Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE NATIONAL INSTITUTES OF HEALTH COULD IMPROVE ITS POST-AWARD PROCESS FOR THE OVERSIGHT AND MONITORING OF GRANT AWARDS

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.



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for Audit Services

February 2022 A-03-20-03001

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: February 2022 Report No. A-03-20-03001

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

How OIG Did This Audit

We obtained a list of all 7,564 extramural grant awards, totaling \$3.8 billion, that NCI made in fiscal year (FY) 2019. We also obtained a listing of 1,678 extramural grant awards, totaling \$2.2 billion, that NCI closed in FY 2019. We interviewed NIH and NCI officials familiar with the grant award process and obtained and reviewed NCI's policies and procedures covering its grant postaward process.

To review the grant post-award process for different types of recipients and awards, we selected a judgmental sample of 17 grants awarded in FY 2019 totaling \$79 million and 20 grants closed in FY 2019 that had awards totaling \$70.6 million.

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

What OIG Found

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 our 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.

What OIG Recommends and NIH Comments

We recommend 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.

In written comments on our draft report, NIH agreed with our recommendation and described the corrective action it plans to take. Specifically, NIH stated that it is planning to add an additional notification on day 90, before the submission deadline of 120 days, to address our recommendation regarding increased outreach efforts to grantees. NIH plans to update its policies and procedures by the end of FY 2022 in response to our recommendation.

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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.¹

OBJECTIVE

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

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) 2019, NCI made 7,564 extramural awards for research grants, fellowships, career development, and training totaling \$3.8 billion.²

To fulfill its role as a steward of Federal funds, NCI must monitor grants after they are awarded to ensure that grantees are meeting the program objectives and to identify any potential problems.³ The information obtained through post-award monitoring is used to measure certain aspects of continued performance and whether additional actions are needed to increase the potential for successful performance or to protect Federal interests. Post-award monitoring generally involves reviewing requests from grantees to make grant changes that require prior approval, reviewing grantee-submitted reports outlining grant progress, and closing out the award at the end of the life cycle of the grant. Closeout of an award is the

¹ The National Eye Institute Generally Had Adequate Procedures To Assess an Applicant's Risk During the Pre-Award Process (A-05-19-00017), issued May 2020; The National Cancer Institute Needs To Strengthen Procedures in Its Pre-Award Process To Assess Risk for Higher Risk Applicants (A-03-19-03004), issued June 2020; and The National Human Genome Research Institute Should Strengthen Procedures In Its Pre-Award Process To Assess Risk For Certain Foreign And Higher Risk Applicants (A-05-20-00026), issued August 2021.

² Extramural grants are grants that NIH awards to external organizations, including universities, medical schools, hospitals, and other research facilities.

³ The Department of Health and Human Services (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 grant's life cycle.

process by which NIH determines that all applicable administrative actions and all required work of an award have been completed by the grantee and NIH. The grant closeout process is primarily a grantee responsibility and involves the grantee submitting final reports to NIH. However, if the grantee does not provide timely reports, NIH may close out the grant unilaterally.

HOW WE CONDUCTED THIS AUDIT

We obtained a list of all 7,564 extramural grant awards, totaling \$3.8 billion, that NCI made in FY 2019. We also obtained a list of 1,678 extramural grant awards, totaling \$2.2 billion, that NCI closed in FY 2019. In addition, we interviewed NIH and NCI officials familiar with the grant award process and obtained and reviewed NCI's policies and procedures covering its grant postaward process. To review the grant post-award process for different types of recipients and awards,⁴ we selected a judgmental sample of 17 grants awarded in FY 2019 totaling \$79 million and 20 grants closed in FY 2019 that had awards totaling \$70.6 million.^{5,6}

We selected grants with characteristics that could warrant increased monitoring, such as if the grant was awarded to a foreign organization, had a foreign component, or had significant prior Single Audit findings. We also reviewed the documentation for the selected awards to determine whether NCI's post-award process 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.

⁴ Examples of types of grant recipients and awards include research grants awarded to public and private institutions, cooperative agreements, and Small Business Innovative Research grants intended to stimulate technological innovation in the private sector.

⁵ The judgmental sample of 17 grants awarded in FY 2019 included 11 grants that also had a FY 2018 award that we reviewed as part of our audit of NCl's pre-award risk process. See *The National Cancer Institute Needs To Strengthen Procedures in Its Pre-Award Process To Assess Risk for Higher Risk Applicants* (A-03-19-03004), issued June 1, 2020.

⁶ For the sampled grants awarded in FY 2019, the award occurred in FY 2019. For the sampled grants closed in FY 2019, the award consists of all award actions during the life of the grant.

⁷ As stated at 45 CFR § 75.501, 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 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.

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

FINDINGS

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 our 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 reports are late. This delays the closeout process. A recipient may draw funds up to the date that its Final Federal Financial Report (Final FFR) 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.

THE NATIONAL CANCER INSTITUTE'S POST-AWARD PROCESS THAT IT FOLLOWED FOR OVERSIGHT AND MONITORING OF GRANT AWARDS WAS GENERALLY EFFECTIVE

Federal Requirements

Post award, the Department of Health and Human Services (HHS) awarding agency must manage and administer an award to ensure that Federal funding is expended in accordance with Federal requirements (45 CFR § 75.300(a)). Accordingly, the HHS awarding agency must require the grantee to submit standardized financial and performance information throughout the life of the grant. The frequency at which the grantee should submit this information should be indicated in the grant's Notice of Award (45 CFR § 75.210(d)). The awarding agency should use this information to measure the award's progress (45 CFR § 75.301).

In addition, the Grants Policy Administration Manual (GPAM) Part H, Chapter 2, states that post-award monitoring is intended to ensure, among other things, that the grantee is making progress towards the award objectives, minimizing the time between transfer of funds and disbursement, providing required matching or cost sharing, maintaining adequate administrative and financial systems, accounting for Federal or grant-generated resources in accordance with the terms and conditions of the award, communicating significant developments that impact the timeframe and performance goals of the award, and complying with other terms and conditions of the award. All monitoring must be documented by the awarding agency. The grants office is responsible for administrative and financial monitoring, while the program office is responsible for monitoring compliance with program requirements.

NCI follows NIH's grants policies and procedures for monitoring its post-award grants. The NIH Grants Policy Statement, section 8.4, states that grantees are responsible for managing their day-to-day operations. The awarding agency's active monitoring is accomplished through a review of grantee reports and correspondence, audit reports, site visits, and other information. Section 8.4.1 states that NIH requires grantees to periodically submit financial and progress reports. Grantees are allowed a specific period of time to submit their required financial and final progress reports. Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions, including withholding of future grant awards, removal of certain NIH Standard Terms of Award, or conversion to a reimbursement payment method. In addition, GPAM Part H, Chapter 2 requires that followup action for late reports must occur no later than 30 days after the established due date and is the responsibility of the grants official.

The National Cancer Institute's Post-Award Process Was Effective

Based on our review of the sample of 17 grants awarded in FY 2019, we concluded that NCI followed its post-award process for reviewing and monitoring awards. We also concluded that that process was generally effective to ensure that grantees were making progress in achieving the objectives of the Federal award and were in compliance with the grant requirements as established by the GPAM.

Monitoring the performance of grants is a responsibility shared by the Program Official and the Grants Management Officer assigned to the grant and continues through the closeout of the grant. NCI requires grantees to submit reports that provide information on grant progress and expenditures. For non-competing awards, the Research Performance Progress Report (RPPR) is a progress report that is used to describe a grant's progress during the current budget year, identify significant changes to the grant, report on the activities of personnel working on the grant, and describe plans for the subsequent budget year. The FFR is used to submit financial information for individual grant awards on an annual basis. The submission dates for these reports are indicated on the grant's Notice of Award and coincide with Federal requirements. These reports allow the Program Official and Grants Management Officer to complete their programmatic and administrative reviews. NCI monitors the receipt of required reports and follows up with grantees whose reports are not submitted timely. Review of the grant for the current budget period does not begin until these reports are received.

NCI documents programmatic and administrative reviews of the reports using checklists called "greensheets." Among other things, the "Program Greensheet" is used to evaluate the scientific merit of continuing the research. The Program Greensheet includes questions that pertain to certain information reported on the RPPR. The intent of these questions is to aid reviewers in identifying any significant changes to the research objectives and goals, determining whether progress is satisfactory for continued funding, and establishing whether there are any new inventions attributed to the grant. The "Specialist Greensheet" checklist covers administrative requirements intended to ensure completeness of an application, compliance with NIH and HHS policies, and compliance with other Federal regulations and

requirements. NCI uses its programmatic and administrative reviews of the current progress of the grant as the basis for deciding whether to continue funding for the next budget period.

NCI requires prior approval of some post-award grant activities, including any change in the scope of project, certain requests for carryover of unobligated balances, any change in the Principal Investigator, and any addition of a foreign component. Grantees are required to submit requests for prior approval in writing, and these requests are reviewed by the Program Official and Grants Management Officer. If approved, a new Notice of Award is issued.

THE NATIONAL INSTITUTES OF HEALTH COULD IMPROVE ITS PROCEDURES FOR ENSURING TIMELY RECEIPT OF FINAL REPORTS FROM GRANTEES

Federal Requirements

Federal requirements at 45 CFR section 75.381(a) state that the grantee must submit all financial, performance, and other reports required by the terms and conditions of the Federal award within 90 calendar days after the end of the period of performance.

Section 8.6 of the NIH Grants Policy Statement states that grantees must submit their Final FFR, the Final RPPR (FRPPR), and the Final Invention Statement and Certification (FIS) within 120 calendar days of the end of the period of performance.^{8,9}

Failure to submit timely and accurate final reports may affect NIH's future funding of the grantee. GPAM Part H, Chapter 5 states that if the awarding agency does not receive final reports in a timely fashion within the closeout period and determines that it cannot complete a closeout with the cooperation of the grantee, the awarding agency may elect to complete a unilateral closeout. If the awarding agency decides that enforcement actions are necessary, the type of action and its scope must be commensurate with the program needs and the actions or inactions of the grantee. NCI uses final reports to ensure that grantees have managed and accurately accounted for grant funds, made progress towards the achievement of scientific aims, and identified significant outcomes and any inventions.

The National Institutes of Health's Monitoring Did Not Ensure Grantee Compliance With Final Report Submission Deadlines

For 12 of the 20 closed grants in our sample, grantees did not submit at least 1 of the required final reports within 120 days as required. These 12 grantees submitted final reports between 1 and 127 days late. Additionally, based upon the final report submission dates reported on NCI's

⁸ NIH received a waiver from HHS to extend its closeout period for all grants from 90 to 120 days for projects ending on or after October 1, 2014.

⁹ The FIS indicates whether the funded project resulted in any inventions and whether those inventions were previously reported. The FIS must list all inventions attributed to the grant and must be submitted regardless of whether the grant resulted in any inventions.

list of all grants closed during FY 2019, we determined that for approximately 60 percent of grants closed in FY 2019, at least 1 final report was not submitted within the required 120 days.

NCI grantees' are required to submit the Final FFR, the FRPPR, and the FIS via the electronic Research Administration (eRA Commons) within 120 days of their grants' end of period of performance, as required by the NIH Grants Policy Statement. NCI must review these reports before closing the award. NCI monitors the review and approval of final reports and tracks the grants as they move through the closeout period. NCI works with grantees to obtain additional information that may be required before the final reports can be approved and also monitors and corresponds with grantees whose reports remain delinquent. If a grantee fails to submit the required final reports after the completion of the grant, NCI has policies and procedures to unilaterally close out the grant award within 270 days. The Grantees who do not submit final reports could be subject to enforcement actions such as corrective actions, withholding of future grants awards, suspension, or termination. Documents related to post-award monitoring activities are maintained in the official electronic grant file.

NIH could improve its monitoring of grantee compliance with final report submission deadlines by following up with grantees who have not submitted final reports before those reports are late. Although NIH grantees are required to submit the final reports within 120 days after the end of the performance period, NIH does not follow up with grantees to ensure compliance until after the final reports are already late. On behalf of NCI, the NIH DGSI/Closeout Center will send up to three letters via email to recipients during the 150 days after the project period end date to obtain required final reports. The DGSI/Closeout Center sends the first letter via email within 10 days after the end of the period of performance to notify the grantee of the due date of the required final reports. If a grantee does not submit all of its final reports within 120 days, the DGSI/Closeout Center will send a second letter at 121 days, advising the grantee that its reports are now late, and then, if necessary, will send a third letter at day 150. After the DGSI/Closeout Center sends its final letter, NCI's Closeout Coordinator obtains a list of grants with reports that are still delinquent after 160 days and follows up with the grantee to obtain missing documentation so that it can close out the grant within 270 days.

Example: Reports Submitted Late

For one grant, the DGSI/Closeout Center notified the grantee that the project end date was June 30, 2018, and that its final reports were due on October 28, 2018, 120 days after the end of the performance period. The grantee did not submit all of its final reports by October 28, 2018, so on October 29, 2018, the DGSI/Closeout Center notified the grantee that the reports were late. On November 28, 2018, 150 days past the end date of the grant, the DGSI/Closeout

¹⁰ eRA Commons is an online interface that grant applicants, grantees, and Federal staff at NIH and grantor agencies can use to access and share administrative information relating to research grants.

¹¹ NCI did not unilaterally close out any of the 20 closed grants in our judgmental sample because of missing required final reports.

Center sent a second notification to remind the grantee that its reports were late and still needed to be submitted. The grantee ultimately submitted its final reports on February 3, 2019, 218 days after the end of the grant and 98 days late. The grant was then officially closed on February 15, 2019, 230 days after the end of the grant.

If grantees do not submit final documents as required, the closeout process may be delayed. A recipient may draw funds up to the date that its Final FFR is due to NIH or up to 120 days past the period of performance end date. Failure to submit required reports timely in accordance with grant requirements may also indicate that a grantee is having issues properly accounting for grant funds and tracking the progress and outcomes of the grant.

RECOMMENDATION

We recommend that the National Cancer Institute coordinate with the National Institutes of Health's DGSI/Closeout Center to update policies and procedures for monitoring grantees' submission of closeout documents to include increased outreach to grantees before the final reports (Final FFR, FRPPR, and FIS) become delinquent.

NIH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, NIH concurred with our recommendation. In its comments, NIH stated that it is planning to add an additional notification on day 90, before the submission deadline of 120 days, to address our recommendation regarding increased outreach efforts to grantees. NIH plans to update its policies and procedures by the end of FY 2022 in response to our recommendation.

NIH also provided technical comments, which we addressed as appropriate. NIH's comments, excluding the technical comments, are included as Appendix B.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We obtained a list of all 7,564 extramural grant awards, totaling \$3,819,083,280, that NCI made in FY 2019. We also obtained a list of 1,678 grant awards totaling \$2,201,780,522, that NCI closed in FY 2019. To review the grant post-award process for different types of recipients and awards, we selected a judgmental sample of 17 grants that had awards in FY 2019 totaling \$78,995,838. We also selected a judgmental sample of 20 grants that were closed in FY 2019 and that had awards totaling \$70,645,276.

We determined that a review of NCI's internal controls was significant to accomplishing our audit objective. We assessed the design, implementation, and operating effectiveness of NCI's policies and procedures that related to the oversight and monitoring of grants post award.

We conducted our audit from March 2020 through November 2021.

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 post-award oversight and monitoring policies and procedures,
- obtained and reviewed NCI's policies and procedures covering its post-award oversight and monitoring process,
- obtained a list of all NCI grants awarded during FY 2019,
- selected a judgmental sample of 17 NCI grants that had awards in FY 2019,
- obtained the grant documentation for the 17 awarded grants and reviewed the postaward oversight and monitoring process for those grants,
- obtained a list of all NCI grants closed in FY 2019 and included in the list final report submission dates for all listed grants,
- selected a judgmental sample of 20 NCI grants that were closed in FY 2019,

¹² We included 11 grants that had FY 2019 awards and that had a FY 2018 award that we reviewed as part of our audit of NCl's pre-award risk process. See *The National Cancer Institute Needs to Strengthen Procedures in Its Pre-Award Process To Assess Risk for Higher Risk Applicants* (A-03-19-03004), issued June 1, 2020.

- obtained the grant documentation for the 20 closed grants and determined whether the final reports were received and reviewed timely and the grant was closed timely, and
- discussed the results of our audit 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: December 20, 2021

TO: Amy J. Frontz

Deputy Inspector General for Audit Services

FROM: Acting Director, National Institutes of Health

SUBJECT: NIH Comments on Draft Report, "The National Cancer Institute Could

Improve Its Post-Award Process For The Oversight and Monitoring Of

Grant Awards" (A-3-20-03001)

Attached are the National Institutes of Health's (NIH) comments on the draft Office of Inspector General's (OIG) report, "The National Cancer Institute Could Improve Its Post-Award Process For The Oversight and Monitoring Of Grant Awards" (A-3-20-03001).

NIH appreciates the review conducted by OIG and the opportunity to provide the clarifications on this draft report. If you have questions or concerns, please contact Tiffany Brown in the Office of Management Assessment at 301-496-2464.

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

Attachments

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH (NIH) ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT ENTITLED: "THE NATIONAL CANCER INSTITUTE COULD IMPROVE ITS POST-AWARD PROCESS FOR THE OVERSIGHT AND MONITORING OF GRANT AWARDS" (A-03-20-03001)

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 Cancer Institute coordinate with the National Institutes of Health's DCGP/Closeout Center to update policies and procedures for monitoring grantees' submission of closeout documents to include increased outreach to grantees before the final reports (FFR, FRPPR, and FIS) become delinquent.

NIH Response:

NIH concurs with OIG's recommendation.

NIH is planning to add an additional notification on day 90, prior to the submission deadline of day 120 to address the increased outreach efforts to grantees. NIH plans to update its policies and procedures by the end of fiscal year 2022 to reflect OIG's recommendation.