Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE NATIONAL INSTITUTES OF HEALTH HAS CONTROLS TO MITIGATE THE RISK THAT GRANTEES RECEIVE DUPLICATE GRANT FUNDING

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Office of Inspector General

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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: March 2020 Report No. A-02-19-02002

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

Why OIG Did This Audit

This audit is part of a larger body of Congressionally directed work to conduct oversight of National Institutes of Health (NIH) grant programs and operations. OIG was directed to examine NIH's oversight of its grantees' compliance with NIH policies, including NIH efforts to ensure the integrity of its grant application and selection processes.

Our objective was to determine whether NIH's internal controls were effective in ensuring that grantees did not receive duplicate NIH grant funding.

How OIG Did This Audit

We held discussions with NIH officials and reviewed NIH's policies and procedures for identifying duplicate grant funding. In addition, from a sampling frame of 51,168 research grants active during our October 2017 through September 2018 audit period, totaling \$26.3 billion, we selected a nonstatistical sample of 116 grants totaling \$33.1 million.

For each sampled grant, we used text recognition software to identify similar grants. We then reviewed the grant documentation of each similar grant to determine if grantees received duplicate NIH grant funding.

The National Institutes of Health Has Controls to Mitigate the Risk That Grantees Receive Duplicate Grant Funding

What OIG Found

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

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

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

What OIG Recommends

This report contains no recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

For fiscal year (FY) 2019, the Department of Health and Human Services (HHS), Office of Inspector General (OIG) received \$5 million in congressional appropriations to conduct oversight of the National Institutes of Health (NIH) grant programs and operations. 1 As indicated by the conference report that accompanied the legislation, "the conferees direct[ed] the OIG to examine NIH's oversight of its grantees' compliance with NIH policies, including NIH efforts to ensure the integrity of its grant application and selection processes."2

A prior review by the Government Accountability Office (GAO) found that NIH had developed formal processes and guidance for identifying potentially duplicative grant award funding.³ GAO's work included interviews with NIH officials as well as a review of existing procedures designed to detect duplication. This audit, which is part of a larger body of HHS-OIG oversight work related to NIH grant programs and operations, involved testing individual grants to identify potential duplication.

OBJECTIVE

Our objective was to determine whether NIH's internal controls were effective in ensuring that grantees did not receive duplicate NIH grant funding.

BACKGROUND

National Institutes of Health

NIH is the largest public funder of biomedical research in the world. NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and apply that knowledge to enhance health, lengthen life, and reduce illness and disability.

¹ 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 (September 28, 2018).

² Department of Defense for the Fiscal Year Ending September 30, 2019, and for Other Purposes, Conference Report to Accompany H.R. 6157, H.R. Rep. No. 115-952 (2018), page 531-532.

³ Grants Management: Selected Agencies Should Clarify Merit-Based Award Criteria and Provide Guidance for Reviewing Potentially Duplicative Awards (GAO-17-113 issued January 2017).

⁴ In September 2019, we issued *The National Institutes of Health Has Limited Policies, Procedures, and Controls in* Place for Helping To Ensure That Institutions Report All Sources of Research Support, Financial Interests, and Affiliations (A-03-19-03003), NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research, But Could Do More (OEI-03-19-00150), and Vetting Peer Reviewers at NIH's Center for Scientific Review: Strengths and Limitations (OEI-01-19-00160).

For FY 2018, NIH awarded extramural grants to more than 300,000 investigators⁵ at more than 2,500 research institutions. Investigators may use the grant funds to support a variety of needs, including staffing laboratories, purchasing supplies and equipment, and attending conferences to discuss research findings. NIH awarded the grants through 24 of its 27 Institutes and Centers that each have their own grants management and program offices responsible for grant oversight. NIH's Office of Extramural Research maintains the NIH Grants Policy Statement, which provides policy requirements that are included in the terms and conditions of NIH grant awards.

Federal Requirements

NIH scientific program and grants management staff are required to review information provided by applicants on other active and pending support ("other support") before making an award to ensure no duplication of NIH funds. Information on "other support" is reviewed to ensure no scientific, budgetary, and commitment overlap, as defined below:

- Scientific overlap occurs when (1) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source.
- Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source.
- Commitment overlap occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person-months), whether or not salary support is requested in the application.6

GAO's Standards for Internal Control in the Federal Government (The Green Book) sets the internal control standards for Federal entities.⁷ The Green Book defines internal control as the plans, methods, policies, and procedures used by management to fulfill the mission, strategic plan, goals, and objectives of the entity. The Green Book approaches internal controls through a hierarchal structure made up of five components: (1) control environment, (2) risk assessment, (3) control activities, (4) information and communication, and (5) monitoring.

⁵ Investigators include project directors, principal investigators, and any other individuals, regardless of title or position, who are responsible for the design, conduct, or reporting of research either funded by the Public Health Service or proposed for such funding.

⁶ U.S. Department of Health and Human Services, National Institutes of Health, NIH Grants Policy Statement (October 2017), section 2.5.1.

⁷ Standards for Internal Control in the Federal Government, GAO-14-704G (September 2014), pg. 1.

HOW WE CONDUCTED THIS AUDIT

We held discussions with NIH officials and reviewed NIH's policies and procedures for identifying duplicate NIH grant funding. In addition, from a sampling frame of 51,168 extramural research grants active during our October 1, 2017, through September 30, 2018, audit period, totaling \$26.3 billion, we selected a nonstatistical sample of 116 grants totaling \$33.1 million. Specifically, we selected 71 grants awarded to 3 investigators who received the highest number of grants⁹ during our audit period and 45 grants randomly selected from the remaining sampling frame.

For each sampled grant, we identified similar NIH grants using NIH's Matchmaker data mining tool. 10, 11 We then reviewed the grant application, scope of work, financial support disclosure, and deliverables of each similar grant to determine if scientific, budgetary, or commitment overlap occurred.

We limited our audit of NIH's efforts to identify duplication to two of the five internal control components detailed in The Green Book that were most relevant to our audit objective: control activities and monitoring.

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.

⁸ The nonstatistical sample of 116 grants did not include grants funded under HHS's Small Business Innovation Research (SBIR) program, of which NIH funds the vast majority of grant awards. In a 2014 report, OIG's Office of Evaluations and Inspections (OEI) raised concerns about vulnerabilities in HHS's SBIR program, including the reliance on self-reported information to determine whether awardees were eligible and were not receiving duplicative funding from other Federal agencies (OEI-04-11-00530, issued April 2014). In a follow-up report (OEI-04-18-00230, issued March 2019), OEI found that HHS had not yet acted upon OEI's earlier recommendation to improve policies and procedures to ensure that HHS does not fund duplicate SBIR awards.

⁹ The top 3 investigators were awarded 11, 18, and 42 NIH extramural research grants, respectively, for a total of 71 grants judgmentally selected for review. We noted that the 42 grants awarded to 1 investigator provided funding for conferences on various research topics.

¹⁰ Matchmaker is a search interface tool that can be used to find similar projects already funded by NIH. Matchmaker analyzes project specific text to search for comparable text in other NIH funded research projects. Once this comparison is completed, Matchmaker lists the match score of similar projects in order of decreasing similarity.

¹¹ We limited our audit to determine whether NIH's internal controls were effective in ensuring that grantees did not receive duplicate NIH grant funding. We did not determine whether NIH's internal controls were effective in ensuring that grantees did not receive duplicate funding from other Federal agencies.

RESULTS OF AUDIT

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

NIH'S CONTROLS FOR IDENTIFYING DUPLICATE GRANT FUNDING

According to NIH officials, NIH receives approximately 80,000 applications for grant funding each year. All applications are submitted through NIH's electronic Research Administration (eRA Commons) system. NIH checks all applications to identify instances of duplicate investigators, application titles, and Data Universal Numbering System (DUNS) numbers. 12 NIH also directs applicants to provide information on active and pending "other support" for all senior/key personnel who would receive grant funding. Other support includes all financial resources, whether Federal, nonfederal, commercial, or institutional, that would be used in direct support of each individual's research endeavors. Applicants must also summarize any support that could lead to scientific overlap, budgetary overlap or any individual's time commitment greater than 12 person-months.

Other support information is submitted later in the application process. NIH uses "Just-in-Time" (JIT) procedures to reduce administrative burden by allowing for the submission of certain, specified application elements (e.g., active and pending other support for senior/key personnel) later in the application process. JIT information is requested only for applications likely to be funded. NIH reviews JIT information to ensure that there is no scientific, budgetary, or commitment overlap. 13

If duplication is discovered during the application phase, NIH resolves the overlap prior to awarding funds through communication with the applicant institution to ensure that the overlap is removed by adjusting the research plan, budget, or commitment of personnel, as necessary. NIH does not specifically reject applications. Rather, they are funded or not funded. Applications that are not funded due to limitation of available funds are administratively carried forward and must compete for funding with all other applications during the next review cycle. Applications not funded because they were not responsive to the funding request, were incomplete, or were submitted after the deadline are not carried forward.

After it awards grants, NIH conducts post-award monitoring using data mining technology to identify NIH awards with potential duplication. If similar awards are identified, subject matter experts review them to determine if there is any duplication. If actual duplication is identified,

¹² NIH requires a DUNS number to be included in every application for a new grant. This number is used for tracking purposes and to validate address and point-of-contact information.

¹³ U.S. Department of Health and Human Services, National Institutes of Health, NIH Grants Policy Statement (October 2017), section 2.5.1 (Just-in-Time Procedures).

the duplicate award will be terminated and the identified duplicate funding will be returned to NIH.

CONCLUSION

Based on our results, this report contains no recommendations.

APPENDIX: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 51,168 NIH extramural research grants, totaling \$26,263,574,044, that were active 14 during our audit period. We selected a nonstatistical sample of 116 grants totaling \$33,116,574. Each sample grant was reviewed to determine if grantees received duplicate NIH grant funding.

We did not audit the overall internal control structure of NIH. Rather, we limited our audit of NIH's efforts to identify duplication to two of the five internal control components detailed in The Green Book that were most relevant to our audit objective: control activities and monitoring.

We performed our fieldwork from July through November 2019.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable laws, regulations, and guidance;
- reviewed NIH's internal controls and held discussions with NIH officials to obtain an understanding of NIH's policies and procedures for identifying duplicate grant funding;
- obtained a list of 51,168 NIH grants, totaling \$26,263,574,044, from the NIH EXPORTER system¹⁵ that were active during our audit period;
- selected a nonstatistical sample of 116 grants, from a sampling frame of 51,168 grants, using the following methodology:
 - 71 grants awarded to 3 investigators that received the highest number of grants during our audit period and
 - 45 grants randomly selected from the remaining sampling frame;
- identified similar grants, for each sampled grant, using NIH's Matchmaker data mining tool;

¹⁴ Research grants whose project period effective date started in the current fiscal year or a prior fiscal year and had not yet expired were considered active grants.

¹⁵ ExPORTER is an online tool available to the public that provides access to reports, data, and analysis of NIH research activities.

- reviewed the grant application, scope of work, financial support disclosure, deliverables, etc., of each similar grant to determine if grantees received duplicate NIH grant funding; 16 and
- discussed the results of our audit with NIH officials.

We provided NIH with a draft audit report on February 18, 2020. NIH elected not to provide written comments.

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.

¹⁶ Funding for a sampled grant was considered duplicative if scientific, budgetary, or commitment overlap occurred.