

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE NATIONAL EYE INSTITUTE
GENERALLY HAD ADEQUATE
PROCEDURES TO ASSESS AN
APPLICANT'S RISK DURING THE
PRE-AWARD PROCESS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
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May 2020
A-05-19-00017

Office of Inspector General

<https://oig.hhs.gov>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: May 2020

Report No. A-05-19-00017

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

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.

Our objective was to determine whether the National Eye Institute (NEI) had adequate policies and procedures in place for its pre-award process to assess risk when awarding grant funds.

How OIG Did This Audit

We obtained and reviewed NEI policies and procedures covering its pre-award risk assessment process to determine whether it was complying with Federal requirements to assess risk before making an award.

We limited our review to 1,642 extramural grant awards, totaling \$610.1 million, that NEI made in fiscal year 2018.

To review the grant award process for different types of recipients and awards, we selected a non-statistical sample of six grant awards.

The National Eye Institute Generally Had Adequate Procedures To Assess an Applicant's Risk During the Pre-Award Process

What OIG Found

NEI generally had adequate policies and procedures in place for its grant pre-award process. However, NEI did not perform or adequately document a required financial capability review for two of the six grant awards in our sample. The HHS *Grants Policy and Administration Manual* (GPAM) requires that, before making a grant award, the awarding agency conduct a financial capability review of a grant applicant that has not received an award from a Federal agency within the preceding 3 years. As a result, not all risks for applicants may have been identified and mitigated before grant funds were awarded.

What OIG Recommends and the National Institutes of Health Comments

We recommend that NIH direct NEI to develop written procedures for conducting and documenting the financial capability review required by the HHS GPAM and provide training to NEI Grants Management Specialists about how to adequately document their review of a grant applicant's financial statements and the organization's financial status.

In written comments on our draft report, NIH concurred with our recommendations. NIH stated that NEI's Grants Management leadership is developing Standard Operating Procedures for reviewing and documenting financial capability reviews. NIH also stated that NEI plans to provide training to Grants Management Specialists by incorporating guidance on how to adequately document the review of grant applicants' financial statements and the organization's financial status into training that is currently provided on an annual basis.

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INTRODUCTION

WHY WE DID THIS AUDIT

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 the Office of Inspector General (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.

OBJECTIVE

Our objective was to determine whether the National Eye Institute (NEI) had adequate policies and procedures in place for its pre-award process to assess risk when awarding grant funds.

BACKGROUND

NIH comprises 27 Institutes and Centers, each with a specific research agenda, often focusing on particular diseases or body systems. As part of NIH, NEI's mission is to conduct and support research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind. In fiscal year (FY) 2018, NEI made 1,642 extramural awards for research grants, fellowships, career development, and training totaling \$610 million.

The six major steps in NIH's grants selection process are summarized below.



- **Funding Announcement:** NIH publishes a funding opportunity announcement on Grants.gov and in the *NIH Guide for Grants and Contracts*.
- **Application for Grant Funding:** Applicants complete and submit an application.¹
- **Receipt & Referral:** NIH assigns applications to an Institute or Center.
- **Peer Review:** The first level of peer review is conducted by an initial review group or a scientific review group to evaluate scientific and technical merit. Applications recommended for further consideration receive a second level of review by the Institute

¹ The grant application asks where the proposed project will primarily be located and whether it involves activities outside the United States or in partnership with international collaborators. The Biographical Sketch within the application includes an area where the applicant can report other research support or affiliations.

or Center's National Advisory Council or Board for scientific and technical merit and relevance to the Institute or Center's programs and priorities.

- **Pre-Award & Award Process:** Following the peer review process, applications are reviewed for other considerations, including the project's budget, applicant eligibility, and an assessment of the applicant's management systems. NEI also uses "just-in-time" procedures for certain programs, which allow certain elements of an application (e.g., active and pending support for senior/key personnel) to be submitted later in the application process, once funding is under consideration. NEI conducts final administrative reviews, including pre-award risk assessments. Once an application is approved, successful applicants receive Notices of Award.
- **Post-Award Monitoring & Reporting:** NEI monitors the awarded grants; monitoring activities include, but are not limited to, corresponding with the recipient, reviewing audit reports, reviewing progress reports, and conducting site visits during the award period.

Before making a Federal award, NEI must comply with Federal regulations at 45 CFR § 75.205, which state that Federal awarding agencies are required to review the risks posed by applicants.² Even if NEI determines that a Federal award will be made, it may impose special conditions on the recipient that correspond to the degree of risk associated with making the Federal award. NEI cannot support research unless it has assurance that the grantee will use its funds appropriately, maintain adequate documentation of transactions, and safeguard assets.

HOW WE CONDUCTED THIS AUDIT

We obtained a list of all 1,642 extramural grant awards, totaling \$610,056,340, that NEI made in FY 2018. We interviewed NIH and NEI officials familiar with the grant pre-award process. We obtained and reviewed NEI policies and procedures covering its grant pre-award process. To review the grant award process for different types of recipients and awards, we selected a non-statistical sample of six grant awards intended to cover a mix of the following characteristics (Table, next page):

² These regulations permit U.S. Department of Health and Human Services (HHS) awarding agencies evaluating risks posed by applicants to consider factors such as financial stability, quality of management systems, ability to meet management standards, history of performance, reports and findings from audits, and ability to effectively meet requirements. The HHS *Grants Policy and Administration Manual* (GPAM) establishes HHS policies for the administration of grants and cooperative agreements. The GPAM provides all HHS grants-awarding agencies with a uniform set of minimum policy requirements that HHS staff must follow throughout a grant's life cycle.

Table: Type of Recipients and Awards We Considered When Selecting Grants for Review

Type of Recipient	Type of Award
<ul style="list-style-type: none">• New NEI awardee• Existing NEI awardee• International awardee• University• For-profit company	<ul style="list-style-type: none">• High dollar award• Cooperative Agreement• Brain Research through Advancing Innovative Neurotechnologies (BRAIN)³ Initiative grant

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.

The Appendix contains the details of our audit scope and methodology.

FINDINGS

NEI generally had adequate policies and procedures in place for its grant pre-award process. However, NEI did not perform or adequately document a required financial capability review for two of the six grant awards in our sample. The HHS GPAM requires that, before making a grant award, the awarding agency conduct a financial capability review of a grant applicant that has not received an award from a Federal agency within the preceding 3 years. As a result, not all risks for applicants may have been identified and mitigated before grant funds were awarded.

THE NATIONAL EYE INSTITUTE GENERALLY HAD ADEQUATE PRE-AWARD POLICIES AND PROCEDURES

NEI generally had adequate policies and procedures in place for its pre-award process to assess an applicant's risk prior to awarding grant funds. Below are the primary steps NEI performs during the pre-award process.

- NEI uses eRA Commons,⁴ an automated system that maintains all of the checklists and worksheets generated to document the application and review process. The checklist items vary based on many factors, including, but not limited to, whether the applicant is a new or an existing recipient; the type of research being conducted (including human, animal,

³ The BRAIN Initiative aims to revolutionize the understanding of the human brain.

⁴ eRA Commons is an online interface where grant applicants, recipients, and Federal staff at NIH can access and share administration information related to research grants.

clinical research, or biohazard); the type of application (including research grants, career development awards, or research training and fellowship program projects); and whether the applicant is foreign or domestic. The worksheets summarize the results of the information gathered from the checklists. In addition, for new or competing continuation grant awards made to a foreign organization or those with a foreign component, NEI obtains the necessary clearances from the U.S. Department of State.⁵

- Two of the checklists used by NEI and maintained in eRA Commons assess the risk of grant applicants during the pre-award process. The Grants Management checklist covers topics that address administrative requirements to ensure completeness of an application, compliance with NIH and HHS policies, and compliance with other Federal regulations and requirements. The Grants Management checklist also prompts NEI staff to assess an applicant's financial management capabilities. The extent of a financial management analysis is a matter of NEI staff judgment based on factors such as the applicant's previous experience in managing grant funds, experience with the applicant, the dollar amount of the grant, and the complexity of the grant. The Program Management checklist is used to ensure compliance with programmatic requirements before the issuance of a competing award and to evaluate the scientific merit of continuing the research.
- Further, the Grants Management checklist is designed to prompt NEI staff to review information about eligibility, financial integrity, and past performance.⁶ Some sources NEI uses include:
 - *The General Services Administration System for Award Management (SAM)*. SAM is an electronic, web-based system that is used to identify those parties excluded from receiving Federal contracts, certain subcontracts, and certain types of Federal financial and non-financial assistance and benefits. NEI Grants Management Specialists (NEI Specialists) are required to check SAM before making an award to determine whether the organization or individuals, or both, supported under the award are excluded or disqualified from participation.
 - *The Federal Awardee Performance and Integrity Information System (FAPIS)*. FAPIS provides publicly available information about an institution's integrity, business ethics, and past performance under financial assistance awards. NEI Specialists are required to check FAPIS before making an award to determine whether an applicant is qualified to receive a Federal award.

⁵ A foreign component is defined as performance of any significant element or segment of the project outside the United States either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended.

⁶ These risk factors are described at 45 CFR § 75.205.

- *National External Audit Review Center (NEAR) Alerts.* Certain recipients of Federal funds are required to conduct a Single Audit and to submit it to the Federal Audit Clearinghouse, which notifies NEAR of any audit findings related to an HHS award. NEAR Alerts are published monthly by the HHS OIG NEAR. NEAR may issue an Alert for negative or potentially negative audit findings based on its review of an applicant's Single Audit.⁷ NIH staff compile and maintain a list of NEAR Alerts in a spreadsheet that is posted to its intranet website. NEI Specialists are required to check the NEAR Alerts list before making an award to investigate the reasons for placement on the NEAR Alert list.
- Once the preparation of an award is complete, eRA Commons generates the Award Worksheet, which summarizes the budget and the results from the Grants Management and Program Management checklists. NEI and NIH officials use the checklist results to determine whether organizations are at-risk and whether issuing awards to such organizations is appropriate.
- The Award Worksheet includes questions specific to foreign grants and grants with a foreign component. The questions on the worksheet are used to ensure that data on each foreign grant or foreign component was entered into the Foreign Award and Component Tracking System (FACTS),⁸ and that U.S. Department of State clearance was received. Additionally, one question is used to determine the viability of the project if U.S. Department of State clearance cannot be obtained.
- Before NEI makes an award, it determines the best method to manage or mitigate any specific risks identified in the pre-award process by including appropriate, specific award conditions; requiring cost reimbursement; or possibly converting the award from a grant to a cooperative agreement,⁹ to help ensure appropriate management of funds.

⁷ Non-Federal entities spending \$750,000 or more during their fiscal year in Federal awards are generally required to have a Single Audit conducted in accordance with 45 CFR § 75.514. Single Audits must be conducted in accordance with Generally Accepted Government Auditing Standards and include an examination of the entity's financial records and financial statements, testing of the entity's internal controls, and a review of the entity's compliance with requirements related to expenditures of selected Federal awards. The final audit report contains comments from the recipient, including corrective actions planned or taken to address the findings.

⁸ The FACTS is designed to meet NIH's need to accurately track and report NIH investments in research grants and contracts involving collaboration in foreign countries. FACTS is also used to process requests for foreign collaborations that require U.S. Department of State clearance.

⁹ A cooperative agreement differs from a grant in that the cooperative agreement provides for substantial interaction between the Federal awarding agency and the non-Federal entity in carrying out the activities covered by the Federal award.

THE NATIONAL EYE INSTITUTE DID NOT HAVE PROCEDURES FOR CONDUCTING AND DOCUMENTING APPLICANT FINANCIAL CAPABILITY REVIEWS TO ENSURE RISK WAS ADEQUATELY MITIGATED

Federal Requirements

When evaluating risks posed by applicants, the HHS awarding agency may use a risk-based approach and may consider a variety of factors, including the applicant's financial stability, quality of management systems, ability to meet certain management standards contained in 45 CFR section 75.302, and past performance in managing Federal funds as well as any reports and findings from previous audits of the applicant (45 CFR § 75.205(c)).

The HHS GPAM, Part G, Chapter 1.b.(41) and (45) requires the HHS awarding agency to evaluate the organization's eligibility, management systems, proposed budget, and financial capability. Specifically, the awarding agency must conduct a financial capability review for newly established organizations, organizations that have not received an award from a Federal agency within the preceding 3 years, and organizations that are experiencing financial difficulty as evidenced by financial reports. In these instances, the GPAM requires the awarding agency to evaluate the organization's financial statements and to verify that the organization's financial stability can support its operation without using Federal funds for unauthorized purposes.

Financial Capability Reviews Were Not Performed or Adequately Documented

NEI did not perform the required financial capability review for one of the six grant awards in our sample. Specifically, NEI did not perform the financial capability review for an organization that had not received an award from a Federal agency within the preceding 3 years. NEI noted on its Grants Management checklist that the applicant met financial eligibility requirements; however, there was no documentation for how the financial eligibility requirements were met, such as by reviewing financial statements. Additionally, for a second of the six audited grant awards in our sample, NEI prepared a financial questionnaire for the organization that had not received funding in the preceding 3 years; however, there was no documentation available in the award file to support any of the responses on the questionnaire to ensure that the organization was financially stable.

NEI either did not perform or properly document financial capability reviews of grantees receiving two of the six grant awards in our sample. This occurred because NEI did not have adequate written policies and procedures for conducting and documenting financial capability reviews for applicants that had not received an award from a Federal agency within the preceding 3 years. As a result, not all risks for applicants may have been identified and mitigated before grant funds were awarded.

RECOMMENDATIONS

We recommend that the National Institutes of Health direct the National Eye Institute to:

- develop written procedures for conducting and documenting the financial capability review required by the HHS GPAM and
- provide training to NEI Specialists about how to adequately document their review of a grant applicant's financial statements and the organization's financial status.

THE NATIONAL INSTITUTES OF HEALTH COMMENTS

In written comments on our draft report, NIH concurred with our recommendations. NIH stated that NEI's Grants Management leadership is developing Standard Operating Procedures for reviewing and documenting financial capability reviews. NIH also stated that NEI plans to provide training to NEI Specialists by incorporating guidance on how to adequately document the review of grant applicants' financial statements and the organization's financial status into training that is currently provided on an annual basis.

NIH'S comments are included in their entirety as Appendix B.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed NEI policies and procedures related to its pre-award risk assessment process to determine whether it was complying with Federal requirements to assess risk before making an award. We limited our review of NEI's internal controls to those that relate to our audit objective.

We limited our review to 1,642 extramural grant awards, totaling \$610,056,340, that NEI made in FY 2018.

We conducted our fieldwork at NEI offices in Bethesda, Maryland, and OIG field offices from February through June 2019.

Methodology

To accomplish our audit objective, we:

- reviewed applicable Federal and HHS regulations and policies,
- interviewed NIH and NEI personnel to obtain an understanding of NEI's pre-award risk assessment policies and procedures,
- obtained a list of all NEI grants awarded during FY 2018,
- selected a non-statistical sample of six NEI grant applicants to review the risk assessment process for those applications,
- determined whether the recipient's risk assessment was completed before the award date, and
- discussed the results of our review with NEI 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: THE NATIONAL INSTITUTES OF HEALTH COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DATE: May 2, 2020

TO: Patrick Cogley
Acting, Assistant Inspector General for Audit Services, HHS

FROM: Director, National Institutes of Health

SUBJECT: NIH Comments on Draft Report, *The National Eye Institute Generally Had Adequate Procedures To Assess an Applicant's Risk During the Pre-Award Process*, (A-05-19-00017)

Attached are the National Institutes of Health's comments on the Office of Inspector General's draft report, *The National Eye Institute Generally Had Adequate Procedures To Assess an Applicant's Risk During the Pre-Award Process*, (A-05-19-00017).

If you have questions or concerns, please contact Meredith Stein in the Office of Management Assessment at 301-402-8482.

/s/ Lawrence A. Tabak, D.D.S., Ph.D.

For Francis S. Collins, M.D., Ph.D.

Attachment

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 EYE INSTITUTE GENERALLY HAD ADEQUATE PROCEDURES TO ASSESS AN APPLICANT'S RISK DURING THE PRE-AWARD PROCESS" (A-05-19-00017)

The National Institutes of Health (NIH) appreciates the review conducted by Office of Inspector General (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 National Institutes of Health direct the National Eye Institute to develop written procedures for conducting and documenting the financial capability review required by the HHS GPAM.

NIH Response:

NIH concurs with OIG's finding and corresponding recommendation regarding the development of written procedures for conducting and documenting the financial capability review required by the HHS Grants Policy Administration Manual (GPAM).

NEI Grants Management Leadership is developing Standard Operating Procedures (SOP) for reviewing and documenting financial capability. NEI anticipates that this SOP will be completed by August 1, 2020.

OIG Recommendation 2:

We recommend that the National Institutes of Health direct the National Eye Institute to provide training to NEI Specialists about how to adequately document their review of a grant applicant's financial statements and the organization's financial status.

NIH Response:

NIH concurs with OIG's finding and corresponding recommendation regarding the training of NEI grants management specialists on how to adequately document their review of grant applicants' financial statements and the organization's financial status.

NEI plans to provide training to grants management specialists by incorporating guidance on how to adequately document the review of grant applicants' financial statements and the organization's financial status into training that is currently provided on an annual basis. NEI plans to offer the first round of enhanced annual grants management refresher training beginning October/November 2020. NEI reviews and updates trainings, as needed, on an annual basis.