

Healthcare Audit and Enforcement Risk Analysis

National Institutes
of Health (NIH) Work
Plan and Audit
Summaries

MARCH 2022



To our Compliance Colleagues and Partners:

SunHawk’s review of OIG Audit statistics in 2020 found that compliance professionals and business risk owners experienced a 58% increase in HHS OIG audit activity over the prior year.¹ In an effort to promote the value of shared learnings, as well as give our colleagues and clients organized summaries of HHS OIG Work Plan and Audit items, SunHawk Consulting, LLC, has gathered, organized, and summarized the HHS OIG Work Plan and Audit Summaries of HHS National Institutes of Health (NIH).

HHS OIG [Office of Audit Services](#) and [Office of Evaluation and Inspections](#) issues approximately 300 audits and evaluations a year. The Work Plan and Audit item summaries provided herein are referenced by their respective Work Plan/Audit numbers at the end of each abstract. The electronic version of this report includes hyperlinks to the original Work Plan and Audit item summaries.

After your review, we would appreciate any feedback on how you are using these reports so we can make them more valuable to you or others. Should you find you would like to proactively conduct a review of activity within your organization to avoid future adverse findings, SunHawk’s team of experts are available to offer their assistance. Visit us at SunHawkConsulting.com and/or [connect with us on LinkedIn](#) for updates on our growing library of Healthcare Audit and Enforcement Risk Analysis Reports. SunHawk looks forward to working with you and your organization.

¹ HHS OIG’s Semi-annual reports to Congress for the April 1, 2019 to March 31, 2020 periods reported 304 new Audits and Evaluations which was an increase of 111 more issued reports during the same prior year period.

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Superfund Financial Activities at the National Institute of Environmental Health Sciences

Expected Issue Date: 2023

Announced or Revised: January 2022

National Institutes of Health's National Institute of Environmental Health Sciences (NIEHS) provides Superfund Research Program funds for university-based multidisciplinary research on human health and environmental issues related to hazardous substances. Federal law and regulations require that OIG conduct an annual audit of the Institute's Superfund activities (Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. § 9611(k)). OIG will review payments, obligations, reimbursements, and other uses of Superfund money by NIEHS.

Work Plan #: W-00-22-59050

Government Program: National Institutes of Health

National Institutes of Health Small Business Innovation Research Awardee Compliance with Award Requirements

Expected Issue Date: 2023

Announced or Revised: December 2021

The Small Business Innovation Research (SBIR) program helps small businesses participate in Federal research and development (R&D). Each year, every Federal agency with an extramural R&D budget that exceeds \$100 million is required to allocate 3.2 percent of that extramural R&D budget to fund small businesses through the SBIR program. From fiscal year (FY) 2016 through FY 2020, HHS obligated \$4.6 billion in SBIR award funds, with funds from the National Institutes of Health making up approximately 98 percent of total obligations. To participate in the SBIR program, a business must be organized for profit with a place of business located in the United States, be more than 50 percent owned and controlled by U.S. citizens, and have fewer than 500 employees. OIG has identified areas of potential risk regarding for-profit organizations receiving SBIR awards such as inappropriate or unsupported charges to Federal awards, deficiencies in internal controls related to financial management systems, and eligibility of organizations to participate in the SBIR program. Other OIGs as well as Congress have also raised concerns about risks of fraud, waste, and abuse in the SBIR program. OIG will determine whether selected SBIR awardees complied with Federal requirements.

Work Plan #: W-00-22-59466

Government Program: National Institutes of Health



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Superfund Financial Activities at the National Institute of Environmental Health Sciences

Expected Issue Date: 2023

Announced or Revised: January 2022

National Institutes of Health's National Institute of Environmental Health Sciences (NIEHS) provides Superfund Research Program funds for university-based multidisciplinary research on human health and environmental issues related to hazardous substances. Federal law and regulations require that OIG conduct an annual audit of the Institute's Superfund activities (Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. § 9611(k)). OIG will review payments, obligations, reimbursements, and other uses of Superfund money by NIEHS.

Work Plan #: W-00-22-59050

Government Program: National Institutes of Health

NIH's Oversight Processes to Ensure Diversity Among Human Subjects Enrolled in Clinical Trials

Expected Issue Date: 2022

Announced or Revised: July 2021

Underrepresentation of racial and ethnic minorities, women, and individuals of all ages in clinical trials has been a longstanding concern and has garnered increased attention due to the COVID-19 pandemic's disproportionate impact on minority populations. The National Institutes of Health (NIH) is the largest funder of biomedical and public health research, supporting over \$31 billion of research across the agency. NIH's responsibilities include reviewing annual progress reports that document grantees' progress toward NIH-approved enrollment plans, which may include a diversity and inclusion component. This study will assess and describe how NIH monitors and ensures enrollment of racial and ethnic minorities, women, and individuals of all ages within the clinical trials it funds and the actions it takes in response to clinical trials that are not meeting approved enrollment plans. This study will also identify NIH's challenges and the steps it takes to address these challenges while monitoring and ensuring that its grantees meet their commitments to inclusive enrollment in their clinical trials.

Work Plan #: OEI-01-21-00320

Government Program: National Institutes of Health

NIH Oversight of Foreign Grant Recipients' Compliance With Audit Requirements

Expected Issue Date: 2022

Announced or Revised: April 2021

The National Institutes of Health (NIH) is the primary Federal agency for conducting and supporting medical research. To realize its mission of extending healthy lifespans and reducing the burdens of illness and disability, NIH funds grants, cooperative agreements, and contracts that support the advancement of fundamental knowledge about the nature and



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behavior of living systems. The 27 Institutes and Centers of NIH provide leadership and financial support to researchers both inside and outside the United States. Approximately 80 percent of NIH funding goes to support research grants, including grants to foreign organizations. Foreign grant recipients that spend \$750,000 or more in HHS funds within one year are subject to certain audit requirements intended to provide assurance to the Federal Government that the recipient has in place adequate internal controls and is generally in compliance with program requirements. OIG will review NIH funding to foreign grant recipients to determine whether: (1) NIH foreign grant recipients submit required audit reports and (2) NIH appropriately maintains and uses the audit reports.

Work Plan #: W-00-21-59457

Government Program: National Institutes of Health (NIH)

Grantee Institutions' Actions to Strengthen Policies in Response to Concerns Regarding Potential Foreign Influence on NIH-Funded Research

Expected Issue Date: 2022

Announced or Revised: March 2020

The National Institutes of Health (NIH) requires grantee institutions to report their researchers' financial interests and affiliations with foreign entities. NIH and Congress have raised concerns that the failure by some NIH-funded researchers to disclose to grantee institutions substantial contributions of resources from other organizations, including foreign governments, threatens to distort decisions about the appropriate use of NIH funds. In response to these concerns, NIH has taken steps to improve the accurate reporting of all sources of research support, financial interests, and affiliations. In July 2019, NIH released a notice to its extramural research community clarifying its policy regarding other support, including foreign affiliations. Given NIH's efforts to increase awareness among its grantee institutions regarding financial interests and foreign influence, this evaluation will focus on grantee institutions' policies and procedures related to (1) ensuring that researchers report all foreign affiliations (including foreign positions and scientific appointments, financial interests in foreign entities, research support from foreign entities, and any other foreign affiliations) and (2) reviewing the foreign affiliations that researchers report. This evaluation will also determine to what extent grantee institutions have updated or revised these policies and procedures to address recent concerns and NIH guidance.

Work Plan #: OEI-03-20-00210

Government Program: National Institutes of Health (NIH)

Review of Institutions of Higher Education Grantees Receiving National Institutes of Health Awards

Expected Issue Date: 2022

Announced or Revised: May 2020

More than 80 percent of National Institutes of Health (NIH) funding is awarded through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions located in every State and around the world. OIG has identified areas of potential risk at institutions of higher education receiving NIH awards such as inappropriate or unsupported charges to Federal awards, lack of financial conflict-of-interest polices, and



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deficiencies in internal control related to the financial management system. In addition, Congress, NIH, and Federal intelligence agencies have raised concerns about foreign threats to the integrity of U.S. medical research and intellectual property at institutions of higher education. OIG's objective will be to determine whether institutions of higher education: (1) managed NIH awards to ensure allowability of costs in accordance with Federal and award requirements, and (2) met Federal conflict-of-interest requirements.

Work Plan #: W-00-20-59445

Government Program: National Institutes of Health (NIH)

Audit of National Institutes of Health's Cybersecurity Provisions and Related Efforts to the Grant Program

Expected Issue Date: 2022

Announced or Revised: May 2020

The purpose of this audit is to determine if NIH has controls in place to ensure grants have appropriate cybersecurity provisions. The National Institutes of Health (NIH) is comprised of 27 separate components called Institutes and Centers and is the primary Federal agency responsible for conducting and supporting biomedical research for the purpose of enhancing health, lengthening life, and reducing illness and disability. Annually, NIH invests nearly \$39.2 billion in medical research projects on a number of common and rare diseases, including cancer, Alzheimer's, diabetes, arthritis, heart ailments, and AIDS. More than 80 percent of the NIH's funding is awarded through approximately 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every State and around the world.

Specifically, the audit will review NIH's policies and procedures to determine if NIH has controls or requirements in place to ensure grants have appropriate cybersecurity provisions, and review NIH's policies and procedures to test and verify that adequate cybersecurity is in place over the grantee research data.

Work Plan #: W-00-20-42027

Government Program: National Institutes of Health (NIH)

Superfund Financial Activities at the National Institute of Environmental Health Sciences

Expected Issue Date: 2021

Announced or Revised: February 2020

National Institutes of Health's National Institute of Environmental Health Sciences (NIEHS) provides Superfund Research Program funds for university-based multidisciplinary research on human health and environmental issues related to hazardous substances. Federal law and regulations require that OIG conduct an annual audit of the Institute's Superfund activities (Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. § 9611(k)). OIG will review payments, obligations, reimbursements, and other uses of Superfund money by NIEHS.

Work Plan #: W-00-20-59050



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Government Program: National Institutes of Health (NIH)

NIH's Pre-Award Process for Assessing Risk of Grant Applicants and Post-Award Process for Oversight of Grantees

Expected Issue Date: 2022

Announced or Revised: February 2019

Extramural research grants accounted for more than 80 percent of the \$37 billion that the National Institutes of Health (NIH) received for FY 2018 from Congress. Before making a Federal award, NIH is required to determine whether a party is eligible to receive Federal funds. Even if eligible, a party may be subject to certain conditions because of the risk(s) associated with making the Federal award. The Departments of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Public Law No. 115-245) and its Accompanying Report directed that OIG examine NIH's oversight of its grantees' compliance with NIH policies, including NIH efforts to ensure the integrity of its grant application and selection processes. OIG will conduct audits at NIH's Institutes and Centers to review their (i) pre-award process for assessing risk of potential recipients of Federal funds, and (ii) post-award process for overseeing and monitoring of grantees on the basis of risks identified during the pre-award process.

Work Plan #: W-00-19-51002; [A-03-19-03004](#); [A-05-19-00017](#); A-05-20-0006; [A-05-20-00026](#) (August 2021); W-00-20-51002

Government Program: National Institutes of Health (NIH)



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[NEW] The National Institutes of Health Could Improve Its Post-Award Process for the Oversight and Monitoring of Grant Awards

The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, P.L. No. 115-245, directed OIG to examine the efforts of the National Institutes of Health (NIH) to ensure the integrity of its grant application evaluation and recipient selection processes. This audit is part of OIG's response to this directive.

OIG's objective was to review the National Cancer Institute's (NCI's) post-award process for providing oversight and monitoring of grants.

SunHawk Summary of OIG Audit Findings and Recommendations

OIG found that NCI's post-award process for providing oversight and monitoring of grants was generally effective in ensuring that grantees met the program objectives and that NCI was able to identify potential problems. However, for 12 of the 20 grants in OIG's sample that were closed in FY 2019, the grantee did not submit final reports within 120 days of the end of the period of performance as required.

NIH's Division of Grants System Integration (DGSI/Closeout Center) provides outreach on NCI's behalf to grantees with respect to the due dates of the final reports within 10 days of the end of the period of performance but does not provide another reminder until after the final reports are late. This delays the closeout process. A recipient may draw funds up to the date that its Final Federal Financial Report is due to NIH or up to 120 days past the period of performance end date.

If grantees submit final reports late, it could indicate an issue with the grantee's ability to comply with grant requirements, including accounting for grant funds and tracking the progress and outcomes of the grant.

OIG recommended that NCI coordinate with NIH's DGSI/Closeout Center to update policies and procedures for monitoring grantees' submission of closeout documents to include more periodic outreach to grantees before the final reports become delinquent.

Work Plan #: [A-03-20-03001](#) (February 2022)

Government Program: National Institutes of Health (NIH)

National Institutes of Health Small Business Innovation Research Awardee Compliance with Award Requirements

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) established the trust fund known as Superfund. The CERCLA requires the Inspector General of a Federal organization with Superfund responsibilities to audit all uses of the fund in the prior fiscal year (FY).



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To meet this requirement, OIG conducts an annual audit of the Superfund program at the National Institutes of Health (NIH), National Institute of Environmental Health Sciences (the Institute), to determine whether NIH administered Superfund appropriations in accordance with applicable Federal requirements.

SunHawk Summary of OIG Audit Findings and Recommendations

OIG found that during FY 2020, NIH administered Superfund appropriations in accordance with applicable Federal requirements. Specifically, NIH obligated and disbursed Superfund appropriations in accordance with Federal requirements and in similar proportions to prior years. In addition, the Institute's monitoring of Superfund grants generally ensured that grantees met requirements for financial, performance, and audit reporting.

This report contains no recommendations.

Work Plan #: [A-04-21-04081](#) (October 2021)

Government Program: National Institutes of Health (NIH)

The National Human Genome Research Institute Should Strengthen Procedures in Its Pre-Award Process to Assess Risk for Certain Foreign and Higher Risk Applicants

The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act 2019, P.L. No. 115-245, directed OIG to examine the efforts of the National Institutes of Health (NIH) to ensure the integrity of its grant application evaluation and recipient selection processes. This audit is part of OIG's response to this directive. Previous OIG audits evaluated the pre-award risk assessment process at NIH's National Eye Institute and National Cancer Institute.

OIG's objective was to determine whether the National Human Genome Research Institute (NHGRI) had adequate policies and procedures in its pre-award process for assessing risk when awarding grant funds.

SunHawk Summary of OIG Audit Findings and Recommendations

OIG determined that NHGRI had inadequate policies and procedures as they relate to assessing the risk to NHGRI grant programs presented by foreign applicants and mitigating potential risk associated with applicants demonstrating higher risk factors. As a result, some risks associated with foreign applicants and applicants demonstrating higher risk factors may not have been identified and mitigated before grant funds were awarded.

OIG recommended that NIH direct NHGRI to: (1) improve its policies and procedures to ensure Grants Specialists monitor whether required audit reports are submitted for foreign applicants; (2) clarify existing procedures to specify when Grants Specialists should take additional steps, including the imposition of specific award conditions, to mitigate risk for new grantees; and (3) update policies and procedures for Grants Specialists to require that they review available Internal Revenue Service (IRS) Form 990s regarding grant applicants' risk factors before awarding grant funds.

Work Plan #: [A-05-20-00026](#) (September 2021)

Government Program: National Institutes of Health (NIH)



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NIH's Implementation of Financial Conflict of Interest Regulations

News reports have raised concerns about foreign threats to the United States biomedical research enterprise. In a letter to institutes receiving National Institutes of Health (NIH) funding, the Director of NIH highlighted concerns about diversion of intellectual property; sharing of confidential information from grant applications; and the failure by some NIH-funded researchers to report substantial financial support from other organizations, including foreign governments.

The Policies, Procedures, And Controls in Place to Ensure That Institutions Report All Sources of Research Support, Financial Interests, And Affiliations ([A-03-19-03003](#))

OIG reviewed the 2011 financial conflict of interest (FCOI) regulations and the NIH Grants Policy Statement to identify any FCOI requirements with which institutions must comply during the grant period and any NIH oversight responsibilities to monitor institutions during the grant period. OIG obtained an understanding of NIH's FCOI compliance program and analyzed the results of reviews conducted after the implementation of the 2011 FCOI regulations.

OIG also reviewed institutions that were required to maintain FCOI policies and that received NIH grants in fiscal year 2018 to determine whether they had publicly accessible FCOI policies.

OIG's objective was to determine whether NIH has policies, procedures, and controls in place for helping to ensure that institutions report all sources of research support, financial interests, and affiliations.

Conflicts of Interest in Extramural Research ([OEI-03-19-00150](#))

NIH awards more than 70 percent of its \$37 billion budget to universities and other extramural grantee institutions (institutions). Identifying and managing investigators' financial conflicts of interest (financial conflicts) is critical to safeguarding the integrity of NIH-funded research. In 2008, OIG identified serious gaps in NIH's oversight of investigators' financial conflicts. More recently, failures by some investigators to disclose substantial contributions of resources from other organizations-including foreign governments-have raised new concerns about threats to research integrity.

OIG collected from NIH the number and type of financial conflicts that institutions reported in fiscal year (FY) 2018. OIG sent a questionnaire and conducted an interview with staff from NIH's Office of Extramural Research (OER). OIG also reviewed guidance and training documents related to investigators' financial conflicts. Finally, OIG interviewed staff at three NIH Institutes and Centers (ICs) regarding their procedures for reviewing the financial conflicts that institutions reported.

This report focuses on the need for robust oversight, follows up on OIG's prior work, and seeks to determine whether NIH has addressed the gaps that OIG previously identified in the oversight of investigators' financial conflicts. It also provides for the first time-information about the total number and types of financial conflicts that institutions are reporting to NIH.

SunHawk Summary of OIG Audit and Evaluation Findings and Recommendations

The National Institutes of Health Has Limited Policies, Procedures, And Controls In Place For Helping To Ensure That Institutions Report All Sources Of Research Support, Financial Interests, And Affiliations ([A-03-19-03003](#))

OIG found that, of the 1,875 institutions that received NIH funding in fiscal year 2018 and were required to have FCOI policies, 1,013 did not have FCOI policies posted on their websites. Of the 90 institutions in OIG's sample that had websites but did not have posted FCOI policies, 41 either did not have FCOI policies or did not respond to OIG's requests that they provide policies. Of the 10 institutions in OIG's sample that did not have websites, three did not have FCOI policies, and



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one did not respond to OIG’s request that it provide its policy. In addition, not all NIH-funded investigators may be aware that they are required to disclose significant financial interests to their institutions, and some institutions stated that they were not aware of their responsibility to create and maintain FCOI policies.

OIG recommended that NIH (1) ensure that the 1,013 institutions OIG identified as not having FCOI policies on their website post those policies as required, (2) enhance its FCOI monitoring program to ensure that institutions resolve identified deficiencies and to review all grantee websites to ensure that FCOI policies are publicly accessible, and (3) implement procedures to ensure that all institutions required to have FCOI policies actually have FCOI policies.

NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research, But Could Do More ([OEI-03-19-00150](#))

OIG found that, over the last decade, NIH has strengthened its reporting requirements and developed an online system for collecting, reviewing, and storing the financial conflicts that institutions report. Overall, three percent of NIH grants in FY 2018 had investigators with financial conflicts. These grants received \$1 billion in funding during FY 2018, and institutions reported a total of 2,755 financial conflicts.

Although NIH has made substantial strides in reviewing the financial conflicts that institutions report, OIG found inconsistencies in the depth of its oversight reviews. Across the three ICs that OIG reviewed, staff differed in the level of scrutiny they applied to their review of financial conflicts. Furthermore, NIH lacks quality assurance procedures in its review process. Lastly, NIH cannot identify-and does not plan to identify-whether investigators' financial conflicts involve foreign interests, but is identifying foreign affiliations through a clarification of its requirements for pre-award reporting.

OIG recommended that NIH (1) perform periodic quality assurance reviews of the financial-conflict information in its online system to ensure the adequacy of its oversight, and (2) use information regarding foreign affiliations and support that it collects during the pre-award reporting process to decide whether to revise its financial-conflict review process to address concerns regarding foreign threats.

Work Plan #: [A-03-19-03003](#) (September 2019); [OEI-03-19-00150](#) (September 2019); [W-00-19-51005](#)
Government Program: National Institutes of Health (NIH)

Independent Attestation Review: National Institutes of Health Fiscal Year 2020 Detailed Accounting Report, Performance Summary Report for National Drug Control Activities, Budget Formulation Compliance Report, and Accompanying Required Assertions

This report provides the results of OIG’s review of the attached National Institutes of Health (NIH) Office of National Drug Control Policy (ONDCP) Detailed Accounting Reports, which include the tables of Drug Control Obligations, related disclosures, and management's assertions for the fiscal year ended September 30, 2020, submitted by NIH's National Institute on Drug Abuse (NIDA) and National Institute on Alcohol Abuse and Alcoholism (NIAAA), respectively. OIG also reviewed the Performance Summary Report, which includes management's assertions and related performance information for the fiscal year ended September 30, 2020, submitted by NIH for NIDA and NIAAA, collectively. Lastly, OIG reviewed the



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Budget Formulation Compliance Reports, which include budget formulation information for the fiscal year ending September 30, 2022, and the Chief Financial Officer's or accountable senior executive's assertions relating to the budget formulation information.

SunHawk Summary of OIG Audit Findings and Recommendations

Based on OIG's review, OIG is not aware of any material modifications that should be made to NIH's Detailed Accounting Reports and Performance Summary Report for fiscal year 2020 and NIH's Budget Formulation Compliance Reports for fiscal year 2022 for them to be in accordance with the ONDCP Circular.

Work Plan #: [A-03-21-00352](#) (January 2021)

Government Program: National Institutes of Health (NIH)

Selected NIH Institutes Met Requirements for Documenting Peer Review But Could Do More To Track and Explain Funding Decisions

Congress, NIH, and Federal intelligence agencies have raised concerns about the integrity of U.S. medical research. In August 2018, the NIH Director stated that the risks to the integrity of peer review were increasing. Subsequently, Congress provided the Office of Inspector General with \$5 million for oversight of NIH.

Peer review is how NIH uses scientific experts to evaluate grant applications for funding. This study assesses the extent to which select NIH institutes and centers (ICs) met NIH's basic requirements for documenting first-level peer review when evaluating applications for extramural research grants and the extent to which ICs made funding decisions not strictly limited to the scores from that review (i.e., the extent of funding of grant applications out of rank order). NIH's peer review process is central to its upholding its values of transparency, impartiality, and fairness, among others. Because of this, it is important to ensure that the process works as intended.

SunHawk Summary of OIG Audit Findings and Recommendations

Based on OIG's review, OIG is not aware of any material modifications that should be made to NIH's Detailed Accounting Reports and Performance Summary Report for fiscal year 2020 and NIH's Budget Formulation Compliance Reports for fiscal year 2022 for them to be in accordance with the ONDCP Circular.

For the six ICs OIG reviewed, NIH met its basic requirements for documenting first-level peer review. It also followed up with applicants, as required, to resolve concerns about protections for human subjects and animals. However, ICs' documentation to justify funding grants out of rank order often appeared to fall short of the requirements in HHS's Grants Policy Administration Manual, and the documentation of reasoning for those funding decisions was missing in 37 out of 109 grants in OIG's sample. A failure to document these justifications reduces transparency and can raise questions about undue influence.

OIG recommended that NIH centrally track and monitor data on funding out of rank order and update its policy and guidance to reflect the latest HHS grants policy on justifying funding out of rank order.

Work Plan #: [OEI-01-19-00140](#) (June 2021)

Government Program: National Institutes of Health (NIH)

Vetting Peer Reviewers at NIH's Center for Scientific Review: Strengths and Limitations

The National Institutes of Health's (NIH's) peer review process is central to the integrity of evaluating and selecting grant applications. The Director of NIH has expressed concern about the increasing risks to the security of intellectual property and to the integrity of peer review. Specifically, peer reviewers who inappropriately share confidential information in grant applications present a risk to intellectual property and undermine the integrity of peer review. The Departments of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Public Law No. 115-245) and its Accompanying Report directed that OIG examine the effectiveness of NIH's and grantee institutions' efforts to protect intellectual property derived from NIH-supported research. In this study, which will result in two reports, OIG will describe and assess NIH's process for vetting prospective peer reviewers, as well as NIH's oversight of peer reviewers beyond the vetting process.

SunHawk Summary of OIG Evaluation Findings and Recommendations

Protecting Confidentiality of Peer Reviewers ([OEI-05-19-00240](#))

OIG found that NIH has policies and procedures to protect the confidentiality of the peer review process and takes action against reviewers who disclose information. To prevent disclosures, NIH requires all peer reviewers to sign electronic nondisclosure certifications and trains peer reviewers to keep the information in grant applications private. To detect potential disclosures, NIH relies primarily on peer reviewers to report suspicious activity by other reviewers, but the agency is starting to use technology to detect disclosures. NIH has taken a range of actions against peer reviewers found to have disclosed confidential information, including terminating the reviewer's service or referring the reviewer to law enforcement for investigation. NIH actively responds to instances of suspected undue foreign influence in peer review, but the agency is in the early stages of addressing this threat systemically. NIH learns of instances of potential undue foreign influence in peer review primarily from its national security partners and from NIH staff. It has responded to these instances on a case-by-case basis. NIH is developing an approach to address foreign-influence concerns systemically—through general oversight—in addition to responding to specific incidents.

OIG recommended that the NIH take steps to address concerns about foreign threats to research integrity, and has an opportunity to more directly address—in a systemic way—concerns about foreign threats to the confidentiality of the peer review process. OIG recommended the NIH to conduct targeted, risk-based oversight of peer reviewers using risk indicators identified from analysis of research integrity threats. In addition, NIH should update its training materials routinely with information about confidentiality breaches and undue foreign influence, and the agency should require all peer reviewers to attend periodic trainings about these risks. NIH should also continue consulting with national security experts about peer review risks and mitigation to inform a risk-based oversight approach.

Vetting Peer Reviewers: Strengths and Limitations ([OEI-01-19-00160](#))

OIG found that NIH's CSR has strengths in its approach to vetting nominees' ability to be effective peer reviewers. CSR verifies nominees' scientific expertise using multiple sources such as their publication and grant histories. It also assesses nominees' communication skills and their ability to leverage those skills in a peer review setting. Peer reviewer nominees are typically well known to CSR even before their nominations, having served as temporary reviewers or having been NIH grantees. This allows CSR to evaluate the nominees on the basis of its past experiences with them. NIH also has controls



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to ensure that it does not select nominees who have engaged in research misconduct or breaches of peer review. However, CSR's vetting of peer reviewer nominees gives little attention to foreign affiliation beyond requiring a justification for reviewers who are not based in North America. Although nearly all of CSR's peer reviewers work at institutions within the United States, they include both U.S. citizens and foreign nationals. CSR vets all of these reviewers in the same way. CSR generally limits the sources it uses in vetting for other concerns (e.g., legal and moral controversies) to publicly reported information, which is unlikely to reveal such things as undisclosed foreign support.

OIG recommended that NIH update its guidance on vetting peer reviewer nominees to identify potential foreign threats to research integrity, in consultation with national security experts, as needed, and that NIH work with the Department of Health and Human Services' Office of National Security to develop a risk-based approach for identifying those peer reviewer nominees who warrant additional vetting.

Work Plan #: [OEI-05-19-00240](#) (March 2020); [OEI-01-19-00160](#) (September 2019)
Government Program: National Institutes of Health (NIH)

Controls over Subcontracting of National Institutes of Health Grant and Contract Work

Cost principles for Educational Institutions at 45 CFR Part 75 are used in determining the allowable costs of work performed by colleges and universities under sponsored agreements. The principles will also be used in determining the costs of work performed by such institutions under subgrants, cost-reimbursement subcontracts, and other awards made to them under sponsored agreements. OIG will assess colleges' and universities' controls over the subcontracting of National Institutes of Health grant and contract work. Specifically, OIG will determine whether colleges and universities effectively monitor the services subcontracted to other organizations and ensure that Federal funds are spent on allowable goods and services in compliance with selected cost principles and the terms and conditions of the grants and subcontracts. OIG will conduct reviews at selected organizations based on the dollar value of Federal grants received and on input from National Institutes of Health.

SunHawk Summary of OIG Audit Findings and Recommendations

Weill Cornell Medicine ([A-02-17-02006](#))

OIG found that as a prime recipient of NIH funds, Weill Cornell Medicine (WCM) awarded subawards and monitored subaward recipients in compliance with Federal regulations and NIH grant policies because it adhered to the subrecipient monitoring procedures that it established in response to the implementation of the Uniform Guidance at 45 CFR part 75. Specifically, WCM performed a risk assessment for each proposed subrecipient that evaluated areas such as prior audit findings, geographic location (foreign or domestic), pending or prior litigation, established financial systems, financial performance, prior working relationship, and the type of research to be performed.

Northwestern University ([A-05-17-00016](#))

OIG found that although Northwestern University (Northwestern) claimed allowable expenditures on subawards it awarded and received, it did not always perform required subaward risk assessments. For 24 of the 30 grants to subrecipients, Northwestern did not perform a risk assessment on one or more of the subrecipients. The 30 grants had subawards to 61 subrecipients, 48 of which should have had a risk assessment, but did not. The remaining 13 subrecipients either had a



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risk assessment or were not required to have a risk assessment. As a result, Federal funds of approximately \$9.7 million were awarded to subrecipients without performing the required risk assessment.

OIG recommended that Northwestern: (1) establish policies to perform subrecipient risk assessments for affiliates, Federal Demonstration Partnership members, and non-Federal subrecipients subject to 45 CFR part 75, and (2) ensure that subrecipient risk assessments are performed on all non-Federal subrecipients subject to 45 CFR part 75.

Work Plan #: [A-02-17-02006](#) (March 2019); [A-05-17-00016](#) (November 2018); W-00-16-51001; various reviews
Government Program: National Institutes of Health (NIH)

The National Institutes of Health Administered Superfund Appropriations During Fiscal Year 2019 in Accordance with Federal Requirements

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) established the trust fund known as Superfund. The CERCLA requires the Inspector General of a Federal organization with Superfund responsibilities to audit all uses of the fund in the prior fiscal year (FY).

To meet this requirement, OIG conducts an annual audit of the Superfund program at the National Institutes of Health (NIH), National Institute of Environmental Health Sciences (the Institute), to determine whether NIH administered Superfund appropriations in accordance with applicable Federal requirements.

SunHawk Summary of OIG Audit Findings and Recommendations

OIG found that, During FY 2019, NIH obligated and disbursed Superfund appropriations in accordance with Federal requirements and in similar proportions to prior years. In addition, the Institute's monitoring of Superfund grants generally ensured that grantees met requirements for financial, performance, and audit reporting.

Work Plan #: [A-04-20-04077](#) (December 2020)
Government Program: National Institutes of Health (NIH)

NIH Information Technology Audits

The National Institutes Of Health Should Improve Its Stewardship And Accountability Over Hardware And Software Asset ([A-18-19-06004](#))

The National Institutes of Health (NIH) has 27 Institutes and Centers, and each has its own specific set of research priorities. As such, the IT resources and information systems used by each of the Institutes and Centers may vary considerably. Federal law requires agencies to maintain an accurate inventory of IT resources and information systems. Revised in 2016, Office of Management and Budget (OMB) Circular A-130, Managing Information as a Strategic Resource, requires that all Federal agencies identify information technology (IT) resources and maintain an inventory of agency information systems. The Departments of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Public Law No. 115-245) and its Accompanying Report directed that OIG examine operations of NIH. OIG will determine whether NIH has complied with the applicable requirements relating to its IT resources and information systems.



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SunHawk Summary of OIG Audit Findings and Recommendations

OIG found that NIH had controls in place to effectively and efficiently track and monitor IT resources. However, NIH did not perform internal control activities in accordance with Federal directives and maintain a continual agencywide software license inventory. Specifically, Institutes and Centers (ICs) did not complete reports and perform investigations and reviews for lost, damaged, or destroyed property; identify accountable property and sensitive items as Government property; complete corrective action for property accountability and management control deficiencies; and meet minimum Department standards for its accountable personal property management program. Additionally, NIH did not maintain a continual agencywide inventory of all software licenses.

OIG also found that there was inadequate oversight to hold the ICs' management accountable for the performance of internal control activities. Additionally, there was no primary software asset management tool employed across all the ICs' operating environments to centralize and automate the capture of software inventory and entitlement data. These factors contributed to the deficiencies in NIH's stewardships of its IT resources. As a result, NIH was more susceptible to ineffective accountable property and control operations, which increased the risk that NIH would be unable to report reliable asset balances, to discover cost-saving opportunities, and to effectively safeguard assets from theft and other losses.

OIG recommended that the NIH establish an oversight body that ensures that property accountability management responsibilities and control activities for Government property are performed. Additionally, OIG recommended the NIH to employ a primary software asset management tool that centralizes and automates the capture of software inventory and entitlement data into each of the IC's operating environments. OIG also made procedural and operational recommendations.

National Institutes Of Health Had Information Technology Control Weaknesses Surrounding Its Electronic Health Record System (A-18-19-06003)

The National Institutes of Health (NIH) comprises 27 separate Institutes and Centers and is the primary Federal agency for conducting and supporting biomedical research to enhance health, lengthen life, and reduce illness and disability. Within NIH, certain Institutes and Centers provide direct patient care. NIH uses an electronic health records (EHR) system to help facilitate effective care. The Departments of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Public Law No. 115-245) and its Accompanying Report directed that OIG examine operations of NIH. OIG will determine whether select EHR system controls are in place in accordance with Federal requirements and assess EHR interoperability challenges.

SunHawk Summary of OIG Audit Findings and Recommendations

OIG found that NIH had certain controls in place to secure EHR information and information systems. However, NIH's information security policies and practices were not operating effectively to preserve the security, confidentiality, integrity, and availability of NIH's EHR information and information systems, resulting in potential risks of unauthorized access, use, disclosure, disruption, modification, or destruction. Specifically, (i) the primary and alternate processing sites were located adjacent to each other on the NIH campus and not geographically distinct; (ii) servers supporting the EHR were still in operation despite nearing end-of-life on extended support without an effective transition plan; and (iii) terminated users and inactive accounts were not deactivated in a timely manner.

OIG reported these weaknesses existed because, at the time of the fieldwork, NIH located their alternate processing site in the same geographic location as their primary site; NIH delayed software upgrades until completion of system upgrades had been completed; and NIH had not yet fully implemented the automated tool that was intended to ensure users and



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inactive accounts were deactivated timely. OIG shared the preliminary findings with NIH in advance of issuing the draft report. Before issuing the draft report, NIH implemented some of the recommendations.

OIG recommended that NIH Clinical Center Management: (1) Complete the NIST requirements for implementing an alternative processing site that is a reasonable and viable option; (2) Identify, document, and implement actions to mitigate risks of using existing alternative site based on the risk assessment results until compliant alternate site is established; (3) implement policies and procedures to ensure all software is upgraded or replaced prior to end of life; and (4) ensure that the automated CRIS User Account Management tool is operating so that all changes to user privileges are authorized, properly documented, and inactive accounts are deactivated.

Work Plan #: [A-18-19-06004](#) (September 2020); [A-18-19-06003](#) (February 2020); W-00-19-42020
Government Program: National Institutes of Health (NIH)

Potential Duplication of NIH Research Grant Funding

The National Institutes of Health (NIH) has 27 Institutes and Centers that manage research initiatives that include awarding grant funding. The Departments of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Public Law No. 115-245) and its Accompanying Report directed that OIG examine the NIH's oversight of its grantees' compliance with NIH policies, including NIH efforts to ensure the integrity of its grant application and selection processes. OIG plans to review NIH's efforts to ensure the integrity of its grant application and selection process by testing NIH's internal controls for identifying and addressing potentially duplicative grant funding and overlap within its 27 Institutes and Centers. The objective of OIG's review will be to determine whether NIH's internal controls were effective in ensuring that grantees did not receive duplicative NIH grant funding.

SunHawk Summary of OIG Audit Findings and Recommendations

OIG found that NIH's internal controls were effective in ensuring that grantees did not receive duplicate funding. Specifically, the 116 grants in OIG's sample did not duplicate other grant activities funded by NIH during OIG's audit period.

OIG reported that NIH receives approximately 80,000 applications for grant funding each year. NIH checks all applications to identify instances of duplication. If duplication is discovered during the application phase, NIH resolves the overlap prior to awarding funds through communication with the applicant institution to ensure that the duplication is removed by adjusting the research plan, budget, or commitment of personnel, as necessary.

OIG reported that after it awards grants, NIH conducts post-award monitoring using data mining technology to identify awards with potential duplication. If similar awards are identified, subject matter experts review them to determine if there is any duplication. If actual duplication is identified, the duplicate award will be terminated and the identified duplicate funding will be returned to NIH.

Work Plan #: [A-02-19-02002](#) (March 2020); W-00-19-51003
Government Program: National Institutes of Health (NIH)



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The University of Minnesota Complied with Federal Requirements to Perform Risk Assessments and Monitor Subrecipients

HHS codified the Uniform Guidance at 45 CFR part 75, which governs awards and award increments made on or after December 26, 2014. The new rule requires prime Federal award recipients to perform pre-award subrecipient risk assessments and monitor the programmatic activities of subrecipients throughout the life of each subaward.

OIG's objectives were to determine whether the University of Minnesota (Minnesota) (1) performed subrecipient risk assessments and monitored subrecipients in compliance with Federal regulations and (2) complied with Federal regulations and National Institutes of Health (NIH) grant policies related to expenditures for subawards.

OIG reported Minnesota was the prime recipient of 250 NIH grants, totaling more than \$515 million that contained subawards to other entities. Minnesota was the subrecipient of 509 grants, totaling more than \$160 million, which other NIH prime recipients awarded to Minnesota. The grants were for the period July 2015 through December 2017.

OIG reviewed 30 grants for which Minnesota was the prime recipient and 30 grants for which Minnesota was the subrecipient. OIG reviewed the awards, monitoring of the subawards, and costs claimed.

SunHawk Summary of OIG Audit Findings and Recommendations

OIG found that Minnesota claimed unallowable costs totaling \$1,924 associated with costs submitted by a subrecipient.

OIG reported that of the 30 subrecipients reviewed, the costs claimed for one subrecipient was not adequately documented. The initial support received from the subrecipient did not match the costs charged to the NIH grant. The subrecipient provided additional documentation for the claimed costs, resulting in a reduction of the costs charged by \$1,924. OIG did not find any underlying systemic issues during OIG's audit period. Minnesota is seeking reimbursement for the unallowable costs and has increased the level of monitoring of the subrecipient.

OIG recommended that Minnesota refund \$1,924 to NIH for unallowable costs claimed.

Work Plan #: [A-05-18-00015](#) (November 2019)

Government Program: National Institutes of Health (NIH)

NIH Inventory of its Information Technology Resources and Information Systems

The National Institutes of Health (NIH) has 27 Institutes and Centers, and each has its own specific set of research priorities. As such, the IT resources and information systems used by each of the Institutes and Centers may vary considerably. Federal law requires agencies to maintain an accurate inventory of IT resources and information systems. Revised in 2016, Office of Management and Budget (OMB) Circular A-130, Managing Information as a Strategic Resource, requires that all Federal agencies identify information technology (IT) resources and maintain an inventory of agency information systems. The Departments of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Public Law No. 115-245) and its Accompanying Report directed that OIG examine operations of NIH. OIG will determine whether NIH has complied with the applicable requirements relating to its IT resources and information systems.



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SunHawk Summary of OIG Audit Findings and Recommendations

OIG found that NIH did not perform internal control activities in accordance with Federal directives and maintain a continual agencywide software license inventory. Specifically, Institutes and Centers (ICs) did not complete reports and perform investigations and reviews for lost, damaged, or destroyed property; identify accountable property and sensitive items as Government property; complete corrective action for property accountability and management control deficiencies; and meet minimum Department standards for its accountable personal property management program. Additionally, NIH did not maintain a continual agencywide inventory of all software licenses.

OIG also found that there was inadequate oversight to hold the ICs' management accountable for the performance of internal control activities. Additionally, there was no primary software asset management tool employed across all the ICs' operating environments to centralize and automate the capture of software inventory and entitlement data. These factors contributed to the deficiencies in NIH's stewardships of its IT resources. As a result, NIH was more susceptible to ineffective accountable property and control operations, which increased the risk that NIH would be unable to report reliable asset balances, to discover cost-saving opportunities, and to effectively safeguard assets from theft and other losses.

OIG recommended the NIH to enhance stewardship activities associated with the management of Government personal property and software management practices. OIG recommended that NIH establish an oversight body that ensures that property accountability management responsibilities and control activities for Government property are performed. Additionally, OIG recommended that NIH employ a primary software asset management tool that centralizes and automates the capture of software inventory and entitlement data into each of the IC's operating environments.

Work Plan #: [A-18-19-06004](#) (September 2020); W-00-19-42020

Government Program: National Institutes of Health (NIH)