

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE NATIONAL CANCER
INSTITUTE NEEDS TO STRENGTHEN
PROCEDURES IN ITS PRE-AWARD
PROCESS TO ASSESS RISK FOR
HIGHER RISK APPLICANTS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
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for Audit Services

June 2020
A-03-19-03004

Office of Inspector General

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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: June 2020

Report No. A-03-19-03004

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 Cancer Institute (NCI) had adequate policies and procedures in its pre-award process for assessing risk when awarding grant funds.

How OIG Did This Audit

We obtained a list of all 7,218 extramural grant awards, totaling \$3.7 billion, that NCI made in fiscal year 2018. We interviewed NIH and NCI officials familiar with the grant award process. We obtained and reviewed NCI policies and procedures covering its grant pre-award risk assessment process.

To review the grant pre-award risk assessment process for different types of recipients and awards, we selected a nonstatistical sample of 14 grant awards, totaling \$79.8 million, intended to cover a mix of the types of research awards that NCI funds.

The National Cancer Institute Needs To Strengthen Procedures in Its Pre-Award Process To Assess Risk for Higher Risk Applicants

What OIG Found

NCI generally had adequate policies and procedures in its pre-award process for identifying an applicant's risk before awarding grant funds. However, NCI did not adequately document its review process to assess financial capability for applicants that did not receive a grant from NCI in the 3 years before the current application. In addition, NCI did not have written policies and procedures for conducting and documenting financial capability reviews required by the HHS Grants Policy Administration Manual (GPAM) for applicants that have received funding from NCI within the past 3 years and are experiencing financial difficulty. To complete its pre-award process, NCI uses an automated system that incorporates checklists used to assess risk and to document the application and review process. NCI used its checklists to assess risk for all 14 grants that we reviewed. NCI designated the recipients of 5 of these 14 grants higher risk applicants because they had not received a grant from NCI within the 3 years before the current application. NCI requires that these applicants undergo an additional review to assess financial capability. We were unable to determine how NCI Specialists conducted the review because the review was not adequately documented in the grant file.

Documentation of applicants' financial capability was lacking because NCI did not have adequate written procedures for conducting and documenting financial capability reviews and for determining how to manage identified risks. In addition, NCI did not provide adequate training to guide NCI Specialists in their evaluation of applicants' financial capability. As a result, NCI may not be identifying and mitigating all risks for applicants before grant funds are awarded.

What OIG Recommends and NIH Comments

We recommend that NIH direct NCI to (1) update and strengthen written procedures for conducting and documenting applicant financial capability reviews as required by the GPAM and for determining how to manage the risks identified by NCI Specialists and (2) provide training to NCI Specialists about how to adequately document their evaluation of the financial capability of applicants.

In written comments on our draft report, NIH partially concurred with our first recommendation and concurred with our second recommendation. NCI described its plan to strengthen its procedures and provide additional training to staff. We agree with these corrective actions.

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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 Cancer Institute (NCI) had adequate policies and procedures in its pre-award process for assessing 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, NCI is the Federal Government's principal agency for cancer research and training. NCI's mission is to conduct and support research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer; rehabilitation from cancer; and the continuing care of cancer patients and the families of cancer patients. In fiscal year (FY) 2018, NCI made 7,218 extramural awards for research grants, fellowships, career development, and training totaling \$3.7 billion.

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 and 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 from the Institute or Center's National

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 in which the applicant can report other research support or affiliations.

Advisory Council or Board a second level of review for scientific and technical merit and relevance to the Institute or Center's programs and priorities.

- **Pre-Award and Award Process:** Following the peer review process, applications are reviewed for other considerations, including the project budget, applicant eligibility, and an assessment of the applicant's management systems. NCI also uses "just-in-time" procedures for programs that allow certain elements of an application (such as active and pending support for senior/key personnel) to be submitted later in the application process once funding is under consideration. NCI conducts final administrative reviews, including pre-award risk assessments. Once an application is approved, successful applicants receive Notices of Award.
- **Post-Award Monitoring and Reporting:** NCI 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, NCI 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 NCI determines that a Federal award will be made, it may impose on the grantee special conditions that correspond to the degree of risk associated with making the Federal award. NCI 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 7,218 extramural grant awards, totaling \$3.7 billion, that NCI made in FY 2018. We interviewed NIH and NCI officials familiar with the grant award process. We obtained and reviewed NCI policies and procedures covering its grant pre-award risk assessment process. To review the grant pre-award risk assessment process for different types of recipients and awards, we selected a nonstatistical sample of 14 grant awards, totaling \$79.8 million, intended to cover a mix of the types of research awards that NCI funds. The grant awards we selected were:

- noncompeting continuation grants,³

² These regulations permit 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 Administration Manual (GPAM) implements HHS's grants regulations and provides a uniform set of minimum policy requirements that HHS staff must follow throughout the grants life cycle.

³ This term refers to awards for a subsequent budget period within a previously approved project for which a recipient does not have to compete with other applicants.

- research grants awarded to public and private institutions,
- Small Business Innovative Research (SBIR) grants intended to stimulate technological innovation in the private sector, or
- Small Business Technology Transfer (STTR) grants intended to stimulate innovation through cooperative agreements between small businesses and research institutions.

We also reviewed specific applicant and grant characteristics that could indicate increased risk. Therefore, we included in our sample grant awards with one or more of the following increased-risk characteristics:

- the applicant was a foreign organization or had a foreign component,
- the applicant did not receive funding from NCI in the 3 years preceding the grant award,
- the grant had the highest dollar amount that NCI funded in 2018,
- the grant was awarded close to NCI's fiscal year-end, or
- the grant had special terms and conditions on the Notice of Award.

We reviewed the documentation for the selected awards to determine whether NCI's process to assess risk was adequate and whether NCI followed its process.

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

NCI generally had adequate policies and procedures in its pre-award process for identifying an applicant's risk before awarding grant funds. However, NCI did not adequately document its review process to assess financial capability for applicants that did not receive a grant from NCI in the 3 years before the current application. In addition, NCI did not have written policies and procedures for conducting and documenting financial capability reviews required by the GPAM for applicants that have received funding from NCI within the past 3 years and are experiencing financial difficulty.

To complete its pre-award process for identifying risk, NCI uses an automated system that incorporates checklists used to assess risk and to document the application and review process. NCI used its checklists to assess risk for all 14 grants that we reviewed. NCI designated the

recipients of 5 of these 14 grants as higher risk applicants because they had not received a grant from NCI within the 3 years before the current grant application. NCI requires that these higher risk applicants undergo an additional level of review to assess financial capability. We were unable to determine how NCI Specialists conducted the review because the review was not adequately documented in the grant file.

Documentation of applicants' financial capability was lacking because NCI did not have adequate written procedures for conducting and documenting financial capability reviews and for determining how to manage identified risks. In addition, NCI did not provide adequate training to guide NCI Specialists in their evaluation of applicants' financial capability. As a result, NCI may not be identifying and mitigating all risks for applicants before grant funds are awarded.

THE NATIONAL CANCER INSTITUTE HAS A PRE-AWARD RISK ASSESSMENT PROCESS THAT IT FOLLOWED TO IDENTIFY AREAS OF CONCERN

Federal Requirements

Before making a Federal award, a Department of Health and Human Services (HHS) awarding agency is required to review, as appropriate, applicant information available through any Office of Management and Budget-designated repository of eligibility qualification or financial integrity information (45 CFR § 75.205(a)). For competitive grants or cooperative agreements, the HHS awarding agency must have in place a framework for evaluating the risks posed by applicants before the applicants receive Federal awards (45 CFR § 75.205(b)). 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 § 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 NIH Grants Policy Statement, section 2.5.5, effective October 1, 2017, states that, for an applicant with previous NIH or other Federal cost-reimbursement awards, NCI may review recent audit reports and other available information to determine whether the applicant's management systems meet the standards established in 45 CFR part 75. NCI will advise the applicant if additional information is required. On the basis of the review results, NCI will determine whether any corrective action is needed and may impose special conditions on the award.

The National Cancer Institute's Risk Assessment Checklist Was Adequate

NCI has risk assessment checklists in its pre-award process for assessing risk when awarding grant funds. These risk assessment checklists met Federal requirements, and NCI followed its process for all 14 grants we reviewed.

NCI uses program and specialist checklists to identify and assess risk. The “Program Greensheet” checklist is used to verify compliance with programmatic requirements before issuance of a competing award and to evaluate the scientific merit of continuing the research. The “Specialist Greensheet” 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. NCI uses eGrants⁴ to complete these checklists and to document the application and review process. The eGrants system identifies and automatically flags any applicant that has not received funding from NCI within the 3 years preceding the application. NCI designates these applicants higher risk applicants. NCI’s checklists instruct NCI Specialists to complete an additional financial review for these higher risk applicants.

Furthermore, the “Specialist Greensheet” checklist is designed to prompt NCI staff to review information about eligibility, financial integrity, and past performance of all applicants.⁵ A description of the sources NCI uses and how NCI uses them is below.

- *The General Services Administration System for Award Management (SAM).* The 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. NCI Specialists are required to check the 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 (FAPIIS).* The FAPIIS provides publicly available information about an institution’s integrity, business ethics, and past performance under financial assistance awards. NCI Specialists are required to check the FAPIIS before making an award to determine whether an applicant is qualified to receive a Federal award.
- *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.⁶ NIH staff compile and maintain a list of NEAR Alerts, and NCI Specialists

⁴ The eGrants system provides electronic document management and was designed to automate the storage and retrieval of documents contained in the official NCI grant files.

⁵ These risk factors are described at 45 CFR § 75.205.

⁶ Non-Federal entities spending \$750,000 or more during their FY 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

are required to check the NEAR Alerts list before making an award and investigate the reasons for placement on the NEAR Alert list.

This checklist requires higher risk applicants to submit financial information so that the NCI Specialist may assess financial capability including the adequacy of their financial management systems. For applicants who have received an award from NCI within the past 3 years, this additional information is not required as part of the checklist; however, the checklist requires the NCI Specialist to review annual financial expenditure reports specific to the grant and look for unobligated balances for continuation awards. The checklist also requires the NCI Specialist to check NEAR audit report findings, and these would also alert the NCI Specialist if any applicant was experiencing financial difficulty.

Additional checklist items vary based on other factors, including whether the applicant is a new applicant or an existing recipient; the type of research (including human, animal, 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 a foreign or domestic organization. In addition, for an applicant that is a foreign organization or has a foreign component,⁷ NCI obtains the necessary clearances from the Department of State.⁸

The checklists include questions specific to foreign grants and financial conflicts of interest (FCOI) to determine whether:

- the grant application has a foreign component and, for a grant continuation, whether any foreign component is new to the grant;
- State Department clearance of the foreign component has been received;
- dollars awarded to the foreign component have been verified or entered into the Foreign Award and Component Tracking System (FACTS);⁹
- there are any FCOI concerns; and

requirements related to expenditure of selected Federal awards. The final audit report contains comments from the recipient, including corrective actions planned or taken to address the findings.

⁷ 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, regardless of whether grant funds are expended (NIH Grants Policy Statement, section 16.2, October 1, 2017).

⁸ NIH's Grants Narrative Process Cycle Memorandum, September 30, 2018.

⁹ 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. The FACTS is also used to process requests for foreign collaborations that require Department of State clearance.

- there are any reports in the FCOI database.¹⁰

On the basis of risks identified by the checklists, NCI determines the best method to manage or mitigate risk. NCI may choose to manage risk by including appropriate conditions in the specific award, requiring the recipient to request reimbursement for expenditures,¹¹ or converting the award to a cooperative agreement¹² to help ensure appropriate management of funds.

Throughout the course of the grants cycle, NCI monitors risk factors by reviewing the recipient's research performance progress reports, which outline the recipient's challenges and changes at the time of the report.

For the 14 grant files we reviewed, we found that NCI used its checklists to ensure that NCI complied with Federal requirements. For example, the checklist for one applicant indicated that there was a potential name match in the SAM to an individual the applicant listed as working on the grant. The grant documentation showed that this potential risk was eliminated by following up with the applicant and verifying that the individual working on the grant was not the same individual identified in the SAM and thus was not disqualified from participating in Federal programs.

Therefore, we determined that NCI's checklists for identifying risk were adequate.

THE NATIONAL CANCER INSTITUTE DID NOT HAVE ADEQUATE 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 § 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 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.

¹⁰ If an institution determines that an FCOI exists, the institution must report that FCOI to the NIH awarding Institution or Center. Institutions fulfill this requirement by submitting an initial report using the FCOI module in NIH's electronic Research Administration Commons, which is NIH's information technology infrastructure used to process and manage grants awarded by NIH and other grantor agencies. Institutions must submit annual FCOI reports for as long as the FCOI exists.

¹¹ Recipients of grant awards that do not have this requirement can draw down grant funds in advance.

¹² A cooperative agreement differs from a grant in that it provides for substantial interaction between the Federal awarding agency and the non-Federal entity in carrying out the activities covered by the Federal award.

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.

According to the NIH Grants Policy Statement, section 2.5.5, "Cost Analysis and Assessment of Management Systems," if an applicant has no previous experience with Federal grants or cost-reimbursement contracts, the grants management officer may review the applicant's financial management and other management systems before award. NCI designates applicants as higher risk if they have not received an award from NCI within the 3 years preceding the application because such applicants generally have a greater risk of not meeting Federal programmatic and administrative requirements. NCI, as part of its risk assessment, required an evaluation of higher risk applicants' financial management systems. To encourage uniformity in the review of these applicants' financial management systems, NIH has developed a questionnaire to evaluate higher risk institutions' financial management capabilities.

Policies and Procedures for Financial Capability Reviews Were Lacking

For the five sampled grant applicants that met NCI's definition of a higher risk applicant, NCI met the Federal requirement that it conduct a financial capability review for applicants that have not received funding within the past 3 years, but there was no evidence in the grant file that NCI Specialists evaluated the applicants' ability to manage funds. For the nine sampled grant applicants that had received funding from NCI within the past 3 years, NCI did not have written policies and procedures requiring the NCI Specialist to conduct and document a financial capability review for any applicants that demonstrated financial difficulty.

For applicants that had not received funding from NCI within the past 3 years, NCI Specialists were required to complete an additional review that included evaluating applicant responses to a financial questionnaire and financial documents to assess the applicant's financial capability. For the five higher risk applicants in our sample, the applicants completed the financial questionnaire and submitted it along with financial documents for the NCI Specialist's review. NCI stated that the NCI Specialist is responsible for considering the ratio of the applicant's assets to liabilities as well as the applicant's sources of income to analyze the applicant's financial viability before a grant may be awarded. The NCI Specialist is also responsible for determining whether the applicant's financial management systems are adequate. If the NCI Specialist's review raised concerns about the applicant's financial capability, the NCI Specialist could request an additional financial capability review from the Division for Financial Advisory Services, which is a division of the Office of Acquisition Management and Policy. However, we were unable to determine what the NCI Specialist did to verify and evaluate applicant responses to the questionnaire and evaluate the financial documents because the review was not adequately documented in the grant file.

For example, for one of the samples we reviewed, the applicant's responses to questions in the financial questionnaire indicated that the applicant had not established internal controls to ensure that accounting entries were supported. Additionally, the applicant indicated that it had written procedures in place to separate cash receipt, cash payment, and cash recording responsibilities. However, no support was found in the grant file to indicate that the NCI Specialist verified that these policies and procedures existed. The only supporting document in the grant file was a balance sheet that showed that the applicant had a relatively low amount of cash and assets. There was no evidence in the grant file showing how the NCI Specialist evaluated the applicant's financial questionnaire responses and the balance sheet to make the determination that the grant should be awarded. Another applicant responded to the questionnaire by stating that it was too small to have separation of cash control responsibilities but did have written cash control procedures. The NCI Specialist did not document how he or she evaluated the risk posed by the lack of separation of duties and what he or she did to mitigate that risk to an acceptable level.

Although none of the nine applicants who received funding from NCI within the previous 3 years demonstrated financial risk, NCI has no written policies and procedures addressing the GPAM requirement that NCI Specialists conduct and document a financial capability review when an applicant is determined to be experiencing financial difficulty.

Documentation of the evaluation of higher risk applicants' financial capability was lacking because NCI did not have adequate procedures for documenting financial capability reviews and for determining how to manage identified risks. In addition, NCI did not provide adequate training to guide NCI Specialists in their evaluation of applicants' financial capability. 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 Cancer Institute to:

- update and strengthen written procedures for conducting and documenting applicant financial capability reviews as required by the GPAM and for determining how to manage risks identified by NCI Specialists and
- provide training to NCI Specialists about how to adequately document their evaluation of the financial capability of applicants.

NIH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, NIH partially concurred with our first recommendation and fully concurred with our second recommendation. NCI stated that it has a written standard operating procedure (SOP) for conducting and documenting applicant financial capability reviews for applicants that have not received funding from NCI in the

preceding 3 years. This SOP was not provided for our review during the audit. After receiving NIH's comments, we requested the SOP, which was in effect during our audit period.

NCI's SOP contains some procedures for conducting and documenting applicant financial capability reviews for most applicants that did not receive funding from NCI in the past 3 years. However, the SOP does not provide instructions for NCI Specialists to follow to document their evaluation of financial capability reviews. In addition, the SOP does not address conducting and documenting applicant financial capability reviews for applicants that have received NCI support in the past 3 years but are experiencing financial difficulties. NIH concurred that its SOP does not address this category of applicants.

The SOP also exempts SBIR and STTR grant applicants from the financial capability review requirement. The GPAM, however, does not. When we asked NCI officials, they stated that the SOP was modified in practice by the "Specialist Greensheet" checklist in FY 2017 and that SBIR and STTR grant applicants are not exempted and must meet the financial capability review requirement. NCI officials further stated that the SOP will be revised and updated to reflect that the financial capability review requirement applies to SBIR and STTR applicants. In our draft report, we stated that we found that NCI did not have written policies and procedures for conducting and documenting applicant financial capability reviews. As a result of our review of this SOP, we have revised the finding to state that NCI's policies and procedures were not adequate.

In its comments, NCI stated that it plans to update and improve its SOP on pre-award risk assessments and finalize an SOP on documenting award decisions. This SOP would include sections on documenting NCI Specialists' evaluation of applicant financial capability and providing training to staff. Therefore, we have revised our first recommendation to recommend that NCI update and strengthen its written procedures for conducting and documenting applicant financial capability reviews as required by the GPAM and for determining how to manage risks identified by NCI Specialists.

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

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed NCI's policies and procedures related to its pre-award risk assessment process to determine whether it complied with Federal requirements for assessing risk before making an award. We obtained a list of 7,218 grants totaling \$3,660,051,993 that NCI awarded in FY 2018. We then judgmentally selected 14 of these transactions, totaling \$79,752,735, for detailed review.

We did not perform an overall assessment of NCI's internal control structure. Rather, we limited our review of NCI's internal controls to those that related to our audit objective.

We conducted our fieldwork at NCI offices in Bethesda, Maryland, from February through September 2019.

METHODOLOGY

To accomplish our audit objective, we:

- reviewed applicable Federal regulations and HHS policy,
- interviewed NIH and NCI personnel to obtain an understanding of NCI's pre-award risk assessment policies and procedures,
- obtained and reviewed NCI's policies and procedures covering its pre-award risk assessment process,
- obtained a list of all NCI grants awarded during FY 2018,
- selected a nonstatistical sample of 14 NCI grant applicants to review,
- obtained the grant documentation for the 14 selected grant applicants and reviewed the risk assessment process for those applications,
- determined whether each grant applicant's risk assessment was completed before the award date, and
- discussed the results of our review with NCI 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: NIH COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DATE: April 2, 2020

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

FROM: Director, National Institutes of Health

SUBJECT: NIII Comments on Draft Report, *The National Cancer Institute Needs To Develop Procedures in Its Pre-Award Process To Assess Risk for Higher Risk Applicants* (A-03-19-03004)

Attached are the National Institutes of Health's comments on the Office of Inspector General's (OIG) draft report, *The National Cancer Institute Needs To Develop Procedures in Its Pre-Award Process To Assess Risk for Higher Risk Applicants* (A-03-19-03004).

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

/s/ **Francis S. Collins, M.D., Ph.D.**

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

Attachment
General Comments

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 CANCER INSTITUTE NEEDS TO DEVELOP PROCEDURES IN ITS PRE-AWARD PROCESS TO ASSESS RISK FOR HIGHER RISK APPLICANTS" (A-03-19-03004)

The National Institutes of Health (NIH) appreciates the review conducted by the 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 Cancer Institute to develop written procedures for conducting and documenting applicant financial capability reviews as required by the GPAM and for determining how to manage risks identified by NCI Specialists.

NIH Response:

NIH does not concur with OIG's finding and corresponding recommendation regarding NCI developing written procedures for conducting and documenting applicant financial capability reviews. As stated in the OIG report, NCI has written procedures for conducting and documenting applicant financial capability reviews for applicants that have not received funding from NCI in the past three years. These procedures are captured in a standard operating procedure (SOP) plus additional information provided to staff on an internal SharePoint site.

However, NIH does concur that those procedures do not address conducting and documenting applicant financial capability reviews for applicants that have received NCI support in the past three years but are experiencing financial difficulties.

NCI plans to update and improve their SOP on pre-award risk assessment and anticipates a target completion date of September 30, 2020.

OIG Recommendation 2:

We recommend that the National Institutes of Health direct the National Cancer Institute to provide training to NCI Specialists about how to adequately document their evaluation of the financial capability of applicants.

NIH Response:

NIH concurs with OIG's finding and corresponding recommendation regarding providing training to NCI specialists about how to adequately document their evaluation of the financial capability of applicants.

NCI plans to finalize an SOP on documenting award decisions, including documenting evaluation of financial capability by June 2020. Once the SOP is completed, staff will receive training to be completed within one month. Second level award reviewers will monitor compliance with the SOP.