Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

NIH POSTAWARD GRANT ADMINISTRATION AND OVERSIGHT COULD BE IMPROVED

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OEI-07-11-00190

EXECUTIVE SUMMARY: NIH POSTAWARD GRANT ADMINISTRATION AND OVERSIGHT COULD BE IMPROVED
OEI-07-11-00190

WHY WE DID THIS STUDY

Effective oversight of grant funds is crucial to the success of programs designed to improve public health and well-being; however, the Inspector General consistently identifies grants management as one of the Department of Health and Human Services' (HHS) top challenges, noting weaknesses in the oversight of grantees. Within HHS, the National Institutes of Health (NIH) is the largest Federal funder of health research and development, awarding $21 billion in extramural grants during fiscal year (FY) 2014. This evaluation assessed NIH's postaward administration and oversight.

HOW WE DID THIS STUDY

We used NIH's electronic storage system for grant files to review a random sample of 100 NIH grant files from new and continuing extramural research awards made in FY 2011. We also collected and reviewed information from NIH staff regarding oversight of postaward administration requirements.

WHAT WE FOUND

NIH grant files were largely complete, but our review found weaknesses in the oversight of grantee progress during the life of the grants. Specifically, we found weaknesses in NIH's review of progress reports. NIH approved 13 percent of awards for funding despite the fact that the awardee did not provide required information regarding its progress towards project objectives. NIH awarded $7.2 million to four awardees that reported not meeting established goals or removing a goal. Although NIH policy requires program staff to determine whether awardee progress towards stated goals is satisfactory or not satisfactory, it does not require a written statement to support those determinations.

WHAT WE RECOMMEND

We recommend that NIH (1) confirm that grants management staff ensure timely submission of required reports from awardees, and (2) revise the NIH Policy Manual and Award Worksheet Report to require a brief narrative documenting awardee progress and whether any change in research goals may influence continued funding. NIH concurred with both recommendations.

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OBJECTIVES

1. To determine the extent to which National Institutes of Health (NIH) grant files contain complete and timely documentation.

2. To assess how NIH program staff monitor awardee progress.

BACKGROUND

NIH's mission is to "enhance health, lengthen life, and reduce illness and disability." NIH is the largest Federal funder of health research and development, with fiscal year (FY) 2014 awards for extramural research totaling $20 billion for 52,034 awards.[1]

NIH is organized into Institutes and Centers (ICs), each of which is dedicated to a specialized area of research. Of the 27 NIH ICs, 24 make awards that support basic and clinical research, research center operations, scientific training and fellowships, and construction projects.

Applicable Federal Regulations, Departmental Directives, and Agency Policies

Federal regulations establish uniform administrative requirements governing Department of Health and Human Services (HHS) awards to institutions of higher education, hospitals, and other nonprofit organizations.[2] Guidance for implementing these requirements is contained in the HHS *Grants Policy Directives,* which applies to all agencies within HHS, and the NIH *Policy Manual*, which applies to all ICs within NIH.

Administrative and Oversight Roles at NIH

Oversight of postaward administration at NIH is divided among the staff of the Office of Extramural Research and the staff of each IC. Within each IC, oversight responsibilities are further divided between grants management and program management staff. Table 1 summarizes administrative and oversight roles and responsibilities.

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[1] Using NIH's ExPorter and RePorter Web-based tools, we included awards with activity codes R, P, M, S, K, U (excluding UC6), DP1, DP2, DP3, DP4, DP5, D42, and G12 and application types 1 (new award), 2 (competing continuation award), and 5 (noncompeting continuation award) awarded in FY 2014.

[2] 45 CFR pt. 74. On December 19, 2014, HHS issued an Interim Final Rule (45 CFR pt. 75) implementing Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards published by the Office of Management and Budget in December 2013. During the study period, however, 45 CFR pt. 74 remained in effect.

Table 1: NIH Staff Responsibilities

Applicability	Type of Staff	Responsibility
NIH-wide	Office of Extramural Research staff	Developing overall policy and conducting oversight
IC grants management	Grants Management Officer (GMO)	Maintaining ultimate financial/administrative accountability Supervising grants management staff
	Grants management staff	Conducting financial/administrative review Maintaining official files Ensuring timely submission of required documents
IC program management	Scientific Division Directors	Supervising program staff
	Program staff	Conducting scientific and/or technical reviews of grants

Source: OIG analysis of NIH staff responsibilities, 2013.

Office of Extramural Research. The Office of Extramural Research issues the NIH *Grants Policy Statement* (GPS), which contains general information about NIH awards, terms and conditions of these awards, and points of contact. The Office of Extramural Research coordinates the development, implementation, and oversight of NIH grant policies and applicable Federal policies. The Office of Extramural Research promotes compliance—both from NIH staff and from awardees—with policies and administers a management control program to review IC compliance with NIH-wide policies.

IC grants management staff. Grants management staff are responsible for maintaining official files. GMOs' responsibilities include ensuring that all awards meet requirements (including monitoring report due dates), that they do not exceed available funds, and that they include appropriate terms and conditions for the award. A Chief GMO is responsible for implementing extramural research award policies and provides guidance for his or her IC. Grants management staff within each IC assist GMOs in ensuring that awards comply with implementation policies and procedures.

IC program management staff. Program staff, under the direction of IC Scientific Division Directors, are responsible for evaluating awardees' scientific/technical progress on an annual basis. If awardees' progress is satisfactory, program staff work with grants management staff to permit continued funding. Program staff must also keep the grants management staff informed of concerns and changes that may impact future funding, require close project monitoring, or result in a need for special terms and conditions for the award.

Official Grant Files and Required Documents

Grant files must allow a third party (e.g., auditor or other reviewer) to follow information regarding decisions made and actions taken throughout the entire award process from initiation through closeout.[3] The contents of grant files must be current, easily identifiable, easily accessible, and—to the extent possible—separated by budget period.[4] Official files must include electronically created or transmitted documents, including email, or these documents must be referenced to a separate file or repository.[5]

NIH's electronic Research Administration system. To maintain official grant files, NIH uses the electronic Research Administration (eRA) system, as well as systems developed by specific ICs and paper documents. NIH staff reported that they use eRA to access official grant files, and that they use different eRA modules depending on their roles. For example, program staff use the Program module to document their review of awardee progress, and grants management staff use the Grants Management module to track adherence to terms and conditions of award. Chief GMOs explained that staff often use eRA to identify overdue reports.

Required grant file documents. HHS permits agencies such as NIH to adopt their own requirements for grant file assembly and structure; however, certain documents are required to be maintained in NIH grant files by Federal and HHS rules as well as by NIH policy. These documents include:

- Progress reports—These describe technical scientific accomplishments toward meeting project objectives and also provide information regarding changes in scope or research objectives.[6] Progress reports must also include reasons for not meeting project goals (if applicable), and plans for activities during the upcoming year.[7] Program staff review progress reports to determine whether progress is satisfactory for continued funding.[8]

- Federal Financial Reports (FFRs)—These are reports of awardees' official accounting records (e.g. spending, obligations, and the balance of funds). Grants management officers may review these

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[3] HHS, *Grants Policy Directives*, pt. 3.06.
[4] Ibid.
[5] Ibid.
[6] NIH, *Policy Manual*, chs. 54444 and 55806.B.
[7] NIH, *Policy Manual*, ch. 55808.
[8] NIH, *Policy Manual*, ch. 54444.

reports to assess whether performance or financial management problems exist.[9] Awardees may extend the expiration date of an award through a no-cost extension.[10]

- Notice of Award—The Notice of Award is the legal document issued to awardees that indicates that an award has been made and that funds may be requested from NIH. A Notice of Award, showing the amount of Federal funds authorized and any future-year commitments, is issued for each budget period in the approved project period.[11]

Each Operating Division must develop an approach to postaward monitoring that ensures that grants management staff and program staff make a formal coordinated determination concerning grantee performance and progress.[12] For NIH awards, staff document their review of progress reports and financial reports (if applicable) in the Grants Management and Program Checklists, that becomes part of the Award Worksheet Report. The NIH *Policy Manual* (ch. 54444) requires program staff to determine whether progress is satisfactory, but does not require a written statement to support staff's review.

- Award Worksheet Reports—NIH staff document their review of awardee progress and approval of continued funding using separate grants management and program checklists in eRA. These two checklists are consolidated to create an Award Worksheet Report. The checklists identify items that must be reviewed and prompt reviewers for further comments when necessary. For example, the program checklist asks program staff to indicate whether the awardee's progress is satisfactory. The checklist includes a notes field that instructs program staff to document and provide direction to the grants specialist, if progress was not satisfactory. In the final

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[9] NIH, *Grants Policy Statement*, ch. 8.4.1.5.2.

[10] A no-cost extension indicates that the awardee has additional work to complete on the project and that necessary resources are available, or that the awardee requires additional time to provide an orderly closeout. NIH, *Grants Policy Statement*, ch. 8.1.1.3. With a no-cost extension, the budget period may be extended up to 1 year beyond the original funding period shown in the Notice of Award if the extension is not prohibited by the terms of the award. NIH need not issue additional funds, and the project's original scope does not change. Ibid.

[11] NIH, *Grants Policy Statement*, pt. I, "Notice of Award" and pt. II "Terms and Conditions of NIH Grant Awards, Subpart A: General."

[12] HHS, *Grants Policy Directives*, pt. 3.06.

year of a project, NIH staff complete separate closeout documentation in lieu of Award Worksheet Reports.

Ensuring timely submission of awardee reports. All NIH awardees must submit annual progress reports and routine FFRs to the awarding IC on a predetermined basis.[13] GMOs may take progressive actions to obtain delinquent required reports, and IC staff should not permit continued funding until all required reports are submitted.[14]

METHODOLOGY

We reviewed a simple random sample of 100 FY 2011 awards from all award-granting ICs to determine the extent to which NIH grant files contained complete and timely documentation. We also assessed how NIH program staff monitored awardee progress during the course of the grant and whether official files enabled a third-party reviewer (i.e., OIG) to assess whether the files were current, easily identifiable, and easily accessible. Appendix A provides a detailed methodology. Appendix B lists point estimates and confidence intervals for the statistics reported in our findings.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

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[13] 45 CFR §§ 74.51 and 74.52. Although the CFR uses the term "performance reports," HHS refers to the annual performance reports as "progress reports." HHS, *Grants Policy Statement*, pt. I.

[14] NIH, *Policy Manual*, ch. 55806.

FINDINGS

Nearly all NIH grant files contained all required documents, but 19 percent of files contained documents that were submitted late

Required documents (e.g., progress reports, FFRs, Award Worksheet Reports, and Notices of Award) were found in all but 1 percent of grant files, but documents were submitted late in 19 percent of NIH grant files. NIH received these reports late even though eRA sends awardees automatic reminders of upcoming due dates for progress reports.

Two percent of required FFRs were missing; all expected Award Worksheet Reports and Notices of Award were found. The one sampled grant that was missing an FFR involved new technology for accelerated manufacturing of cancer drugs.

Progress reports and FFRs—the only documents that we reviewed that have required deadlines—were submitted late in 19 percent of grant files. Specifically, 14 percent of required progress reports and 16 percent of required FFRs were submitted late. Late progress reports were submitted from 1 to 111 days past the deadline (median of 6 days past the deadline). The sampled grant with the progress report that was 111 days late involved staff development in the field of vascular medicine. Late FFRs were submitted from 2 to 247 days past the deadline (median of 100 days past the deadline). The sampled grant with the FFR that was 247 days late involved public health research related to the 2010 oil spill in the Gulf of Mexico.

Table 2 provides information on the number of grant files with required documents that were not found in the grant files or were submitted late.

Table 2: Required Documents Not Found or Submitted Late in Grant Files, FY2012

Type of Document	Not Found (Percentage)	Submitted Late (Percentage)
Progress Report	0%	14%
FFR	2%	16%
Award Worksheet	0%	N/A
Notice of Award	0%	N/A
Total Files	1%	19%

Note: See Appendix A for details regarding the number of expected documents for each document type.

Source: OIG analysis of NIH grant files, 2015.

We found weaknesses in NIH's review of progress reports

HHS Grants Policy Directives require that each HHS operating division (e.g., NIH) develop an approach to postaward monitoring that ensures that program staff make a formal coordinated determination concerning grantee performance and progress. NIH policy requires program staff to determine whether progress is satisfactory, but it does not require a written statement to support their review.

NIH staff approved progress reports for 13 percent of grant files even when required information was absent

Thirteen percent of progress reports were approved, and funding was continued even though the progress reports did not contain required information from the awardee regarding the awardee's progress toward project objectives. The sampled awardees were funded nearly $11 million in FY 2012. Six percent of progress reports lacked information as to whether progress was made toward each stated project goal. Nine percent of progress reports lacked a description of planned activities for the coming year.

NIH staff did not always document their review of progress reports when awardee goals were not met or were removed

When progress reports contained all of the required information, the extent to which program staff reviewed that information was unclear. In FY 2012, NIH awarded $7.2 million to four awardees that reported not meeting established goals or removing a goal. Given the nature of scientific research, there may be legitimate reasons for goals to be revised or modified for certain grants. This underscores the importance of NIH having a system for reviewing awardee-proposed revisions to differentiate between modifications that do not negatively impact the overall effectiveness of the grant and modifications that may warrant reconsideration of grant funds.

NIH staff are not required to document the reasons why progress is not satisfactory, but there are comment fields in the program checklist in which program staff may enter this information. In particular, the program checklist contains instructions to program staff to document concerns and provide direction to grants specialists should progress not be satisfactory. This information could prove useful in evaluating whether to continue funding for awardees.

NIH staff oversight of progress report reviews was limited

Eleven of twenty-seven Scientific Division Directors stated that they did not conduct any reviews to determine whether program staff had

sufficiently reviewed awardees' annual progress. Several Scientific Division Directors—some of whom also conducted reviews themselves, and some of whom did not—reported that there were automatic system checks (i.e., the program checklist on Award Worksheet Reports) that ensured proper review.

CONCLUSION AND RECOMMENDATIONS

Although NIH grant files were largely complete, our review found weaknesses in the oversight of grantee progress during the life of the grants. Specifically, we found weaknesses in NIH's review of progress reports. NIH approved 13 percent of awards for funding despite the fact that the awardee did not provide required information regarding its progress towards project objectives. In addition, although NIH policy requires program staff to determine whether awardee progress towards stated goals is satisfactory or not satisfactory, it does not require a written statement (other than a checklist) to support those determinations. In four files, awardees reported not meeting or removing goals but there was no documented acknowledgment from program staff that they were aware of the lack of progress or removal of goals.

To ensure adequate postaward administration and oversight that supports NIH's mission to improve public health, we recommend that NIH:

Confirm that grants management staff ensure timely submission of required awardee reports

There are a variety of methods NIH could use to accomplish this. For instance, NIH could direct Chief GMOs and Scientific Division Directors or other appropriate staff to establish a formal quality assurance program to confirm that staff across all ICs meet requirements for ensuring timely submission of required awardee reports and review of awardee progress. NIH could also ask why untimely awardees are late in filing reports and use the answers to develop appropriate awardee trainings and/or issue appropriate incentives and/or penalties as necessary.

Revise the NIH Policy Manual and Award Worksheet Report to require a brief narrative documenting awardee progress and stating whether any change in research goals influences continued funding

When NIH reviews awardee progress, NIH should ensure that it documents awardee accomplishments toward meeting project goals; reasons for not meeting project goals, if applicable; and plans for activities during the coming year. To ensure complete documentation of monitoring of awardee progress, NIH could:

- Dynamically link stated goals from original applications to progress report forms each year. Such linking could prompt awardees to provide required information annually and to flag changes in approved goals, and

- revise the program checklist to allow for more complete documentation of review of awardee progress and documentation of whether any change (e.g., modification or removal) of research goals should result in reconsideration of funding.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

NIH concurred with both of our recommendations.

In responding to our first recommendation, NIH stated that it continues to devote resources to enhance oversight and monitoring and that it has provided grantees with tools to assist them in submitting timely reports. NIH requires grantees to submit electronic reports to provide consistency and has established a centralized point for the receipt and review of all progress reports. NIH's electronic grants system sends automatic emails and notifications of late reports to grantees to promote timely submission of progress reports. However, the system does not send automated reminders to grantees regarding the submission of their FFRs. If such reminders were sent, they could help to reduce or eliminate the percentages of FFRs that were late (16 percent) or missing (2 percent). Although submission criteria for FFRs are described in notices of award, NIH should consider enhancing its electronic grants system to provide reminder functions for FFRs similar to those that are already in place for progress reports to help grants management staff ensure timely submission of required reports.

In responding to our second recommendation, NIH stated that it currently requires program staff to determine if awardee progress is satisfactory through the use of the program checklist. NIH stated that it is considering enhancing the checklist to include a provision for program officials to document their affirmation that progress is satisfactory.

For the full text of NIH's comments, see Appendix C.

APPENDIX A: DETAILED METHODOLOGY

Scope

We did not independently review the scientific outcomes or the attainment of goals described in the progress reports. Rather, we assessed the decisions NIH made and the actions NIH took throughout the award process, including NIH's review and approval of each awardee's progress.

Limitations

When reviewing the files, we considered only the most recent year for which files would be complete (FY 2012) in order to report the most recent information, although we did review earlier documents for context.[15]

We excluded the 14 awards that were in the final year of the project period from our analysis of whether files were complete with regard to Award Worksheet Reports.

Population and Sample Selection

We randomly selected a sample of 100 awards from all 24 award-granting ICs and the Office of the Director. This sample allowed us to project overall results to the population of 59,803 new and continuing extramural research awards that were administered from FY 2011 through 2012, which amounted to $20.2 billion.[16] Table A.1 lists the number of awards by IC.

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[15] We focused our review on documents from FYs 2011 and 2012 because NIH officials reported that older documents may be in paper files rather than the eRA system. The timing of our file review was approximately 4 months after the latest reports for FY 2012 were due. We reviewed files between May and July of 2013 to allow adequate time for awardee submission of any reports that were due for FY 2012.

[16] We used NIH's ExPorter and RePorter Web-based tools to obtain the list of awards. We included only activity codes R, P, M, S, K, U (excluding UC6), DP1, DP2, DP3, DP4, DP5, D42, and G12 and application types 1 (new award), 2 (competing continuation award), and 5 (noncompeting continuation award) awarded in FY 2011. We did not review intramural research awards.

Table A.1: Extramural Research Awards by Institutes and Centers

IC Name	Total Number of Awards	Total Value of Awards
Eunice Kennedy Shriver National Institute of Child Health and Human Development	2,785	$894,322,444
Fogarty International Center	181	$45,416,109
National Cancer Institute	8,981	$2,895,394,313
National Center for Complementary and Integrative Health	271	$87,709,430
National Center for Research Resources (now known as the National Center for Advancing Translational Sciences)	6,821	$1,129,717,846
National Center on Minority Health and Health Disparities	478	$164,046,284
National Eye Institute	1,302	$546,927,074
National Heart, Lung, and Blood Institute	5,697	$2,197,933,998
National Human Genome Research Institute	370	$368,228,440
National Institute of Allergy and Infectious Diseases	5,851	$2,567,746,937
National Institute of Arthritis and Musculoskeletal and Skin Diseases	1,433	$411,898,626
National Institute of Biomedical Imaging and Bioengineering	646	$251,528,679
National Institute of Dental and Craniofacial Research	780	$276,288,109
National Institute of Diabetes and Digestive and Kidney Diseases	3,989	$1,515,894,771
National Institute of Environmental Health Sciences	1,224	$357,562,410
National Institute of General Medical Sciences	4,904	$1,646,626,257
National Institute of Mental Health	3,105	$1,093,586,615
National Institute of Neurological Disorders and Stroke	3,785	$1,244,495,380
National Institute of Nursing Research	305	$105,309,132
National Institute on Aging	2,544	$833,855,687
National Institute on Alcohol Abuse and Alcoholism	984	$319,747,424
National Institute on Deafness and Other Communication Disorders	984	$302,240,573
National Institute on Drug Abuse	2,148	$750,761,433
National Library of Medicine	102	$31,409,846
Office of the Director	133	$177,149,553
All	**59,803**	**$20,215,797,370**

Source: OIG analysis of NIH grant files, 2015.

Grant File Review

We confirmed with NIH staff the locations of relevant documents within NIH's eRA system, which is the official file repository. We accessed the sampled grant files using eRA. After extensive pre-testing and coordination with NIH staff, we developed a document review checklist to determine compliance with the following selected elements of postaward administration:

Maintaining Official Files. We determined whether files contained the following documentation required by Federal regulations and by HHS and NIH policies:

- Signed copies of applications and signed copies of required performance reports (i.e., progress reports)—Should be present in all official files because files for continuing awards should contain progress reports or competing continuation applications, and files at the end of a project period should contain final progress reports.

- FFRs—Should be present in all official files for all years of non-Streamlined Non-Competing Award Process (SNAP)[17] awards, and for the final year of SNAP awards.

- Notices of Award—Should be present in all official files except for the final year of a project period.

- Documentation (i.e., Award Worksheet Report) that supports the review and approval of the applications and evidence of review and acceptance of performance reports by NIH—Should be present for all official files except for the final year of a project period.

When determining which types of documents were required during our review period, we considered no-cost extensions, competing continuation applications that featured progress reports, and other factors to which NIH alerted the team during pre-testing. Of the 100 files we reviewed, 99 were expected to have progress Reports (1 file was in a no-cost extension period for FY 2012 that extended beyond the date of our review, so a progress report would not yet have been due), 48 were expected to have FFRs, and 65 were expected to have Award Worksheet Reports and Notices of Award.

At the conclusion of our data analysis, we followed up with NIH staff regarding required documents that we could not locate in the grant file. NIH staff clarified that final FFRs would not display in the eRA module

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[17] SNAP awards—which NIH implemented in 1994—undergo a streamlined award process that requires less documentation than the process for non-SNAP awards.

that we accessed until they were accepted by NIH staff. NIH staff
provided us with additional documents to complete our review.

Ensuring Timely Submission of Required Reports. We reviewed sampled
files to determine whether required progress reports and FFRs were
submitted timely according to their respective due dates. We compared
the budget period end date to the progress report submission date.
Table A.2 shows the due dates for progress reports and FFRs.

Table A.2: Due Dates for Progress Reports and FFRs

Required Document	Type of Award[1]	Due Date
Progress Report	Research Performance Progress Report	the 15th of the month preceding the month in which the budget period ends
	SNAP	45 days prior to the end of the budget period
	Non-SNAP	(generally) 2 months before the beginning of the next budget period[2]
	Final (both SNAP and non-SNAP)	90 days after the end of the project period
FFR	SNAP	N/A (annual FFR is not required)
	Non-SNAP	(when required on an annual basis, must be submitted for each budget period) no later than 90 days after the end of the calendar quarter in which the budget period ended[3]
	Final (both SNAP and non-SNAP)	90 days after the end of the project period[3]

[1] SNAP awards undergo a streamlined process that requires less documentation. The due dates for progress reports and some FFRs for SNAP awards differ from those for non-SNAP awards. NIH began implementing Research Performance Progress Reports in fall 2012.

[2] DHHS, Non-Competing Continuation Progress Report (PHS 2590), 2014.

[3] 45 CFR § 74.52(iv). NIH, Grants Policy Statement, chs. 8.4.1.4.2 and 8.6.

Source: OIG analysis of HHS and NIH grants policy documents, 2015.

At the conclusion of our data analysis, we followed up with NIH staff
regarding the timeliness of documents located in the grant file. NIH staff
provided us with additional documents to complete our review.

Monitoring Awardee Progress. For continuing awards, we reviewed
progress reports to determine whether awardees included the following
required information in the reports:

- awardee accomplishments toward meeting project goals;

- reasons for not meeting project goals, if applicable; and

- plans for activities during the coming year.

We then reviewed Award Worksheet Reports to determine whether
program staff documented their review of annual awardee progress for
continued funding. We determined whether program staff indicated that
progress was satisfactory and whether they provided any written
statements to support their review. If we found that awardees did not

include required information in the progress report, we noted whether staff commented on the absent information (in the Award Worksheet Report checklist or elsewhere in the file) or whether they completed the checklist and moved the award forward for continued funding without further comment.

Interviews and Surveys of NIH Staff

We reviewed documents, conducted interviews with Office of Extramural Research staff, and surveyed IC staff to confirm our understanding of postaward administration and oversight.

We reviewed procedures specifying how the Office of Extramural Research disseminates and enforces policies across ICs, and how it detects and corrects noncompliance with policies. We also conducted two interviews with Office of Extramural Research staff to understand how they administer and oversee policies related to the selected elements of postaward administration.

For all 24 award-granting ICs, we collected relevant documents regarding policies related to the selected elements of postaward administration, such as procedure manuals. We also reviewed each IC's staff training processes in regard to these policies. Additionally, at least 1 Chief GMO from each of the 24 ICs and at least 1 Scientific Division Director from 23 of the 24 ICs responded to our surveys.[18] Questions for Chief GMOs focused on maintenance and obtaining timely reports, and on efforts to detect noncompliance with requirements. Questions for Scientific Division Directors focused on guidance provided to program staff regarding review of awardee progress and efforts to detect noncompliance with requirements.

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[18] Three ICs each identified not one, but two Chief GMOs and Scientific Division Directors for our surveys.

APPENDIX B

Table B.1: Point Estimates and Confidence Intervals for Selected Statistics

Description	Sample Size (n)	Point Estimate	95-Percent Confidence Interval
Files that did not contain at least one required document	100	1.0%	0.14–7.0%
Files with a required report that was late	99	19.2%	12.5–28.3%
Files that did not contain a FFR	46	2.2%	0.3–14.3%
Files with progress reports that were submitted late	93	14.0%	8.2–22.8%
Files with FFRs that were submitted late	45	15.6%	7.5–29.5%
Files that did not contain a progress report	93	0.0%	0.0–3.9%
Files that did not contain an Award Worksheet Report	86	0.0%	0.0–4.2%
Files that did not contain a Notice of Award	100	0.0%	0.0–3.6%
Files with progress reports that were approved even though required information was absent	80	12.5%	6.8–21.9%
Files with progress reports that lacked a description of progress toward stated goals	80	6.3%	2.6–14.3%
Files with progress reports that lacked a description of planned activities for the coming year	80	8.8%	4.2–17.4%

Source: OIG analysis of NIH grant files, 2015.

APPENDIX C

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

TO: Suzanne Murrin
            Deputy Inspector General for Inspection and Evaluations, HHS

FROM: Director, NIH

DATE: **JUL 2 9 2015**

SUBJECT: NIH comments to the draft report *NIH Postaward Grant Administration and Oversight Could Be Improved* (OEI-07-11-00190)

Attached are the National Institutes of Health's comments on the draft Office of Inspector General (OIG) report *NIH Postaward Grant Administration and Oversight Could Be Improved* (OEI-07-11-00190).

The NIH appreciates the review conducted by the OIG and the opportunity to provide clarifications on this draft report. Should 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.

Attachments:
   NIH General Comments
   NIH Technical 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: "NIH POSTAWARD GRANT ADMINISTRATION AND OVERSIGHT COULD BE IMPROVED" (OEI-07-11-00190)

The National Institutes of Health (NIH) appreciates the review conducted by OIG and the opportunity to provide clarifications on this draft report. The NIH respectfully submits the following general comments.

OIG Recommendation 1: Confirm that grants management staff ensure timely submission of required awardee reports.

NIH Response: The NIH concurs with the OIG's recommendation that the NIH confirm that grants management staff ensure timely submission of required awardee reports. The NIH agrees that this is part of its oversight responsibility, and, as such, the NIH continues to devote resources to enhancing oversight and monitoring and has provided grantees with tools to assist them in submitting timely reports.

Recent examples include:

- Since October 17, 2014, the NIH has required grantees to use the Research Performance Progress Report (RPPR) module in the electronic Research Administration (eRA) Commons to submit all annual progress reports. Prior to this date, paper progress reports (PHS 2590 forms) were accepted for non-SNAP progress reports while the NIH continued to develop eRA systems to enable full implementation of the electronic RPPR. Since November 2013 and prior to October 17, 2014, the Division of Extramural Activities Support (DEAS), Office of Extramural Research, was the central point of receipt for paper progress reports and was responsible for scanning these reports into the IMPAC II system, which houses the official grant file. DEAS was also responsible for following up on delinquent non-competing progress reports and maintaining the associated file documentation, which is also part of the official grant file. The current system of electronic submissions provides consistency and facilitates oversight with the centralized receipt and review for all progress reports.

- The NIH's eRA system sends automatic monthly emails and/or late notifications as reminders to grantees to promote timely submission of annual progress reports. The system sends the e-mail reminders to the project director/principal investigator (PD/PI) two months before the annual progress report due date. The PD/PI and the applicable NIH awarding IC also receive e-mail notifications when the progress report is late. The late notification e-mails are saved to the official grant file repository, established by the IC (e.g., eGrants, eAdditions in IMPAC II), and serve as the official file documentation.

  The NIH provides a tool on the Status page in eRA Commons for grantees to determine when progress reports are due by providing a list of progress reports that are due by grant number, sorted by due date. The NIH also maintains a publically accessible website from which grantees can access progress report due date information for monitoring: https://public.era.nih.gov/chl/public/search/progressReportByIpf.era

- The NIH has implemented a new closeout policy for NIH grants that emphasizes the requirement for timely and accurate grantee reporting. The policy and its implementing systems and procedures enhances the NIH's monitoring and oversight of closeout activities for grants with project end dates after September 30, 2014. The new policy stipulates that if the NIH cannot undertake a "bilateral closeout"—i.e., closeout with the cooperation of the grantee— because one or more acceptable final grant closeout reports have not been submitted by the grantee, it must initiate "unilateral closeout"—i.e., closeout without grantee cooperation within 180 days of the

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project end date. The close out policy also sets a deadline for the NIH to internally complete close out. The NIH is required to closeout a grant as soon as possible after the end date of the period of performance but no later than 270 days after the project period end date. For financial closeout, if a grantee fails to submit a correct final expenditure FFR, the NIH will close the grant using the last recorded cash drawdown level. The NIH will also consider enforcement actions for grantee institutions with recurring reporting delinquencies.

- Implementation of unilateral closeout includes;

    1. Increased notification and correspondence with the NIH grantees. Grantees receive notice of the status of final reports due 10 days from the project period end date, and notification of delinquent reports at 90, 120, and 150 days after the project period end date.
    2. Enhancing our electronic systems to monitor grants. For example, our system will generate automatic monthly reports for grants (that have not yet been closed) at 150 days or more past their project end date in cases where one or more required final report is unacceptable or has not been submitted. The purpose of this report is to provide a 30 day lead time for IC extramural staff to work with the grantee to avoid a grant reaching unilateral closeout status.

For more information on close out, see the NIH Grants Policy Statement Section 8.6 Close Out, here: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm

To ensure the timely submission and review of annual awardee progress, the NIH currently takes the following measures that meet the role of a quality assurance program:

- The NIH will not issue subsequent awards until required progress reports are submitted, reviewed, and accepted. This is both an internal control and a quality control measure.
- The NIH may take remedies for non-compliance with the reporting requirements that are terms and conditions of an award, which could include special award conditions in the grant award to require correction of identified financial or administrative deficiencies as a means of protecting the NIH's interests and effecting positive change in a recipient's performance or compliance, or the withholding of further awards, or wholly or partly suspending the grant, pending corrective action.
- The NIH emphasizes the importance of timely submission of required reports through our outreach efforts (e.g. regional seminars) and grant policies (i.e., the NIH Grants Policy Statement, which is a term and condition of all the NIH grant awards).

Given the importance of timely reporting, the NIH will place an increased focus on the requirement for timely submission of reports through its outreach efforts to the grantee community and the NIH extramural staff.

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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: "NIH POSTAWARD GRANT ADMINISTRATION AND OVERSIGHT COULD BE IMPROVED" (OEI-07-11-00190)

OIG Recommendation 2: Revise the NIH Policy Manual and Award Worksheet Report to require a brief narrative documenting awardee progress and whether any change in research goals may influence continued funding.

NIH Response: The NIH concurs with the OIG's finding, although the NIH already documents awardee progress and changes in research goals. Current NIH policy requires program staff to determine if awardee progress is satisfactory which is accomplished through the use of the program checklist.

The NIH is currently working on a revision of the program checklist as part of the NIH's risk management strategy to improve programs and operations. The NIH uses program and grants management checklists to ensure grant awards are issued in compliance with applicable laws, regulations, and policies, to document satisfactory progress, and address any change in research goals, among other things, prior to the issuance of an award. Information from the checklists is included in the Award Worksheet Report when a grant award is issued. As part of the checklist revision initiative, the NIH is considering enhancing the checklist to include a provision that program officials document their affirmation that progress is satisfactory.

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ACKNOWLEDGMENTS

Office of Inspector General
http://oig.hhs.gov

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Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

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The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

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