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The National Institutes of Health Generally Implemented the Safe Workplace Federal Reporting Requirement, but Opportunities Exist To Improve the Reporting and Monitoring Processes

## REPORT HIGHLIGHTS



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# The National Institutes of Health Generally Implemented the Safe Workplace Federal Reporting Requirement, but Opportunities Exist To Improve the Reporting and Monitoring Processes

#### Why OIG Did This Audit

- <u>National Institutes of Health</u> (NIH)-funded recipient institutions are expected to provide safe and healthful
  working conditions for their employees and foster work environments conductive to high-quality
  research.
- The Consolidated Appropriations Act, 2022 (CAA), mandated the NIH Director to require recipient
  institutions to report to NIH when individuals identified as principal investigators (PIs) or as key
  personnel in an NIH Notice of Award are removed from their position or are otherwise disciplined due
  to concerns about harassment, bullying, retaliation, or hostile working conditions.
- This audit determined whether NIH has implemented the CAA reporting requirement and how NIH has used the reported information to address work environments at recipient institutions.

#### What OIG Found

- NIH has generally implemented the CAA reporting requirement. However, NIH did not take any actions to address the delayed institutional reporting in some sampled cases subject to the CAA reporting requirement. NIH did not have policies and procedures describing actions that should have been taken to address delayed reporting by the recipient institutions.
- NIH used the reported information to address work environments at recipient institutions by taking PI, grant award, and recipient institution-specific actions in response to reported harassment or other inappropriate conduct cases. However, NIH did not have policies and procedures to facilitate consistent, timely, and proper actions in response to reported cases.

#### What OIG Recommends

We recommend that the National Institutes of Health: (1) educate recipient institutions on the importance of compliance with the CAA reporting requirement; (2) develop policies and procedures for monitoring recipient institutions' compliance with the CAA reporting requirement; and (3) develop policies and procedures to facilitate NIH's consistent, timely, and proper actions in response to reported harassment and inappropriate conduct cases. NIH concurred with our recommendations and described actions it plans to take to address them.

#### **TABLE OF CONTENTS**

INTRODUCTION	1
Why We Did This Audit	1
Objectives	1
Background	
National Institutes of Health	
Federal Requirements for Institutional Reporting	2
NIH Process for Handling Allegations and Notifications of Harassment	2
and Other Inappropriate Conduct at Recipient Institutions	3
How We Conducted This Audit	4
FINDINGS	5
NILL Congrally Implemented the CAA Benerting Requirement	6
NIH Generally Implemented the CAA Reporting Requirement	
	0
NIH Did Not Address Delayed Institutional Reporting of Harassment and Other Inappropriate Conduct	7
mappi opriate conduct	/
NIH Used Reported Information To Take PI, Grant Award, and Institution-Specific	
Actions	8
NIH Took PI, Grant Award, and Institution-Specific Actions	
When Allegations Were Substantiated	8
NIH Did Not Have Authority To Conduct Independent Investigations at	
Recipient Institutions	10
NIH Did Not Always Use Reported Information To Take Timely Actions	
To Address Work Environments	11
NIH May Not Have Followed Up With Some Recipient Institutions in a Timely	
Manner	
RMARS Date Fields Were Not Always Populated	
Alerts Were Not Always Added or Updated in a Timely Manner	
NIH Did Not Have Policies and Procedures for Timely Case Processing	13
CONCLUSION	13
RECOMMENDATIONS	14
NATIONAL INSTITUTES OF HEALTH COMMENTS	14

#### **APPENDICES**

A: Audit Scope and Methodology	15
B: Federal Requirements for Safe and Healthful Working Conditions at Recipient Institutions During Our Audit Period	18
C: National Institutes of Health Comments	20

#### INTRODUCTION

#### WHY WE DID THIS AUDIT

The National Institutes of Health (NIH) expects NIH-funded institutions (recipient institutions) to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research. The Consolidated Appropriations Act, 2022 (P.L. No. 117-103, March 15, 2022) (CAA), mandated the NIH Director to require recipient institutions to report to NIH when individuals identified as principal investigators (PIs) or as key personnel in an NIH Notice of Award (NoA) were removed from their position or were otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions (CAA reporting requirement).<sup>1, 2, 3</sup>

The Department of Health and Human Services (HHS) Office of Inspector General's (OIG) oversight efforts help to ensure the integrity and effective management of NIH's grant application and selection processes, and OIG has reviewed recipient institutions' compliance with Federal requirements and NIH policies that establish controls over NIH grants, contracts, and other transactions. This audit builds upon our prior work and examines NIH's efforts to ensure safe and healthful working conditions at recipient institutions.

#### **OBJECTIVES**

Our objectives were to determine: (1) whether NIH has implemented the Federal requirement for recipient institutions to report individuals who have been removed or disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions and (2) how NIH has used the reported information to address work environments at recipient institutions.

<sup>&</sup>lt;sup>1</sup> A PI is an individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the award. The applicant organization may designate multiple individuals as PIs who share the authority and responsibility for leading and directing the project, intellectually and logistically. Key personnel could include a PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way (section 1.2 of the <a href="NIH Grants Policy Statement">NIH GPS</a>)). For the purposes of this report, we use the term "PI" to collectively refer to PIs and key personnel associated with NIH awards.

<sup>&</sup>lt;sup>2</sup> The NoA is the legal document issued to notify the recipient that an award has been made and that funds may be requested from the designated HHS payment system or office.

<sup>&</sup>lt;sup>3</sup> The phrase "otherwise disciplined" refers to any administrative action or other disciplinary action taken by the recipient institution against a PI due to any and all concerns related to harassment, bullying, retaliation or hostile working conditions (NIH, <u>Frequently Asked Questions (FAQs)</u>). Last accessed on May 20, 2025.

#### **BACKGROUND**

#### **National Institutes of Health**

NIH is the agency responsible for the Nation's medical and behavioral research. Its mission is to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance health, lengthen life, and reduce illness and disability. In Federal fiscal year (FY) 2022, NIH awarded more than \$34.6 billion in extramural research awards. In FYs 2023 and 2024, NIH awarded more than \$35.6 billion and \$34.9 billion, respectively.

#### **Federal Requirements for Institutional Reporting**

The CAA required recipient institutions that received funds through a grant or cooperative agreement during FY 2022 and in future years to report to NIH when PIs or key personnel listed in an NoA were removed from their position or were otherwise disciplined by the recipient institution due to concerns about harassment, bullying, retaliation, or hostile working conditions. In its Guide Notice Number NOT-OD-22-129, NIH clarified that the notification must have been provided by the Authorized Organization Representative (AOR) within 30 days of the removal or disciplinary action and must have been submitted to NIH through a dedicated web form.<sup>4</sup> NIH updated sections 8.1.2.6 and 8.1.2.7 of the NIH GPS to include the CAA reporting requirement.<sup>5</sup>

In addition, the existing requirement to obtain a prior approval for any significant change in the status of the PI named in an NOA or change of recipient institution remained in effect.<sup>6</sup> The request for approval should have included mention as to whether the change was related to concerns about safety, work environments (bullying, retaliation, or hostile working conditions), or both.<sup>7</sup>

<sup>&</sup>lt;sup>4</sup> NIH specified that the requirement was effective on July 9, 2022 (60 days from the publication of the Notice). NIH, <u>Updated Requirements for NIH Notification of Removal or Disciplinary Action Involving Program Directors/Principal Investigators or Other Senior/Key Personnel</u> (NOT-OD-22-129) (issued May 10, 2022). Last accessed on May 20, 2025.

<sup>&</sup>lt;sup>5</sup> The NIH GPS made available, in a single document, the policy requirements that served as the terms and conditions of NIH grant awards. By accepting an award, recipients agreed to comply with the requirements in the NIH Grants Policy Statement except where the NOA stated otherwise.

<sup>&</sup>lt;sup>6</sup> NIH prior approval is required for the transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the completion date of the approved project period (section 8.1.2.7 of the NIH GPS).

<sup>&</sup>lt;sup>7</sup> Appendix B lists Federal requirements for safe and healthful working conditions at recipient institutions.

## NIH Process for Handling Allegations and Notifications of Harassment and Other Inappropriate Conduct at Recipient Institutions

At NIH, allegations and notifications of harassment and other inappropriate conduct that could result in a hostile work environment are reviewed by the Office of Extramural Research (OER).<sup>8</sup>

OER has specific procedures to address allegations and notifications of harassment and other inappropriate conduct that could result in a hostile work environment. The procedures indicate that the process begins by institutions or individuals submitting allegations or notifications using the web form, email address, designated phone number, or contacting OER staff directly.

Next, the procedures describe the steps for OER to review allegations of harassment and other inappropriate conduct. If an allegation does not involve harassment, it is forwarded to the appropriate agency or office with that oversight responsibility. In conducting its review, OER should assess whether sufficient information exists to proceed and follow up with the institution or individual who submitted the allegation (complainants) if necessary. OER should determine whether NIH-funded grant awards are involved and whether a person of concern is involved in and should be removed from peer review service. <sup>10</sup>

If OER determines that sufficient information exists to proceed and that NIH-funded grant awards are involved, the NIH Deputy Director for Extramural Research sends a letter to the institution regarding the allegation. The letter contains a description of the allegation, NIH's concerns about harassment in extramural science, a reminder of NIH's expectations and requirements related to harassment, and a request for additional information about the allegation to be submitted to NIH within 30 days.

After receiving the institutional response, OER should assess whether the institution investigated the allegation, and if so, whether the allegation was substantiated (in other words, whether the institution found evidence of misconduct) and any identified risks to research staff, students, or both had been mitigated. OER also should consider the impact of the institutional response on NIH research, what actions were taken and what safeguards were put in place, and whether any other factors and actions were relevant to the allegation. The subsequent step is

<sup>&</sup>lt;sup>8</sup> NIH defined "[H]arassment" as "unwelcome conduct that is based on race, national origin, accent, color, religion, sex, national origin, age (40 or older), disability, equal pay/compensation, or genetic information (including family medical history)." NIH further defines it as a form of employment discrimination prohibited by certain Federal laws. NIH defines "Inappropriate conduct" as "a separate, broader category of misconduct that may not meet the definition of harassment." NIH, *Definitions*. Last accessed on May 20, 2025.

<sup>&</sup>lt;sup>9</sup> NIH, <u>NIH Process for Handling Allegations of Harassment on an NIH-Funded Project at a Recipient Institution</u> and <u>Institutional Reporting</u>. Last accessed on Sept. 26, 2025.

<sup>&</sup>lt;sup>10</sup> Applications for NIH grant awards, including renewals and revisions, were subject to peer review to ensure that applications were evaluated on the basis of a process that was fair, equitable, timely, and conducted in a manner that strived to eliminate bias (section 2.4 of the NIH GPS). Pls could serve as peer reviewers for NIH.

for OER to take appropriate administrative and regulatory actions to ensure that NIH-funded research occurs in a safe environment. For example, OER could request a recipient institution to identify a replacement PI on an NIH grant award, suspend or terminate grant awards, or impose special reporting requirements on the recipient institution.

#### **HOW WE CONDUCTED THIS AUDIT**

Our audit covered NIH's implementation of the CAA reporting requirement related to institutional reporting of harassment, bullying, retaliation, or hostile working conditions on or after the implementation date of July 9, 2022. We also reviewed how NIH has used the information reported between January 1, 2018, and May 9, 2024, to address work environments at recipient institutions.<sup>11</sup>

We obtained a list of 848 allegations and notifications of harassment and other inappropriate conduct (further, "cases") individuals and institutions submitted to NIH between January 1, 2018, and May 9, 2024. We removed 18 cases from the list because the PI names were not listed.

The remaining 830 unique cases comprised 699 cases reported by individuals, 71 cases reported by recipient institutions after the CAA reporting requirement was implemented, and 60 cases reported by recipient institutions prior to the CAA reporting requirement. We selected a nonstatistical sample of 37 cases for detailed review. The sampled cases included 20 cases submitted by individuals, 15 cases that were subject to the CAA reporting requirement and submitted by recipient institutions, and 2 cases that were not subject to the CAA reporting requirement and submitted by recipient institutions. <sup>13, 14</sup> In selecting the 37 sampled cases, we considered whether: (1) cases were submitted by individuals or institutions, (2) a PI had multiple allegations against them, (3) a PI left the institution, (4) an institution conducted an investigation, (5) an institution had multiple allegations against its PIs, (6) the cases were open or closed, and (7) cases that were originally reported from 2018 through 2021 were still open at the start of our fieldwork.

We interviewed NIH officials familiar with the CAA reporting requirement and reviewed NIH's policies and procedures covering the reporting process. We obtained and reviewed documentation from NIH and the Research Misconduct Allegations Review System (RMARS)

<sup>&</sup>lt;sup>11</sup> NIH provided the audit team with data that covered the period January 1, 2018, through May 9, 2024.

<sup>&</sup>lt;sup>12</sup> NIH clarified that institutions did not notify NIH of each allegation they received or of each investigation they conducted. Institutions notified NIH only when they had taken administrative and disciplinary actions.

<sup>&</sup>lt;sup>13</sup> Unique records were defined as a non-duplicated combination of the PI name, respondent institution, year a case was submitted to NIH, and type of harassment or other inappropriate conduct.

<sup>&</sup>lt;sup>14</sup> Each of the two sampled cases submitted by recipient institutions before the CAA had a corresponding sampled case for the same PI submitted after implementation of the CAA.

associated with the 37 sampled cases to determine how NIH processed the sampled cases and what actions NIH took to address work environments at recipient institutions.

We limited our review of NIH's internal controls to those related to NIH's processing, reviewing, and monitoring of the harassment and other inappropriate conduct cases.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A describes our audit scope and methodology. Appendix B lists Federal requirements for safe and healthful working conditions at recipient institutions.

#### **FINDINGS**

NIH has generally implemented the Federal requirement for recipient institutions to report PIs who have been removed or disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions. However, NIH did not take any actions to address the delayed reporting of such actions in 4 of the 15 sampled cases that were subject to the CAA reporting requirement.

NIH used the reported information in the 24 sampled cases with substantiated allegations to address work environments at recipient institutions by taking PI, grant award, and institution-specific actions. NIH relied on recipient institutions to conduct investigations and share relevant information.

NIH did not have internal policies and procedures to facilitate consistent, timely, and proper actions in response to substantiated harassment and inappropriate conduct cases. This affected NIH's ability to take appropriate actions with respect to the recipient institutions, potentially extending ongoing harm to those subjected to harassment or other inappropriate conduct. In addition, having policies and procedures would allow for NIH to facilitate consistency of decision-making and continuity through staffing changes. NIH also cited its staffing levels that affected timely processing of cases and entering and updating relevant data and system alerts.

#### NIH GENERALLY IMPLEMENTED THE CAA REPORTING REQUIREMENT

#### NIH's Implementation of the CAA Reporting Requirement

NIH officials explained that in 2018, NIH began directing cases of sexual harassment at recipient institutions to OER to ensure that such cases were handled in a consistent manner. In 2019, NIH created a website, a dedicated mailbox, and a public web form for reporting of sexual harassment at recipient institutions. 15, 16

NIH collected, managed, and stored the reported information in a confidential RMARS module of the electronic Research Administration (eRA) system. <sup>17, 18</sup> As the number of harassment cases reported to NIH grew, in 2021, NIH expanded language on its website and web form to include support of safe and respectful work environments that were free from harassments or other inappropriate conduct that could result in a hostile work environment.

The CAA mandated the NIH Director to require recipient institutions to report to NIH when individuals identified as PIs or key personnel in an NoA were removed from their position or were otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions. NIH implemented the CAA reporting requirement on July 9, 2022, and instructed AORs at recipient institutions to provide notifications to NIH within 30 days of a removal or disciplinary action using NIH's web form. This requirement was added to sections 8.1.2.6 and 8.1.2.7 of the NIH GPS and therefore incorporated by reference as a term and condition of a grant award. NIH officials stated that to accommodate AOR reporting, the web form was adapted so that visitors could select whether they were reporting as an AOR or as an individual. Information submitted via the web form automatically created a new file in RMARS. NIH also clarified that recipient institutions were required to report cases independent of whether NIH grant awards had been directly impacted or not.

<sup>&</sup>lt;sup>15</sup> NIH, <u>Supporting a Safe and Respectful Workplace at Institutions that Receive NIH Funding</u>. Last accessed on May 20, 2025.

<sup>&</sup>lt;sup>16</sup> NIH's Anti-Harassment Portal, <u>Inform NIH About Harassment or Discrimination Concerns</u>. Last accessed on May 20, 2025.

<sup>&</sup>lt;sup>17</sup> eRA is a web-based system for applicants and institutions to participate in the electronic grant administration process. In eRA, grant applicants, recipients, and Federal staff at NIH and grantor agencies can access and share administrative information relating to research grants. eRA contains an Alert Module that allows OER staff to create, enter, and manage alerts associated with NIH grants. These alerts may affect special award terms, require a hold placed on an award, or be purely informational in nature.

<sup>&</sup>lt;sup>18</sup> The RMARS is a web-based electronic module within eRA for managing submissions of research misconduct allegations against NIH grantees, applicants, and anyone involved with the application review or research. RMARS allows for efficient sharing of documents and communications regarding the allegations between OER, NIH Research Integrity Officers, the Office of Management Assessment, the Office of Research Integrity, and other HHS agencies.

<sup>&</sup>lt;sup>19</sup> NIH, NIH Grants Policy Statement (December 2022). Last accessed on May 20, 2025.

NIH officials stated that the CAA reporting requirement was one of the factors leading to the increase of the harassment and other inappropriate conduct self-disclosures by institutions. As visualized in Figure 1, cases reported by institutions increased from 24 in 2021 (15 percent of total reported cases) to 42 in 2023 (22 percent of total reported cases). In addition, NIH's outreach efforts and recipient institutions' heightened awareness about the CAA reporting requirement may have also contributed to the increase in cases reported by institutions.

Figure 1: Number of Cases Reported by Institutions: Calendar Years 2021 to 2023

Cases Reported to NIH	2021	2022	2023
Number of cases reported by institutions	24	30	42
Total reported cases	162	186	192
Number of cases reported by institutions as	15%	16%	22%
a percentage of total reported cases			

Receiving harassment and other inappropriate conduct cases allowed NIH to learn about work environment concerns earlier and work with recipient institutions to address such concerns. NIH's oversight was strengthened as a result.

## NIH Did Not Address Delayed Institutional Reporting of Harassment and Other Inappropriate Conduct

NIH required recipient institutions to notify NIH using the web form within 30 days after removing or disciplining a PI. NIH clarified that the 30-day deadline was based on the date when a recipient institution took an official action against a PI. Institutional internal policies and procedures determined how such action was taken, but typically it included a notification to a PI.

NIH reminded the recipient institutions about the 30-day deadline in its request letters in response to submitted cases. However, NIH did not address the recipient institutions' delayed reporting of removal of or disciplinary action against PIs associated with 4 of the 15 sampled cases the institutions submitted after the CAA reporting requirement was implemented. The recipient institutions submitted the cases to NIH 32 to 50 days after removing or taking disciplinary actions against the PIs. Due to delayed reporting, the recipient institutions were not compliant with the CAA reporting requirement, affecting NIH's ability to take timely actions with respect to the situations at such institutions.

We determined that NIH did not have internal policies and procedures describing actions that should have been taken to address delayed reporting by the recipient institutions.

<sup>&</sup>lt;sup>20</sup> NIH, <u>How Implementing a 2022 Law is Helping Us Ensure Safe and Respectful Workplaces</u>. Last accessed on May 20, 2025.

## NIH USED REPORTED INFORMATION TO TAKE PI, GRANT AWARD, AND INSTITUTION-SPECIFIC ACTIONS

## NIH Took PI, Grant Award, and Institution-Specific Actions When Allegations Were Substantiated

NIH expected recipient institutions to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research.<sup>21</sup> To ensure compliance, NIH required institutions and allowed individuals to report harassment and other inappropriate conduct incidents involving PIs on NIH-funded projects.

When harassment or other inappropriate conduct cases were reported to NIH, NIH followed established procedures to address the matter.<sup>22</sup> After an allegation was substantiated by a recipient institution, NIH could:

- take PI-specific actions, such as:
  - removing the PI from peer review,
  - o processing institutional requests to remove the PI from a grant award,
  - submitting suspension or debarment referrals to the HHS Suspension and Debarment Official, or
  - o referring the case to HHS Office of Civil Rights or OIG; or
- take grant award-specific actions, such as:
  - approving institutional requests to transfer the grant award to another institution,
  - suspending the grant award,
  - terminating the grant award,
  - o adding restrictions to the grant award, or

<sup>&</sup>lt;sup>21</sup> NIH, NIH Grants Policy Statement (December 2022), section 4. Last accessed on May 20, 2025.

<sup>&</sup>lt;sup>22</sup> NIH, <u>NIH Process for Handling Allegations of Harassment on an NIH-Funded Project at a Recipient Institution</u> and <u>Institutional Reporting</u>. Last accessed on Sept. 26, 2025.

- requesting that the institution identify a replacement PI on an active or pending NIH grant award;
- take institution-specific actions, such as:
  - o requiring quarterly or monthly reports on the work environment or
  - o requesting updates on ongoing administrative or disciplinary actions.<sup>23</sup>

Of the 37 sampled cases, allegations were substantiated in 24 cases, allegations were not substantiated in 12 cases, and an institutional investigation was pending in 1 case.

In the 24 sampled cases with substantiated allegations, NIH took PI, grant award, and institution-specific actions. Figure 2 highlights NIH's actions in response to the 24 substantiated sampled cases submitted by recipient institutions and individuals.

Figure 2: NIH Actions in Response to Substantiated Allegations

Type of NIH Action	Sampled Cases Submitted by Recipient Institutions After the CAA	Sampled Cases Submitted by Individuals	Sampled Cases Submitted by Recipient Institutions Before the CAA	Total Number of Cases
PI-specific actions	15	8	1	24
Grant award-specific actions	12	2	1	15
Institution-specific actions	1	3	0	4

#### Specifically, NIH:

- took PI-specific actions in all 24 cases by removing PIs from peer review and work on the grant awards and adding alerts in eRA requiring a Grants Management Specialist to get OER clearance prior to issuing or modifying a grant award;<sup>24</sup>
- took grant award-specific actions in 15 cases by replacing PIs working on the grant awards, terminating or closing out grant awards, allowing grant awards to be transferred to another institution, or imposing additional reporting requirements; and

<sup>&</sup>lt;sup>23</sup> There could be overlaps among the three categories of NIH actions. For example, a PI's replacement on a grant award would affect the PI and grant award.

<sup>&</sup>lt;sup>24</sup> The Grants Management Specialist whose name appears in the NoA is assigned responsibility for day-to-day management of a portfolio of grant awards (section 2.1.1 of the NIH GPS).

 took institution-specific actions in 4 cases by requesting reports on climate assessments of the PIs' labs or institution.<sup>25</sup>

In the 12 sampled cases with unsubstantiated allegations (11 cases submitted by individuals and 1 case submitted by a recipient institution), institutional investigations did not find any incidents of harassment or other inappropriate conduct, reported allegations related to a single or isolated incident, complainants chose not to discuss reported allegations with the institutions, a reported allegation was based on a several-year-old incident, or no NIH funding was involved.

#### NIH Did Not Have Authority To Conduct Independent Investigations at Recipient Institutions

There was neither a Federal requirement nor legal authority for NIH to conduct investigations into allegations of harassment and other inappropriate conduct at recipient institutions. NIH relied on recipient institutions to conduct such investigations. NIH officials stated that strict confidentiality rules at institutions could make communication of the institutional investigation results to NIH challenging.

With certain exceptions, NIH received applications from institutions and not from individual scientists. <sup>26</sup> As such, NIH funded recipient institutions that were responsible for managing grant awards and overseeing work of individual scientists. NIH officials explained that recipient institutions were responsible for having systems, policies, and procedures in place to protect the rights and safety of individuals working on NIH-funded projects. When allegations of harassment or other inappropriate conduct arose, the recipient institutions had to follow their own procedures to investigate and take appropriate actions. NIH's PI, grant award, and institution-specific actions were determined by the outcome of the institutional investigation as well as administrative and disciplinary actions imposed by the recipient institution.

NIH was limited to the extent of information shared by recipient institutions. If an institution was not fully transparent about harassment or other inappropriate conduct allegation proceedings, NIH may not have been able to obtain information necessary to take appropriate actions. For example, in one sampled case, an institution was not fully transparent about a harassment case against a PI. As a result, NIH allowed several grant awards to be transferred to a successor institution that hired the PI. After NIH learned about the extent of the harassment case against the PI, NIH engaged extensively with both institutions regarding the measures in place at each institution to ensure compliance with the terms and conditions of NIH grant awards.

<sup>&</sup>lt;sup>25</sup> NIH indicated that the climate assessment should include issues related to workplace environment, harassment, and discrimination.

<sup>&</sup>lt;sup>26</sup> NIH, Frequently Asked Questions (FAQs). Last Accessed on May 20, 2025.

NIH officials also stated that they did not interview PIs before taking PI, grant award, or institution-specific actions because the business relationship existed between NIH, as a Federal awarding agency, and a recipient institution. We observed that in two sampled cases, PIs submitted harassment allegations to NIH. However, institutional investigations did not substantiate the PIs' allegations and instead found that these PIs violated various institutional policies. NIH accepted the institutional determinations and opened cases against the PIs.

Though NIH officials explained that they considered the unique circumstances of each case, we noted that NIH did not have internal policies and procedures to facilitate consistent application of PI, grant award, and institution-specific actions in response to substantiated harassment and other inappropriate conduct cases. Policies and procedures would allow for NIH to facilitate consistency of decision making and continuity through staffing changes.

## NIH DID NOT ALWAYS USE REPORTED INFORMATION TO TAKE TIMELY ACTIONS TO ADDRESS WORK ENVIRONMENTS

#### NIH May Not Have Followed Up With Some Recipient Institutions in a Timely Manner

After reviewing a harassment or inappropriate conduct case and determining that sufficient information existed to proceed and NIH funding was involved, NIH sent a request letter to a recipient institution. NIH asked for an institutional response within 30 days of receipt of the request letter.

NIH officials explained that there were no specific timing requirements for case resolution, and the time it took to conduct reviews varied widely across cases and institutions. Recipient institutions had to follow their own policies and procedures for investigations and implementation of administrative or disciplinary actions. NIH could request status updates from the institutions on the implementation of any interim measures.

We identified timeliness concerns for 5 of the 37 sampled cases we reviewed. Specifically:

- in two cases, NIH did not follow up on the status of administrative or disciplinary actions for over 5 months;
- in two cases, NIH did not follow up on the status of institutional investigation for over 1 year; and
- in one case, NIH followed up with the institution 6 months after the institution did not respond to NIH's initial request.

#### **RMARS Date Fields Were Not Always Populated**

As a case transitioned through the NIH investigative process, the case was marked with the appropriate status to indicate its progress through the stages and its ultimate resolution. Complete and accurate information entered in RMARS could help NIH to follow up with the institutions in a timely manner and take appropriate PI, grant award, or institution-specific actions.

For 11 of the 37 sampled cases, relevant dates were not always entered or entered incorrectly in the screen tracking dates in RMARS. Specifically, NIH did not enter or entered incorrectly the dates of the Pl's removal from peer review, administrative leave or other institutional administrative actions (such as climate assessment reviews), and the Pl's resignation or employment termination.

NIH explained that not populating date fields was an error, but information was available elsewhere in RMARS. NIH also maintained an external spreadsheet outside of RMARS for tracking harassment and other inappropriate conduct cases, as well as due dates for institutional and NIH actions.

#### Alerts Were Not Always Added or Updated in a Timely Manner

The Alert Module in eRA allowed NIH to create, enter, and manage alerts associated with NIH grant awards. These alerts could affect special grant award terms, require a hold be placed on a grant award, restrict PIs from working on grant awards, or be informative in nature. When OER staff placed an alert on an individual, institution, or specific grant award, a corresponding alert also appeared in the Grants Management module. Any alerts or findings required a Grants Management Specialist to get OER clearance prior to issuance of the grant award.

OER typically added alerts after an allegation was substantiated or when a PI was unable to work on a grant award due to, for example, an administrative leave during an institutional investigation. When an alert was added, how long it stayed in place, and when it was removed varied based on circumstances of each case. NIH explained that if the formal investigation of a PI returned no findings, the alert was removed. If findings against a PI resulted in the establishment of a remediation plan (for example, climate assessments of a PI's lab), NIH could require updates from the recipient institution and keep the alert in place for the length of the monitoring. If findings against a PI resulted in a disciplinary action that led to termination from the recipient institution or removal from NIH grant awards, the alert stayed in place until such actions were completed.

We determined that in 4 of 37 sampled cases, NIH did not add or update alerts in a timely manner. Specifically, NIH:

did not add alerts after allegations were substantiated in two cases,

- added an alert 6 months after the institution notified NIH about conducting climate assessments of a PI's lab environment in one case, and
- did not remove an alert after a PI left the institution in one case.

#### NIH Did Not Have Policies and Procedures for Timely Case Processing

Though NIH developed standard operating procedures for processing of harassment and other inappropriate conduct cases, it did not have internal policies and procedures for monitoring of such case processing. NIH maintained an external spreadsheet outside of RMARS for tracking relevant dates and NIH's and institutional actions, but this method was not always effective in ensuring that NIH communicated with recipient institutions in a timely manner or shared relevant and accurate information within NIH or with other parties. In addition, reminders to prompt NIH staff to follow up on outstanding requests or actions either did not exist in RMARS or, after reminders were implemented, OER did not always use them.<sup>27</sup> NIH also cited its staffing levels that affected timely processing of cases and entering and updating relevant data and system alerts.

Without monitoring of case processing, NIH may not have taken timely and proper PI, grant award, and institution-specific actions, potentially extending ongoing harm to those affected by harassment or other inappropriate conduct.

#### **CONCLUSION**

While we found that NIH has generally implemented the Federal requirement for NIH-funded institutions to report PIs who were removed or disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions, NIH did not take any actions to address the delayed institutional reporting in some sampled cases subject to the CAA reporting requirement. We believe that NIH could improve its reporting and monitoring processes to ensure that recipient institutions report such incidents on a timely basis by educating recipient institutions on the importance of compliance with the CAA reporting requirement and developing internal policies and procedures for monitoring of recipient institutions' compliance with the CAA reporting requirement.

In addition, NIH could improve its monitoring of case processing by developing internal policies and procedures to facilitate consistent, timely, and proper actions in response to reported harassment and other inappropriate conduct cases.

<sup>&</sup>lt;sup>27</sup> The RMARS User Guide from Dec. 5, 2023, indicated that reminder and task fields were added to RMARS on May 4, 2023. NIH stated that the reminder and task fields were not used for tracking harassment and other inappropriate conduct cases.

#### RECOMMENDATIONS

We recommend that the National Institutes of Health:

- educate recipient institutions on the importance of compliance with the CAA reporting requirement;
- develop policies and procedures for monitoring of recipient institutions' compliance with the CAA reporting requirement; and
- develop policies and procedures to facilitate NIH's consistent, timely, and proper actions in response to reported harassment and other inappropriate conduct cases.

#### NATIONAL INSTITUTES OF HEALTH COMMENTS

In written comments on our draft report, NIH concurred with our recommendations and described actions it plans to take to address them. NIH's actions include: (1) hosting a webinar for and sharing relevant examples with the recipient community to detail the relevant policies, requirements, and importance of maintaining a safe work environment; (2) documenting whether institutional notification was received within 30 days of the time of the disciplinary action if it was subject to the CAA reporting requirement and sending a warning letter to the recipient institution if the notification was not received within 30 days; and (3) developing a decision matrix or flow chart to guide internal staff decision making regarding appropriate administrative actions in response to concerns of harassment or inappropriate conduct.

We acknowledge the corrective actions NIH plans to take to address our recommendations. NIH also provided technical comments, which we addressed as appropriate. NIH's comments, excluding the technical comments, are included as Appendix C.

#### APPENDIX A: AUDIT SCOPE AND METHODOLOGY

#### SCOPE

Our audit covered NIH's implementation of the CAA reporting requirement related to institutional reporting of harassment, bullying, retaliation, or hostile working conditions on or after July 9, 2022. We also reviewed how NIH has used the information reported between January 1, 2018, and May 9, 2024, to address work environments at recipient institutions. We obtained a list of 848 cases reported to NIH from January 1, 2018, through May 9, 2024, and removed 18 cases from the list because the PI names were not listed. The remaining 830 unique cases comprised 699 cases reported by individuals, 71 cases reported by institutions after the CAA reporting requirement was established, and 60 cases reported by institutions prior to the CAA reporting requirement.

We selected a nonstatistical sample of 37 cases for detailed review. The sampled cases included 20 cases submitted by individuals, 15 cases submitted by institutions after the CAA, and 2 cases submitted by institutions before the CAA. In selecting the 37 sampled cases, we considered whether: (1) cases were submitted by individuals or institutions, (2) a PI had multiple allegations against them, (3) a PI left the institution, (4) an institution conducted an investigation, (5) an institution had multiple allegations against its PIs, (6) cases were open or closed, and (7) cases that were originally reported from 2018 through 2021 were still open at the start of our fieldwork.

We interviewed NIH officials familiar with the CAA reporting requirement and reviewed NIH's policies and procedures covering the reporting process. We obtained and reviewed documentation from NIH and in RMARS associated with the 37 sampled cases to determine how NIH processed the sampled cases and what actions NIH took in response to the reported harassment and other inappropriate conduct by PIs.<sup>28</sup>

We limited our review of NIH's internal controls to those related to NIH's processing, reviewing, and monitoring of the harassment and other inappropriate conduct cases.

We established reasonable assurance of the authenticity and accuracy of the allegation data provided by NIH. We verified the completeness of the allegation data by reconciling the provided data to the data published on NIH's website.<sup>29</sup> However, we could not establish whether all harassment and other inappropriate conduct cases that should have been reported to NIH were reported by recipient institutions.

We conducted fieldwork for our audit from November 2023 to August 2025.

<sup>&</sup>lt;sup>28</sup> The cutoff date for the review of the RMARS cases was Sept. 30, 2024.

<sup>&</sup>lt;sup>29</sup> NIH, <u>Data - Harassment and Discrimination Concerns</u>. Last accessed on May 20, 2025.

#### **METHODOLOGY**

To accomplish our objective, we:

- reviewed applicable Federal law and NIH guidance related to the CAA reporting requirement;
- met with NIH officials to gain an understanding of NIH's implementation of the CAA reporting requirement and how NIH used reports of harassment and other inappropriate conduct to address work environments at recipient institutions;
- gained an understanding of NIH's internal controls over: (1) NIH's compliance with the CAA reporting requirement and (2) processing of harassment and other inappropriate conduct at NIH-funded institutions cases submitted to NIH;
- obtained a list of 848 cases submitted to NIH by individuals and institutions between January 1, 2018, and May 9, 2024, and removed 18 cases from the list because the PI names were not listed;
- selected from the remaining 830 cases a nonstatistical sample of 37 cases for detailed review: 20 cases submitted by individuals, 15 cases submitted by institutions after the CAA, and 2 cases submitted by institutions before the CAA;
- reviewed RMARS records for the 37 sampled cases to determine as of September 30, 2024:
  - the nature of harassment or other inappropriate conduct allegation or report,
  - o whether a respondent was a PI on an NIH-funded grant award,
  - what actions NIH and institutions took in response to the reported allegations,
  - whether institutions complied with the CAA reporting requirement and NIH monitored institutional compliance, and
  - whether NIH followed its policies and procedures for review of harassment or other inappropriate conduct cases, and
- discussed the results of our audit with NIH officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions

based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.					

## APPENDIX B: FEDERAL REQUIREMENTS FOR SAFE AND HEALTHFUL WORKING CONDITIONS AT RECIPIENT INSTITUTIONS DURING OUR AUDIT PERIOD

Section 239 of the Consolidated Appropriations Act, 2022 (P. L. No. 117-103) mandated the NIH Director to require recipient institutions that received funds through a grant or cooperative agreement during FY 2022 and in future to notify the Director when individuals identified as PIs or key personnel in an NOA were removed from their position or otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions.

On May 10, 2022, NIH issued *Updated Requirements for NIH Notification of Removal or Disciplinary Action Involving Program Directors/Principal Investigators or other Senior/Key* Personnel (NOT-OD-22-129), which announced that the new reporting requirements would take effect 60 days from the publication of the notice.<sup>30</sup> Notification must have been provided by the Authorized Organization Representative within 30 days of the removal or disciplinary action and must have been submitted to NIH through a dedicated web form. All required notifications must have included, at a minimum, the name of the Authorized Organization Representative submitting the notification, the name of the individual of concern, a description of the concern, the action(s) taken, and any anticipated impact of the NIH-funded award(s). If it was determined that the concerns shared with NIH would impact the PI's ability to continue as the scientific lead on the project, NIH required prior approval for a replacement PI. The NOT also added that this disclosure requirement did not replace the existing requirements to obtain a prior approval for any significant change in the status of the PI named in an NOA.

Sections 8.1.2.6 and 8.1.2.7 of the NIH GPS stated that NIH recipients were expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research. When seeking NIH's prior approval for a change in PI, recipient institution, or both, these sections required the request for approval to include mention as to whether the change(s) was related to concerns about safety, work environments (bullying, retaliation, or hostile working conditions), or both. NIH recipient institutions were required to notify NIH when PIs or key personnel in an NOA were removed from their position or were otherwise disciplined by the recipient institution due to concerns about harassment, bullying, retaliation, or hostile working conditions. Notification must have been provided by the Authorized Organization Representative within 30 days of the removal or disciplinary action and must have been submitted to NIH through a dedicated web form. All required notifications must have included, at a minimum, the name of the Authorized Organization Representative submitting the notification, the name of the individual of concern, a description of the concerns, the action(s) taken, and any anticipated impact on the NIH-funded award(s). If it was determined that the concerns shared with NIH impacted the PI's ability to continue as the scientific lead of the project, NIH required prior approval for a replacement PI. NIH was, in turn, better positioned to enable informed grant-stewardship decisions regarding matters including, but not limited to, substitute personnel and institutional management and oversight.

<sup>&</sup>lt;sup>30</sup> NIH, <u>Updated Requirements for NIH Notification of Removal or Disciplinary Action Involving Program</u>
<u>Directors/Principal Investigators or other Senior/Key Personnel</u> (NOT-OD-22-129). Last accessed on May 20, 2025.

Section 4 of the NIH GPS sets forth the expectation that recipient institutions provide safe and healthful working conditions for their employees and foster work environments conductive to high-quality research.

#### APPENDIX C: NATIONAL INSTITUTES OF HEALTH COMMENTS



#### DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service** 

National Institutes of Health Bethesda, Maryland 20892 www.nih.gov

**DATE:** September 19, 2025

TO: Carla J. Lewis

Acting Deputy Inspector General for Audit Services

FROM: Principal Deputy Director, National Institutes of Health

SUBJECT: NIH Comments on Draft Report: "The National Institutes of Health

Generally Implemented the Safe Workplace Federal Reporting Requirement, but Opportunities Exist to Improve the Reporting and

Monitoring Processes (A-05-24-00002)

Attached are the National Institutes of Health's (NIH) comments on the Office of Inspector General (OIG) draft report, "The National Institutes of Health Generally Implemented the Safe Workplace Federal Reporting Requirement, but Opportunities Exist to Improve the Reporting and Monitoring Processes (A-05-24-00002).

NIH appreciates the review conducted by the OIG and the opportunity to provide clarifications on this draft report. If you have questions or concerns, please contact Meredith Stein in the Office of Management Assessment at 301-402-8482.

Matthew J. Memoli, M.D., M.S.

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Attachments

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH (NIH) ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT ENTITLED: "THE NATIONAL INSTITUTES OF HEALTH GENERALLY IMPLEMENTED THE SAFE WORKPLACE FEDERAL REPORTING REQUIREMENT, BUT OPPORTUNITIES EXIST TO IMPROVE THE REPORTING AND MONITORING PROCESSES" (A-05-24-00002)

The National Institutes of Health (NIH) appreciates the review conducted by OIG and the opportunity to provide clarifications on this draft report. NIH respectfully submits the following general comments.

#### **OIG Recommendation 1:**

We recommend that the NIH educate recipient institutions on the importance of compliance with the CAA reporting requirement.

#### **NIH Response:**

NIH concurs with OIG's finding and corresponding recommendation that NIH enhance education and outreach efforts aimed at recipient institutions regarding the CAA reporting requirements and the importance of maintaining compliance with these requirements.

To address this recommendation, NIH is planning to host a webinar for the recipient community to detail the relevant policies, requirements, and importance of maintaining a safe work environment. This webinar will provide a reminder of the long-standing policies for recipient institutions and will also include discussion of several case studies and examples. We anticipate the webinar will occur in Spring/Summer 2026.

In addition to this webinar, NIH will build upon past Nexus articles/Blogs by developing 1-2 new communications each year detailing relevant examples and reminders to the community.

Information on these efforts will be posted on the public-facing website: <a href="https://grants.nih.gov/policy-and-compliance/policy-topics/harassment">https://grants.nih.gov/policy-and-compliance/policy-topics/harassment</a>

#### **OIG Recommendation 2:**

We recommend that the NIH develop policies and procedures for monitoring of recipient institutions' compliance with the CAA reporting requirement.

#### **NIH Response:**

NIH concurs with OIG's finding and corresponding recommendation that NIH formalize procedures for monitoring recipient institution compliance and timeliness of actions per the CAA reporting requirements.

To address this recommendation, for each institutional notification subject to the CAA reporting requirement, NIH staff will document in the RMARS file if the notification was received within 30 days of the time of the disciplinary action, as stated in the CAA. For situations in which the institutional notification was received more than 30 days from the time of the disciplinary action, NIH will send a warning letter to recipient institution. This letter will inform the recipient that their report was not in compliance with requirements set forth in the CAA and issue a warning

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH (NIH) ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT ENTITLED: "THE NATIONAL INSTITUTES OF HEALTH GENERALLY IMPLEMENTED THE SAFE WORKPLACE FEDERAL REPORTING REQUIREMENT, BUT OPPORTUNITIES EXIST TO IMPROVE THE REPORTING AND MONITORING PROCESSES" (A-05-24-00002)

that further noncompliance may result in enforcement actions per <u>NIH Grants Policy Statement 8.5</u>. This letter may also request a description from the recipient for how their internal controls will be enhanced to ensure future compliance. Furthermore, if recipient institution responses are significantly delayed or inadequate, NIH will escalate communications to the highest level of institutional leadership, for example President, Chancellor, or CEO.

#### **OIG Recommendation 3:**

We recommend that the NIH develop policies and procedures to facilitate NIH's consistent, timely, and proper actions in response to reported harassment and other inappropriate conduct cases.

#### **NIH Response:**

NIH concurs with OIG's finding and corresponding recommendation that NIH formalize internal policies and procedures to ensure the consistency and timeliness of NIH actions in response to reported concerns or harassment or inappropriate conduct.

To address this recommendation, NIH is developing a decision matrix/flow chart to guide internal staff decision making regarding appropriate administrative actions in response to concerns of harassment or inappropriate conduct. While there are many individual factors that must be taken into consideration for each case, this internal document will enhance the consistency of how actions are applied across cases. This decision matrix/flow chart is in development, and we anticipate having a final version for internal use by December 1, 2025.

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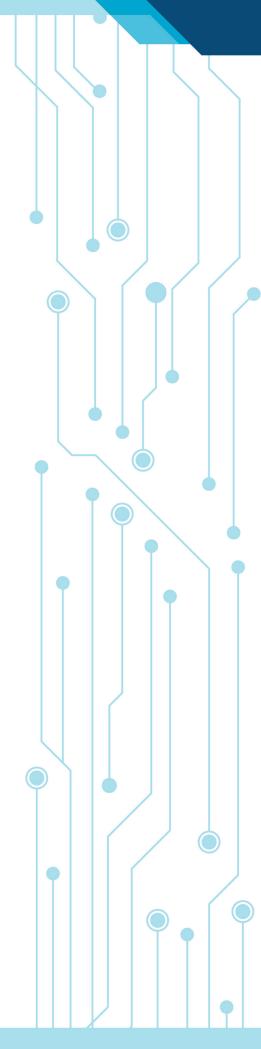
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