Department of Health and Human Services OFFICE OF INSPECTOR GENERAL

NATIONAL CANCER INSTITUTE'S MONITORING OF RESEARCH PROJECT GRANTS



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OBJECTIVE

To determine the extent to which the National Cancer Institute (NCI) monitors Research Project Grants in accordance with Federal regulations, departmental directives, and agency policies regarding: (1) progress reports, (2) financial reports, (3) grant closures, and (4) grant files.

BACKGROUND

For fiscal year (FY) 2007, the National Institutes of Health (NIH) disbursed 54 percent of its \$29.1 billion budget via more than 38,000 Research Project Grants. NCI is the largest of the NIH institutes and had responsibility for over \$2.1 billion in Research Project Grants in FY 2007. In FY 2007, the Office of Inspector General (OIG) identified grants management (including the monitoring of grants) as a top management challenge.

NCI monitors grants by reviewing reports (e.g., progress and financial), correspondence from grantees, audit reports, site visit reports, and other available information. We requested and received from NCI a list of Research Project Grants that received funding in at least 1 year during FYs 2004, 2005, or 2006. This list contained 4,578 grants totaling more than \$3 billion. From the population, we selected a random sample of 100 grants for review. We reviewed each grant for NCI's postaward monitoring in the following areas: progress reports, financial reports, grant closeouts, and grant files (i.e., the completeness and accuracy of grant file materials).

FINDINGS

All grant files contained progress reports that had evidence of agency review; however, 41 percent of progress reports were received late. All required progress reports for FYs 2004, 2005, and 2006 for all 100 grants were present in the files. In addition, the case files contained documentation of assessments of all of the progress reports by the grants management specialist and the program staff assigned to each grant. However, 41 percent of progress reports were not received within the required timeframes (i.e., 2 months before the next budget period for hard copy or 45 days before the next budget period for electronic reports). Of these, electronic reports were received an average of 18 days late and hard copy reports averaged 16 days late.

We note that grantees' delay in submitting progress reports posed a low risk because NCI did not disburse funds until it had received and reviewed progress reports.

Deficiencies exist in financial oversight of Research Project Grants. NCI grants management staff indicated that they rely on NIH's Office of Financial Management to monitor quarterly financial reports to ensure that grantees are properly drawing funds. However, an Office of Financial Management official indicated that this office does not examine or maintain copies of quarterly financial reports; these are submitted to the Payment Management System only. In our sample of 100 grants, 23 had reached the end of their grant periods during our period of review and all 23 grant files contained Financial Status Reports. However, 11 of the Financial Status Reports were submitted late and 12 indicated dates that did not reflect the entire budget periods.

Five of the nine required grant closeouts in our sample were not completed within the general timeframes specified in departmental guidelines. Of the 100 grants in our sample, 9 were closed or eligible for closeout. For five of the nine grants, the closeout process was not completed within 180 days as generally required by departmental policy. In addition, one closed grant lacked the required final Invention Statement and Certification. Upon request, NCI staff could not provide the statement; however, staff located it after we shared a draft of this report.

Insufficient documentation impedes third-party review of grant files in some cases. Departmental grant policy directives require awarding agencies to create and maintain files that allow a third party (e.g., auditor or other reviewer) to follow the paper trail, from program inception through closeout of individual awards, and decisions made and actions taken in between. While conducting a review of grant files, we encountered documents with inaccurate dates and an inconsistent filing structure and found that some files were missing, all of which impeded the review process.

RECOMMENDATIONS

OIG recommends that NCI:

Initiate earlier and more frequent followup with grantees to obtain required documents. Such diligence could promote grantee compliance with Federal regulations and agency policies for submitting progress reports, Financial Status Reports, and closeout documents.

Improve grants monitoring by:

- annually verifying grantees' self-reported fund balances with external sources and developing an approach for financial reviews that is not based solely on exceptions, and
- consistently documenting grantee correspondence and organizing grant documents to assist NCI staff and third-party reviewers with following grantees' actions from inception of the grant to closeout.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

NIH generally agreed with our recommendations and described actions it plans to take in response to the recommendations. Regarding late submission of progress reports, Financial Status Reports, and closeout documents, NIH will continue to address this issue in education outreach sessions with grantee officials and stress the need for institutions to monitor and adhere to all report deadlines. In addition, NIH expects to increase timeliness of reporting by grantees through continued development and deployment of its electronic grants management system, enabling electronic submission of certain progress and closeout reports. Regarding the recommendation to improve grants monitoring by annually verifying grantees' self-reported fund balances with external sources and developing an approach for financial reviews that is not based solely on exceptions, NIH agreed that there may be value in using the Federal Cash Transaction Report on a broader scale and will conduct a pilot study to review the Federal Cash Transaction Report prior to issuing the award for a specific pool of grants. At the end of the pilot study, NIH will identify the population of grants for which review of the Federal Cash Transaction Report will be required. as well as best practices for the review and for resolution of any issues that arise from the review. Additionally, NIH agreed with the recommendation that grant files be properly documented and

EXECUTIVE SUMMARY

organized. NIH will continue to monitor the use of its electronic grant system and update procedures for file documentation as necessary. We did not make any revisions to the report based on NIH's comments.

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OBJECTIVE

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BACKGROUND

(4) grant files.

For fiscal year (FY) 2007, the National Institutes of Health (NIH) disbursed 54 percent of its \$29.1 billion budget via more than 38,000 Research Project Grants.¹ The NIH budget constitutes approximately 38 percent of all discretionary spending for the Department of Health and Human Services (HHS) and nearly 50 percent of Federal civilian spending for research and development.² Extramural research, performed by non-Federal scientists using NIH grant or contract money, includes more than 200,000 scientists and research personnel working in over 3,100 universities, academic health centers, hospitals, and independent research institutions in the United States and abroad.³ NCI is the largest of the NIH institutes and had responsibility for over \$2.1 billion in Research Project Grants in FY 2007.⁴

In FY 2007, the Office of Inspector General (OIG) identified grants management (including the monitoring of grants) as a top management challenge.⁵ A previous OIG report on grants monitoring in one HHS agency found that financial reports either were not received or were late and that Federal requirements for grant closeout were not met.⁶

¹ NIH, "Summary of the Fiscal Year (FY) 2009 President's Budget," February 4, 2008.

² Congressional Research Service (CRS) Report for Congress, "The National Institutes of Health (NIH): Organization, Funding and Congressional Issues," October 19, 2006. Available online at http://www.nih.gov/about/director/crsrept.pdf. Accessed on December 12, 2006.

³ Ibid., p. 6.

⁴ NCI, "The Nation's Investment in Cancer Research," January 2008.

⁵ OIG, "FY 2007 Top Management and Performance Challenges Identified by the Office of Inspector General." Available online at

http://www.hhs.gov/afr/information/challenges/index.html. Accessed on February 27, 2008.

⁶ HHS, OIG, "Agency for Healthcare Research and Quality: Monitoring Patient Safety Grants" (OEI-07-04-00460), June 2006.

The National Cancer Institute

NCI, established under the National Cancer Institute Act of 1937, is the principal Federal agency for cancer research and training. It coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer; rehabilitation following cancer; and the continuing care of cancer patients and their families. As part of its responsibilities, NCI awards, monitors, and closes grants related to the National Cancer Program.

NCI awards Research Project Grants to support research into the causes, diagnosis, prevention, or treatment of cancer. These grants account for the largest share of the NIH extramural research budget and include grants to individual investigators, small teams, and groups of researchers who work in collaborative programs or in multidisciplinary centers that focus on particular diseases or areas of research. An NCI Research Project Grant typically lasts 4 to 5 years—an award period termed a competitive segment. The grantee does not need to compete annually for continuation of funding when it has received a multiyear Research Project Grant. A grantee may seek extensions of the grant or apply for a new award, leading to another competitive segment.

Applicable Federal Regulations, Departmental Directives, and Agency Policies

Federal regulations contained in 45 CFR Part 74 establish uniform administrative requirements governing HHS grants to institutions of higher education, hospitals, and other nonprofit organizations.

The HHS Grants Policy Directives (GPD) provide guidance on grants management issues to affected program offices at all organizational

⁷ CRS Report for Congress, "The National Institutes of Health (NIH): Organization, Funding and Congressional Issues," October 19, 2006, p. 6. Available online at http://www.nih.gov/about/director/crsrept.pdf. Accessed on December 12, 2006.

levels within the Department.⁸ The GPD is the highest level of grants policy issued by HHS. Part 1.01 of the GPD instructs agencies such as NIH not to merely repeat the language in the GPD or reissue the GPD in its entirety when developing their own implementation manuals. Rather, HHS agencies are required to develop more detailed grants administration manuals that reflect their implementation of the directives. The NIH Grants Policy Statement, dated December 1, 2003, is the policy document that contains the terms and conditions of NIH grant awards. A glossary of grant-related terms can be found in Appendix A.

Grants-Monitoring Responsibilities

To fulfill its role in regard to the stewardship of Federal funds, NCI monitors its grants to identify potential problems and areas in which technical assistance might be necessary. NCI monitors grants by reviewing reports (e.g., progress and financial), correspondence from the grantee, audit reports, site visit reports, and other available information. Grants monitoring continues for as long as NCI retains a financial interest in the project or activity. As a result, property accountability, auditing, and other requirements may continue after the grant is closed out and NCI is no longer providing active grant support.⁹

NCI's Office of Grants Administration is the focal point for all business-related activities associated with the negotiation, award, and administration of grants. Its Web site indicates responsibilities for the following activities related to grants management:

- monitoring the financial and management aspects of grants to ensure the effective utilization of Federal funds;
- building and maintaining a partnership with the grantee and NCI program and review staff to ensure the issuance of award documents that clearly communicate grant requirements and protect NIH from waste, mismanagement, and costly disputes; and

⁸ Grants Policy Directives are issued as an instrument of internal Department management to direct Department staff regarding HHS's policies, standards, and procedures. For grantees and other interested parties, the Department also issues the HHS Grants Policy Statement to provide grantees up-to-date policy guidance and information on HHS and its discretionary grant process. Available online at http://www.hhs.gov/grantsnet/adminis/gpd/index.htm. Accessed on February 26, 2008.

⁹ NIH, "Grants Policy Statement," December 1, 2003, pp. 128-129.

 providing quality service promptly within NIH and to the grantee community to reflect a continuing commitment to improve grants management, thus enabling the grantee to perform its research unfettered, in an open Federal research environment free of unnecessary record collection and reporting requirements.¹⁰

Documentation Requirements

HHS GPD Part 3.06 requires awarding agencies to create and maintain files that allow a third party to follow the paper trail, beginning with program inception through closeout of grants, and decisions made and actions taken in between. An official file must be created for each grant and must contain the following documentation, as applicable:

- signed copies of applications and all documentation related to review and approval of the applications;
- all notices of grant award;
- any approved deviations;
- site visit reports, records of telephone calls, and postaward technical assistance provided;
- prior approval requests and other postaward correspondence;
- documentation related to enforcement actions, including any grant appeals;
- required financial and progress reports and evidence of review and acceptability;
- invention statements;¹¹ and
- closeout documentation.

In 2000, NCI began using an electronic imaging system called eGrants to store and retrieve documents contained in the official NCI grant files. eGrants is an Internet-based data system that allows its users access to grant information, including grant applications, progress reports, and review checklists. Grant documents are organized by grant identification number, award year, and document type. Site visit information is

¹⁰ NCI Office of Grants Administration function. Available online at http://www3.cancer.gov/admin/gab/function.htm. Accessed on December 20, 2007.

¹¹Grantees are required to submit Form HHS 568, Final Invention Statement and Certification, within 90 days of the end of grant support. NIH Grants Policy Statement, December 1, 2003, p. 139.

maintained separately within eGrants in the Institutional File, which is organized alphabetically by institution name.

Grantee Requirements and the Streamlined Non-Competing Award Process Grantees must periodically submit progress and financial reports to NIH. Other required reports may include invention reports, lobbying disclosures, audit reports, and specialized programmatic reports.¹²

As part of the notice of grant award, NIH states whether a grantee is permitted to use the Streamlined Non-Competing Award Process (SNAP). Most NIH Research Project Grantees are subject to SNAP.¹³ Under SNAP, NIH negotiates the direct costs for the entire competitive segment at the time of award. This eliminates the need for annual budget submissions and negotiations and reduces the information that NIH requires to review, approve, and monitor noncompeting awards.

Grantees with SNAP awards are allowed to submit abbreviated annual progress reports. These can be submitted via the Grant Progress Report (Form PHS 2590) or an eSNAP report. NIH grant policy requires grantees to submit an annual Grant Progress Report 2 months before the beginning of the next budget period or an eSNAP report 45 days before the beginning of the next budget period.¹⁴

For financial reporting, grantees with SNAP awards are required to submit the Federal Cash Transaction Report (Form PMS 272) within 15 days following the end of the quarter. The Federal Cash Transaction Report is submitted to the HHS Division of Payment Management. At the end of the award, the grantee is required to submit a Financial Status Report (FSR) (Form SF 269) covering the entire competitive

¹² NIH, "Grants Policy Statement," December 1, 2003, p. 129.

¹³ Grantees may be excluded from SNAP if their grants require close project monitoring or technical assistance or the grantees have a consistent pattern of failure to adhere to appropriate reporting or notification deadlines.

¹⁴ Instructions for "U.S. Department of Health and Human Services, Public Health Service, Non-Competing Grant Progress Report (PHS 2590)," Revised November 2007. Forms approved through November 30, 2010, Office of Management and Budget (OMB) No. 0925-0001, p. 2. Available online at

http://grants1.nih.gov/grants/funding/2590/phs2590.doc. Accessed on January 9, 2008. Instructions for submitting the eSNAP. Available online at

http://grants.nih.gov/grants/submitapplication.htm. Accessed on November 6, 2007. NCI staff confirmed that submission requirements for FYs 2004, 2005, and 2006 were the same as those described in these more recent instructions.

¹⁵ Due dates for Federal Cash Transaction Reports. Available online at http://www.dpm.psc.gov/grant-recipient/reports/due_dates.aspx?. Accessed on February 21, 2008.

segment no later than 90 days after the end of the competitive segment. According to NCI, the submission of timely and accurate FSRs is central to ensuring prudent and efficient stewardship of public resources. 17

Grant Closeout

Grant closeout is the final stage of the grants-monitoring process. The HHS GPD Part 4.02 states that awarding agencies generally shall close out grants within 180 days of the end of grant funding. The NIH Grants Policy Statement states that NIH will close out a grant as soon as possible after expiration if the grant will not be extended or after termination. Unless NCI grants an extension, grantees are required to submit a final progress report, a final FSR, and a final Invention Statement and Certification (Form HHS 568) within 90 days of the end of the grant period. 18

Grantee Interaction With NIH

Each grantee is assigned a grants management specialist from the NCI Grants Administration Branch to whom it may address any questions. In addition, grantees interact with NIH's Office of Financial Management, the receipt point for FSRs. Grant payments and Federal Cash Transaction Reports are administered through the HHS Payment Management System. Grantees request payments via an Internet-based application, and these are electronically transmitted to the grantees' bank accounts.

Enforcement Actions

When a grantee fails to comply with the terms and conditions of the grant, NCI may take one or more enforcement actions depending on the severity and duration of the noncompliance. NCI generally will afford the grantee an opportunity to correct the deficiencies before taking enforcement action unless public health or welfare concerns require immediate action. However, even if a grantee is taking corrective action, NCI may take action to protect the Federal Government's interests, including placing special conditions on awards or precluding the grantee from obtaining future awards for a specified period, or may

¹⁶ NIH, "Grants Policy Statement," December 1, 2003, p. 131.

¹⁷ NCI, "Everything You Wanted to Know About the NCI Grants Process But Were Afraid to Ask," revised August 2005, p. 70.

¹⁸ NIH, "Grants Policy Statement," December 1, 2003, p. 139.

take action designed to prevent future noncompliance, such as closer monitoring.¹⁹

METHODOLOGY

We requested and received from NCI a listing of Research Projects Grants (R01) that received funding in at least 1 year during FYs 2004, 2005, or 2006. This listing contained 4,578 grants totaling more than \$3 billion. From the population, we selected a random sample of 100 grants for review. In the population, all but 0.5 percent of the grants were awarded subject to SNAP. In our sample, all of the grants were SNAP awards.

Grant File Review

For the purpose of reviewing the grant files, the study team members obtained read only access to NCI's eGrants system. In instances in which we could not locate documentation electronically, we requested hard copy documents from NCI staff.

Using a structured instrument, we reviewed each grant for NCI's postaward monitoring in the following areas with respect to Federal regulations, HHS Grants Policy Directives, and NIH policies and procedures:

<u>Progress reports</u>. We determined whether progress reports were complete and submitted timely. Pursuant to 45 CFR § 74.51, we reviewed the progress report for (1) a comparison of actual accomplishments with the goals and objectives established for the period, the findings of the investigator, or both; and (2) the reasons established goals were not met, if appropriate. Grantees are required to submit annual Grant Progress Reports 2 months before the beginning of the next budget period or the eSNAP reports 45 days before the beginning of the next budget period.²⁰ In total, we reviewed 256 progress reports (202 were Form PHS 2590 and 54 were eSNAP).

¹⁹ NIH, "Grants Policy Statement," December 1, 2003, p. 136.

²⁰ Instructions for "U.S. Department of Health and Human Services, Public Health Service, Non-Competing Grant Progress Report (PHS 2590)," revised November 2007. Forms approved through November 30, 2010, OMB No. 0925-0001, p. 2. Available online at http://grantsl.nih.gov/grants/funding/2590/phs2590.doc. Accessed on January 9, 2008. Instructions for submitting the eSNAP. Available online at http://grants.nih.gov/grants/submitapplication.htm. Accessed on November 6, 2007. NCI staff confirmed that submission requirements for the years FYs 2004, 2005, and 2006 were the same as those described in these more recent instructions.

We projected timeliness of progress reports to the universe of NCI Research Project Grants that received funding in at least 1 year during FYs 2004, 2005, or 2006. Because progress reports are required to be submitted annually on every grant, we were able to project this statistic. The point estimate and 95 percent confidence interval can be found in Appendix B.

<u>Financial Status Reports</u>. We determined whether FSRs were complete and timely. Pursuant to 45 CFR § 74.52, grantees are to submit FSRs no later than 90 days after the end of the reporting period. An FSR is required from SNAP grantees only at the end of a competitive segment.²¹ Because a competitive segment is typically 4 to 5 years for a SNAP grantee and our period of review was 3 years, only 23 FSRs were within the scope of our review. We reviewed those 23 FSRs.

Grant closeout. For grants that were closed or eligible for closeout, we reviewed the grant files to determine whether NCI complied with departmental and agency guidance concerning grant closeout procedures. Nine grants in our sample were either closed or in the process of closeout. We reviewed these grant files for documentation of grantee submission of the final progress report, the final FSR, and the final Invention Statement and Certification within 90 days after completion of the grant.²² We also determined whether NCI closed out these grants within 180 days of the end of grant support pursuant to HHS GPD part 4.02.

Grant files. To assess the documentation, we reviewed the grant files to determine whether NCI's monitoring processes (1) followed up with grantees to obtain any delinquent reports; (2) escalated enforcement actions in the event of continued delinquency; (3) reviewed and provided feedback to the grantee; and (4) accepted revised reports from grantees, if applicable, in accordance with GPD Part 3.06B. We also reviewed the grant files for documentation of enforcement actions (e.g., temporarily withholding cash payment pending the receipt of a required financial report).²³

²¹ NIH, "Grants Policy Statement," December 1, 2003, p. 131.

²² 45 CFR § 74.71 and NIH, "Grants Policy Statement," December 1, 2003, p. 139.

²³ NIH, "Grants Policy Statement," December 1, 2003, p. 136.

Grant File Followup and Interviews

We also consulted NCI staff throughout our review for answers to questions concerning the documentation found in the grant files. We conducted structured telephone interviews with officials from the Office of Financial Management and the HHS Payment Management System to obtain information on their functions with respect to monitoring the financial aspects of NCI Research Project Grants.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

All grant files contained progress reports that had evidence of agency review; however, 41 percent of progress reports were received late

GPD Part 3.06 emphasizes the importance of postaward monitoring of grants. The guidance states that the monitoring approach should be consistent with

45 CFR Part 74 and include review of performance reports (i.e., progress reports), related audits, and other required reports. The assessment should take place on an ongoing basis, but must be documented at least annually and the results included in the grant file.

NCI grants management staff review progress reports

All required progress reports for FYs 2004, 2005, and 2006 for all 100 grants were present in the files, totaling 256 progress reports. In addition, the case files had documentation of the assessments of all of the progress reports by the grants management specialist and the program staff assigned to each grant. We observed that grants management specialists focused their review of progress reports on the responses that grantees provided in three required areas: (1) changes in the sources of salaries for key personnel occurring since the last reporting period, (2) anticipated changes in the level of effort for key personnel from what was approved, and (3) potential unobligated funds greater than 25 percent of the current year's total budget.

Program staff also reviewed progress reports for changes in research goals and objectives, the use of human and/or animal subjects, and indications of whether the grantee's progress was satisfactory for continued funding. We observed that grants management specialists followed up with grantees concerning any omissions from the progress reports or clarifications needed for the information provided. NCI did not award additional funds until the progress report was received and reviewed, demonstrating a relationship between monitoring and continued grant funding. For each of the sampled grants, NCI established the beginning date of the new budget period based on receiving a complete progress report that satisfied all requirements.

Forty-one percent of progress reports were not received timely

For the period of our review, NCI accepted either hard-copy progress reports or electronically submitted eSNAP reports. NIH grant policy requires grantees to submit the hard-copy progress reports 2 months before the beginning of the next budget period or the eSNAP reports 45 days before the beginning of the next budget period.

Forty-one percent were not received within the required timeframes. We note that grantees' delay in submitting progress reports posed a low risk because NCI did not disburse funds until it had received and reviewed progress reports. Table 1 shows the range and average number of days past due for progress reports that we reviewed.

Table 1: Late Progress Reports for 100 Sampled Grants					
Report Format	Number Received	Number Received Late	Range of Number of Days Late	Average Number of Days Late	
Electronic	54	7	1–39	18	
Hard copy	202	99	1–86	16	
Total	256	106	N/A	N/A	

Source: OIG analysis of progress reports, 2007.

The grant files for some of the late progress reports contained copies of letters that NCI sent to grantees informing them that a progress report was due but had not yet been received. As evidenced in the grant file, NCI sent a letter on March 5, 2004, to a grantee stating that a progress report had been due on or before February 1, 2004. The letter advised the grantee that if the report was not received by March 17, 2004, funding might be jeopardized.

Deficiencies exist in financial oversight of Research Project Grants

NIH guidance states that NIH awarding offices fulfill their role in regard to the stewardship of Federal funds by monitoring grants to

identify potential problems and areas where technical assistance might be necessary. Although we observed consistent review of progress reports, we did not observe the same level of examination of financial reports. We identified three deficiencies with respect to NCI's financial oversight of grants: (1) Federal Cash Transaction Reports are not monitored; (2) long periods of time elapse between funding and grantees' submission of FSRs; and (3) some FSRs are received late and contain incorrect budget period dates. The amount of Federal funds represented in our sample of 100 grants totaled \$106 million.

Federal Cash Transaction Reports are not monitored; NCI relies on self-reported information regarding unobligated funds

We asked NCI grants management staff whether they monitor the submission of the quarterly Federal Cash Transaction Reports. They told us that they do not. Instead, NCI grants management staff indicated that they rely on the Office of Financial Management to monitor Federal Cash Transaction Reports to ensure that grantees are properly drawing funds. NCI grants management staff told us that some, but not all, grants management specialists have access to the Payment Management System, and very rarely would they check Federal Cash Transaction Reports unless a grantee reported a problem. However, an Office of Financial Management official told us that his office "does not get involved with Federal Cash Transaction Reports." The official indicated that Federal Cash Transaction Reports are submitted only to the Payment Management System and that the Office of Financial Management does not examine or maintain copies of them. We were unable to identify anyone who regularly reviewed the Federal Cash Transaction Reports.

The annual progress report requires grantees to report unobligated funds greater than 25 percent of the current year's total budget. We asked grants management staff whether they verify this information with an external source. NCI grants management staff indicated that the grantee is the only source that they would check for the current balance.

Long periods of time elapse between funding and submission of FSRs NCI grants management staff indicated that they monitor the

submission of the FSR to see whether it has been submitted to and approved by the Office of Financial Management. For SNAP awards, the FSR is required at the end of the project period, which is typically 4 to 5 years. However, even more time may elapse before submission of the FSR, depending on whether the grantee requests a project extension of 1 to 2 years. For example, from July 1, 2001, to June 30, 2006, a grantee received \$1,117,672. The grantee requested and received two 1-year extensions to complete the project, making the new project end date June 30, 2008. The FSR is not due until September 30, 2008—more than 7 years after funds were first awarded.

Eleven of twenty-three Financial Status Reports in our sample were received late and some contained incorrect budget period dates

In our sample of 100 grants, 23 reached the end of their competitive segments during FYs 2004, 2005, or 2006. All 23 FSRs were present in the files. However, 11 of the 23 FSRs were submitted more than 90 days after the end of the project periods. These reports were submitted between 8 and 573 days late. The grant files for some of the

late FSRs contained letters that NCI sent to grantees informing them that an FSR was due but had not yet been received. For example, NCI sent a letter on March 22, 2006, to a grantee stating that an FSR was past due. Because the project period had ended April 30, 2005, the FSR was 237 days past due when the letter was sent. Grants management staff explained that they check for the receipt of an FSR for a prior project period before awarding the second year of funding in a new project period. If the FSR is not on file, then a deficiency letter is sent to the grantee as a reminder of the requirement to submit the FSR, and the annual grant award is not issued until the FSR has been received and accepted.

For SNAP awards, the FSR must report on the cumulative support awarded for the entire competitive segment.²⁴ For 12 of the 23 FSRs that we reviewed, the grantee reported dates on the FSR that did not reflect the entire budget periods. Often, a grantee reported a period of only 1 year. NCI grants management staff indicated that grantees often mistakenly list the last year of the project period for the applicable dates on the FSR but that this is an oversight. These FSRs usually included the full amounts awarded in the project period but attributed these amounts to an incorrect time period.

At the time of our review, the deficiency letter sent to grantees when FSRs were late instructed grantees to submit "a completed <u>Financial Status Report</u> (FSR) for the grant year prior to the <u>last award</u>." We asked NCI grants management staff why the letter was worded in that manner. They explained that the letter was a form letter that is generally not altered for SNAP awards to indicate the entire prior project period. (Grantees that are not subject to SNAP must submit FSRs annually.) NCI grants management staff reported that the letter is sufficient to notify the grantee of the need for an FSR. However, the language, which is inaccurate for grantees of SNAP awards, may lead to these grantees' reporting on periods of shorter duration than the entire competitive segment. Subsequent to our review, this deficiency letter was revised to reflect that grantees should submit an FSR for the entire competitive segment.

²⁴ NIH, "Grants Policy Statement," p. 131.

Five of the nine required grant closeouts in our sample were not completed within the general timeframes specified in departmental guidelines

Of the 100 grants in our sample, 9 grants were closed or eligible for closeout. For five of the nine grants, the closeout process was not completed within 180 days as

generally required by departmental policy. ²⁵ In one of these instances, the grantee had received a 1-year project extension, which made the new project end date December 31, 2005. The grantee submitted the final FSR on January 27, 2006, but neither the final progress report nor the final Invention Statement and Certification had been received as of October 2007. When we asked NCI grants management staff about the closing of this grant, the staff responded that delinquency letters were sent on April 4 and October 24, 2006. The grant remained open at the time of our review. In addition, one closed grant lacked the required final Invention Statement and Certification. Upon request, NCI staff could not provide the statement. After we shared a draft of this report, NCI staff conducted additional research to locate the statement and uploaded the form to eGrants.

During our review, we noted a particular practice that may delay closing grants. When a grantee approaches the end of the current competitive segment, it may submit a new application to continue the research for an additional competitive segment. Such applications require assessment and scoring by the review committee to determine whether the application will receive funding. When an application does not receive funding, the grantee has two opportunities to submit amended applications. During this time, the grant remains open. For example, a grantee received an award with the competitive segment of July 1, 2000, to June 30, 2005. The grantee submitted an application for an additional competitive segment on April 14, 2005, but it did not receive funding. The grantee submitted an amended application on December 7, 2005, which also did not receive funding. The grantee submitted a second amended application on July 26, 2006, that was approved by the review committee in January 2007. The new competitive segment began April 1, 2007, nearly 2 years after the end of the original competitive segment.

 $^{^{25}}$ GPD Part 4.02 states that grants generally shall be closed out within 180 days of the end of grant support.

Insufficient documentation impedes third-party review of grant files in some cases

The HHS GPD Part 3.06 requires awarding agencies to create and maintain files that allow a third party (e.g., auditor or other

reviewer) to follow the paper trail, from program inception through closeout of individual awards, and decisions made and actions taken in between. While conducting a review of grant files, we generally were able to follow the documentation throughout the course of the grants. However, we encountered the following examples that impeded the review process:

- Inaccurate dates—We found incorrect budget period dates on
 progress reports and incorrect dates of proposed periods of support
 on applications. In some instances, the correct dates were penciled
 in, but this was not done in all cases, necessitating additional file
 review to determine the correct dates.
- Inconsistent filing structure—NCI officials told us that grant applications were located in an electronic folder labeled Application File. Although we found this to be true in the majority of grant files, we found some with the first page of the application located in the middle of a large (75+ page) folder labeled Grant File.
- Missing files—NCI maintains an Institutional File in which grantees are listed in alphabetical order. This file contains audit and site visit reports. When we accessed the Institutional Files in November 2007, we could not locate the files for grantees beginning with the letter "Y" (e.g., Yale University). It appeared that the electronic files for grantees beginning with the letter "W" were erroneously copied over the area where the Y files should have been. No files existed for institutions beginning with the letter Y and the W files appeared twice.

NCI lacks a consistent approach for documenting communication between NCI and grantees

The NIH Grants Policy Statement emphasizes that NIH awarding agencies, in regard to fulfilling their role as stewards of Federal funds, monitor grants to identify potential problems and areas where technical assistance might be necessary. In addition to reviewing progress and financial reports, monitoring is accomplished through correspondence

and site visits.²⁶ NCI officials told us that, if there are questions on information reported in the progress report, the grants management specialist may e-mail or call the grantee for clarification.

Documentation of communication with the grantee is up to the discretion of the grants management specialist and can occur different ways. E-mails may be scanned and appended to the end of the progress report and filed in the Application File, or notes of a telephone conversation may be transcribed and included with a grants management specialist's review checklist in the Award File. The lack of a consistent approach makes it more difficult for a third-party reviewer to locate grant file documents.

²⁶ NIH, "Grants Policy Statement," p. 128.

Most significant to the overall monitoring of grants is ensuring the completeness and accuracy of progress reports. NCI has several grants monitoring practices aimed at ensuring that progress reports are reviewed and that grant funds are not awarded until progress reports are received and accepted. In fact, NCI reviewed all progress reports to monitor grantee performance. However, 41 percent were received late. In some instances, NCI sent late notices 35 days after the grantees' due date for the report. Furthermore, deficiencies exist in financial oversight of Research Project Grants. Federal Cash Transaction Reports are not monitored for unobligated fund balances, but instead NCI relies on grantee reported information. In our sample, 11 of 23 Financial Status Reports were late and five of nine required grant closeouts were not completed within general departmental guidelines. Finally, we generally were able to follow NCI's monitoring of Research Project Grants in the files, but insufficient documentation impeded our efforts in some cases.

Therefore, we recommend that NCI:

Initiate Earlier and More Frequent Followup With Grantees To Obtain Required Documents Timely

Such diligence could promote grantee compliance with Federal regulations and agency policies for submission of progress reports, Financial Status Reports, and closeout documents.

Improve Grants Monitoring By:

- annually verifying grantees' self-reported fund balances with external sources and developing an approach for financial reviews that is not based solely on exceptions, and
- consistently documenting grantee correspondence and organizing grant documents. This action could assist NCI staff, as well as third-party reviewers, in following grantees' actions from inception of the grant to closeout.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

NIH generally agreed with our recommendations and described actions it plans to take in response to the recommendations. Regarding late submission of progress reports, Financial Status Reports, and closeout documents, NIH will continue to address this issue in education outreach sessions with grantee officials and stress the need for institutions to monitor and adhere to all report deadlines. In addition. NIH expects to increase timeliness of reporting by grantees through continued development and deployment of its electronic grants management system, enabling electronic submission of certain progress and closeout reports. Regarding the recommendation to improve grants monitoring by annually verifying grantees' self-reported fund balances with external sources and developing an approach for financial reviews that is not based solely on exceptions, NIH agreed that there may be value in using the Federal Cash Transaction Report on a broader scale and will conduct a pilot study to review the Federal Cash Transaction Report prior to issuing the award for a specific pool of grants. At the end of the pilot study, NIH will identify the population of grants for which review of the Federal Cash Transaction Report will be required, as well as best practices for the review and for resolution of any issues that arise from the review. Additionally, NIH agreed with the recommendation that grant files be properly documented and organized. NIH will continue to monitor the use of its electronic grant system and update procedures for file documentation as necessary.

We did not make any revisions to the report based on NIH's comments. For the full text of NIH's comments, see Appendix C.

OEI-07-07-00120

Glossary of Grant Terms

Application—Applicants seeking financial assistance for a project formally request funds via an application. Applications are evaluated for their scientific merit and scored based on the project's potential impact. The National Cancer Advisory Board conducts a second level of review, evaluating grant applications in relation to the needs and priorities of the National Cancer Institute (NCI). The entire process can take approximately 10 months from application receipt to award.

Award—The provision of funds by NCI to an organization to carry out a Research Project Grant based on an approved application and budget.

Budget Period—The interval of time (usually 12 months) into which the grant project period is divided for funding and reporting purposes.

Competitive Segment—The initial project period recommended for support (usually 1 to 5 years) or each extension of the prior project resulting from the award of a competing continuation grant.

Financial Status Report (FSR)—The FSR shows the status of awarded funds for the competitive segment as maintained in the official accounting records of the grantee institution.

Notice of Grant Award—The legally binding document that notifies the grantee and others that an award has been made. This document contains or references all terms and conditions for the award and documents the obligation of Federal funds. The award notice may be in letter format and/or may be issued electronically.

Source: National Cancer Institute (NCI), "Everything You Wanted to Know About the NCI Grants Process But Were Afraid to Ask." Revised August 2005.



Finding	Point Estimate	95-Percent Confidence Interval
Percentage of FYs 2004, 2005, and 2006 progress reports that were not received timely	41.4%	33.6%–49.2%

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health Bethesda, Maryland 20892

JUN 20 2008

TO:

Daniel R. Levinson

Inspector General, HHS

FROM:

Director

National Institutes of Health

SUBJECT:

National Institutes of Health Comments on the Draft OIG Report,

National Cancer Institute's Monitoring of Research Project Grants

(OEI-07-07-00120)

Attached are our comments on the Office of Inspector General draft report on grant monitoring at the National Cancer Institute. We appreciate the opportunity to review and comment on this report.

We believe that our comments will help you in preparing your final report on this important issue. If you have any questions, please contact Patricia Quast, in the NIH Office of Management Assessment, at 301-402-8264.

Elias A. Zerhouni, M.D.

Attachment

COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH (NIH)
ON THE OFFICE OF INSPECTOR GENERAL DRAFT REPORT, NATIONAL CANCER INSTITUTE'S
MONITORING OF RESEARCH PROJECT GRANTS (OEI-07-07-00120)

OIG RECOMMENDATION

Initiate earlier and more frequent followup with grantees to obtain required documents timely. Such diligence could promote grantee compliance with Federal regulations and agency policies for submission of progress reports, Financial Status Reports, and closeout documents.

NIH RESPONSE

The NIH agrees in principle that earlier and more frequent follow up with grantees could result in greater grantee compliance. In fact, we have taken extensive actions, including earlier and more frequent follow up with grantees, to improve grantee compliance with respect to timely submission. We will continue to address this issue by exploring and testing different approaches to optimize grantee performance. The NIH fully expects that grantee performance will improve with the full deployment of its electronic systems, as evidenced by the data presented in the report. In addition, we will continue to remind grantees of their responsibility to submit accurate and timely reports, as described elsewhere in this document.

The NIH and NCI have been working diligently to resolve the problem of late progress reports as evidenced by the extensive actions already taken. As documented by a previous OIG report, grantees frequently submit incomplete or late progress reports. We agree that grantees' delay in submitting progress reports poses a low risk because it is NIH policy that additional funds are not awarded until progress reports are received, reviewed, and approved, as evidenced by NCI actions. Grantees are responsible for ensuring timely and accurate reporting. The NIH continues to achieve efficiencies and improve performance of grantee institutions in this area.

We have developed and implemented many initiatives to address the problems associated with late progress reports. It is important to understand, however, that although the NIH has and continues to develop tools for its grant recipients, it is absolutely imperative that grantees have policies, procedures, and monitoring systems in place to ensure compliance with reporting requirements. Actions taken to specifically address late annual (Type 5) progress reports include:

• The NIH and NCI continue to address late as well as incomplete reports in education outreach sessions, clarifying NIH requirements and focusing on grantee responsibilities, including those of the PI, and the need for institutions to monitor and adhere to all report deadlines. The NCI continues to stress the importance of timely and complete reports, specifically citing data that illustrates the magnitude of the problem and the negative and costly impact late and incomplete reports have on NCI staff. NCI staff stress the

importance of grantees monitoring their own performance and implementing appropriate measures to ensure reporting compliance. The NIH and NCI will continue to stress reporting requirements and compliance at all outreach meetings with grantee officials.

- In 2004, the NIH implemented a system through the eRA Commons, an electronic grants management system, enabling grantees to submit an electronic version of the Streamlined Noncompeting Award Process (e-SNAP) Type 5 progress reports.
 - E-mail reminders are sent to Principal Investigators (PIs) two months before a Type 5 progress report is due.
 - E-mail reminders are sent to Principal Investigators when a Type 5 progress report is more than 15 days late.
 - Similar e-mail reminders are in development for business officials at grantee institutions.
 - As noted above, grantees are responsible for monitoring and meeting reporting deadlines. To assist that effort, we have created a Web site that grantees can access for noncompeting progress report (Type 5) due date information. This allows grantee officials to obtain a list of when all Type 5 progress reports for their institution are due and when reports are delinquent (http://era.nih.gov/userreports/pr due.cfm). Due date information is also available in the eRA Commons Status system accessible by both PIs and institutional Administrative Officials.

Final progress reports are one element of grant closeout documentation. To address late final progress reports, we have taken the following actions:

- In June 2005, we introduced a new Closeout feature in the eRA Commons that provides
 the capability to electronically submit required Closeout Reports: final progress report,
 final Financial Status Report (FSR), and final inventions statement.
- All grantee institutions are required to be registered in the eRA Commons, which allows
 them to query in the Commons Status system for those grants that are in a closeout
 status. Commons users can then enter the Closeout screens to electronically process and
 submit the required reports.
- A Term of Award is automatically included in the Notice of Award for the final year of
 the project period reminding grantees of the requirement to submit closeout information
 using the eRA Commons within 90 days of the end of the project period.
- To assist NIH grants management staff in addressing the problem of late closeout, we developed an electronic closeout module in IMPAC II. In 2004, we made it a

requirement that all NIH Institutes and Centers use the closeout module for all grant awards expiring on or after October 1, 2004.

- In fiscal year 2008, we completed the transition of administrative closeout functions from all NIH Institutes and Centers (ICs) to the Division of Extramural Activities Support (DEAS). The DEAS is responsible for grants closeout, in accordance with standard operating procedures, for all of the NIH awarding components.
- NIH grants management staff no longer perform closeout functions.

The data in the report indicate that for the 100 sampled NCI grants, 13 percent of the electronic progress reports were received late in contrast to 49 percent of paper progress reports that were received late. We believe that when the NIH electronic systems are fully developed and electronic submission of Type 5 progress reports is required, timeliness will improve, as suggested by the data in this report. Until then, we will continue our efforts to address late Type 5 progress reports.

OIG RECOMMENDATION

Improve grants monitoring by annually verifying grantees' self-reported fund balances with external sources and developing an approach for financial reviews that is not based solely on exceptions.

NIH RESPONSE

The NCI agrees there may be value in using the Federal Cash Transaction Report (FCTR) (PMS 272) on a broader scale than is currently being done. In order to determine the best, most productive use of the 272 report, NCI will conduct a pilot study.

The annual progress reports for SNAP applications require that the grantee answer three questions, including whether they anticipate an unobligated balance greater than 25 percent of the current year's total budget. Similar information on significant balances (25 percent of the current year's total authorized budget) is also requested as part of the budget justification in non-SNAP progress reports. NCI Office of Grants Administration (OGA) staff review the information provided in conjunction with program staff review of the progress reported in the application. If there appear to be discrepancies between the reported balance and the progress made in the project, they are discussed with the grantee. In addition, if the grantee reports a large balance, OGA staff will contact the grantee to verify the magnitude of the balance and discuss options for use of the funds based on the circumstances (e.g., reducing the pending award, allowing the carryover on the pending award, or restructuring timelines). The FCTR (PMS 272) will also be reviewed in grants for which there appear to be problems or discrepancies in reporting of balances in the progress report.

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Submission of the FCTR is monitored by staff of the Payment Management System (PMS). All OGA staff have access to the PMS and review the FCTR on an as-needed basis. The FCTR is one of the tools used by OGA staff to monitor balances in grant awards, when necessary. However, the limitations of this data as a monitoring tool need to be noted.

The PMS is based on the calendar year, so information rarely coincides with the budget period for any particular grant. In addition, the FCTR reports are based on quarterly draw downs (March 31, June 30, September 30, and December 31), and reports are not due from the grantee until 45 days after the end of the quarter, so expenditure analysis is not current. However, because the reports provide a general indication of the balance remaining in a grant account, they are used as an additional monitoring tool, as the particular situation warrants. A worksheet is available for grants management staff to assist them in using the FCTR information as a fiscal monitoring tool.

In response to the recommendation, the NCI will conduct a pilot study to develop and evaluate best practices for reviewing FCTR reports and to determine for which population of grants this review is appropriate, given the limitations of the PMS reports noted above.

Specifically, the NCI plans to institute:

- A pilot study to conduct a review of the FCTR (PMS 272) report prior to issuing the award for a specific pool of grants.
- If the PMS 272 reflects that the grantee has accurately reported the anticipated unobligated balance in the progress report, the file will be documented accordingly.
- If a review of the PMS 272 raises questions or concerns about the grantee's
 reporting of the balance, the specialist will request additional information from the
 grantee, will take appropriate action as necessary, and will document the file
 accordingly.
- At the end of the pilot study, the NCI will evaluate the data and develop appropriate standard operating procedures. The procedures will identify the population of grants for which the Grants Specialist will be required to review the FCTR PMS 272 report, as well as the best practices for the review and for resolution of any issues that arise from the review.

OIG RECOMMENDATION

Improve grants monitoring by consistently documenting grantee correspondence and organizing grant documents to assist NCI staff and third-party reviewers with following grantees' actions from inception of the grant to closeout.

NIH RESPONSE

The NCI agrees with the recommendation that official files be properly documented and organized. We note that the reviewers were generally able to follow the documentation

throughout the course of the grants and confirm that the NCI had proper documentation for its actions. As discussed below, the NCI has and will continue to monitor and improve eGrants for all users.

The NCI has developed and implemented a fully integrated state-of-the-art electronic grant file system known as eGrants, which staff continually monitor, evaluate, and improve. The NCI's primary goal is to maintain and enhance an electronic grant file system that is current, complete, consistently organized, and user friendly. The eGrants system allows authorized users to easily follow and review the flow of grant documents from inception to closeout.

The NCI OGA has always recognized the need to have a consistent and efficient electronic grant file. In order to promote consistency in file documentation, OGA has developed and continually updates guidance to staff. "The List of Standard Practices for Electronic Review and Documentation of Grant Files," dated November 2007, has a list of standard practices for electronic documentation of grant files. We will continue to monitor the use of eGrants and to update our procedures for file documentation as necessary.

A history of the evolution of eGrants is attached for further reference.

6/19/08

ATTACHMENT

The NCI Office of Grants Administration (OGA) transition from working with a well-organized official paper-based grant file to an electronic document management system has taken place over the last 14 years. It has been a process incremental in nature, with transitional stages being implemented to take advantage of the most recent advances in technology. During this time period-specific guidelines for staff regarding file documentation, indexing standards, bookmaking, etc., have periodically been revised and updated based on user feedback from grants management and program staff, as well as external comments made by independent entities.

The transition from paper to electronic files began in 1993, with a feasibility study regarding the transition of the application file back-up from microfiche to an Electronic Imaging Management System.

In 1996, the conversion system was implemented—a back-file conversion of grant applications to indexed electronic images—this went back to the last competing year. The back-file conversion was completed in 1999 with 2.5 million pages scanned into the eGrants database.

In 1998, we began running demonstrations of the electronic file system in multiple small group settings to a variety of NCI, NIH, and grantee staff. A significant purpose of these demonstrations was to get user feedback. In March 2000, eGrants was rolled out for extensive NCI extramural use as a Web-based system.

In November 2002 (fiscal year 2003), the NCI began processing SNAP applications exclusively using eGrants, eliminating the paper files for these mechanisms.

In April 2004, we moved into processing other types of mechanisms using eGrants. This amounted to approximately 70 percent of the workload. However, for the more complex mechanisms, staff was still marking up paper copies that were then rescanned into eGrants.

In August 2004, three flat panel LCD configurations were introduced to OGA staff to enable them to work the remaining 30 percent of their portfolio electronically.

In October 2004 (fiscal year 2005), NCI Grants staff began working 100 percent of the grant portfolio electronically—meaning no paper files at all—and we began destroying existing paper files.

In FY 2006, over 20 percent (1,200 linear feet) of the OGA's records management center shelves were empty. Currently, the OGA does not have any paper files in the records management center, over 35,000 active paper grants files have been shredded, and all of our official files are kept in the eGrants database.

As previously stated, the OGA manages 100 percent of grant portfolios electronically. This business practice is possible by utilizing the eGrants database and the Adobe Acrobat software. In order to maintain a consistent and efficient grant folder, the OGA has once again updated its guidance to staff. "The List of Standard Practices for Electronic Review and Documentation of Grant Files," dated November 2007, is a compilation of standard practices for electronic documentation of grant files, and the OGA has shared this document with the nine other ICs that are currently using eGrants.

We feel that we have consistently documented the grant files and organized grant documents to assist and facilitate NCI staff and third-party reviewers with following grantees' actions from inception of the grant to the closeout.

6/19/08

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ACKNOWLEDGMENTS

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Tricia Fields served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Kansas City regional office who contributed to the report include Michael Barrett, Rae Bozworth, and Dennis Tharp; other central office staff who contributed include Robert Gibbons and Mark Richardson.