to-know principle to include officials at other institutions, when those institutions (a) may possess records relevant to allegations under review, or (b) employ or fund research being conducted by a respondent found to have committed research misconduct. We also suggest that with ongoing investigations, ORI mediate communication between institutions particularly when a respondent seeks to leave an institution to avoid a research misconduct process. Further, we recommend that journal editors and/or publishers be explicitly included as those who need to know when sufficient fact-finding has identified that data are incorrect or unreliable, while remaining silent on the issue of culpability or intent, in ongoing research misconduct proceedings.

7. **Finally, [redacted] supports revision of the hearing process described under Subpart E.** One key recommendation we suggest, limiting the complexity of institutional research misconduct proceedings, is revision of the hearing process under Subpart E. The current hearing process in the Department of Health and Humans Services (HHS) is before an administrative law judge (ALJ), in the Departmental Appeals Board (DAB), who makes a recommendation to the Assistant Secretary for Health (ASH). The ALJ is bound by all Federal statutes and regulations, Secretarial delegations of authority, and applicable HHS

policies. However, research misconduct proceedings are academic reviews of research practice, evaluating behavior in relation to the accepted practices of the relevant research community, and are not legal proceedings. Thus, Subpart E places stringent and demanding legal requirements for ORI to make independent research misconduct findings, which may concur with an institution's findings. ORI often must reach out to institutions, sometimes years after institutional findings are made, to request additional information. The legal burden for ORI, therefore, seeps into the institutional procedures increasing the burden for carrying out institutional misconduct processes. We believe the hearing process should be replaced with a simpler appeal process that would make research misconduct proceedings easier for ORI, institutions, and respondents to navigate. We recommend a respondent appeal ORI research misconduct findings directly to the ASH in HHS. Departmental appeals of research misconduct are currently performed in other federal agencies, including the National Aeronautics and Space Administration, the National Science Foundation, the Veterans Administration and the Department of Defense, and it simplifies the appeals process while still ensuring due process rights. Moreover, the proposed harmonization with other agencies would have the added benefit of returning the process to its roots and avoiding the misunderstandings that arise when legal conventions are applied to an academic review process.

[redacted] appreciates the opportunity offered by ORI to provide input into the revisions of 42 C.F.R Part 93. We hope that the recommendations offered in this letter, based on extensive experience of [redacted] as well as the [redacted] letter, will help ORI make suitable and beneficial changes to simplify research misconduct proceedings. Further, any effort by ORI to harmonize procedures with other federal agencies would benefit institutional reviews, particularly for research funded by multiple federal agencies. [redacted] remains committed to working with ORI with respect to the research misconduct regulations and welcome any opportunity to partner with or assist ORI in related activities.

Sincerely,

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Cc: [redacted]
Subject: Regulations RFI
Date: Monday, October 31, 2022 4:25:14 PM
Attachments: [redacted] Reponse to ORI RFI Research Misconduct Policies Oct 31 2022V2 .pdf
Final [redacted] response to ORI RFI Research Misconduct Policies Oct 30 2022 PDF.pdf

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Sent on behalf of [redacted]

Dear Dr. Jones:

[redacted] consistently provides an outstanding return on federal investments in its students, institutions, and research. With [redacted] campuses and approximately [redacted] students, the [redacted] is the [redacted], providing access and success for unprecedented numbers of underserved and low-income students. Every year, [redacted] graduates enter the workforce across all economic sectors.

As such, [redacted] harmonized approaches to promote compliance and minimize administrative burden.

Recently, on October 30, 2022, [redacted] to the Office for Research Integrity's (ORI) Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct published in the September 1, 2022, Federal Register. [87 FR 53750] (the "RFI"). [redacted] are concerned with the impact of federal regulations, policies, and practices on the performance of research conducted at their member institutions, and research integrity is one area of significant interest and concern.

Therefore, [redacted] and significantly aligns with the specific comments which are provided for in their letter (attached), dated [redacted] 2022.

Furthermore, we urge the ORI to use its review process as an opportunity to work with other federal research funding agencies toward harmonization of research misconduct policies.

Respectfully,

[redacted]

[redacted]

October 31, 2022

Submitted electronically to: OASH-ORI-Public-Comments@hhs.gov

Dr. Wanda K. Jones, Acting Director
Office of Research Integrity 1101
Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Dear Dr. Jones:

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As such, [redacted] campuses rely upon federally harmonized approaches to promote compliance and minimize administrative burden.

Recently, on [redacted] 2022, [redacted] to the Office for Research Integrity's (ORI) Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct published in the September 1, 2022, Federal Register. [87 FR 53750] (the "RFI"). [redacted] concerned with the impact of federal regulations, policies, and practices on the performance of research conducted at their member institutions, and research integrity is one area of significant interest and concern.

[redacted]

[redacted]

Therefore, [redacted] and significantly aligns with the specific comments which are provided for in their letter (attached), dated October 30, 2022.

Furthermore, we urge the ORI to use its review process as an opportunity to work with other federal research funding agencies toward harmonization of research misconduct policies.

Respectfully,

[redacted]

Attachments:

[redacted] to ORI RFI, dated Oct 30, 2022.

[redacted]

October 30, 2022

Submitted electronically to: OASH-ORI-Public-Comments@hhs.gov

Dr. Wanda K. Jones, Acting Director
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Dear Dr. Jones:

[redacted] submit this letter in response to the Office for Research Integrity's Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct published in the September 1, 2022, Federal Register. [87 FR 53750] (the "RFI"). [redacted] is an association of over 200 public and private United States research universities and affiliated academic medical centers and research institutes. [redacted] is an [redacted] that shares best practices and strategies for handling research misconduct allegations and promoting ethical research. Both [redacted] are concerned with the impact of federal regulations, policies, and practices on the performance of research conducted at their member institutions, and research integrity is one area of significant interest and expertise among [redacted]

Ensuring the responsible and ethical conduct of research, free from fabrication, falsification, and plagiarism, is a primary responsibility and focus of every university that conducts research, regardless of funding source. Given the prominence of Public Health Service (PHS) funding for so much of the research that is conducted at many United States universities and the fact that current regulations have been in place since 2005, universities have had ample opportunity to see how the Public Health Service (PHS) Policies on Research Misconduct at 42 CFR Part 93 ("Research Misconduct Policies") work in practice. Accordingly, we appreciate the Office of Research Integrity's (ORI) solicitation of stakeholder input as it contemplates changes to the Research Misconduct Policies, and we hope that this RFI will serve as the beginning of continuing dialog with the research community regarding any such changes.

We also point out that for over 20 years there has been a federal-wide research misconduct policy promulgated by the White House Office of Science and Technology Policy (OSTP).[1] Universities rely upon such federally harmonized approaches to promote compliance and minimize administrative burden, and we urge ORI to use its review process as an opportunity to work with other federal research funding agencies toward harmonization of research misconduct policies. Of course, consistency as a singular goal may produce either consistently bad or consistently good outcomes. Thus, any harmonization efforts should focus on identifying/developing requirements that effectively provide for the review of research misconduct allegations in a manner that is fair to the parties and does not unnecessarily burden the institutions charged with administering the process. In this regard, given that both NIH and the National Science Foundation (NSF) have had long-standing research misconduct regulations,[2] consideration should be given to comparing how each agency's regulatory framework has worked in practice and using this information in developing any new, harmonized regulatory model.

Our specific comments are organized below under each question posed in the RFI, and they are presented in order of the regulations at 42 CFR Part 93 to which they pertain. At the beginning of each response, we have included a bulleted list of the main points addressed. Note, that our comments do not encompass every section or aspect of the regulations at 42 CFR Part 93, but rather focus on our primary concerns.

QUESTION 1: WHICH SECTION(S) SHOULD BE CHANGED OR AUGMENTED WHEN REVISING 42 CFR PART 93? WHY? HOW SHOULD THE SECTION(S) BE CHANGED OR AUGMENTED?

a. ***42 CFR §93.105, Time limitations, including the interplay of this section with §93.310(h), Pursue leads and §93.316, Completing the research misconduct process***

Major Topics Addressed in this Response:

- Provide institutions with more discretion to terminate proceedings at assessment or inquiry
- Retain health or safety of public exception at §93.105(b)(2)
- Delete or substantively revise the subsequent use exception at §93.105(b)(1)
- Set clear limitations on the phrases "pursue diligently all significant issues and leads discovered" in §93.310(h) and "pursue diligently all significant issues" in §93.316(a)

One of the most important recommendations that we offer in this letter is for ORI to rethink the provisions of §93.105, §93.310(h) and §93.316 as they pertain to the scope of inquiries/investigations and the circumstances under which an inquiry or investigation may be

[1] 65 Fed. Reg. 235 (Dec. 6, 2000).
[2] NSF Research Misconduct Policies (45 CFR Part 689).

closed. ORI has interpreted these provisions to greatly expand the scope of investigations beyond what the allegations and evidence suggest. Institutions recognize that they may uncover additional instances of research misconduct during their review of initial allegations, and they take seriously their obligations to conduct a robust review. However, an overly broad scope may require universities to spend countless hours attempting to locate and assess information about rarely cited publications, unfunded proposals, unpublished research activities, and laboratory research records many years after their creation. This problem is compounded, and raises key process fairness concerns, when the respondent and/or key witnesses have left the institution and cannot be located or remain non-responsive to requests for information. Requiring institutions to allocate scarce institutional resources to these frequently fruitless tasks hampers institutional efforts to address new or higher-impact concerns, as well as to conduct preventative and educational activities. For these reasons, and other factors detailed below, we urge ORI to take the following actions to better enable institutions to prioritize their activities in the review of the research misconduct matters to optimize the ultimate goals of fair proceedings and meaningful correction of the scientific record:

(1) Provide institutions with discretion to terminate research misconduct proceedings at assessment or inquiry based on factors including, but not limited to the following items[3]:

- Scope of the allegations
- Respondent's status/non-status as an active researcher in the U.S.
- Institution's inability, after diligent efforts, to establish any factual basis that supports culpability of a respondent
- Impact of the questioned research on federal funding (e.g., was funding awarded based on questioned research) and the public scientific record (e.g., was the questioned research limited to the lab, did it result in a publication, and was that publication highly cited)
- Impact of the questioned research on public health or safety (e.g., does the questioned research impact practices that could influence public health and safety)
- Impact of the questioned research on the research record (e.g., has or will the research record be corrected).

(2) Retain the health or safety of the public exception at §93.105(b)(2), while deleting the subsequent use exception at §93.105(b)(1). If the subsequent use exception is retained, ORI should revise the exception to make clear that it applies only to the citation, republication, or use of the questioned data, or the conclusions or results derived from the questioned data.

(3) Clarify that the phrase "pursue diligently all significant issues and leads discovered" in §93.310(h) and the phrase "pursue diligently all significant issues" used in §93.316(a) are

[3] *See, also,* comments below concerning §93.307(d).

limited to issues and leads the institution discovers from evidence and testimony obtained during the inquiry or investigation, and that any review of a researcher's publications and proposals is limited to those implicated by such allegations/evidence.

Per §93.105(a), the Research Misconduct Policies apply to "research misconduct occurring within six years of the date HHS, or an institution receives an allegation of research misconduct." Sequestering the evidence and identifying witnesses necessary to substantiate allegations becomes more difficult with the passing of each year after the questioned event occurs, and beyond six years, it may become exceedingly difficult, thus raising questions of fair process for the respondent. Further, application of this limitation is complicated by the "subsequent use exception" detailed at §93.105(b)(1). The broad and vague language of this exception states that the "respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized." Given that the definition of "research record" in §93.224 includes research proposals, many, if not all, of which will include citations to a respondent's entire body of research work, the "exception" ends up swallowing the rule. Additionally, the lack of any firm time limitation sends institutions on time-consuming and expensive historical "paper chases," combing through ancient computers, lab instruments, file cabinets, and document storage facilities for data associated with papers that were published decades ago. Frequently, these data are no longer technically accessible (e.g., equipment or software that is no longer supported, damaged computers), or it has been lost or destroyed, and in many cases any information that is obtained through these pursuits does little to contribute to the advancement of a case.

Section §93.310(h) requires institutions to "pursue diligently all significant issues and leads discovered that are determined relevant to the investigation." The Research Misconduct Policies do not define the term "significant issues and leads," but on its face, this term indicates that institutions should follow the evidence they have discovered in the investigation. ORI's guidance on the scope of research misconduct,[4] however, goes beyond the plain language of §93.310(h) and calls for institutions to perform "a cursory review of other papers and grant applications within the six-year time limitation (§93.105(a)) to eliminate the possibility of any additional instances of research misconduct." First, the notion of a "cursory" review to "eliminate" the possibility of additional instances of research misconduct is unrealistic in cases in which images must be analyzed or figures compared from one publication to the next. Second, ORI calls for this review even though there may be no evidence or allegations to suggest that the papers contain fabrication, falsification, or plagiarism. In other words, ORI considers the mere existence of any paper or proposal authored during the six-year period to constitute a "significant issue or lead discovered" that must be pursued. Moreover, when ORI's interpretation of §93.310(h) is considered in connection with the subsequent use exception under §93.105(b)(1), the scope of the investigation

[4] ORI, Scope of Research Misconduct (May 27, 2021).

can quickly become limitless, imposing a tremendous burden on the investigating institution, and causing the respondent to undergo a lengthier investigation that may be completely unwarranted by the actual evidence.

[redacted] strongly support the need to ensure that the scientific record is correct, and we advocate for prioritizing institutional resources to investigating allegations and leads from actual evidence because they present a greater likelihood of producing dispositive conclusions that lead to appropriate retractions and other corrections. For similar reasons, we also encourage limiting the investigation to a reasonable number of years for which data, reliable testimony, and other evidence can be obtained and accurately assessed. Importantly, this approach also supports the rationale behind "statutes of limitations": to refrain from putting a respondent in the position of defending against allegations that are so old the respondent can no longer obtain the evidence or witnesses necessary to refute the allegations. At a minimum, ORI should develop criteria that would enable institutions to limit the review of additional papers or grant applications in research misconduct proceedings, to those that have a significant potential impact on the field, the funding agency, and/or public health and safety. Requiring unlimited review of *all* papers and grant applications in a researcher's body of work (especially those over six-years old) without regard to their scientific impact/value or the nature of the evidence results in institutions diverting scarce time and resources away from more important and productive pursuits such as the review of other, more serious misconduct concerns and/or educational and preventative efforts. Additionally, in many cases, there often are alternative methods to address concerns subsequent to the proceedings through communications with authors and journals concerning correction of the scientific record.

Finally, we also recommend that the "health or safety of the public exception," in §93.105(b)(2) be retained, so that ORI maintains the ability to require an institution to look beyond the six-year limitations period in the most important cases concerning research with major public impacts.

b. ***§93.104, Requirements for findings of research misconduct***

Major Topics Addressed in this Response:

- Define all state-of-mind terms used in the Research Misconduct Policies.

The requirement for a finding of research misconduct set forth in §93.104, includes an intent requirement, i.e., that the misconduct be committed "intentionally, knowingly, or recklessly." The determination of the intent of the respondent in performing activities that may constitute research misconduct is vital, yet, surprisingly, none of these terms are defined under Subpart B, the Research Misconduct Policy's definitions section.

Although the terms "intentionally," "knowingly," and "recklessly," may be commonly used in legal settings, the committees of scientists that review research misconduct cases are generally not

familiar with how these terms are used to frame intent. Additionally, as a matter of fundamental fairness, these terms should be defined in the regulations to ensure the respondent fully understands the allegations against them and to promote their consistent application in proceedings. Accordingly, [redacted] urge ORI to amend the regulations to include a definition of each of these terms and to provide guidance to the community that includes examples illustrating the differences among the terms and discussing common situations in which they apply.

c. ***93.108, Confidentiality***

Major Topics Addressed in this Response:

- Clarify the "need to know principle" in §93.108 to address:
  - Multiple entities involved in research misconduct proceedings;
  - Institution that hires a researcher during the conduct of a proceeding; and
  - Communications with journals.

Section 93.108 states as follows:

> Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, ***to those who need to know*** consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. . . . (***Emphasis added***).

[redacted] recognize the potential damage that unproved allegations of research misconduct may cause to a researcher's reputation, and we fully support strong regulations to ensure that the confidentiality of research misconduct proceedings is maintained. Yet, we are also cognizant of the fact that increasingly research misconduct proceedings, including interviews of witnesses, sequestration of evidence, and inquiry and investigation proceedings, span multiple institutions inside and outside of the United States. In these circumstances, it can be extremely difficult to determine who falls into the scope of "those who need to know." Should ORI proceed with changes to the Research Misconduct Policy, we urge it to consider updating this section on confidentiality to expressly acknowledge that a research misconduct proceeding may involve multiple entities, i.e., "to those who need to know consistent with a thorough, competent, objective and fair research misconduct proceeding, ***that may involve multiple entities and require communications among those entities . . ."***

The "need to know principle" also frequently arises when a respondent departs for employment at another institution during the misconduct proceedings. Institutions have no desire to interfere with a respondent's employment. Yet circumstances often require that the institution that initiated the proceedings communicate with the respondent's new employer to carry out the proceeding (e.g., need for additional testimony or sequestration of additional data). To facilitate such

communications, we recommend that ORI clarify that the phrase "those who need to know" may include the Research Integrity Officer, or other institutional officials, at the institution that employs the respondent, if the respondent ceases employment with the institution conducting the research misconduct proceedings during the process.

Finally, we believe that ORI also should consider providing guidance concerning the applicability of the "need to know" principle in the context of communications with journals. Correction of the scientific record is at the core of research misconduct proceedings, yet the confidentiality provisions do not explicitly address communications between the institution conducting the proceeding and journals that review and publish affected manuscripts. ORI should make clear that during the conduct of research misconduct proceedings, journals may be considered as having a "need to know" if substantive fact-finding has confirmed that data underlying materials provided to the journal are unreliable/inaccurate/false; provided, however, that communications should separate the matters of data reliability/accuracy/veracity from the issue of culpability until the proceedings on that issue have concluded. Being able to take this action when the need arises will allow for speedier correction of the scientific record.

d. ***§93.307(d) Criteria Warranting an Investigation***

Major Topics Addressed in this Response:

- Limit the criteria for proceeding to an investigation in §93.307(d) to circumstances in which there is reasonable basis for:
  - Finding the allegation falls under definition of research misconduct; and
  - Allegation has substance; and
  - Allegation does not stem from honest error or difference of opinion

This section states that an investigation is warranted if there is:

(1) A reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS supported biomedical or behavioral research, research training, or activities related to that research or research training as provided in §93.102; and
(2) Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

The use of the term "may have substance" in subsection (2) is so broad that it prevents the closing at inquiry of many cases that should not proceed to investigation because a realistic evaluation of the evidence demonstrates that it will be insufficient to support a finding of research misconduct after investigation. Although a "reasonable basis" is required for finding that the allegation falls within the definition of research misconduct, there is no similar requirement of reasonableness for

the evidence gathered at the inquiry stage. Yet, a vast amount of evidence is collected and reviewed at the inquiry stage because of rigorous sequestration requirements. Despite this fact, mandating only that an allegation ***may have*** substance often propels an inquiry with even minimal evidence into the investigation stage. It also requires an investigation even when sufficient evidence from preliminary information-gathering and preliminary fact-finding demonstrates that an honest error or mistake occurred. Rather than compel institutions to continue with investigations in virtually all these types of cases, [redacted] urge ORI to revise this provision as follows (changes shown in ***bold italicized text***) to (a) incorporate a "reasonableness" standard in both prongs of the test for moving to investigation; and (b) add a new provision to expressly recognize that an investigation is not warranted if preliminary information and fact-finding demonstrate credible evidence of honest error or a difference of opinion as a defense to the allegations:

(2) Preliminary information-gathering and fact-finding from the inquiry provides a ***reasonable basis*** for concluding that the allegation has substance**; *and***
(3) Preliminary information-gathering and fact-finding from the inquiry provide credible evidence that the allegations do not stem from honest error or a difference of opinion.

e. ***§93.307(g), Inquiry report and §93.311(a) Time limit for completing an investigation***

Major Topics Addressed in this Response:

- Eliminate 60-day deadline for inquiry in §93.307(g)
- Eliminate 120-day deadline for investigation in §93.311(a)
- Acknowledge that the timeline depends on facts and circumstances of each case and replace each deadline with a requirement for the institution and ORI to develop a schedule for completion of the inquiry/investigation
- Acknowledge extensions may be granted per reasonable request and progress reports may be required.

Section 93.307(g) states that the time for completion of the inquiry is 60 days from the date of initiation, and §93.311(a) states that the time for completing an investigation is within 120 days of its initiation. Each of these timelines is an arbitrary number that applies regardless of the nature of the case and neither has proved to be a realistic estimate of the time required to conduct an inquiry or investigation. In fact, many investigations may take a year or more to complete, and ORI has addressed this issue by granting extensions in response to institutional requests.

The time required to conduct either an inquiry or investigation is completely dependent upon the individual circumstances of the case and calculating this time is complex. Accordingly, rather than attempt to determine a specific completion period that applies in all cases, [redacted] suggest that in the case of inquiries, ORI require institutions to diligently pursue their conduct,

while affording the institution the discretion to set its own timetable based on the circumstances of the case. In the case of investigations, we suggest that the current 120-day deadline be deleted, and the institution propose, for ORI's acceptance, a schedule for the completion of the investigation, with full recognition by the institution and ORI that this schedule may require adjustment as circumstances develop. Below, suggested revised provisions are set forth:

> **§93.307(g): Time for completion**: The institution must undertake and diligently conduct the inquiry and complete it within a reasonable time based on the facts and circumstances of the case. In the event ORI reasonably believes that the inquiry is not being conducted diligently, it may require the institution to provide a progress report that describes remaining steps and an estimate of the time by which the inquiry will be completed, with follow-up reports, as necessary.
>
> **§93.311(a), Time limit for completing an investigation:** An institution must diligently conduct the investigation and complete all aspects of the investigation (including conducting the investigation, preparing the report of the findings, providing the draft report for comment in accordance with §93.312, and sending the final report to ORI under §93.315) within a reasonable time based on the facts and circumstances of the case. At the beginning of the investigation, the institution shall provide ORI, for ORI's approval, a tentative schedule indicating when the investigation will be completed. Recognizing that the complexity of research misconduct proceedings makes it difficult to predict a completion date, ORI may grant an institution one or more extension(s) of the investigation period, based on written request(s) of the institution that identifies reasonable facts and circumstances supporting the extension. In the event ORI reasonably believes that the investigation is not being conducted diligently, it may require the institution to provide a progress report that describes remaining steps and an estimate of the time by which the investigation will be completed, with follow-up reports, as necessary.

QUESTION 2: WHICH SECTION(S) SHOULD BE RETAINED AS IT CURRENTLY IS IN 42 CFR PART 93? WHY?

42 CFR §93.103, Research Misconduct

Major Topics Addressed in this Response:

- Do not expand definition of "research misconduct" under §93.103 to address:
  - Behaviors encompassed under scientific or research integrity.
  - Misconduct beyond falsification, fabrication, or plagiarism
- Reconsider the current definition of "plagiarism" under §93.103(c).

A key provision of the current Research Misconduct Policies that should remain unchanged is the definition of the term "Research Misconduct," which is limited to "fabrication, falsification, or

plagiarism [FFP] in proposing, performing, or reviewing research, or in reporting research results." The term research misconduct should not be replaced by or conflated with the terms "research integrity" or "scientific integrity," each of which encompass a more diverse array of behaviors and threats, including bias, reproducibility, and data security.[5] The process set forth in the Research Misconduct Policies for examining and adjudicating allegations of "research misconduct" is tailored to examining allegations of FFP and would be unwieldy when applied to broader terms. Rather, the concepts of "research integrity" or "scientific integrity," should continue to be addressed through separate requirements such as those pertaining to training in the responsible and ethical conduct of research.[6]

Along the same lines, we contend that the definition of research misconduct should not be altered to incorporate behavior beyond FFP. For example, certain individuals and groups recommend that behavior such as failure to disclose "foreign research ties" should be investigated as "research misconduct."[7] Similarly, some individuals/groups believe that sexual harassment should be treated as research misconduct.[8] We strongly disagree. Institutions have developed mature programs to meet the requirement for handling allegations of research misconduct that include elements specifically developed for scientists to effectively review claims of fabrication, falsification, or plagiarism. These programs include elements such as sequestration of evidence and consideration of whether there has been a significant departure from the scientific standards of the relevant research community, and these processes that would be ineffective and inappropriate for the assessment of other types of allegations.

We fully support steps already taken to improve related reporting, investigation, and sanctions for research security concerns, harassment, and bullying. However, we firmly believe that these activities should ***not*** be reviewed under an investigational process that was specifically designed to examine accuracy of the scientific record. Instead, existing pathways designated for the investigation of malign foreign influence or sexual harassment should be utilized, as these processes were developed specifically for, and contain procedural protections that are unique to, these subject areas Similarly, if the review of research misconduct allegations unearths evidence of harassment, undisclosed conflicts of interest, or other prohibited behaviors, referrals are made to the appropriate institutional officials/processes specifically designated for investigating those

[5] *See, e.g.,* National Science and Technology Council (STC), Scientific Integrity Fast-Track Action Committee, Protecting the Integrity of Government Science (Jan. 2022) at p. 1-2 (identifying principles of scientific integrity); U.S. Dept. of Agriculture, Scientific Integrity and Research Misconduct webpage (accessed Oct. 5, 2022) (identifying research misconduct as compromised subset of research integrity).
[6] National Institutes of Health (NIH), *FY 2022 Updated Guidance: Requirement for instruction in the Responsible Conduct of Research* (NOT-22-055) (Feb. 17, 2022).
[7] Mervis, J., *U.S. Scientists who Hide Foreign Ties Should Face Research Misconduct Sanctions, Panel Says*, SCIENCE (Dec. 11, 2019).
[8] Marin-Spiotta, E., *Harassment Should Count as Scientific Misconduct*, NATURE (May 9, 2018); Kuo, M., *Scientific Society Defines Sexual Harassment as Scientific Misconduct*, SCIENCE (Sept. 20, 2017) (American Geophysical Union adopts policy that considers sexual harassment to be a type of scientific misconduct).

allegations. To do otherwise, risks running afoul of laws, regulations, policies, processes, and concerns specific to these areas.

Additionally, we believe that ORI should take this opportunity to reconsider its definition of plagiarism. Section 93.103(c) currently defines plagiarism as the "appropriation of another person's ideas, processes, results, or words without giving appropriate credit," yet the plagiarism of "ideas" is extremely difficult to prove (e.g., the accused may have access to many different public documents that would disprove a complainant's allegation of plagiarism of ideas). Similarly, ORI has recognized in guidance that collaborators' use of joint research without appropriate attribution is an authorship matter, as opposed to plagiarism. ORI should consider these concerns and address them through revisions to the definition.

QUESTION 3: WHICH SECTION(S) SHOULD BE CONSIDERED FOR REMOVAL WHEN REVISING 42 CFR PART 93? WHY?

Major Topics Addressed in this Response:

- Eliminate Subpart E and revise appeals process to call for direct appeal to the Assistant Secretary of Health.

[redacted] advocate for eliminating the current Subpart E and replacing it with an appeals process that is simpler for respondents to navigate. Currently, Subpart E calls for a hearing before an administrative law judge (ALJ), who makes a recommendation to the Assistant Secretary for Health (ASH). The ASH may modify or reject the ALJ's decision if it is found to be arbitrary and capricious or clearly erroneous as detailed in §93.523. If debarment or suspension is part of the recommended administrative actions, the debarring official makes the final Department of Health and Human Services (HHS) decision on those actions.

A much simpler process would be to have a respondent direct their appeal to the ASH, who would review it and make a recommendation to the Secretary of HHS or the Deputy Secretary of HHS (or their designee), who would decide the appeal. This type of process is currently in use at the National Aeronautics and Space Administration,[9] the National Science Foundation,[10] the Veterans Administration,[11] and the Department of Department of Defense,[12] and adopting this recommendation would align the HHS appeals process with that of other federal agencies.

[9] 14 CFR §1275.108.
[10] 45 CFR §689.10.
[11] Veterans Health Administration Directive 1058.02 (Jul. 10, 2020).
[12] Dept. of Defense, Instruction 3.7 (Oct. 15, 2018).

CONCLUSION

It is always good practice to periodically review regulations to determine whether changes need to be made to better achieve regulatory goals. [redacted] support ORI in its efforts to undertake such a review of the Research Misconduct Policies, and we are grateful to ORI for not undertaking this review in a vacuum, but rather reaching out to the stakeholder community for input. We hope that the comments and recommendations set forth herein will assist ORI in its mission, and any questions regarding this transmittal may be directed to [redacted] We look forward to continuing the dialog with ORI on any proposed changes to the regulations at 42 CFR Part 93, and once again thank the agency for this opportunity to submit comments.

Sincerely,

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Cc: [redacted]
Subject: Comments on RFI (F.R. Doc Doc. 2022–18884)
Date: Monday, October 31, 2022 4:31:40 PM
Attachments: 2022-10-31 LTR ORI Req for Info on 2022–18884.pdf

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Dear Dr. Jones,

Please find attached comments in response to the "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct," published on September 1, 2022 (*F.R. Doc Doc. 2022–18884*). We deeply appreciate the collaboration of ORI and your efforts to gather feedback directly from the community.

Best,

[redacted]

[redacted]

October 31, 2022

Delivered via Email to: OASH-ORI-Public-Comments@hhs.gov
Wanda K. Jones, Dr.P.H.
Acting Director
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

Dear Dr. Jones,

This letter is submitted in response to the "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct," published on September 1, 2022 (*F.R. Doc Doc. 2022–18884*). On behalf of the signatory institutions, our thanks to the Office for Research Integrity (ORI) for seeking feedback from the community in advance of anticipated work toward an updated regulation at 42 CFR Part 93. This letter is a supplement to and additional endorsement of views provided by the signatory institutions through other organizations' submissions, including in particular, [redacted]. This additional letter is intended to provide a more direct perspective from members of our faculty community as represented by the [redacted] As you may be aware, the [redacted] is a [redacted] standing committee comprised of senior faculty members charged with the oversight of completed investigations of allegations of research misconduct[1] against any member or former member of the [redacted] academic community, including academic appointees who may be or have been employed by any one of [redacted] when the alleged misconduct occurred. The [redacted] oversight covers approximately [redacted] appointees at any given time and some of its members have served on this Committee for decades. In addition, the [redacted] is responsible for making recommendations to the institutions' Deciding Officials regarding appropriate sanctions and/or other institutional actions in response to investigations' findings. During the last [redacted] years, members of this committee have also

[1] The [redacted] is also responsible for the [redacted] that concludes additional [redacted] is not required.

[redacted]

directly staffed, as a single member panel, each inquiry commenced by [redacted] in collaboration, as applicable, with its affiliated institutions. This has provided them with additional practical experience about the beginning stages of our process.

As faculty members with [redacted] the members of the [redacted] also have broad [redacted] and have witnessed, through their service, the impact of research misconduct matters on those involved, including respondents, complainants, witnesses and staff. Members of the [redacted] were asked to provide individual and representative feedback from peers on the application of the PHS Policies on Research Misconduct through 42 CFR Part 93. Importantly, like the views of the larger faculty community it serves, the [redacted] views were neither static nor uniform. Members stressed that the world of science is predicated on trust and breaches of such trust harm not only those who may be directly impacted in the field, but also the larger scientific community comprised of truly exceptional and dedicated individuals for whom any loss of trust by the public may be devastating. At the same time, members of the committee highlighted that scientists are only human and that labeling any error as possible misconduct, particularly when it took place many years earlier and records may not be available, can undermine our goal of nurturing a professional community that is motivated to transparently acknowledge, accept, rectify and learn from mistakes.

Nonetheless, important themes emerged that we convey in this letter. Critically, each comment should be read in the context of the larger goals of the policies' framework: the process should be designed to effectively foster an environment that *promotes research integrity and discourages research misconduct*.

With this background, we offer the following comments for consideration by ORI:

1. Statute of Limitations & Subsequent Use Exception: 42 CFR §93.105(a) states that the regulation "*applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation of research misconduct." Among the exceptions is the subsequent use exception, which states: "The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized*."

    - While several members of the committee supported eliminating the subsequent use exception altogether, citing the unfairness of a potentially indefinite look back for misconduct allegations consistent with views expressed by [redacted] others were more concerned about the impact of allowing continual personal benefit from wrongdoing, whether past or present.

- That said, it was generally agreed that, regardless of the mechanism by which this is achieved, the subsequent use exception should be better harmonized with records retention policies and expectations (e.g., NIH), as the status quo currently leads to unfair situations in which people who complied appropriately with record retention policies at the time are nonetheless unable to defend themselves from allegations years later.
- There was also general consensus that ORI should provide additional guidance on: (i) the kinds of citations that should be interpreted as renewing and/or continuing alleged misconduct; and (ii) the types of activities that are "for the potential benefit" of a respondent. The boundaries of the subsequent use exception should be communicated clearly to the research community as deterrent goals may be achieved only with better understanding of the scope of the required review.

2. Required mental state for finding of research misconduct: 42 CFR §93.104 states: "*A finding of research misconduct made under this part requires that (a)There be a significant departure from accepted practices of the relevant research community; and (b)The misconduct be committed intentionally, knowingly, or recklessly; and (c)The allegation be proven by a preponderance of the evidence*.
    - Several members of the committee supported eliminating the term "reckless" from the required mental state pointing to: (i) the ambiguity of the term; (ii) the experience of the committee that most panel members struggled with its application; and (iii) a general concern that the serious consequences of a research misconduct finding may not be appropriate for reckless conduct. These members encouraged PHS to consider whether NIH's ongoing efforts to require data management and sharing plans might be more effective at motivating institutions and laboratory leaders to target resources to address the root cause of some of the issues that result in findings of recklessness in research misconduct proceedings.
    - Other members of the committee expressed concern that the impact of reckless conduct, particularly by a principal investigator charged with the oversight of research in their laboratory, can have potentially an even greater negative impact on research integrity than an individual contributor's knowing or intentional conduct. These members wanted to retain recklessness in the definition of research misconduct.
    - All agreed, however, that additional guidance from ORI on the application of the reckless standard is needed. Inconsistent application and misunderstanding from the larger academic community, particularly principal investigators, regarding the kind of conduct that may be considered reckless, undermines the goals of including this term in the definition of misconduct and complicates the process.

3. Timeliness & Special Circumstances/Expedited Process:

    - All members of the committee agreed that a timely and efficient review is critical to an effective research misconduct proceeding. Nonetheless, each matter is different and ORI should work closely with institutions to decrease the barriers to efficiency with goals of process in mind. Members did not believe that arbitrary deadlines were effective and cautioned regarding the unrealistic expectations they may set to the detriment of individuals and the process. At the same time, direct experience of the committee supports the negative impact of prolonged review on respondents, complainants, witnesses, panels and the larger scientific community. To this end, ORI should provide additional opportunities for expedited review when: (i) data are unpublished; (ii) the respondent is no longer affiliated with the institution; (iii) the respondent is willing to provide admission in whole or in part; and/or (iv) other specific circumstances that allow for an abridged process without undermining overall goals of the PHS policies.

5. Confidentiality

    - The committee agreed that, in view of the high sensitivity and stakes, respondents should be presumed to have not committed research misconduct unless or until there is a finding of research misconduct. ORI should bear in mind that as the scope of the regulations expand (i.e., low bar to initiating inquiry, longer look back as a result of subsequent use exception and continued inclusion of reckless standard), the importance of strict confidentiality while a review is ongoing increases. The impact of irreversible reputational harm caused by premature disclosure on a scientist who may be wrongfully accused damages not only that individual, but also undermines the trust of the entire scientific community in the integrity of the process. Although the current regulations provide appropriate emphasis on an institution's obligation for confidentiality, they fail to codify ORI's obligations of confidentiality. The committee is troubled by the lack of transparency regarding communication between agencies and any erosion of the respondent's rights to a full review.
    - In recent years, ORI has seemed to exclude an institution's communications with the NIH from the institution's obligations for confidentiality. Although it is indisputable that institutions must take appropriate steps to safeguard NIH funds, the enumerated exigent circumstances (42 CFR Section 93.318) for disclosure set forth in the current regulation do not extend to notification of sponsor agencies prior to conclusion of an investigation unless the institution, in good faith, has assessed there to be an ongoing risk that (i) HHS resources or interests are threatened or (ii) research activities should be suspended; In those cases, the

institution is obligated to notify ORI of the special circumstances. Whereas the committee applauds the good intentions of the NIH Office for Research Integrity's directives on communication during a misconduct matter, interpretation of these directions and the obligations they impose with regard to timing, content and detail vary. We remain concerned that such directives place an institution in the untenable position of choosing whether to abide by the confidentiality obligations set forth in 42 CFR Part 93 or the NIH's instructions.

- We encourage ORI to work closely with its partner HHS funding agencies to clarify: (i) what, with whom and when ORI shares information with partner agencies; and (ii) other than the enumerated special circumstances in Section 93.318, whether an institution can communicate with other agencies or sponsors during a research misconduct proceeding even if such communication is not required to carry out the investigation.

In conclusion, we extend our deep appreciation to ORI for seeking the perspectives of the community with regard to the Research Misconduct Policy and proposed changes. We reiterate our deep desire for ORI to take additional steps to seek meaningful feedback from the scientific community, including faculty, researchers and research support staff most impacted by these regulations. We ask that changes be narrowly tailored to our collective goal of safeguarding the integrity of scientific work for the benefit of the larger scientific community and building trust in the fairness, equity and reliability of institutional processes. We look forward to continuing our discussion with ORI on any proposed changes to the regulations at 42 CFR Part 93. Our thanks again for considering these comments.

Yours truly,

From: [redacted]
To: OASH ORI Public Comments
Cc: [redacted]
Subject: Regulations RFI
Date: Monday, October 31, 2022 4:34:53 PM

To whom it may concern,

In August 2022, [redacted] in Retraction Watch about a PI who published data in his peer-reviewed paper, without properly attributing that the source of the data was another laboratory. [redacted] this is fabrication, since the individual who published the data implied it was his own and in subsequent review articles described the work as having been done by his laboratory [redacted] the data given to him from the other laboratory were likely fabricated by that laboratory, since it seems unlikely that animals used in the experiments were transferred between institutions. ORI could easily determine this by asking the PIs and their institutions for the animal transfer records.

[redacted] it is essential that all sources of published data be clearly stated in papers and that publishing someone else's data without proper attribution should be research misconduct. One can easily envision scenarios in which two separate groups publish each other's data without proper attribution to make findings appear to have be independently discovered. In the case that [redacted] in Retraction Watch, [redacted] this has cost taxpayers millions of NIH dollars to support faulty, and probably fraudulent, research.

Pasted below is the link [redacted] Retraction Watch post.

https://retractionwatch.com/2022/08/31/when-an-independent-replication-isnt-really-independent/

Sincerely,

[redacted]

From: [redacted]
To: OASH ORI Public Comments
Subject: 42 C.F.R. Part 93 Research Misconduct - Regulations RFI
Date: Monday, October 31, 2022 4:40:00 PM

To Whom It May Concern,

The following are some suggested modifications of 42 CFR part 93, dealing with the handling of research misconduct, made in response to a Request for Information (RFI) by the HHS Office of the Secretary. Recommended changes to relevant text of the code are presented within brackets, or by strikethroughs of existing text. Associated comments follow suggested changes. (Font emphasis was added here to parts of the regulatory text.)

I. Recommended modifications to 42 C.F.R. § 93.100 (General Policy) part (b):

"(b) The U.S. Department of Health and Human Services (HHS) and institutions that apply for or receive Public Health Service (PHS) support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training ***share*** responsibility for the integrity of the research process. **HHS has *ultimate* oversight [**RECOMMENDED ADDITION: **RESPONSIBILITY and] authority** for PHS supported research, and for taking other actions ***as appropriate or necessary***, including ***the*** **[**RECOMMENDED REPLACEMENT: **DUTY and REQUIREMENT]** ~~***right***~~ ***to assess allegations*** and perform inquiries or investigations at any time."

"Institutions and institutional members have an ***affirmative duty*** to protect PHS funds from misuse by ensuring the integrity of all PHS supported work, and ***primary responsibility*** for ***responding to and reporting allegations*** of research misconduct, as provided in this part." [RECOMMENDED ADDITION: **"HHS has a MANDATORY DUTY and REQUIREMENT to establish and maintain FULL AUDIT FUNCTIONS AND CONTROLS over all aspects of the research misconduct process. In performing its audit functions, HHS is required to meet FULL INDEPENDENCE and other FEDERAL AUDIT STANDARDS, as applied specifically to EVIDENTIARY and PROCEDURAL AUDIT of the research misconduct process.**"

Comments: HHS takes ultimate responsibility for oversight. However, doing so effectively will require making many more of ORI's functions mandatory, rather than discretionary, and most importantly, instituting independent audit procedures of research misconduct program.

II. Recommended modifications to 42 C.F.R. 93.105 (Time limitations) parts (a) and (b)(1):

(a) ~~*Six-year limitation.* This part applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation of research misconduct.~~ [**RECOMMENDATION TO STRIKE** the limitation in 93.105(a).

Comment: The time limitation can produce **clashes with grant funding clawback provisions,** and **it can also produce an incentive to obfuscate, delay, and otherwise promote acceptance of misconduct**. Requirements to retain laboratory and administrative records in primary and/or archival forms should be adjusted as necessary to permit subsequent reviews.

(b) *Exceptions to the six-year limitation.* Paragraph (a) of this section does not apply in the following instances:
(1) *Subsequent use exception.* The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized. [RECOMMENDED

ADDITION: "**CONTINUING GRANT RENEWALS based in any part on allegedly falsified or fabricated evidence shall be considered within the scope of this exception.**"

Comment: At least one federal court has interpreted grant renewals as not falling under such continuing fraud prohibitions. Therefore, making such coverage explicit could be helpful, in particular in allowing ORI and NIH to effectuate grant fund clawback provisions, and avoiding other statute of limitation problems in court.

III. Section 93.307 (Institutional inquiry) part (a)(3), (b), and (c)

(a) *Criteria warranting an inquiry.* **An inquiry is warranted if the allegation**-
(1) Falls within the definition of research misconduct under this part;
(2) Is within §93.102; and
(3) Is ***sufficiently credible and specific*** so that potential evidence of research misconduct may be identified.

Comment: Auditability of the inquiry initiation process would encompass the handling of allegations. But what is "sufficient" about credibility, and how "specific" must evidence be? This is an example of why federally compliant evidentiary audit standards should be instituted within these regulations. (See also Sci Eng Ethics. 2016 Aug;22(4):1027-1049.) **It is strongly recommended that this RFI be presented to the federal CIGIE for comment,** along with other U.S. and international audit societies, such as the Institute of Internal Auditors.

(b) *Notice to respondent and* ***custody of research records****.* At the time of ***or before beginning an inquiry***, an institution must make a good faith effort to notify in writing the presumed respondent, if any. If the inquiry subsequently identifies additional respondents, the institution must notify them. ~~To the extent it has not already done so at~~ [RECOMMENDED STRIKES and REPLACMENTS: "[**At**] the allegation stage, the institution must, **on or before the date on which the respondent is notified** or the inquiry begins, whichever is earlier, **promptly take** ~~***all reasonable and practical steps to obtain***~~ **custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner**, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

Comment: Recommendation is made to strike out language permitting any intuitional discretion, e.g. by their own interpretations of "reasonable and practical", to not take timely custody of all relevant records at the earliest moment. Ensuring the acquisition of all relevant evidence would promote more effective assessment and auditability of allegations. If comprehensive acquisition and archiving of research records really cannot be accomplished, the institution can document why not, and such claims can themselves be audited.

(c) *Review of evidence.* The purpose of an inquiry is to conduct an initial review of the evidence to determine whether to conduct an investigation. Therefore, an inquiry does not require a ***full*** **[EXPERT]** ***review*** of all the evidence related to the allegation, [RECOMMENDED ADDITION: "**which would be a function of an investigating committee.**"]

Comment: The use of the term "full" is not clear, unless by "full review" the authors were trying to say that a full EXPERT review was not necessary. That would presumably be the purpose of an investigatory panel.

IV. Section 93.308 (Notice of the results of the inquiry) (b)

(b) *Notice to complainants.* [RECOMMENDED STRIKEOUTS, REPLACEMENTS, and ADDITIONS: "The institution ~~*may*~~ [**MUST**] notify the complainant who made the allegation whether the inquiry found that an investigation is warranted. The institution [**MUST**] ~~***may***~~ **provide [ALL]** ~~***relevant***~~ **portions of the report to the complainant for comment**."
[ADDITION: "**The complainant's comments at the conclusion of the inquiry process must be included with all other auditable materials and records."]**

[Comment: Protect the integrity of the process by keeping the complainant fully informed and involved. Otherwise, a disincentive to report could be exacerbated.

V. Section 93.402 (ORI allegation assessments) parts (a) and (b)

(a) When ORI receives an allegation of research misconduct directly or becomes aware of an allegation or apparent instance of research misconduct, it ~~***may***~~ conduct an initial assessment ***or*** refer the matter to the relevant institution for an assessment, inquiry, or other appropriate actions.
[RECOMMENDED CHANGE: "**When ORI receives an allegation of research misconduct directly,** it **MUST** conduct an initial assessment. It **may** refer the matter to the relevant institution for further assessment, inquiry, or other appropriate actions, **and/or directly investigate the matter further through use of an expert external panel**."]

(b) ~~*If*~~ **[WHEN]** ORI conducts an assessment, it considers whether the allegation of research misconduct appears to fall within the definition of research misconduct, appears to involve PHS supported biomedical or behavior research, research training or activities related to that research or research training, as provided in §93.102, and whether it is sufficiently specific so that potential evidence may be identified and sufficiently substantive to warrant an inquiry. ORI ~~*may*~~ **[MUST]** review all ~~*readily accessible*~~, relevant information related to the allegation.

Comments: Amending this section to **make ORI's performance more mandatory** could provide a means of comparing the interest of informants in contacting ORI directly, rather than working solely within their institutions. The latter is known to be a very highly risky prospect to the informant. By contrast, ORI might be less conflicted than the affected institution in honoring confidentiality and anti-retaliation requirements needed to protect the confidential informant/complainant. (Anonymous reporting options could also be specified in these regulations). The addition of an expert panel option to assist ORI could potentially allow auditors to compare such outcomes with those produced by using a fully institutional route.

VI. Additional recommendations

There are many other points which could be revised or written with greater stringency in these regulations. For instance:

> Section 93.316 (Completing the research misconduct process) part (a)
"(a) ORI **[REQUIRES]** ~~***expects***~~ institutions to carry inquiries and investigations through to completion"

> Section 93.300 (General responsibilities for compliance) part (b)
"Institutions under this part **must** -
(b) ***Respond*** to each allegation of research misconduct for which the institution is responsible under this part in a ***thorough, competent, objective and fair manner***, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses;

Comment: The specification of part 93.300 (b) are too vague and undefined to provide for any required actions. Definitive requirements should be specified and the standards for such referenced. Similar concerns exist for the phrase “all reasonable and practical steps” in parts (d) and (f) of this section.

> Section 93.319 (Institutional standards) part (a)

(a) Institutions may have internal standards of conduct **[**RECOMMENDED REPLACEMENT AND STRIKE: **“*~~different from~~* [MORE STRINGENT THAN] the HHS standards for research misconduct under this part.** Therefore, an institution may find conduct to be actionable under its standards even if the action does not meet this part's definition of research misconduct.”

Comment: Consider a scenario whereby the institution's standards are more lax than those within federal regulations. This possibility should be ruled out explicitly.

> A section specifically addressing audit functions should be added to these regulations.

For example, new language could be added along the lines of “HHS will also fully comply with regular **PERFORMANCE AUDITS** of its own functions under this Section, including by providing full and direct access to all records which auditors may deem relevant at any institution over which HHS has oversight authority, as well as access to its own staff, records, and any other materials independent auditors may seek." Also potentially of value: "All audit records and reports shall be made **PUBLIC** in a fully detailed but anonymized form.”

In conclusion, in furtherance of the above recommendations, HHS is urged to bring in expert audit organizations, in particular the federal CIGIE, to comprehensively address improvements to 42 C.F.R. Part 93, including with reference to the suggestions made above.

If further recommendations along the lines of the preceding are desired, the author can be reached at [redacted] For example, conflict of interest provisions could also be added to these regulations such as by instituting external assessment of allegations. (Sci Eng Ethics. 2016 Aug;22(4):1027-1049.)

Thank you.

[redacted]

From:	[redacted]
To:	OASH ORI Public Comments
Cc:	[redacted]
Subject:	Regulations RFI
Date:	Monday, October 31, 2022 4:55:09 PM
Attachments:	[redacted] Comment Letter on ORI RFI on Research Misconduct_FINAL_sig_10-31-22.pdf

To Whom It May Concern:

I write on behalf of [redacted] with regard to the Request for Information (RFI): Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct (87 FR 53750) issued on September 1, 2022.

The [redacted] is submitting comments electronically via email. Please see the attached letter.

If you have any questions concerning our comments, please feel free to reach out to me at [redacted]

Sincerely,
[redacted]

[redacted]

[redacted]

Submitted electronically to *OASH-ORI-Public-Comments@hhs.gov*.

October 31, 2022

Dr. Wanda K. Jones
Acting Director, Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: [redacted] Comments in Response to the HHS Regulations RFI, "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct"

Dear Dr. Jones:

I am writing on behalf of the [redacted] with regard to the "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct" posted in the *Federal Register* on September 1, 2022.

The [redacted] is comprised of [redacted] campuses, [redacted] academic health centers, and [redacted] affiliated [redacted] national laboratories. As a system, [redacted] receives approximately [redacted] annually of [redacted] NIH and NSF funding than any other institution in the country. The funds support research conducted throughout all [redacted]

The [redacted] maintains a longstanding commitment to adhere to the highest standards of intellectual honesty and integrity in research. [redacted] which highlights rigor, carefulness, and accountability as hallmarks of good scholarship. These values are mirrored in the 2005 Public Health Service (PHS) Policies on Research Misconduct. [redacted] appreciates the effort that the Department of Health and Human Services (HHS), Office of Research Integrity (ORI) is taking to re-evaluate the existing regulations and the opportunity to provide input on the direction of the policies [redacted] appreciates the working relationship it has with HHS when conducting investigations related to research misconduct, and emphasizes the need for the continued flexibilities to address each unique situation. While we believe most of the sections should be retained, there are certain areas where further guidance and clarity would be helpful. Our specific comments are provided below and were informed by those who work directly with the PHS Polices on Research Misconduct, 42 C.F.R. 93. We recognize that HHS asks for feedback on sections that should be changed, retained, or removed. While our comments respond to this request,

we provided our comments in order of priority. In addition, we highlight areas where changes to the regulations may not be necessary, but additional guidance would be helpful.

Lastly, [redacted] supports the sentiments captured in the comment letter submitted by [redacted]

1. **Sections that should be changed, retained, or removed**

    a. Definition of Research Misconduct [§ 93.103]

[redacted] recommends the definition of research misconduct as fabrication, falsification, or plagiarism in proposing, performing or in reviewing research or in reporting research results should remain the same and not be changed. [redacted] is concerned that efforts to expand the definition of research misconduct at § 93.103, incorporating questionable research practices or poor behavior in research as part of research misconduct, would result in the inappropriate application of the standards used to investigate research misconduct to questionable research practices, e.g., authorship disputes, or dishonest or poor behavior during peer review, or even abusive conduct. Such questionable or problematic research practices should remain outside of the definition of research misconduct. [redacted] believes the current procedures that apply to research misconduct are not suitable for addressing these other behaviors. Additionally, institutions often have other, sometimes state law mandated procedures, to deal with these questionable research practices and behavior. Expansion of the definition could bring these separate and distinct procedural actions in direct conflict with each other.

    b. Requirements for Findings of Research Misconduct [§ 93.104(b)]

[redacted] recommends that the regulations be changed to define the terms "intentionally," "knowingly," and "recklessly." Absent clear definitions and examples, institutions now apply differing standards. Clarification of the terms, with appropriate research misconduct related examples, especially as they relate to the term "recklessly," would help ensure consistency in investigations and assist institutions in making determinations of culpability.

    c. Distinction between Inquiries and Investigations

[redacted] recommends that ORI maintain its current distinction between an Inquiry and an Investigation. The distinction allows for determining whether sufficient evidence exists without undertaking additional obligations and responsibilities under an Investigation.

d. Timelines [§§ 93.307(g) & 93.311]

[redacted] understands that timelines serve as an important checkpoint for maintaining timely and forward momentum on responses to allegations of research misconduct and continuing communication with ORI. At the same time, [redacted] appreciates the flexibilities that ORI provided when [redacted] has sought extensions for completing an investigation.

At a minimum, [redacted] recommends that ORI harmonize its timelines with other agencies, such as National Science Foundation standards (90 days for inquiries; 180 days for investigations). This enables consistency in the conduct of inquiries and investigations. At the same, we strongly recommend that ORI continue to honor necessary extension requests. Finally, because research misconduct cases have levels of complexity not easily anticipated, [redacted] asks for ORI to consider modifications to timelines that take into consideration individual complexities.

e. Confidentiality [§§ 93.108, 93.300(e), & 93.304(a)]

[redacted] recommends confidentiality provisions include the protection of the confidentiality of witnesses. The regulations already provide for the protection of respondents and complainants, but are silent on witnesses. [redacted] feels strongly that ORI should extend confidentiality protection to witnesses. Witnesses can also be subject to retaliation from principals involved in the cases and may experience reputational harm from being involved in a research misconduct investigation. This extension of confidentiality would allow institutions to take extra steps to prevent these repercussions from happening or address them appropriately if they do.

Finally, [redacted] requests clarity on an institutions ability to maintain confidentiality standards in complex cases, such as those involving multiple institutions with potentially multiple principals at each location. In complex cases such as these, institutions can set expectations amongst themselves on how to apply confidentiality standards and what can be shared amongst the institutions to minimize breaches of confidentiality that may impact cases.

f. Subsequent Use Exception to the Six-year Time Limitation [§ 93.105(b)(1)]

The subsequent use exception as currently written is not sufficiently specific. This results in institutions going through time-consuming searches through old systems and paper records for data on publications from many years ago. Clarity and specificity in the regulations would help reduce over-expansive searches while still ensuring older instances of research misconduct may be investigated. In addition, [redacted] requests guidance on how to apply the subsequent use exception, specifically on the limitations to subsequent use, and requests ORI provide relevant examples of how the subsequent use exception be applied to research misconduct cases.

In addition, [redacted] recommends the regulations describe or provide definitions on what constitutes "other use for the potential benefit of the respondent." Does this refer to monetary benefit or professional benefit? Without parameters institutions are unsure of how to assess potential benefit to the respondent.

2. Areas where guidance would be helpful

a. Activities conducted within an Inquiry versus Investigation

[redacted] understands that an inquiry is a fact-finding and information gathering exercise. An investigation examines that evidence in depth to determine whether research misconduct has been committed by a particular respondent. Nonetheless, the line between inquiry and investigation is not always clear and often times inquiry committee actions bleed into investigative activities. For example, it can be difficult to distinguish the depth of review of the evidence between the two phases. [redacted] recommends ORI provide additional guidance or descriptive examples of the distinction between inquiry and investigation. Clearer parameters would allow institutions to better and more efficiently transition between the inquiry and investigation phases of research misconduct actions.

b. Accepted Practices of the Relevant Research Community [§ 93.104(a)]

[redacted] requests guidance on how institutions identify the "accepted practices of the relevant research community" and what constitutes a significant departure from those practices. There are differing understandings of what this phrase means, depending heavily on different fields of research. This can lead to broad scale review of a respondent's publications, grant applications, etc., which can divert time and effort from the immediate allegation and delay final conclusions and findings. [redacted] recommends ORI provide relevant examples that might be illustrative of a significant departure from accepted research practices.

Thank you for the opportunity to comment. We look forward to continued engagement on this important issue.

Sincerely,

From: [redacted]
To: OASH ORI Public Comments
Cc: [redacted]
Subject: Regulations RFI
Date: Monday, October 31, 2022 4:58:40 PM
Attachments: Response to ORI RFI (10.31.22).pdf

Dear Dr. Jones,

Please find attached a letter submitted on behalf of [redacted] and the [redacted], as well as the undersigned officials of some of the nation's leading academic and research institutions, in response to the request for information and comments on the 2005 Public Health Service Policies on Research Misconduct issued by the Office of Research Integrity on September 1, 2022. We greatly appreciate this opportunity to provide comments regarding the regulations governing research misconduct proceedings.

Should you have any questions regarding this letter, please do not hesitate to contact [redacted]

Best regards,

[redacted]

[redacted] [redacted]

October 31, 2022

BY EMAIL

Re: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Dear Dr. Jones:

This letter is submitted on behalf of [redacted] and the [redacted],[1] as well as the undersigned officials of some the nation's leading academic and research institutions,[2] in response to the request for information and comments (the "RFI") on the 2005 Public Health Service Policies on Research Misconduct (42 C.F.R. Parts 50 and 93), issued by the Department of Health and Human Services ("HHS"), Office of Research Integrity ("ORI") on September 1, 2022.[3]

[redacted] is a global law firm [redacted]. [redacted] associated with [redacted] and is dedicated to improving [redacted].

[redacted], [redacted], and officials of other institutions signing below (collectively referred to herein as the "undersigned," "us," or "we") have identified sections of 42 C.F.R. Part 93 that we believe warrant amendment or supplementation in order to revise, augment, or clarify existing requirements, as described below. Our specific comments and recommendations, offered in response to the RFI, are set forth below.

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[1] The responsibility for the content of this document rests with its authors, and not with the institutions with which [redacted].

[2] The officials are signing in their personal capacities and not on behalf of the institutions with which they are affiliated, with the exception of [redacted], which is signing as an organization.

[3] 87 Fed. Reg. 53750 (Sept. 1, 2022).

1. Guidance on the Multi-Part Structure of Research Misconduct Proceedings

Current Requirements

42 C.F.R. Part 93 requires research misconduct proceedings to follow a multi-part structure, beginning with a threshold review of the allegation and proceeding to an inquiry and an investigation, if warranted. The purpose of the inquiry is "to conduct an initial review of the evidence to determine whether to conduct an investigation," and the inquiry "does not require a full review of all the evidence related to the allegation[s]."[4] If the inquiry results in a finding that an investigation is warranted under the standards set forth at 42 C.F.R. § 93.307(d),[5] the institution must report to ORI the findings of the inquiry and provide the inquiry report.[6]

Suggested Revision, Augmentation, or Clarification

While the regulations provide for an inquiry to be a more preliminary, less exhaustive process than an investigation, we have observed that institutions often convene a committee to conduct a robust, investigation-like process at the inquiry stage, interviewing witnesses and reviewing research records, only to repeat this process at the investigation stage. It would be useful if ORI were to issue guidance that specifies the ways in which institutions have flexibility at the inquiry stage; may, in compliance with the regulations, conduct a more streamlined and simple process at the inquiry stage; and can incorporate findings from the inquiry into the investigation. ***Explicit guidance regarding the steps institutions do not need to take in order to satisfy regulatory obligations at the inquiry and investigation stages would be particularly helpful.*** For example, institutions would benefit from express ORI guidance that they do not need to (1) convene committees of experts to conduct reviews at the inquiry stage to determine whether an investigation is warranted; (2) call witnesses for full recounts of the facts at the inquiry stage, if such recounts are not needed to determine whether the investigation is warranted; or (3) repeat in the investigation stage an interview conducted in the inquiry, unless the investigation committee believes that another interview could reasonably be expected to yield additional material information.

It would also be of enormous practical help if ORI could ***clarify that institutions may close out a proceeding at the inquiry stage if the evidence is straightforward and overwhelming or if honest error explains the data problems***. In cases in which the institution expects to close out proceedings at the inquiry stage due to a clear finding that there was no research misconduct, such as a finding of honest error, it would be reasonable for ORI to expect institutions to have conducted a robust inquiry, in order to justify the abbreviated proceeding. Finally, it would be useful if ORI could adopt the position, either in regulation or in guidance, that the Research Integrity Officer or another designated institutional official could perform the inquiry, with, if needed, one or more appropriate subject matter experts, without the need for a committee with multiple members. Although the current provisions of Part 93 would appear to allow this, many institutions self-defer from this alternative because it is not cited as an explicit option in Part 93. We believe that such ORI guidance would provide comfort to institutions that

[4] 42 C.F.R. § 93.307(c).

[5] 42 C.F.R. § 93.307(d).

[6] 42 C.F.R. § 93.309(a).

they can conduct a more streamlined process at the inquiry stage in full compliance with the regulations, thereby preserving resources and allowing for more rapid completion of research misconduct proceedings.

2. Definition of Recklessness

Current Requirements

42 C.F.R. Part 93 states that a finding of "research misconduct" requires demonstration by a preponderance of the evidence that falsification, fabrication, or plagiarism was committed ***intentionally***, ***knowingly***, or ***recklessly***.[7] The intentional, knowing, or reckless action must constitute "a significant departure from accepted practices of the relevant research community."[8] We have observed through our experience that the "intentionally" and "knowingly" standards are readily understood with reference to the plain meanings of such terms in everyday use. "Intentionally" means that the research was carried out with the respondent's specific intent to falsify, fabricate, or plagiarize. It equates to the highest level of culpability of the three standards set forth in the regulatory text. "Knowingly" means that the respondent knew the research was falsified, fabricated, or plagiarized. "Knowingly" equates to a lower standard of culpability than "intentionally" because, while it implies the respondent ***knew*** the research misconduct was carried out, it does not require the respondent to have ***intended*** the research misconduct to have been carried out. Unlike knowing and intentional conduct, however, reckless conduct cannot be defined with reference to an everyday standard, and "reckless" is not defined under 42 C.F.R. Part 93. Participants in the research misconduct proceeding typically understand the "recklessness" culpability standard to fall below intentional and knowing (both of which constitute research misconduct and are included in its definition) and above honest error and negligence (neither of which constitutes research misconduct, as set forth in the regulatory text).[9] In our experience, a broad range of conduct often exists between "knowing" conduct and "negligent" conduct in the context of a research misconduct proceeding, and fact-finders and decision-makers struggle to frame and apply an appropriate "recklessness" standard to the respondent conduct they are charged with reviewing.

In our experience, this issue arises most often in research misconduct proceedings concerning respondents who supervised, but did not directly perform, the research at issue. In such instances, the respondent often is, for example, the senior or corresponding author on a publication that uses data found to have been falsified, fabricated, or plagiarized. Evidence in these cases often suggests that the supervising respondent did not know of the problematic data at the time the paper was submitted, but as supervisor, the individual undoubtedly possesses essential responsibility for ensuring the integrity of the research (*e.g.*, if the research at issue was disseminated from the individual's lab). In the absence of knowing or intentional conduct, the question then becomes whether the failure to ensure the integrity of the research should be construed as "reckless," such that the respondent should be judged guilty of research misconduct, or mere negligence or honest error, such that the respondent should be judged not to have engaged in research misconduct. The lack of a clear standard or guidance articulated for

[7] 42 C.F.R. §§ 93.103 and 93.104 (*emphasis added*).
[8] 42 C.F.R. § 93.104.
[9] 42 C.F.R. § 93.103.

"recklessness" leads to problematic outcomes, such as time spent seeking to articulate the appropriate standard, and, most alarmingly, inconsistency in outcomes for respondents when, in different proceedings, the individuals charged with judging respondent conduct come to different conclusions regarding the definition of "recklessness" to be applied.

Suggested Revision, Augmentation, or Clarification

For the reasons noted above, we respectfully request further guidance on the standard required for respondent conduct to be determined "reckless." Within sub-regulatory guidance, for example, ORI could incorporate a definition of "recklessness" and examples of actions that do and do not amount to "recklessness," giving stakeholders a more detailed and helpful framework by which to assess the conduct with which they are presented. ORI could consider making clear in such guidance that a finding that conduct did not rise to the level of "recklessness" does not preclude a determination that the conduct constituted a violation of professional standards warranting remediation under an institution's policy.

We believe that these or other changes to the recklessness framework under 42 C.F.R. Part 93 would help to ensure that different fact-finders can reach more consistent decisions under similar fact sets, leading to more efficient and fair outcomes.

3. <u>Confidentiality and Communications with Journals</u>

Current Requirements

42 C.F.R. § 93.108 governs the confidentiality of research misconduct proceedings, limiting the disclosure of "the identity of respondents and complainants" and "records or evidence from which research subjects might be identified" only to those who "***need to know***" such information. Various stakeholders, including institutions, respondents, and their respective counsel have struggled to limit any publicity of the facts surrounding the research misconduct proceeding, in particular the identity of the respondent, and have grappled with defining an appropriate standard for when there is a "need to know." We have observed this issue in particular when allegations are raised amidst institutional personnel issues, such as respondents being put up for tenure or junior investigators or staff at risk of losing employment; additional compliance concerns at the institution stemming from the alleged misconduct, such as suspensions of grant draw-downs or institutional review board proceedings; and most acutely, questions over the appropriate course of conduct with respect to journal articles that include research that is the subject of an ongoing or completed research misconduct proceeding.

Suggested Revision, Augmentation, or Clarification

ORI would do a great service to the regulated community if, in guidance, ORI would provide examples of circumstances in which there is a legitimate need to inform persons outside of the research misconduct process of aspects of that process, even though the process has not yet concluded. The examples should not be exclusive, but having such examples drawn from common institutional circumstances would assist institutions in dealing with operational challenges. We also believe that it would be helpful for ORI to distinguish more clearly if any confidentiality obligations continue to apply following a finding that there was research misconduct or that there was not research misconduct. We would suggest that if,

following conclusion of the research misconduct proceeding, a respondent is found to have engaged in research misconduct, the priority should become the institution's ability to address the necessary follow-up in response to such a finding. The confidentiality obligation should be relieved such that institutions may address such follow-up through, for example, notification to administration, funders, institutional review boards, prospective employers of the respondent who inquire about past proceedings, journal co-authors and editors, and other entities and individuals without fear of violating the "need to know" standard.

If, on the other hand, the respondent is found not to have engaged in research misconduct, the priority should shift to rehabilitation and protection of the respondent's reputation. The confidentiality obligation in that case should remain, continuing to bind those who are aware of the proceedings from disclosing in the absence of a "need to know" scenario but permitting disclosure when required to clear the respondent's name – as when, for example, a prospective employer inquires about a past proceeding. We recommend that ORI specifically address, in guidance, situations in which a "need to know" requires the disclosure of information relating to a research misconduct proceeding in order to restore a respondent's reputation, and whether the respondent's prior consent must be obtained to make such a disclosure.

4. Statute of Limitations

Current Requirements

42 C.F.R. § 93.105(a) states that 42 C.F.R. Part 93 "applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation of research misconduct," with certain exceptions. One of these exceptions, which we refer to herein as the "Subsequent Use Exception," provides that the six-year statute of limitations period does not apply to the extent "[t]he respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized."[10] Moreover, we understand that ORI personnel have opined in recent months that mere inclusion of a paper in a researcher's curriculum vitae or in a grant biographical sketch could constitute a "use for the potential benefit of the respondent" and therefore could trigger the Subsequent Use Exception and, accordingly, re-toll the six-year statute of limitations period. Such an interpretation of the Subsequent Use Exception, if enforced by ORI, would divert critical institutional resources and attention away from more consequential subsequent uses of research, such as citations or republications in seminal, recent papers.

In our experience, the Subsequent Use Exception, as currently written, has created a significant burden for institutions. Institutions often are required to expend time and resources investigating allegations regarding papers that were cited within the last six years but that were themselves published decades ago, and yet to do so requires the expenditure of time and resources that could otherwise be dedicated to investigating allegations regarding more recently published, high-impact papers. Such efforts involve a particularly large expenditure of resources as institutions must seek to explore a body of work authored by individuals who have likely long moved on in their careers and may no longer be focused on the particular subject matter at issue.

[10] 42 C.F.R. § 93.105(b)(1).

We think it is important that institutions be allowed to focus their efforts and resources in the course of a research misconduct proceeding on investigating allegations relating to timelier or more significant uses of research, which have a greater present-day impact on the scientific community.

Suggested Revision, Augmentation, or Clarification

Given the issues described above, ***we request that ORI revoke or amend the Subsequent Use Exception.*** ORI could still encourage institutions, whether by regulation or through guidance, to provide for a longer statute of limitations period under certain circumstances as a matter of institutional policy, such as when a paper published more than six years before the institution received a related allegation of research misconduct is a landmark work in its field and is still frequently cited by other papers, or has formed the basis for patented intellectual property. We support the ability of institutions to use their discretion to review older published research on a case-by-case basis, rather than be required by regulation to review such older research. Further, we recommend that ORI not interpret "use for the potential benefit of the respondent" for purposes of the Subsequent Use Exception as including mere mention of a paper in a researcher's curriculum vitae or in a grant biographical sketch.

5. Retention of Data

Current Requirements

Neither ORI regulations nor ORI guidance specifies a minimum time period for which institutions must retain data to allow for subsequent confirmation of research findings and to facilitate the sequestration of evidence in the event that a related allegation of research misconduct arises. ORI guidance generally recommends that institutions maintain "a clear retention policy that balances the best interests of society with those of the research institution and the individual researcher," which may vary depending on the field and the institution.[11] As ORI guidance recognizes, different government agencies and programs set forth different requirements regarding the period of retention of data by researchers or institutions.[12] For instance, the National Institutes of Health ("NIH") Grants Policy Statement generally requires grant recipients to retain all records required by the terms of, or reasonably related to, a grant for a period of three years following the submission of the final financial report to NIH.[13] NIH's policy on Data Management and Sharing, set to go into effect on January 25, 2023, encourages researchers to follow longer retention periods than specifically required by NIH policy when factors such as value of the data set to the scientific community and the public warrant such longer retention.[14]

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[11] *See* ORI, *Data Protection – ORI Introduction to RCR: Chapter 6. Data Management Practices*, https://ori hhs.gov/content/Chapter-6-Data-Management-Practices-Data-protection.

[12] *See id.*

[13] *See* NIH, *NIH Grants Policy Statement*, https://grants nih.gov/grants/policy/nihgps/nihgps.pdf, § 8.4.2; *see also* 2 C.F.R. § 200.334 and 45 C.F.R. § 75.361 (providing for a three-year retention period).

[14] *See* NIH, *Final NIH Policy for Data Management and Sharing*, NOT-OD-21-013, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013 html.

By contrast, the Food and Drug Administration regulations require sponsors and investigators for Investigational New Drug and Investigational Device Exemption research to retain records for a period of two years from certain points set forth at 21 C.F.R. §§ 312.62 and 812.140, respectively. Meanwhile, under the Privacy Rule issued under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, research subjects generally have the right to receive an accounting of certain disclosures of their protected health information made in the six years preceding the request for an accounting, thus requiring study investigators to retain records of disclosures of certain study information for at least six years.[15] It therefore has fallen to institutions to develop their own standards regarding the period of retention of data in compliance with various, divergent regulatory requirements.

Suggested Revision, Augmentation, or Clarification

We recommend that ORI work with federal funding agencies whose research grants are governed by 42 C.F.R. Part 93 to ensure that the various agencies' data retention requirements are compatible. Further, we propose that ORI incorporate into the regulations at 42 C.F.R. Part 93 a requirement for institutions to retain data for a period of at least six years from the date of publication or at least six years from the final financial close-out of the grant that funded the project, whichever is later. This timeline would generally align with the six-year statute of limitations period discussed in Section 4 above. ORI could consider including in guidance the recommendation that, in the case of data relating to a published paper that is a seminal work, institutions should retain such data in perpetuity, and in the case of data that underlie the application for a patent in force, institutions should retain such data for the life of the patent.

6. Subsequent Allegations at Investigation

Current Requirements

42 C.F.R. § 93.310(h) requires institutions to "[p]ursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion."

We understand the importance of conducting a robust, timely assessment of any instances of possible research misconduct, including new allegations that arise during the course of an ongoing investigation pertaining to the respondent who is the subject of that investigation. However, in practice, the requirement set forth at 42 C.F.R. § 93.310(h) often makes proceedings unpredictably long and unforeseeably sprawling in scope. While we support ORI's authority and prerogative to direct evidence of additional instances of possible research misconduct to an institution at any point, including during a proceeding, we believe that institutions would be better able to pursue such leads diligently if they were permitted, but not required, to assess those allegations outside an ongoing investigation and to pursue any additional allegations in a later, separate proceeding or, in consultation with ORI, to use their discretion to resolve the allegations through methods outside the research misconduct process (*e.g.*, seeking retractions or corrections

[15] *See* 45 C.F.R. § 164.528.

to publications). Relatedly, the rise in online fora for discussing potential data integrity and research integrity issues, such as PubPeer.com, has compounded the problems of an institution being deluged with possible leads, which range widely in terms of significance and credibility, while the institution is trying to conduct a robust investigation regarding pending allegations of research misconduct. The repeated addition of new allegations to ongoing investigations is particularly onerous for smaller institutions with more limited resources.

Suggested Revision, Augmentation, or Clarification

Recognizing ORI's goal of balancing assurance that all allegations of potential research misconduct are adequately examined and assurance that allegations are appropriately resolved in a timely manner, ***we propose that ORI amend 42 C.F.R. § 93.310(h) to make clear that once a proceeding is at the investigation stage, the institution is not obligated to (but may choose to) add to the ongoing investigation new allegations pertaining to the same respondent that come to its attention during the investigation. Further, we would like to reinforce our position that anonymous allegations of data integrity or research integrity issues published on PubPeer.com or other websites should not be considered per se allegations of research misconduct under 42 C.F.R. Part 93 unless they have gone through the institution's process for reviewing allegations and conducting preliminary assessments of those allegations.*** We ask that ORI consider issuing guidance to make this point clear and definitive.

7. Time Limits

Current Requirements

42 C.F.R. Part 93 requires an institution to "complete the inquiry within 60 calendar days of its initiation unless circumstances clearly warrant a longer period," in which case "the inquiry record must include documentation of the reasons for exceeding the 60-day period"[16] and to "complete all aspects of an investigation within 120 days of beginning it, including conducting the investigation, preparing the report findings, providing the draft report for comment . . . and sending the final report to ORI."[17]

Suggested Revision, Augmentation, or Clarification

In our experience, these time limits are exceedingly difficult to meet (even when institutions are presented with relatively uncomplicated fact sets or "simple" cases, and particularly when additional allegations are added throughout the proceeding), requests for extensions (borne out of necessity) are common, and the possibility of seeing an inquiry or investigation through to a thorough completion in the required timeframes is remote. ***We therefore recommend that the regulatory timeframes be doubled to permit 120 days for completion of the inquiry and 240 days for completion of the investigation.*** Many proceedings would still necessitate requests for extensions due to the sheer volume of issues that must be chased down. However, we expect such requests would become less frequent and more

[16] 42 C.F.R. § 93.307(g).
[17] 42 C.F.R. § 93.3111(a).

institutions would find it possible to complete the inquiry and investigation within the stated time limits, thereby reducing the administrative burden both on ORI and on institutions.

8. Reporting to Federal Funding Agencies

Current Requirements

NIH has stated that an institution's "engagement with ORI as provided in 42 CFR Part 93 does not substitute for its engagement with NIH to ensure ongoing compliance with the terms and conditions of [an] award."[18] 42 C.F.R. Part 93 does not specifically address when and how institutions or respondents should report the status of ongoing proceedings or the results of such proceedings to NIH or other federal agencies that fund research falling under ORI's jurisdiction. Further, 42 C.F.R. Part 93 also does not specifically address if this reporting is consistent with the strict confidentiality requirements in 42 C.F.R. § 93.108.

Suggested Revision, Augmentation, or Clarification

It would be helpful if ORI could work with NIH and other federal funding agencies, including agencies that fund research not directly subject to 42 C.F.R. Part 93, such as the Department of Defense and the Department of Energy, to determine an appropriate standard for what should be reported to federal funding agencies regarding research misconduct proceedings, when those reports should be made, and whether these agencies meet the "need to know" criteria in 42 C.F.R. § 93.108.

9. Appeals

Current Requirements

42 C.F.R. Part 93, Subpart E governs appeals to administrative law judges in the event that findings of research misconduct are made by ORI. 42 C.F.R. § 93.519 applies the Federal Rules of Evidence to certain aspects of the appeals hearing process, such as admissibility standards for character evidence, and the inadmissibility of evidence about offers of compromise or settlement made in the action. Further, 42 C.F.R. § 93.519(b) allows administrative law judges to apply the Federal Rules of Evidence more broadly "where appropriate" (such as "to exclude unreliable evidence").

The appeals process, as set forth at 42 C.F.R. Part 93, Subpart E, is reportedly laborious in terms of time and resources for ORI staff, which is disadvantageous to the regulated community, and which can be demoralizing to institutions, especially after conducting long, thorough, and fair research misconduct proceedings. Moreover, the appeals process applies standards that were not required to be used in the original research misconduct proceeding, such as the evidentiary standards described above.

[18] *See* NIH, *Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH*, Notice Number: NOT-OD-19-020 (Oct, 17, 2018), https://grants nih.gov/grants/guide/notice-files/NOT-OD-19-020.html.

Suggested Revision, Augmentation, or Clarification

We encourage ORI to consider amending the appeals process to allow for more expedient resolutions in general, or at least under certain circumstances. We defer to ORI to determine whether this would warrant amending the evidentiary standards articulated in 42 C.F.R. § 93.519 and/or amending other regulations set forth in 42 C.F.R. Part 93, Subpart E.

Conclusion

[redacted], [redacted], [redacted], and the undersigned officials greatly appreciate the opportunity to provide input on the foregoing in response to the RFI and to impress upon ORI the challenges faced by well-intended stakeholders in conducting research misconduct proceedings. We hope and expect that, with the regulated community's collective input and collaboration, ORI can improve the crucial processes surrounding all aspects of research misconduct proceedings and create a better process for institutions charged with reviewing research misconduct, a fairer procedure for respondents, and, ultimately, an even higher reliability of the integrity of research performed with federal funds.

Should you have any questions regarding this letter, do not hesitate to contact the undersigned.

Sincerely,

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