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NIH GRANTS MANAGEMENT: LATE CLOSEOUTS

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ABSTRACT

Grants management is a priority area for both the Secretary of Health and Human Services and the Office of Inspector General. In fiscal year 2002, the National Institutes of Health (NIH) awarded $19 billion to support 49,000 extramural grants to researchers affiliated with more than 2,800 universities, hospitals, and other research facilities. When a grant is terminated, Federal regulations require the grantee to submit, within 90 days, a final financial status report, scientific progress report, and invention statement. This grant closeout process is critical because it is the final point of accountability for the grantee. NIH staff must review and approve these documents in order to close out the grant. We have defined, in consultation with NIH, an on-time closeout as one that occurs within 150 days after the grant has been terminated. In August 2002, NIH implemented a new computer system to monitor closeouts, referred to as the NIH closeout module.

Based on our analysis of data in the NIH closeout module, we found that 88 percent (8,941) of all grants in the module were closed out late. The primary cause of late closeouts is grantees submitting closeout documents late. Tracking down these late closeout documents requires significant time and effort for NIH staff. NIH experiences several challenges in taking corrective actions against grantees for submitting late closeout documents. While the closeout module is a promising tool to help NIH monitor closeouts, it has some limitations. To address late closeouts we recommend that NIH (1) develop an automated reminder system to alert grantees about upcoming due dates for closeout documents, (2) facilitate the electronic submission of all closeout documents, (3) enhance the closeout module's capabilities, and (4) address late closeouts more systematically by focusing on grantee institutions. NIH concurred with our recommendations.

OBJECTIVE

To determine the extent to which the National Institutes of Health closes out grants on time.

BACKGROUND

The National Institutes of Health (NIH) is the largest Federal funder of health research and development. In fiscal year 2002, NIH awarded $19 billion to support 49,000 extramural grants to researchers affiliated with more than 2,800 universities, hospitals, and other research facilities. Extramural grants fund scientists and organizations outside the agency. NIH awards grants through 24 distinct institutes and centers (institutes) that are responsible for the day-to-day management and oversight of their grants.

Grants management is a priority area for both the Secretary of Health and Human Services and the Office of Inspector General. Given that grant closeouts are the final point of accountability for the grantee, their timeliness is an important aspect of grants management at NIH. When a grant is terminated, Federal regulations require the grantee to submit, within 90 days, a final financial status report, scientific progress report, and invention statement (45 CFR § 74.70-73). The financial status report confirms the final accounting of grant funds. At this time, any unobligated funds are released. The progress report documents the course and results of the research. Finally, the invention statement confirms if any inventions were developed under the grant.

We have defined an on-time closeout, in consultation with NIH, as one that occurs within 150 days of the end of the project period. We have allowed 60 calendar days for NIH staff to review and approve the closeout documents submitted by grantees, in addition to the 90 days allowed by Federal regulations for grantees to submit their closeout documents.

In August 2002, NIH implemented a new computer system to monitor closeouts, referred to as the NIH closeout module. The purpose of the closeout module is to help NIH staff closeout grants on time and, when necessary, follow up with grantees to obtain late documents. This new module provides an opportunity to document late closeouts and their causes. At the time of our review, the module was in use for only about 8 months, and institutes used it to varying extents.

Therefore, we cannot make any conclusions about the entire population of closeouts based on that data. This limitation applies to all data analysis based on the closeout module.

This inspection is primarily based on an analysis of all data in the NIH closeout module, a survey of grantee institutions, and interviews with NIH staff.

This report is one of two that resulted from our inquiry. Our companion report, *NIH Grants Management: Late Awards* (OEI-01-03-00020), applies a similar methodology to determine the extent to which NIH awards noncompeting continuation grants on time.

FINDINGS

Eighty-eight percent of all grants in the NIH closeout module were closed out late. As of April 2003, the NIH closeout module contained 10,122 grants, of which 8,941 were closed out late. This includes 3,118 grants that were closed out after 150 days, and 5,823 grants that were still pending after 150 days passed. Fifty grantee institutions accounted for almost half of these late closeouts. Research project grants, which are one of 10 funding categories, accounted for 79 percent of these late closeouts. Late closeouts appeared to be common across all funding mechanisms, years, and institutes.

Grantees submitting closeout documents late is the primary cause for late closeouts. Based on data in the closeout module, grantees submitted final financial status reports late for 49 percent of the grants. Grantees submitted final progress reports late for 37 percent of the grants. And grantees submitted at least 31 percent of final invention statements late. NIH does not remind grantees about upcoming due dates for closeout documents as the due date approaches. However, NIH does remind grantees about their closeouts at the time they receive the final year of funding.

Tracking down missing closeout documents requires significant time and effort for institute staff. As late closeouts accumulate, institute staff reported to us that they find it difficult to address the backlog. Closeouts that are several years old are especially difficult, because principal investigators (the scientists who lead the research) may have moved on to other institutions and records may not be readily available. In order to obtain closeout documents, staff must follow up, often multiple times, with grantees. To address this

workload, several institutes have hired staff and/or contractors that are dedicated solely to addressing closeouts.

NIH experiences challenges in taking corrective actions against grantees for submitting closeout documents late. Institute staff indicated that they rarely resort to withholding future funding from an institution due to late closeouts, because it is too severe a penalty and slows down future research. And in many cases, the option of withholding future funding is not possible, as the principal investigator is no longer conducting NIH research. Twelve percent of grantee institutions indicated that NIH had withheld future funding from their institution due to late submission of closeout documents. And yet, 85 percent of grantee institutions indicated on our survey that they had submitted at least one set of closeout documents late in the past 3 years.

While the closeout module is promising, it has some limitations. The current closeout module does not automatically include all grants eligible for closeout. Institute staff manually enter grants ready for closeout into the module; therefore, completeness is dependent on the staff updating the system. (Manual entry is necessary in order to verify the grant is ready for closeout.) Even for those institutes that have entered information, it is uncertain how diligent they are at keeping the information up to date. Many records contain missing information, which raises questions about whether the information was not submitted by the grantee or whether the institute failed to enter the information in the module.

RECOMMENDATIONS

NIH is taking several important steps toward addressing late closeouts, especially in developing the closeout module and planning to manage the closeout function from a central office. We encourage NIH to continue these efforts. We also recommend NIH:

- **Develop an automated reminder system for grantees to alert them of upcoming closeouts**
- **Facilitate the electronic submission of all closeout documents**
- **Enhance the closeout module's capabilities by ensuring that all the information is entered into the module**

- **Address late closeouts more systematically by focusing on grantee institutions**

Agency Comments

NIH reveiwed a draft of this report and concurred with our recommendations. In its comments, NIH indicated additional steps that it is planning to address these issues.

TABLE OF CONTENTS

INTRODUCTION

OBJECTIVE

To determine the extent to which the National Institutes of Health closes out grants on time.

BACKGROUND

The National Institutes of Health (NIH) is the largest Federal funder of health research and development. NIH grants support basic and clinical research, research centers, scientific training and fellowships, and construction projects.

Recent increases in appropriations have allowed NIH to significantly increase its grant-making capacity over the past 5 years. In fiscal year (FY) 2003, NIH received $27 billion in total funding, compared to $13.6 billion in FY 1998. The President's proposed budget for FY 2004 requests $28 billion for NIH.

About 80 to 85 percent of NIH's budget supports extramural grants. Extramural grants fund scientists and organizations outside the agency. In FY 2002, NIH's total budget was $23.2 billion, of which NIH awarded $19 billion in extramural grants. NIH awarded $16.8 billion to support 43,520 extramural *research* grants; the remaining $2.2 billion went to support 6,196 other extramural grants, such as training and fellowship grants. Combined, these funds supported about 49,700 extramural grants to researchers affiliated with more than 2,800 universities, hospitals, and other research facilities.

Grants Administration

Grants management and oversight are critical to ensure that Federal funds are used properly. Grants management is a priority area for both the Secretary of Health and Human Services and the Office of Inspector General, and is among the top management challenges identified by the Office of Inspector General for FY 2003.[1] As the largest funder of health research, NIH must have appropriate policies and procedures in place to effectively and efficiently manage its grants. The recent increases in NIH funding make it particularly important to ensure that NIH has the proper infrastructure to handle its increased grant workload.

The general requirements for grants management at NIH are set forth by the Office of Management and Budget and codified in regulation by the Department of Health and Human Services.[2] These

regulations establish requirements for the financial and administrative management of each award.

Additional requirements are provided in the NIH Guide for Grants and Contracts, the NIH Grants Policy Statement, and the NIH Manual. The NIH Guide for Grants and Contracts is the official publication of NIH policies, procedures, and availability of funds. The NIH Grants Policy Statement provides a general overview of the grant application and review process, including terms and conditions for NIH grant awards. (NIH can establish other terms for particular institutions.) It emphasizes the importance of good grants management by stating, "NIH, as a Federal grantor agency, is responsible to Congress and the U.S. taxpayer for carrying out its mission in a manner that not only facilitates research but also does so cost effectively and in compliance with applicable rules and regulations."[3] The NIH Manual contains NIH policies regarding internal operations, including requirements for the awarding and oversight of extramural grants.

NIH's Office of Extramural Research is central to the development and maintenance of agency policies regarding extramural grants. It also develops program guidelines and information systems related to extramural research grants administration.

NIH awards grants through 24 distinct institutes and centers (hereafter referred to as institutes) that are responsible for the day-to-day management and oversight of their grants.[4] Each institute has its own grants management office to handle administrative functions and to conduct ongoing monitoring of its grants. Grants management specialists in these offices are primarily responsible for reviewing applications for administrative content and compliance with key laws and regulations, reviewing all correspondence and reports from grantees, and providing technical assistance to grantees as needed throughout the grant process. A chief grants management officer oversees the grant specialists. Each institute also has its own program office. Program officers establish scientific program goals and objectives, which serve as a guide for funding decisions, and monitor scientific issues that arise throughout the course of the grant.

Typically, NIH awards grants with project periods that span several years. The project period is the total time for which NIH agrees to support the project. NIH divides a multi-year project period into budget periods, usually 12-month increments. The budget period may

start at any point during the year. Grants management staff assign project periods and budget periods for each grant.

Grant Closeouts

Grant closeouts are the final point of accountability for the grantee. Failure to close out grants can have negative consequences for NIH as well as the grantees. For NIH staff, the consequence of late closeouts is that they need to spend significant time and effort following up with grantees to obtain late closeout documents. As for the grantees, the consequence of late closeouts is that future funding could be in jeopardy if NIH chooses to take enforcement actions.

The closeout process occurs when the grant project period ends or when a grant transfers to another institution. At such time, Federal regulations require grantees to submit a closeout packet that consists of a final financial status report, scientific progress report, and invention statement. The financial status report confirms the final accounting of grant funds. At this time, any unobligated funds are released. The progress report documents the course and results of the research. Finally, the invention statement confirms if any inventions were developed under the grant.

Federal regulations require grantees to submit a closeout packet no later than 90 calendar days following the termination of a grant.[5] After 150 days, the NIH Manual states that sanctions may be imposed.[6]

The principal investigator, the scientist who is responsible for the direction and conduct of the research, and the grantee institution, the organization where the principal investigator is affiliated, are both responsible for submitting closeout documents. Typically, the principal investigator completes and submits the progress report and the invention statement. The grantee institution's accounting department typically submits the financial status report.

Once the institute receives the closeout documents, the appropriate institute staff review and approve the documents. The program officer is responsible for reviewing and approving the final scientific progress report and the grants management specialist ensures that all documents are complete.

We have defined, in consultation with NIH, an on-time closeout as one that occurs within 150 days of the end of the project period. We have allowed 60 calendar days for NIH staff to review and approve the

documents submitted by the grantees, in addition to the 90 days allowed by Federal regulations for grantees to submit their closeout documents.

Prior Work

Prior work by the Office of Inspector General (OIG) and others has found late closeouts to be a problem for NIH. The OIG reported in its Independent Audit Report for FY 2002 that NIH had about 15,283 grants that were eligible for closeout but had not been closed as of September 30, 2002.[7] A 1998 General Accounting Office report found that 85 percent (628 of 736) of grants at one institute were delinquent in providing the complete closeout packages.[8] Data from the National Cancer Institute, which has its own system to monitor closeouts, show that in FY 2000 and FY 2001 nearly 100 percent of grantees did not submit required documentation for closeouts within 90 days.[9]

NIH Closeout Module

In August 2002, NIH implemented a new computer program to monitor closeouts, referred to as the NIH closeout module. The purpose of the closeout module is to help NIH staff closeout grants on time and, when necessary, follow up with grantees to obtain late documents. This new module provides an opportunity to document late closeouts and their causes. The module pulls information from the Information for Management, Planning, Analysis and Coordination (IMPAC II) database and, based on this information, institutes can enter grants into the module that are ready for closeout. Once a grant is in the module, the institute staff can readily determine which closeout documents are missing and automatically generate emails to the grantee institution requesting the missing information.

METHODOLOGY

We based our analysis of late closeouts on five sources of data. For a detailed description of our methodology and confidence intervals, see Appendices A and B.

First, we analyzed all 10,130 grants in NIH's closeout module as of April 2003. The closeout module is a computer system implemented in August 2002 that allows the institutes to monitor grants that are ready for closeout. We eliminated 8 grants from our analysis because of missing information or apparent data entry errors. The revised dataset had a total of 10,122 records.

Second, we obtained computer printouts from the closeout module for a stratified sample of 300 grants that were closed out late (at least 150 days after the project end date) or were still open at least 150 days after the project end date. We limited our population to three of the largest institutes: the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, and the National Institute of General Medical Sciences. We excluded the largest institute, the National Cancer Institute, because it already has an active monitoring system in place to identify late closeouts and their causes. We stratified our sample by institute. We randomly selected 100 late closeouts from the National Heart, Lung, and Blood Institute (N=522), the National Institute of Allergy and Infectious Diseases (N=784), and the National Institute of General Medical Sciences (N=254).

Third, we requested the specific operating procedures related to closeouts for all 24 institutes with grant-making authority.

Fourth, we selected a simple random sample of 135 grantee institutions from the 375 locations that received 10 or more research grants from NIH in FY 2002. We received 111 replies to our survey, for a response rate of 82 percent.

Finally, we interviewed grants management staff at the National Heart, Lung, and Blood Institute; the National Institute of Allergy and Infectious Diseases; and the National Institute of General Medical Sciences, as well as staff in the Office of Extramural Research.

Data Limitations

In order for a grant to be captured in the closeout module, institute staff must manually enter the grant into the module. Because the module depends on someone to enter the grants, it is unlikely that the module contains all grants ready for closeout. This is further complicated by the fact that at the time of our review, the module was in use for only about 8 months, and institutes used it to varying extents. For example, some institutes have entered closeouts from the past several years, whereas other institutes have only entered the most recent closeouts. Therefore, we cannot make any conclusions about the entire population of closeouts based on that data. This limitation applies to all data analysis based on the closeout module.

Standards

We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

A COMPANION REPORT

This report is one of two that resulted from our inquiry. Our companion report, *NIH Grants Management: Late Awards* (OEI-01-03-00020), applies a similar methodology to determine the extent to which NIH awards noncompeting continuation (type 5) grants on time. A late noncompeting continuation award results in a situation in which NIH has not issued funding for the next budget period until after the end of the previous budget. This causes a gap in funding.

FINDINGS

Eighty-eight percent of all the awards in the NIH closeout module were closed out late.

As of April 2003, the NIH closeout module contained 10,122 closeouts, of which 8,941 were closed out late. This includes 3,118 grants that were closed out after 150 days and 5,823 grants that were still pending, but 150 days had already passed.

The late closeouts in the module were at least 2 years late. Three-quarters of the late closeouts were at least 1 year late. Almost half were 3 years or more late. (See Table 1.) These are conservative estimates because 65 percent of the late closeouts remain open, thus, they become even later over time.

Table 1. Closeouts By Extent of Lateness

Extent of Lateness	Number of Late Closeouts	Percent of All Late Closeouts*
151 days to < 1 year	2,374	27%
1 year to < 2 years	1,087	12%
2 years to < 3 years	1,483	17%
3 years to < 4 years	1,421	16%
4 years to < 5 years	1,183	13%
5 years and above	1,393	16%
Overall Total	8,941	100%

* Numbers do not equal a 100% due to rounding.

Source: OIG analysis of data from NIH's Closeout Module, 2003

Three percent of the grantee institutions in the module accounted for 45 percent of all the late closeouts in the module. There were 1,721 grantee institutions in the module, yet 50 of these grantee institutions represent 4,018 (45 percent) of late closeouts in the module. These 50 grantee institutions also represent 45 percent of all grants in the closeout module. The proportion of late closeouts for those 50 grantee institutions ranged from 70 to 96 percent. Thirteen of those 50 grantee institutions had at least 100 late closeouts. Given that some grantee institutions are very large and receive thousands of grants from NIH each year, it is not surprising that a small number of large grantees accounted for almost half of the late closeouts. These large grantees had the largest *absolute number* of late closeouts, but this does not necessarily indicate that they had a greater *proportion* of late closeouts than other grantees.

Late closeouts were common across funding mechanisms in the module. The closeout module included 73 types of funding mechanisms, rolled up into 10 categories ranging from research project grants (R) to cooperative agreements (U). The proportion of late closeouts ranged from 46 percent to 100 percent across the 10 categories of funding mechanisms. Research project grants (R), which

Table 2. Late Closeouts by Grant Mechanism

Category of Grant Mechanisms	Number of Closeouts in the Module	Number of Late Closeouts in the Module	Percent of Late Closeouts in the Module
Research Projects (R)	7,974	7,242	91%
Research Career (K)	701	658	94%
Fellowship (F)	310	245	79%
Research Programs and Centers (P)	274	239	87%
Research-Related Programs (S)	447	205	46%
Cooperative Agreements (U)	165	155	94%
Training Programs (T)	103	96	93%
Resource (G)	85	58	68%
Research Construction (C)	62	42	68%
General Clinical Research Center (M)	1	1	100%
Overall Total	**10,122**	**8,941**	**88%**

Source: OIG analysis of data from NIH's Closeout Module, 2003

are the most common type of grant mechanism used by NIH, accounted for 79 percent of all grants in the closeout module. Of those research grants, 91 percent were closed out late. (See Table 2 on the previous page.)

Within the module, late closeouts appeared to be a problem across all years. NIH began using the closeout module starting in August 2002. At that time, some institutes entered the most current grants into the module, while others entered grants that had been pending closeout for several years, as far back as 1994. Considering these varying approaches to entering data into the closeout module, and recognizing that some institutes have entered all closeouts and others have entered more recent closeouts, it is difficult to look at the trend of closeouts across the years. Still, for the more recent years of 1999 to 2002, over 1,000 grants were closed out late per year. In 2002, the year in which the closeout module was launched, 2,803 grants were closed out late. (See Table 3.)

Table 3. Late Closeouts by Project Period End Date

Calendar Year of the Project Period End Date	Number of Closeouts in Module	Number of Late Closeouts in Module	Percent of Late Closeouts in the Module
1994	8	8	100%
1995	217	216	100%
1996	401	396	99%
1997	454	439	97%
1998	690	670	97%
1999	1,352	1,318	98%
2000	1,711	1,528	89%
2001	1,756	1,563	89%
2002	3,425	2,803	82%
2003	103	0	0%
No year provided	5	n/a	n/a
Overall Total	10,122	8,941	88%

Source:OIG analysis of data from NIH's Closeout Module, 2003

Twenty-three institutes have used the closeout module to varying degrees. Considering the varying approaches to entering data into the closeout module, it is difficult to look at the trend of closeouts across the institutes. Some institutes have entered as few as 2 grants (National Institute on Drug Abuse) while others have entered over 2,000 (National Institute of Neurological Disorders and Stroke). [10] Fourteen institutes have at least 100 late closeouts in the module. (See Appendix C.) Of the institutes that have the most closeouts in the module (500 or more grants in the module), the proportion of late closeouts ranged from 55 to 100 percent. (See Table 4.) Although it has provided training on the use of the closeout module to institute staff, at the time of our review, NIH did not require institutes to use the module.

Table 4. Late Closeouts for the Institutes with the Most Grants in the Closeout Module

Institute or Center	Number of Closeouts in the Module	Number of Late Closeouts in the Module	Percent of Late Closeouts in the Module
Nat. Inst. of Neurological Disorders & Stroke	2,016	1,887	94%
Nat. Cancer Institute	1,228	1,108	90%
Nat. Inst. of Child Health & Human Development	964	953	99%
Nat. Inst. on Deafness and other Communication Disorders	1,008	922	92%
Nat Inst. Of Allergy & Infectious Diseases	1,060	917	87%
Nat. Inst. of Dental & Craniofacial Research	593	584	99%
Nat. Heart, Lung, & Blood Institute	621	566	91%
Nat. Center for Research Resources	1,005	557	55%
Nat. Inst. of Diabetes & Digestive & Kidney Diseases	541	540	100%

Source: OIG analysis of data from NIH's Closeout Module, 2003

Grantees submitting closeout documents late is the primary cause for late closeouts.

Federal regulations require grantees to submit all closeout documents no later than 90 calendar days following the termination of a grant.[11]

Financial status reports were submitted late most often. Based on data from the closeout module, grantees submitted final financial status reports late for 49 percent of grants that were closed out late. On average, financial status reports were at least 191 days late. Grantees submitted final progress reports late in 37 percent of grants closed out late, averaging at least 467 days late. The closeout module does not have a date for final invention reports, as the module was not designed to capture it. Instead, the receipt is indicated by a "Yes" or "No." Therefore, it is difficult to accurately report the extent of late invention statements. However, grantees submitted at least 31 percent of final invention statements late of grants closed out late. This is assuming that all grants with a "Yes" were received on time, which is unlikely. (See Table 5.) Grantees submitted at least 2 of the documents late in 35 percent of the grants closed out late, and 5 percent of grantees submitted all three documents late.

Table 5. Percent of Late Closeout Documents

Document	Percent Late	No Information in Module*	Percent on Time
Financial Status Report	49%	26%	26%
Progress Report	37%	54%	9%
Invention Statement	31%	31%	31%

Source: OIG analysis of data from NIH's Closeout Module, 2003

*No information could reflect that the institute has not received the information from the grantee or that the system has not been updated to reflect the receipt.

Grantees experience several challenges in submitting closeout documents on time. Eighty-five percent of grantee institutions indicated that they had submitted at least one closeout package late in the past 3 years. Several reasons may account for this. First, grantee institutions commented on our survey that 90 days is not always enough time to reconcile accounts and prepare the financial status report, especially when subgrantees are involved. Second, they also acknowledged that they have difficulty obtaining the necessary information in a timely manner from principal investigators at their institutions, who are often busy with other grants and may not view the final progress report as a high priority. Third, grantee institutions commented that limited staff resources and other competing priorities hinder their ability to stay on top of closeouts, especially as late closeouts accumulate. And finally, grantees must submit their invention statements and progress reports on paper through regular mail. Only financial status reports can be submitted electronically to NIH. Paper submission may contribute to late closeouts.

NIH lacks a reminder system to alert grantees about upcoming due dates for closeouts. As the end of the project period nears, NIH does not routinely send a reminder or notice to the grantee about the upcoming due date for closeout documents. Instead, NIH informs the grantee in the notice-of-grant award for the last budget period, which is typically a year before the closeout documents are due. Grantee institutions that responded to our survey commented that the lack of reminders immediately prior to due dates contributed to late closeout documents.

When grantees submit closeout documents on time, NIH does close out the grant in a timely manner. Based on data from the closeout module, we found that when all closeout documents were submitted within 90 calendar days, NIH reviewed and approved the documents within 60 days 96 percent of the time. Seventeen of the 24 institutes with grant-making authority have procedures to manage closeouts.*

* Since the time of our review, NIH has centralized its grants closeout function, such that individual institute's procedures are being replaced by standard operating procedures.

Tracking down missing closeout documents requires significant time and effort by the institutes.

As late closeouts accumulate, institute staff commented that they find it difficult to address the backlog given other competing priorities, especially issuing new grants. They also raised concerns about the amount of resources they have to manage the closeout process and follow-up with grantees regarding late closeout documents. Obtaining missing closeout documents is especially difficult for grants that are several years old, because principal investigators may have moved on to other institutions and records may not be readily available.

To address this workload, the three institutes we reviewed in-depth (the National Heart, Lung, and Blood Institute; the National Institute of Allergy and Infectious Diseases; and the National Institute of General Medical Sciences) hired contractors or staff, who are dedicated solely to processing closeout documents from grantees. The chief grants management officers at these three institutes mentioned dedicated staff as key for processing closeouts, especially the backlog of late closeouts.

In order to obtain missing documents, institutes must follow up, often multiple times, with grantees. The NIH Manual recommends institutes follow-up with grantees if the closeout documents have not been submitted after 90, 120, and 150 calendar days. [12]

The closeout module allows institutes to record up to two follow up correspondences with grantees. Because we could not readily obtain the correspondence data for all grants in the closeout module, we reviewed printouts that contained correspondence data for a sample of 300 out of 1,560 grants that were closed out late in FY 2002 at the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, and the National Institute of General Medical Sciences. We found that 80 percent of these grants had at least 1 recorded correspondence in the closeout module, and 39 percent had a second recorded correspondence. It is possible that institutes conducted additional follow-up that was not recorded in the closeout module.

NIH experiences several challenges in taking corrective actions against grantees for submitting closeout documents late.

According to the NIH Manual, institutes may impose one of several sanctions if the grantee has not submitted its closeout documents within 150 days. [13] If the principal investigator has other pending awards with the same institute, the institute may withhold future funding from the grantee institution for that particular principal investigator until the closeout documents are submitted. If the principal investigator has other pending awards at other institutes, the institute with the late closeout could request that the other institutes also withhold future funding from the principal investigator's institution. However, it is up to each individual institute to determine whether or not to withhold future funding.

Because the closeout module does not capture such information, we were unable to quantify how often institutes withheld future funding. However, in interviews, institute staff indicated that they rarely resort to withholding future funding from a principal investigator due to late closeouts, because it is viewed as too severe a penalty and slows down future research. Withholding funds often means coordinating with other institutes where the principal investigator and grantee institution has pending awards, which can be difficult. And in many cases, the option of withholding future funds is not possible, as the principal investigator is no longer conducting any NIH-funded research.

Even though we are unable to quantify definitively the number of times NIH withheld future funding, 12 percent of grantee institutions reported to us that NIH had withheld future funding from their institutions due to late submission of closeout documents. However, 86 percent of grantee institutions indicated that they had submitted at least 1 set of closeout documents late in the past 3 years.

Besides withholding future funding, NIH can impose special award conditions on the grantees, such as additional monitoring, for grantee institutions with a history of poor performance. [14] However, NIH's policy makes no explicit mention of imposing special conditions. [15] Instead, it discusses the possibility of taking corrective actions when there is a pattern of late closeouts, but it provides few specifics about what type of corrective actions are appropriate and when they should be taken.

While the closeout module is promising, it has some limitations.

The closeout module is NIH's main effort to help reduce late closeouts. While the closeout module is designed to facilitate the closeout process, current limitations hinder its ability to do so.

Institute staff manually enter grants ready for closeout into the module; therefore, completeness is dependent on the staff updating the system. (Manual entry is necessary in order to verify the grant is ready for closeout.) Based on the number of records entered in the module, some institutes are clearly using the module more than others. For example, the National Institute of Neurological Disorders and Stroke has over 2,000 grants entered in the module while the National Institute on Drug Abuse only has 2. As we have already indicated, at the time of our review, NIH did not require institutes to use the module.

Even for those institutes that have entered information, it is uncertain how diligent they are at keeping the information up to date. Many of the records contain missing information, which raises questions about whether the information was not submitted to the institute or whether the institute failed to enter it. Data on the progress report are the most commonly missing information (54 percent were blank), followed by data on the invention statement (31 percent were blank), and the financial status report (26 percent were blank). (See Table 5 on page 11.)

In addition, as we have already pointed out, the closeout module records only two dates of correspondence between the institute and the grantee and does not record any corrective or enforcement actions taken by the institutes.

RECOMMENDATIONS

In NIH's closeout module we found 8,941 late closeouts. This presents a vulnerability to NIH, as closeouts are the final point of accountability for the grantee. NIH staff spend significant time and effort following up with grantees to obtain late closeout documents. As for the grantees, late closeouts can jeopardize their future funding.

NIH is taking important steps toward addressing this problem, especially by implementing the closeout module. In addition, NIH plans to manage the closeout process from a new central office; this approach will help to bring additional attention to closeouts as well as create efficiencies. NIH also plans to address closeouts more systematically by following up with grantee institutions that have a pattern of late closeouts. NIH will continue to conduct outreach to grantees about the importance of on-time closeouts and plans to require institutes to use the closeout module. Finally, NIH has a workgroup as part of its Compliance, Education and Review Team, that is examining ways to improve the closeout process. We encourage NIH to continue these efforts.

We also offer four recommendations to NIH on how to further address late closeouts.

Develop an automated reminder system for grantees to alert them of upcoming closeouts.

Given that grantees regularly fail to submit closeout documents on time, an automatic reminder system could be a simple yet beneficial way to foster grantee compliance. NIH has already developed an automatic email notification system to remind principal investigators about upcoming due dates for noncompeting applications, which NIH requires at the end of each budget period to renew funding. NIH could use a similar system to remind grantees about upcoming due dates for closeout documents. This reminder should be sent to both the principal investigator and the appropriate business official at the grantee institution.

Facilitate the electronic submission of all closeout documents.

NIH is moving towards electronic grants management to facilitate other parts of the grant-making process. We suggest that NIH also include the closeout

process by developing a system by which grantees can submit all closeout documents electronically to NIH. Currently only the financial status reports can be submitted electronically. The electronic submission of closeout documents should help to facilitate on-time closeouts.

Enhance the closeout module's capabilities.

NIH has taken an important step toward addressing late closeouts by implementing the closeout module. We recognize that NIH continues to make improvements to the module and we believe that this module has the potential to help NIH address late closeouts. However, as we have pointed out, not all institutes are using it to the fullest extent possible. We recognize that at the time we conducted our review the module was less than a year old, and therefore institutes may not have been fully aware of how best to use it.

It is important that NIH ensure that all the information in the module is up-to-date by requiring all closeouts to be entered into the system. We encourage NIH to proceed with its plans to require all institutes to use the module. In addition, to ensure the integrity of the data, NIH should conduct regular validity checks of the system.

Not only should NIH ensure the information in the module is complete and up-to-date, but it should also improve the structure of the closeout module. First, NIH should capture the date of receipt of the final invention statement. Currently, this information is not recorded in the system. Second, we recommend that NIH capture additional dates of correspondence. The current version only allows institutes to record up to two dates of correspondence. Institute staff indicated that more follow-up is often necessary. Third, we recommend that NIH create a field to capture any type of corrective or enforcement action that has been taken. This will allow NIH to monitor these actions across all institutes and ensure consistency. Fourth, we recommend NIH improve the reporting functions of the closeout module so that NIH staff can more readily identify patterns of late closeouts for grantee institutions and/or principal investigators.

Finally, we encourage NIH to proceed with its plans to make this module available for grantees to access on a read-only basis.

Providing this closeout information will allow grantees to take a more active role in monitoring their own closeouts.

Address late closeouts more systematically by focusing on grantee institutions.

We found that 50 grantee institutions represent 45 percent of the late closeouts in the module. Efficiencies could be gained if NIH followed up with key administrators at these institutions, rather than having institute staff follow up on individual grants. NIH should routinely identify patterns of late closeouts by grantee institutions and principal investigators. We recognize NIH plans to move in this direction and we encourage NIH to do so. Ideally, the new central office managing closeouts could identify these patterns across all of NIH.

Once NIH identifies either a principal investigator or a grantee institution with a pattern of late closeouts, it should take appropriate corrective actions to address the situation. In addition to withholding any future funding from individual principal investigators at particular grantee institutions, we suggest that NIH consider providing technical assistance to grantee institutions with a pattern of late closeouts. This could be accomplished through general outreach efforts or through targeted follow-up with individual grantees. This could involve a review of the grantee institutions' policies and procedures for processing closeouts internally and training for principal investigators and other key staff.

NIH should also consider using its authority to impose special conditions on grantee institutions with poor performance, to address late closeouts. In order to do so, NIH should identify what special conditions are appropriate for grantee institutions with a pattern of late closeouts.[16]

Agency Comments

NIH reviewed a draft of this report and concurred with our recommendations. In its comments, NIH indicated additional steps that it is planning to address these issues, such as requiring the inclusion of all grants expiring on or after October 1, 2004 in the closeout module and centralizing the grants closeout function. We appreciate NIH's

attention to these important issues. For the full text of the agency's comments, see Appendix D.

APPENDIX ~ A

Methodology

NIH Closeout Module Data Analysis

The National Institutes of Health (NIH) provided us with records of all grants in the closeout module as of April 2003. The records supplied from the module originated from the database management system known as the Information for Management, Planning, Analysis, and Coordination (IMPAC II). NIH uses IMPAC II for managing and monitoring grants. NIH has used IMPAC II for managing and monitoring grants for the past 10 years.

We received a dataset of 10,130 records. For each grant, the dataset included the grant number, grantee institution name and identification number, grant mechanism and type, total award amount, awarding institute, budget end date, project end date, final financial status report receipt date, final financial status acceptance date, final progress report date, final invention statement receipt (yes/no), and grant closeout date. We eliminated eight grants from our analysis because of missing information or apparent data entry errors. The revised dataset had a total of 10,122 records.

In consultation with NIH, we classified a closeout as late if the closeout date was 150 days or more after the project end date. The grantee has 90 calendar days to submit the closeout documents (final financial status report, final progress report, and final invention statement) following the termination of the grant. In addition, we added 60 calendar days to allow NIH staff to review and approve the documents submitted by the grantees.

We tallied the number of late closeouts overall, as well as by year, by grantee institution, by institute, by grant mechanism, and by number of months/years late. We performed our analyses using SAS® software version 8.0, a statistical software package.

Data limitation. NIH's closeout module allows the institutes to track grants that are ready for closeout. In order for a grant to be captured in the closeout module, institute staff must enter the grant in the module. Because the module depends on someone to enter the grants, it is unlikely that the module contains all grants ready for closeout. This is further complicated by the fact that at the time of our review, the module had been in use for only about 8 months, and institutes use it to varying extents. For example, some institutes have entered closeouts

from the past several years, whereas other institutes have only entered the most recent closeouts. Therefore, we cannot make any conclusions about the entire population of closeouts based solely on that data. This limitation applies to all data analysis based on the closeout module.

NIH Closeout Module Correspondence Analysis

We obtained computer printouts from the closeout module for a stratified sample of 300 grants that were closed out late (at least 150 days after the project end date) or were still open at least 150 days after the project end date. From these printouts, we obtained the dates of the correspondence from the institutes to the grantees to obtain missing closeout documents. We relied on these printouts because we could not readily obtain this information electronically for all grants in the closeout module.

In order to concentrate on the most prominent funding sources, we limited our population to three of the largest institutes: National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, and the National Institute of General Medical Sciences. (For fiscal year (FY) 2002, these three institutes were in the top four in terms of number of extramural research grants and amount funding for extramural research grants.) We excluded the largest institute, the National Cancer Institute, because it already has an active monitoring system in place to identify late closeouts and their causes. We stratified our sample by institute. (See Table 6.)

Table 6. Sample Design

Strata for File Review	Population of Late Closeouts	Sample of Late Closeouts
National Heart, Lung, & Blood Institute	522	100
National Institute of Allergy & Infectious Diseases	784	100
National Institute of General Medical Sciences	254	100
Total	1,560	300

Source: OIG analysis, 2003

For each of the 300 late closeouts, we recorded the follow-up the institutes had with the grantee to obtain the closeout documents. We noted the dates of any letters sent to the grantee and any comments added to the remarks section. We analyzed the data to determine what percent of late closeouts received one follow-up and what percent of late closeouts received a second follow-up.

Institute Procedure Review

We requested operating procedures related to closeouts from all 24 institutes with grant-making authority. Seventeen of the 24 institutes with grant-making authority provided us with materials; the other 7 (National Institute of Child Health and Human Development, National Center for Complementary and Alternative Medicine, National Institute of Biomedical Imaging and Bioengineering, National Eye Institute, National Institute on Aging, National Institute of Nursing Research, and National Center on Minority Health and Health Disparities) did not maintain operating procedures specific to closeouts at the time of our review. We included in our review any written procedures, instruction manuals, checklists, worksheets, timelines, flowcharts, and form letters sent to us by the institutes. We assessed the number of institutes that maintained guidelines related to (1) tracking closeouts, (2) following up with grantees, and (3) instructions on the closeout process.

Survey of NIH Grantee Institutions

We selected a simple random sample of 135 grantee institutions from the 375 locations that received 10 or more research grants from NIH in FY 2002. We restricted our sample to institutions with 10 or more research grants to ensure that they had a wide range of experiences with NIH, so that any problems they reported with closeouts would not reflect an anomaly. We drew our sample from a list of 2,532 institutions provided by NIH.

We oversampled by an additional 18 locations in order to obtain our desired sample size. From 153 grantee institutions, we eliminated 2 foreign institutions, 2 institutions with incomplete contact information, and 14 duplicates (where 2 or more divisions of a research institution were included in our sample, we kept only the first entry in order to avoid duplication.)

The survey contained seven questions on late closeouts, which addressed the main factors that cause late closeouts, the extent to which late closeouts create problems, and recommendations for

improving the closeout process. We pretested our survey with grantee institutions.

We addressed the survey to the business official identified by NIH. In cases where NIH had not identified a business official, we addressed the survey to a senior grants administrator. In both instances, we indicated in our cover letter that a senior grants administrator who is knowledgeable about NIH grants was to complete the survey.

To ensure a high response rate, we first sent an introductory letter to each institution in our sample, explaining the significance of the survey. One week later, we mailed the survey. We followed up with a second survey for institutions that did not send back our survey within 3 weeks.

We received 111 responses to our survey, for a response rate of 82 percent. Nonrespondent analysis found no significant difference between respondents and nonrespondents in terms of average number and funding of research awards. The estimates given in the report are within plus or minus 7 percentage points at the 95 percent confidence level (See Table 7 below and Table 8 on the following page.)

Table 7. Nonrespondent Analysis by Number of Research Awards

	Average Number of Awards
Sample (n=135)	108
Respondents (n=111)	107
Nonrespondents (n=24)	112
t=0.15	Degrees of freedom=133

Source: OIG survey of NIH grantees, 2003

Table 8. Nonrespondent Analysis by Amount of Funding

	Average Amount of Funding
Sample (n=135)	$37,550,528.82
Respondents (n=111)	$37,303,671.78
Nonrespondents (n=24)	$38,692,242.60
t=0.12	Degrees of freedom=133

Source: OIG survey of NIH grantees, 2003

Interviews of NIH officials

We interviewed a program officer, a grants management specialist, and the chief grants management officer at the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, and the National Institute of General Medical Sciences. We discussed the causes and effects of late closeouts, any systems that the institutes had in place to track and monitor closeouts, and any barriers to closing out grants on time. We also solicited their recommendations for improving the closeout process and the closeout module.

We also spoke with staff at the Office of Extramural Research and with institute administrators involved in NIH-wide grants administration efforts, who described the initiatives that NIH has planned or underway to reduce the likelihood of closeouts. We discussed the causes and effects of late closeouts, and any barriers to closing out grants on time. We also solicited their recommendations for improving the closeout process.

APPENDIX ~ B

Confidence Intervals for Key Findings

Below, we provide the point estimate and 95 percent confidence interval for each of our key findings. The point estimates and confidence intervals for the findings vary based on the standard error for each individual finding.

Data Source	Key Findings	Sample Size	Point Estimate*	Confidence Interval
NIH closeout module correspondence analysis	Percent of grants with at least 1 recorded correspondence in the closeout module	300	80%	+/- 5%
	Percent of grants with at least 2 recorded correspondence in the closeout module	300	39%	+/- 6%

*Note: Point estimates are weighted.
Source: OIG analysis, 2003

APPENDIX ~ C

Late Closeouts for All Institutes in the NIH Closeout Module*

National Institute of Neurological Disorders & Stroke	2,016	1,887	94%
National Cancer Institute	1,228	1,108	90%
National Institute of Allergy & Infectious Diseases	1,060	917	87%
National Institute on Deafness & Other Communication Disorders	1,008	922	92%
National Center for Research Resources	1,005	557	55%
National Institute of Child Health & Human Development	964	953	99%
National Heart, Lung, & Blood Institute	621	566	91%
National Institute of Dental & Craniofacial Research	593	584	99%
National Institute of Diabetes & Digestive & Kidney Diseases	541	540	100%
National Institute of General Medical Sciences	386	323	84%
National Institute of Nursing Research	169	156	92%
Fogarty International Center	154	131	85%
National Institute of Mental Health	120	108	90%
National Institute of Arthritis & Musculoskeletal & Skin Diseases	113	112	99%
National Institute on Alcohol Abuse & Alcoholism	51	17	33%
National Library of Medicine	28	15	54%
National Human Genome Research Institute	21	7	33%
National Institute on Aging	12	12	100%
National Center for Complementary & Alternative Medicine	12	12	100%
National Eye Institute	10	10	100%
National Institute of Biomedical Imaging & Bioengineering	6	0	0%
National Institute on Drug Abuse	2	2	100%
National Institute of Environmental Health Sciences	2	2	100%

Source: OIG analysis of data from NIH's Closeout Module, 2003

*24 ICs have grant-making authority but the National Center for Minority Health and Health Disparities was established in 2000 and has not yet closed out a grant.

APPENDIX ~ D

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

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

MAR 3 1 2004

TO: Ms. Dara Corrigan
Acting Principal Deputy Inspector General

FROM: Director, National Institutes of Health

SUBJECT: NIH Response to the OIG Draft Reports: "NIH Grants Management: Late Closeouts" (OEI-01-03-00021) and "NIH Grants Management: Late Awards" (OEI-01003-00020)

We appreciate the opportunity to provide the attached comments on the two draft reports related to grants management at NIH and to meet with your staff to discuss the findings and conclusions. The reports address your review objectives and provide Department and NIH officials with worthwhile information to further enhance our grants management program.

NIH was pleased to see that the OIG acknowledged our efforts and the significant improvements that have been made to address these two problematic areas of late closeouts and late awards.

Elias A. Zerhouni, M.D.

Attachments

NIH Response to the Office of Inspector General (OIG) Draft Report on NIH Grants Management: Late Closeouts, OEI-01-03-00021
Late Closeouts

This draft report contained four recommendations and five findings. Included below are NIH comments on each.

OIG RECOMMENDATION: Develop an automated reminder system for grantees to alert them of upcoming closeouts.

NIH RESPONSE: NIH concurs with this recommendation. As discussed in greater detail below, a reminder system is currently in place, and NIH will be concentrating efforts on enhancing the NIH Commons and IMPAC II to provide tools for grantees and IC grants management staff to improve oversight of closeout requirements.

OIG RECOMMENDATION: Facilitate the electronic submission of all closeout documents.

NIH RESPONSE: NIH concurs with this recommendation. As explained in greater detail below, this is currently under active consideration by the NIH Commons development team.

OIG RECOMMENDATION: Enhance the closeout module's capabilities by ensuring that all information is entered into the module.

NIH RESPONSE: NIH concurs with this recommendation. As NIH enhances the IMPAC II and Commons closeout module, we fully expect that these recommendations will be addressed.

OIG RECOMMENDATION: Address late closeouts more systematically by focusing on grantee institutions.

NIH RESPONSE: NIH concurs with this recommendation. As described in greater detail below, NIH plans to develop a systematic approach to identifying grantee institutions that consistently submit late closeout documentation. The Compliance Education and Review Team (CERT) will continue to work to identify such institutions. The CERT is a Grants Management Advisory Committee subcommittee that has as part of its mission the development of a team trained to research identified external compliance issues and facilitate appropriate outcomes.

OIG Finding # 1 – Eighty-eight percent of all grants in the NIH closeout module were closed out late.

OIG Finding #2 – Grantees submitting closeout documents late is the primary cause for late closeouts.

OIG Finding # 3 – Tracking down missing closeout documents requires significant time and effort for institute staff.

OIG Finding # 4 – NIH experiences challenges in taking corrective actions against grantees for submitting closeout documents late.

OIG Finding # 5 – While the closeout module is promising, it has some limitations.

Additional information in response to the IG's findings and recommendations

The report stated that the closeout module had been functional for only 8 months when this review was completed. Therefore, the data cited in the report was incomplete and, as noted by the auditors, could not be used to draw conclusions about the entire population of closeouts. Nevertheless, NIH recognizes late closeouts as a problem area that we are addressing.

NIH agrees that the primary cause for late closeouts is the late submission of closeout documentation by grantees and that tracking down missing closeout documents requires significant time and effort for IC grants management staff. NIH provides guidance to grantee institutions through the NIH Grants Policy Statement, which stipulates the requirements for timely closeout of terminated grants. As a service to grantees, IC grants management staff places a footnote on the final year award notice to remind investigators and grantee institutions of the impending requirement to submit final reports. NIH also continues to address closeout in education outreach sessions, stressing the importance of timely closeout.

To assist NIH grants management staff in addressing this problem, an electronic closeout module was developed in IMPAC II. The report states that because the closeout module is not automatically populated with all grants eligible for closeout, the usefulness of the module is limited. It is NIH's experience that the closeout module is a useful tool for IC grants management staff. The closeout module was specifically designed for data to be entered manually; this is necessary because it cannot be assumed that the final year of a competitive segment will be the final year of the entire project. Placing a record in a closeout status prematurely actually adds a burden for both NIH staff and the grantee institution. Many ICs have intentionally populated the close out module with grants that are known to be overdue for closeout expressly so that staff can use the module as a resource when working toward completing the closeout process.

NIH plans to require the use of the close out module for all grant awards expiring on or after October 1, 2004. The newly formed Division of Extramural Activities Support (DEAS) will assume the responsibility for grants closeout, including prior years, in accordance with standard operating procedures. DEAS will also be responsible for tracking missing closeout documents from grantee institutions. IC grants management offices will no longer perform these functions. NIH anticipates greater efficiencies will be gained in the closeout of grant awards by moving to this more centralized model. Again, NIH expects that IMPAC II data will become more consistent and will provide

NIH with the basis for identifying and taking appropriate actions against grantee institutions that consistently submit late closeout documentation. We would also like to note that although the report correctly stated that seven ICs did not have operating procedures related to grant closeout at the time of the review, this is now a moot point because of the responsibilities of DEAS in this area.

The report states that Financial Status Reports (FSRs) were submitted late most often. With the advent of a Web-based system that permits grantees to submit electronic FSRs linking directly to the closeout module, NIH expects to see significant improvement in grantee compliance as this system will greatly facilitate the closeout process. Further development of an electronic closeout module is in process, including an enhancement of the NIH Commons that will allow grantee institutions to electronically submit invention statements and final progress reports. We are also developing a closeout report that will be available to grantees as a monitoring tool. The closeout module currently features a report that allows IC grants management staff to run a list of all grants that are open (i.e., should be closed) by IC or by grantee institution.

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END NOTES

[1] U.S. Department of Health and Human Services, *Performance and Accountability Report Fiscal Year 2002*, Appendix A.

[2] 45 CFR § 74 and 92.

[3] NIH Grants Policy Statement, March 2001, p. 25.

[4] NIH is comprised of 27 institutes and centers, such as the National Cancer Institute. Only 24 institutes have grant-making authority.

[5] 45 CFR § 74.70-73.

[6] NIH Manual, 5805-Closeout of NIH Grants, Release Date 2/16/00.

[7] *U.S. Department of Health and Human Services FY 2002 Performance and Accountability Report, Independent Auditor's Report and Management Response*, p. 12.

[8] General Accounting Office, *NIH Research: Improvements Needed in Monitoring Extramural Grants* (GAO/AIMD-00-139), May 2000.

[9] National Cancer Institute, Office of Management, *Grants Administration Branch Business Plan*, February 2002.

[10] There are 24 institutes with grant-making authority. However, the National Center on Minority Health and Health Disparities was established in 2000 and has not yet closed out a grant.

[11] 45 CFR § 74.70-73.

[12] NIH Manual, 5805-Closeout of NIH Grants, Release Date 2/16/00.

[13] NIH Manual, 5805-Closeout of NIH Grants, Release Date 2/16/00.

[14] 45 CFR § 74.14.

[15] NIH Manual, 5805-Closeout of NIH Grants, Release Date 2/16/00.

[16] 45 CFR § 74.14.