

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NIH GRANTS MANAGEMENT:
LATE AWARDS**



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A B S T R A C T

Grants management is a priority area for both the Secretary of Health and Human Services and the Office of Inspector General. In fiscal year (FY) 2002, the National Institutes of Health (NIH) funded \$16.8 billion in extramural research grants. Noncompeting continuation (type 5) awards account for the majority, about 70 percent, of NIH's extramural research funding. The timeliness of type 5 awards is an important aspect of grants management at NIH. NIH policy is to issue all grant awards prior to the beginning of the budget period (*i.e.*, the time period for which NIH provides funding, usually 12 months). NIH awarded 35 percent of type 5 awards late for 3 common funding mechanisms in FYs 2000 through 2002, accounting for \$9.2 billion in late funding. Potential factors contributing to late awards are grantees submitting late applications, grantees submitting incomplete applications, process delays at NIH, and late congressional budget appropriations. For example, 55 percent of awards that were 30 days or more late at 3 institutes had late applications, 39 percent had incomplete applications, and 12 percent had process delays. Late awards can create problems at NIH and, to some extent, at grantee institutions. NIH has several initiatives planned or underway to help facilitate timely type 5 awards. In addition to these, we recommend that NIH develop a centralized system to monitor late type 5 awards and address late awards more systematically by focusing on grantee institutions. NIH concurred with our recommendations.



OBJECTIVE

To determine the extent to which the National Institutes of Health awards noncompeting continuation (type 5) awards on time.

BACKGROUND

The National Institutes of Health (NIH) is the largest Federal funder of health research and development. In fiscal year (FY) 2002, NIH funded \$16.8 billion in extramural research grants supporting a total of 43,520 awards. 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.

Typically, NIH awards grants with a multi-year project period (*i.e.*, the total time for which NIH agrees to support the project), divided into budget periods. As a budget period comes to a close, the grantee must submit an application to receive funding for the next budget period. A noncompeting continuation (type 5) award renews funding for a project that is currently underway and does not require peer review. Type 5 awards represented about 70 percent of NIH's extramural research grant funding in FY 2002, totaling almost \$12 billion and supporting 30,343 grants.

Grants management is a priority area for both the Secretary of Health and Human Services and the Office of Inspector General. Given that type 5 awards represent the majority of NIH's extramural research funding, their timeliness is an important aspect of grants management at NIH. NIH policy is to issue all grant awards prior to the beginning date of the budget period of the award, provided that the grantee has submitted the necessary documentation on time. A late type 5 award results in a situation in which NIH has not issued funding for the next budget period until after the end of the previous year's budget period. This causes a gap in funding, although grantees may incur preaward costs (at their own expense).

This inspection is based on multiple sources of data: analysis of the 3 most common type 5 funding mechanisms for FYs 2000 through 2002, a file review of 272 late type 5 awards, a survey of grantee institutions that resulted in 111 responses, and interviews with grants management staff.

A companion report, *NIH Grants Management: Late Closeouts* (OEI-01-03-00021), applies a similar methodology to determine the extent to which NIH closes out grants on time.

FINDINGS

NIH awarded about one-third of awards late for three common funding mechanisms in Fiscal Years 2000 through 2002. NIH awarded 35 percent of its 60,993 type 5 research project awards (R01), program awards (P01), and cooperative agreements (U01) late in FYs 2000 through 2002. These late type 5 awards combined represented \$9.2 billion in funding to grantee institutions. On average, these awards were 24 days late. The proportion of late type 5 awards was relatively constant across the years in our sample, but varied by institute and among the three most common funding mechanisms.

Potential factors contributing to late awards are grantees submitting late applications, grantees submitting incomplete applications, process delays at NIH, and late congressional budget appropriations. Fifty-five percent of type 5 awards at 3 institutes that were 30 days or more late had a late application and 39 percent had applications that were missing 1 or more required elements. Twelve percent of the awards that were 30 days or more late also had internal process delays, such as delayed reviews, lost files, and data entry errors. Institutes may also have been delayed in issuing funding for type 5 awards at times when Congress was late in approving the agency's budget.

Late awards can create problems at NIH and, to some extent, at grantee institutions. NIH staff can quickly become inundated with type 5 awards, between overcoming the backlog caused by late awards and dealing with each month's incoming applications. Twenty-five percent of grantee institutions noted that late type 5 awards have caused problems for their institutions to a large or moderate extent. Grantees cited increased burden on grants administrators and having to use funding from other sources as particular problems.

NIH has several initiatives planned or underway to help facilitate timely awards. NIH is in the process of launching an automated, online research administration system, which will electronically notify grantees of application deadlines, allow grantees to submit applications and financial status reports electronically, and enable grants management staff to electronically review and approve type 5

applications. NIH also has a workgroup that is developing approaches to improving compliance among grantees with patterns of late type 5 applications, as well as preventing future delinquencies.

RECOMMENDATIONS

To facilitate timely awards, we recommend that NIH

- **Develop a centralized system to monitor late awards and to identify and address the key problems and bottlenecks that are causing late awards**
- **Address late awards more systematically by focusing on grantee institutions, specifically by following up with a key administrator at grantee institutions with patterns of late applications or late awards**

Agency Comments

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

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OBJECTIVE

To determine the extent to which the National Institutes of Health awards noncompeting continuation (type 5) awards 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 government-wide standards 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 program 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 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 a project period that spans 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. Grants management staff within each institute negotiate the terms of the award with the grantee. As each budget period comes to a close, the grantee must submit an application to the institute in order to update the institute about the status of the research and receive funding for the next budget period.

Type 5 Awards

A type 5 (noncompeting continuation) award renews funding for a project that is currently underway and does not require peer review.⁵ In FY 2002, NIH awarded 30,343 type 5 awards, totaling almost \$12 billion. Type 5 awards accounted for about 70 percent, in terms of both number of awards and amount of funding, of all extramural research funding that NIH awarded in FY 2002. (In FY 2002, NIH awarded \$16.8 billion in extramural research grants supporting 43,520 awards.)

The three most common funding mechanisms for type 5 extramural research grants are R01, P01, and U01.⁶ Combined, these 3 funding mechanisms accounted for about 72 percent, in terms of number, of all type 5 extramural research grants NIH awarded in FY 2002 and \$8.5 billion in funding. (See Table 1.) Research project grants, otherwise known as R01 grants, support individual research projects led by one primary investigator. Research program projects, or P01 grants, support groups of researchers who are all conducting studies related to a particular research objective. Cooperative agreements, or U01 grants, are partnerships between researchers and NIH.

Funding Mechanism	FY 2000	FY 2001	FY 2002	Total
Research project (R01)	17,218	18,964	20,394	56,576
Program project (P01)	703	752	780	2,235
Cooperative agreement (U01)	553	744	885	2,182
Overall Total	18,474	20,460	22,059	60,993

Source: OIG analysis of NIH data from IMPAC II, 2003

In order to receive a type 5 award, the grantee must submit to the institute an Application for Continuation of a Grant (PHS-2590) at least 60 days before the end of its current budget period for a paper application, or 45 days before the end of its current budget period for an online application.⁷ The principal investigator (the scientist who is responsible for the direction and conduct of the research) must submit a progress report, which summarizes the grantee's work on the project to date. The grantee institution (the organization where the principal investigator is affiliated) may also include a detailed description of the budget for the project, if the researchers have made significant changes since NIH initially approved the research, and assurances that the research protocol meets NIH standards for the use of human subjects and animals, where applicable.

Late Type 5 Awards. The NIH Manual states that "it is the policy of the NIH to issue all grant awards in a timely manner, which means prior to the beginning date of the budget period of the award," provided that the grantee has submitted the necessary documentation on time.⁸

A late type 5 award results in a situation in which NIH has not issued funding for the next budget period until after the end of the previous year's budget period. This causes a gap in funding.

Many grantee institutions may continue to incur preaward costs, at their own expense, if the agency is late in issuing an award.⁹ Essentially, grantee institutions who authorize such spending borrow against their expectations of the funding for the next budget period, anticipating that they will be able to recoup their spending once NIH issues the new award. Until NIH issues the award, however, that reimbursement is not guaranteed, leaving grantee institutions at risk for any expenses they incur during this period. Further, some grantee institutions are unable to cover their researchers' expenses in the interim.

Given that type 5 awards represent the majority of NIH's extramural research funding, their timeliness is an important aspect of grants management at NIH. Data from the National Cancer Institute, which has an active monitoring system in place to identify late awards and their causes, showed that 40 percent of its type 5 awards were late in FY 2001, and 33 percent of its type 5 awards were late in FY 2002. In each year, roughly one-third of the late awards were due to internal delays, and two-thirds were due to the grantees. (See Appendix A for more information.)

METHODOLOGY

We based our analysis of late type 5 awards on five sources of data. For a detailed description of our methodology and confidence intervals, see Appendix B and C.

First, we analyzed 60,993 records in NIH's database system for managing and monitoring grants, known as the Information for Management, Planning, Analysis, and Coordination (IMPAC II), for all R01, P01, and U01 awards issued in FY 2000, 2001, and 2002.

Second, we reviewed NIH's files for a stratified sample of 272 active research project (R01) awards in which NIH had issued type 5 funding at least 30 days late between FY 2000 and FY 2002. 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 awards and their causes. We stratified our sample by institute. The sample included all 76 awards from the National Institute of General Medical Sciences and random samples of 100 awards each from the 220 National Heart, Lung, and Blood Institute awards and the 174 National Institute of Allergy and Infectious Diseases that met our criteria. Four awards in our sample were missing files at the National Institute of Allergy and Infectious Diseases, so the final number of awards included in our file review was 272.

Third, we requested the specific operating procedures related to type 5 applications and type 5 awards 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.

I N T R O D U C T I O N

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 Closeouts* (OEI-01-03-00021), applies a similar methodology to determine the extent to which NIH closes out grants on time. The closeout process occurs when the grant project period ends, or when a grant transfers to another institution. Grant closeouts serve as the final point of accountability for the grantee.

► FINDINGS

NIH awarded about one-third of awards late for three common funding mechanisms in Fiscal Years 2000 through 2002.

Between FY 2000 and FY 2002, NIH awarded 35 percent of its 60,993 type 5 research project (R01) awards, program project (P01) awards, and cooperative agreement (U01) awards late. (See Table 2.) These late awards account for \$9.2 billion in NIH funding to grantee institutions. This is 43 percent of NIH's total type 5 funding for that 3-year period.

Funding Mechanism	FY 2000	FY 2001	FY 2002	FY 2000 – FY 2002 Combined
Research project (R01)	31%	36%	31%	33%
Program project (P01)	62%	66%	55%	61%
Cooperative agreement (U01)	72%	80%	72%	75%
R01, P01, and U01 Combined	33%	39%	34%	35%

Source: OIG analysis of NIH data from IMPAC II, 2003

Twenty-eight percent of these late awards were at least a month late. The late awards ranged between 1 day late and 603 days late. On average, late type 5 awards were issued 24 days after the end of the previous budget period. (See Table 3.)

Weeks Late	Number of Late Awards	Percent of All Late Awards
Less than 1 week	6,586	31%
Between 1 and 2 weeks	4,394	20%
Between 2 and 4 weeks	4,506	21%
Between 4 and 8 weeks	3,584	17%
More than 8 weeks	2,425	11%
Overall Total	21,495	100%

Source: OIG analysis of NIH data from IMPAC II, 2003

F I N D I N G S

The proportion of late awards was relatively constant over the past 3 years. NIH awarded 33 percent of all type 5 awards late in FY 2000. In FY 2001, it awarded 39 percent of all type 5 awards late. And in FY 2002, it awarded 34 percent of all type 5 awards late. (See Table 2 on p. 7.)

The proportion of late awards by institute ranged from 10 percent to 70 percent. The National Library of Medicine had the greatest proportion of late type 5 awards between FY 2000 and FY 2002, at 70 percent. However, the National Library of Medicine only issued 82 type 5 awards during that time period. The National Institute on Alcohol Abuse and Alcoholism and the National Institute of Deafness and Other Communication Disorders had the smallest proportion of late type 5 awards between FY 2000 and FY 2002, at 10 percent. Each of those 2 institutes issued more than 1,000 type 5 awards during that time period. (See Appendix D for the proportion of late awards by institute.)

Among the 10 institutes that issued the most type 5 awards between FY 2000 and FY 2002, 4 institutes awarded 50 percent or more of their type 5 awards late. (See Table 4.) The frequency of lateness at the remaining top institutes ranged from 15 percent to 38 percent.

Table 4. Proportion of Late Awards at the 10 Institutes that Issued the Most Type 5 Awards, FY 2000 - FY 2002

Institute	Number of Late Awards	Percent of Awards That Were Late	Average Number of Days Late
Nat. Cancer Inst.	3,076	37%	31
Nat. Heart, Lung, & Blood Inst.	2,788	36%	18
Nat. Inst. of Neurological Disorders & Stroke	2,472	50%	23
Nat. Inst. of Diabetes & Digestive & Kidney Diseases	2,111	38%	31
Nat. Inst. of Allergy & Infectious Diseases	1,717	28%	24
Nat. Inst. of Mental Health	1,871	56%	26
Nat. Inst. of Child Health & Human Development	1,463	50%	34
Nat. Inst. on Drug Abuse	1,216	52%	20
Nat. Inst. of General Medical Sciences	1,189	15%	13
Nat. Eye Inst.	1,051	47%	22

Source: OIG analysis of NIH data from IMPAC II, 2003

Cooperative agreement awards were most likely to be awarded late. NIH awarded 75 percent of type 5 cooperative agreement awards, 61 percent of type 5 program project awards, and 33 percent of type 5 research project awards late between FY 2000 and FY 2002. (See Table 2 on p. 7.) Because research project awards account for the largest proportion of awards, they drive down the overall proportion. The fact that a greater proportion of cooperative agreements and program grants were awarded later than research grants may reflect that cooperative agreements and program grants are more complex funding mechanisms, involving research at multiple sites with multiple primary investigators.

Eight percent of grantee institutions accounted for 56 percent of all late awards. NIH awarded type 5 research project (R01) awards, program project (P01) awards, and cooperative agreement (U01) awards to 892 grantee institutions between FY 2000 and FY 2002. Yet, 50 of these grantee institutions accounted for 56 percent of the late type 5 awards (and 56 percent of type 5 awards overall). Given that some grantee institutions are so large that they receive several thousand grants from NIH each year, while others receive only a few, it is not surprising that a small number of these large grantees made up more than half of all late awards during this time. These large grantees had the largest *absolute number* of late awards, but this does not necessarily indicate that they had a greater *proportion* of late awards than other grantees.

Potential factors contributing to late awards are grantees submitting late applications, grantees submitting incomplete applications, process delays at NIH, and late Congressional budget appropriations.

NIH does not have a centralized system to monitor the underlying causes of late type 5 awards. However, our analysis found four potential factors that may contribute to late awards.

Grantees submit applications late more than half of the time where data is available. NIH requires grantees to submit type 5 applications 60 days prior to the end of the current budget period. NIH's grants management database had application receipt dates for 65 percent (39,939) of the type 5 awards for the 3 years in our review. Sixty-four percent of those applications were late. On average, these applications were 44 days late. In 38 percent of the cases with late applications, the resulting award was late. On average, those awards were 26 days late.

In addition, we reviewed the files for 272 active type 5 research project (R01) awards that were at least 30 days late, at the National Institute of

General Medical Sciences, the National Institute on Allergy and Infectious Diseases, and the National Heart, Lung, and Blood Institute. Fifty-five percent of the applications were received past the 60-day deadline. On average, these applications were 43 days late.

NIH's IMPAC system now automatically generates letters to grantee institutions when an application is more than 15 days late. During the time period in our review, however, this system was not yet in place, leaving the institutes responsible for following up with delinquent grantees. Fourteen institutes provided us with their follow-up procedures for late applications.* These generally called for the institute to send the grantee a reminder letter between 10 and 16 days after the application due date, requesting the information.

Grantees may be late in submitting type 5 applications for several reasons, according to NIH officials and grantee institutions. First, principal investigators are sometimes slow to provide information, because they are busy conducting the research and balancing additional responsibilities, such as teaching. Second, some grantees do not understand the NIH requirements for type 5 applications. Grants specialists reported that grantee institutions with less experience with NIH grants may especially encounter this problem. Third, some grantee institutions may not have adequate systems in place to monitor type 5 award deadlines.

Grantees often submit applications that are missing financial information or assurances of research integrity. The instructions for the Application for Continuation of a Grant (PHS-2590) lay out the required elements of the type 5 application. The institutes cannot process a type 5 application until the grantee submits all of the required elements.

Thirty-nine percent of the awards that were 30 days or more late at the National Institute of General Medical Sciences, the National Institute of Allergy and Infectious Diseases, and the National Heart, Lung, and Blood Institute lacked one or more of the required elements. The most common missing elements were human subjects assurances (49 percent), financial status reports (25 percent), and animal research assurances (23 percent).

Grantees may submit incomplete applications to show that they are making an effort to meet NIH's deadline, even if they have not collected all

* Since the time of our review, NIH has centralized its tracking and processing of type 5 applications, such that individual institute's procedures are being replaced by standard operating procedures.

of the required information. However, institute staff told us that they would prefer grantees to notify the institute of the delay, and agree on a revised due date.

Five institutes provided us with specific procedures related to follow-up for incomplete applications. Their guidelines instruct grants management staff to contact the grantee institution to request the missing information, but do not provide a timeline for follow-up.

Incomplete applications should become less of a problem once NIH implements its system for submitting applications electronically, which is currently being tested. The electronic system will reject an application if one or more of the required elements is missing.

Heavy workload and processing problems at NIH limit the ability of grants management staff to review applications. Twelve percent of the late awards that were 30 days or more late at the National Institute of General Medical Sciences, the National Institute of Allergy and Infectious Diseases, and the National Heart, Lung, and Blood Institute had process delays on the part of institute staff: 6 percent had delayed reviews by staff; 4 percent had either a lost file or data entry problem; and 2 percent experienced other types of delays.

Institute staff may be responsible for hundreds of grants at a time, of many types and with different requirements. The size of this workload, compounded by other priorities such as issuing new competing awards, may lead to delays in the review of a type 5 application by either the project officer or the grants specialist. Several institute officials who we interviewed noted that this was a problem. Eleven percent of grantee institutions cited experience with delayed reviews, and another 17 percent cited problems with institute staffing in general as factors for late type 5 awards. Eleven institutes provided us with the worksheets, checklists, flowcharts, or sets of instructions related to the processes that project officers and grants management specialists must follow in reviewing a type 5 application. Only one institute included a timeline for these processes, however.

Processing problems can create delays if files are lost or data is incorrectly entered. Several institute officials said that they were aware of delays in routing the application to the project officer or grants specialist. Five percent of grantee institutions said that NIH had lost one of their type 5 applications, and 4 percent of grantee institutions had experienced problems due to administrative errors such as computer failures.

Institutes might also delay awards because of late congressional budget appropriations. Although NIH’s fiscal year begins on October 1, the agency’s budget may not be finalized for several months after that. In the meantime, the agency operates under continuing resolutions, which may allow spending at the same level as the previous fiscal year, or may restrict spending. Officials at the Office of Extramural Research cited late budget appropriations as a prominent cause of late type 5 awards, because many institutes tend to issue funding more conservatively under continuing resolutions, and some withhold funding altogether. However, institute staff who we spoke to seemed less concerned about the effect of continuing resolutions, and said that, in most years with continuing resolutions, they have been able to continue operating normally with respect to issuing type 5 awards.

Late awards can create problems at NIH and, to some extent, at grantee institutions.

Institute staff were concerned with the added workload caused by late awards. In addition,

grantee institutions noted that late awards created difficulties in terms of the administration of their research.

Grants management staff can become inundated with type 5 awards as late awards accumulate. The heavy workload caused by late awards can be difficult for institute staff to stay on top of, especially as they continue to deal with each month’s incoming type 5 applications, as well as the backlog. They depend on consistency and timeliness in issuing type 5 awards to manage their workloads effectively.

In addition, late awards often become time consuming when they require follow-up with the grantee institution. Among the awards that were 30 days or more late at the National Institute of General Medical Sciences, the National Institute of Allergy and Infectious Diseases, and the National Heart, Lung, and Blood Institute with a late or incomplete application, 60 percent included documentation that the institute followed up with the grantee.

Grantee institutions reported problems for both researchers and administrators due to late awards. Twenty-five percent of grantee institutions reported that late type 5 awards have caused problems for their institutions to a large or moderate extent, and another 67 percent reported that late type 5 awards have caused problems to a small extent. In particular, 97 percent of grantee institutions indicated that the increased administrative burden was a problem for their institutions

(27 percent said that this was a major problem). When an award is late, grants administrators must expend additional time and effort to communicate with NIH and, if necessary, obtain missing paperwork from primary investigators or business officials at their institution. In addition, 75 percent of grantee institutions responded that having to use funding from other sources was a problem (26 percent said that this was a major problem). Grantee institutions also mentioned that late awards could create problems for primary investigators, in terms of delaying or slowing research temporarily (53 percent), creating difficulties for primary investigators in meeting scientific progress deadlines (49 percent), or stopping research permanently (7 percent). Sixty-one percent of the grantee institutions noted that late awards become a problem for them when they are awarded more than 1 month after the end of the previous budget period.

To help mitigate these difficulties, NIH provides preaward authority, which allows grantee institutions to incur expenses before the award is issued. NIH also generally authorizes grantee institutions to carry over unused funds from the previous budget period. While these authorities can significantly lessen the effects of late type 5 awards for the conduct of research at some grantee institutions, other grantee institutions that cannot cover preaward expenses still face potentially serious constraints on their research. Further, coordinating preaward spending and carrying over funds creates additional work for administrators and business officials at these institutions.

NIH has several initiatives planned or underway to help facilitate timely awards.

Staff at the Office of Extramural Research continue to emphasize to grantees the importance of

submitting type 5 applications on time. They conduct outreach and education efforts through conferences, in newsletters and notices to the grantee community, and through site visits.

In addition to ongoing outreach, NIH is in the process of implementing several initiatives that address underlying causes of late type 5 awards. These initiatives are related to launching an automated, online research administration system and targeting problem grantees.

Electronic reminders to grantees about progress reports. In the summer of 2003, NIH developed an electronic system that notifies grantees of upcoming deadlines for type 5 applications. This is part of a wider NIH initiative, called Electronic Research Administration, to computerize all

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aspects of grants management into one integrated system. The system generates an email to the appropriate principal investigator 2 months prior to the application due date. Before this system was in place, NIH sent hardcopy reminders to grantees, but discontinued that approach in August 2002. Prior to implementing the automated system, NIH created a Web site for grantees to check on due dates periodically.

Many grantee institutions remarked that NIH's old system of notifying grantee institutions about due dates through paper reminders had been very helpful, and that they looked forward to the electronic notification system. (The system went into effect after we administered our survey.)

NIH is developing a similar system for business officials at grantee institutions. NIH will send a monthly email to the appropriate business officials at grantee institutions, listing all the upcoming due dates for type 5 applications.

Electronic submission of noncompeting applications. As another component of Electronic Research Administration, NIH has developed a system for many grantees to submit selected noncompeting applications electronically. This system makes it easier for grantees to complete and submit their applications and automatically checks the completeness of applications before accepting them. As a result, electronic submissions will likely help to mitigate the problem of incomplete applications. NIH piloted this program in November 2002 and implemented it more fully in the winter of 2004.

Electronic submission of financial status reports. As of January 2003, grantees can submit financial status reports electronically to NIH. This helps to facilitate grantees submitting these reports, as well as NIH review. It also assists NIH in tracking which financial status reports have been reviewed and approved.

Electronic review of type 5 applications by program officers. To facilitate the timely review of type 5 applications by program officers, NIH has developed a new application that will allow program officers to review and approve type 5 applications electronically.

Targeting problem grantees. NIH's Grants Management Advisory Committee, which is composed of the chief grants management officers of all the institutes, has formed a subcommittee, called the Compliance Education and Review Team, to address issues of grantee compliance. This group has plans to identify grantees with a pattern of submitting late type 5 applications. A workgroup of the Compliance, Education and

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Review Team, composed of institute grant specialists and officials from the Office of Extramural Research, is currently developing approaches to improve compliance and reduce future delinquencies.

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Thirty-five percent of type 5 awards have been issued late in the past few years, due to late and incomplete applications, process delays, and late budget appropriations. This has created problems at both NIH and grantee institutions.

We recognize that NIH is already taking steps to address this issue through electronic research administration and targeting problem grantees, and that NIH's resources are limited. Taking into account these considerations, we recommend that NIH:

Develop a centralized system to monitor late awards.

A centralized system to monitor late awards across institutes would allow the Office of Extramural Research to identify

and address the key problems and bottlenecks that are causing late awards. The current approach, documenting these problems and bottlenecks in the individual grant files, is inefficient because it limits systematic review and analysis.

The most straightforward way to accomplish this type of tracking is to require all institutes to document in the Information Management, Analysis and Coordination (IMPAC II) system, which is NIH's grants management database, the reason(s) why an award was late. Some institutes (such as the National Heart, Lung, and Blood Institute) already have internal systems that do this; these may provide useful models.

This system should distinguish whether a late award was due to the grantee or institute process delays (or a combination). For grantee causes, the system could capture when the application is late, and how late it is; it could also capture when the application is incomplete, and which element(s) is missing. For institute delays, the system could capture delayed reviews by program officers or grants specialists, problems with computer systems, and lost documents. This type of tracking would allow NIH to detect patterns of problems, at the grantee and institute levels, and note specific problems with particular grantees or institutes. The National Cancer Institute has developed a prototype system that may be a good starting point in terms of identifying specific elements related to the grantee and the institute that contribute to late awards. (See Appendix A).

Address late awards more systematically by focusing on grantee institutions.

As we noted, 50 grantee institutions accounted for more than half of all late awards in the past 3 years.

Efficiencies could be gained if NIH followed up with a key administrator at these institutions, on the basis of an overall pattern of late applications or late awards. This approach could go far to reduce patterns of late or incomplete applications, thereby reducing the time and resources that NIH currently devotes to follow-up with individual grantees.

NIH could provide feedback to grantee institutions through a Web site as part of electronic research administration. Each grantee institution could link to a summary report for its grantees. Ideally, the feedback would address each grantee institution's overall performance for all the awards it received across NIH institutes; another option is for the institution to receive feedback on its performance for each NIH institute separately.

NIH has taken an important first step through the Compliance, Education and Review Team committee's efforts to identify institutions with patterns of late applications. We encourage the committee to maintain this focus as it develops a plan for addressing these problems, and to expand its scope to also look at the patterns of incomplete applications and other delinquencies.

Agency Comments

NIH reviewed a draft of this report and concurred with our recommendations. In its comments, NIH indicated additional steps that it is taking to address the timeliness of type 5 awards, such as developing a Web site as part of electronic research administration where grantees can obtain a list of all type 5 awards for their institutions and their due dates, implementing a monitoring tool to assist grants management officers with tracking the award process, and centralizing the receipt and tracking of type 5 applications. We appreciate NIH's attention to these important issues. For the full text of the agency's comments, see Appendix E.



Findings of the National Cancer Institute on late type 5 awards

Several institutes monitor late type 5 applications and awards in some way, typically through an internal computer program. The National Cancer Institute's system is particularly noteworthy in that it captures both late type 5 awards and their causes, and goes back to 1992.

Analysis by the National Cancer Institute found that 33 percent of its type 5 awards were late in fiscal year (FY) 2002. Ten percent were late due to internal delays, and 23 percent were late due to the grantee institution. In addition, 41 percent of its type 5 applications were late in FY 2002. Twenty percent were at least 30 days late, and 10 percent arrived after the original budget period start date. Since 1992, an average of 33 percent of its type 5 applications have been late. Further, 30 percent of type 5 applications were incomplete in FY 2002. The major deficiencies were assurances for human and animal research, streamlined noncompeting application questions, invention statements, and financial status reports.

The National Cancer Institute developed a form that identifies internal and external barriers that may prevent awards from being issued on time. For each type 5 award, the grants specialist uses this form to identify any problems in issuing the award, the follow-up action that was taken, and how long it took to resolve the problems.

Methodology

Data Analysis

The National Institutes of Health (NIH) provided us with records of all type 5 research project (R01), program project (P01), and cooperative agreement (U01) grants awarded in fiscal year (FY) 2000 through FY 2002 across all institutes. These data came from a 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 focused specifically on R01, P01, and U01 awards, which are the three most common funding mechanisms for type 5 extramural research grants. R01 grants support individual research projects led by one primary investigator. P01 grants support groups of researchers who are all conducting studies related to a particular research objective. U01 grants are partnerships between researchers and NIH. We selected these types of awards for our analysis of late awards because they account for the greatest proportion of type 5 extramural research grants awarded by NIH in terms of number and amount of funding, about 70 percent.

We received a dataset of 60,993 records. For each grant, the dataset included the grant number, grantee institution, awarding institute, amount of funding, end date of the previous budget period, start date of the current budget period, and initial encumbrance date of the award. We classified an award as late if the award issue date was 1 day or more after the end date of the previous budget period, since NIH policy is to issue the award before the start of the budget period.

We tallied the number and funding of late type 5 awards overall, as well as by year, by grantee institution, by NIH institute, by funding mechanism, and by number of weeks late. We performed our analyses using SAS[®] software version 8.0, a statistical software package.

File Reviews

We reviewed the files for a stratified sample of 272, active type 5 R01 awards that were at least 30 days late at 3 institutes between FY 2000 and FY 2002. In order to concentrate on the most prominent funding sources, 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. (For 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 awards and their causes. We stratified our sample by institute.

We intended to review the files associated with 300 awards. But, because the National Institute of General Medical Sciences had only 76 active type 5 R01 awards that were at least 30 days late between FY 2000 and FY 2002, our sample became 276 awards. The sample included all 76 awards from the National Institute of General Medical Sciences and a randomly selected sample of 100 awards each from the 220 National Heart, Lung, and Blood Institute files and the 174 National Institute of Allergy and Infectious Diseases that met our criteria. Four awards in our sample were missing files at the National Institute of Allergy and Infectious Diseases, so the final number of awards included in our file review was 272 (See Table 5).

Strata for File Review	Population of Active R01 Awards 30 Days or More Late	Sample of Active R01 Awards 30 Days or More Late	Missing Files	Final Dataset of Active R01 Awards 30 Days or More Late
National Heart, Lung, & Blood Institute	220	100	0	100
National Institute of Allergy & Infectious Diseases	174	100	4	96
National Institute of General Medical Sciences	76	76	0	76
Total	470	276	4	272

Source: OIG analysis, 2003.

An active awards is one that was still being funded by the institute at the time of our review; we restricted our sample to active awards because NIH stores files for inactive awards at off-site warehouses, where they would not be readily available for our review.

We selected awards that were 30 days late or more in order to focus on delays that are significant enough to become problematic for grantees. Sixty-one percent of the grantee institutions indicated that late type 5 awards become a problem for them when more than 4 weeks late.

We limited our sample to one grant mechanism. We selected R01s because that mechanism is the most commonly used (accounting for 67 percent of all type 5 awards in terms of number for FY 2002). For each late award in the sample, we documented the reason(s) why the award was late and whether the institute followed up with the grantee to notify them of the problem. If we could not determine why the award was late or whether follow-up occurred, we noted that. (Institutes may document the reason for a late type 5 award on the grants management worksheet [which the grants specialist fills out after reviewing the application], through records of correspondence with the grantee institution, or within the Notice of Grant Application. We could not find such documentation for 21 percent of the awards that we reviewed. Each institute also maintains internal computer systems where such information may be recorded, but staff told us that any information entered into those systems would be included in the grant files as well.) We also recorded the dates on which the program officer, grants management specialist, and chief grants management officer signed off on the funding.

Institute Procedure Review

We requested operating procedures related to type 5 applications and type 5 awards from all 24 institutes with grant-making authority. Nineteen of the 24 institutes with grant-making authority provided us with materials; the other 5 (the National Center for Research Resources, the National Eye Institute, the National Institute on Aging, the National Institute of Nursing Research, and the National Center on Minority Health and Health Disparities) did not maintain operating procedures specific to type 5 applications or awards at the time of our review. We included in our review any written procedures, instruction manuals, checklists, worksheets, timelines, flowcharts, and form letters that the institutes sent to us. We assessed the number of institutes that maintained guidelines related to (1) processing type 5 applications, (2) follow-up for late applications, (3) follow-up for incomplete applications, and (4) dealing with process delays.

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 type 5 awards 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 awards, addressing the main factors that cause late type 5 applications and awards, the extent to which late type 5 awards create problems, and recommendations for improving the type 5 award 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, 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. (See Table 6 on this page and Table 7 on the next page.)

The estimates given in the report are within plus or minus 7 percentage points at the 95 percent confidence level.

Table 6. 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 7. 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 with 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 type 5 awards, any systems that the institutes had in place to monitor type 5 awards, and any barriers to issuing type 5 awards on time. We also solicited their recommendations for improving the type 5 award process.

We also spoke with staff at the Office of Extramural Research and with institute administrators involved with NIH-wide grants administration efforts, who described the initiatives that NIH has planned or underway to reduce the likelihood of late type 5 applications and awards. We discussed the causes and effects of late type 5 awards, and any barriers to issuing type 5 awards on time. We also solicited their recommendations for improving the type 5 award process.

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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	Subfindings	Sample Size	Point Estimate*	Confidence Interval
File review of late awards	Percent of type 5 applications that were received late		272	55%	+/-4%
	Average number of days that type 5 applications were late		156	43	+/-10
	Percent of type 5 applications that were missing information		272	39%	+/-4%
		Percent of <i>incomplete</i> type 5 applications missing information on human subject assurances	116	49%	+/-6%
		Percent of <i>incomplete</i> type 5 applications missing financial status reports	116	25%	+/-4%
		Percent of <i>incomplete</i> type 5 applications missing information on animal research assurances	116	23%	+/-6%
		Percent of incomplete or late applications that received documented follow-up from National Institutes of Health (NIH) staff	206	60%	+/-5%
		Percent of late awards with any kind of NIH process delay	272	12%	+/-3%
		Percent of late awards with a delayed review by NIH	272	6%	+/-2%
		Percent of late awards with lost file or data entry problem due to NIH	272	4%	+/-2%

*Note: Point estimates are weighted

Source: OIG analysis, 2003

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Late Type 5 Awards Among All Institutes, FYs 2000-2002 *

Institute/Center	Number of Late Type 5 Awards	Number of Total Type 5 Awards	Percent of Late Type 5 Awards	Amount of Funding Associated with the Late Type 5 Awards
Nat. Cancer Inst.	3,076	8,264	37%	\$1,565,162,883
Nat. Heart, Lung, & Blood Inst.	2,788	7,841	36%	\$1,331,563,063
Nat. Inst. of Neurological Disorders & Stroke	2,472	4,984	50%	\$883,557,719
Nat. Inst. of Diabetes & Digestive & Kidney Diseases	2,111	5,565	38%	\$811,115,919
Nat. Inst. of Mental Health	1,871	3,340	56%	\$684,988,441
Nat. Inst. of Allergy & Infectious Diseases	1,717	6,238	28%	\$1,061,935,328
Nat. Inst. of Child Health & Human Development	1,463	2,949	50%	\$657,576,517
Nat. Inst. on Drug Abuse	1,216	2,336	52%	\$480,865,965
Nat. Inst. of General Medical Sciences	1,189	7,908	15%	\$349,934,137
Nat. Eye Inst.	1,051	2,235	47%	\$306,203,339
Nat. Inst. of Arthritis & Musculoskeletal & Skin Diseases	834	1,592	52%	\$283,015,157
Nat. Inst. on Aging	554	2,148	26%	\$332,468,252
Nat. Inst. of Environmental Health Sciences	420	1,030	41%	\$168,309,313
Nat. Inst. of Dental & Craniofacial Research	223	1,041	21%	\$87,354,637
Nat. Inst. on Deafness & other Communication Disorders	140	1,355	10%	\$60,050,718
Nat. Inst. on Alcohol Abuse & Alcoholism	114	1,152	10%	\$45,405,392
Nat. Inst. of Nursing Research	59	393	15%	\$20,642,872
Nat. Library of Medicine	57	82	70%	\$17,480,321
Nat. Center for Research Resources	49	212	23%	\$17,695,662
Nat. Center for Complementary & Alternative Medicine	45	103	44%	\$28,237,221
Nat. Human Genome Research Inst.	40	194	21%	\$41,700,105
John E. Fogarty International Center	6	31	19%	\$1,185,950
Overall Total	21,495	60,993	35%	\$9,236,448,911

Source: OIG analysis of NIH data from IMPAC II, 2003

*Although 24 Institutes have grant-making authority, only 22 issued type 5 awards in this timeframe

Agency comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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MAR 8 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.

A handwritten signature in black ink, appearing to read "Elias A. Zerhouni", written in a cursive style.

Elias A. Zerhouni, M.D.

Attachments

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

NIH agrees that the vast majority of the causes of late awards rests with our grantee institutions, especially submission of incomplete and/or late progress reports. The data cited in the report clearly support that conclusion. This is an issue that NIH has been working diligently to resolve for some time as evidenced by the extensive actions already taken or planned for implementation.

As part of NIH's continuing efforts to achieve efficiencies and improve performance of grantee institutions, NIH has developed and implemented many initiatives to address the problems associated with late awards. It is important to note, however, that although NIH is developing these initiatives as a tool for its grant recipients, it is incumbent on the grantee to have monitoring systems in place to track requirements, such as application due dates.

- NIH continues to address late progress reports in education and outreach sessions that clarify NIH requirements and focus on grantee responsibilities, including those of the PI, and the need for institutions to monitor type 5 progress report deadlines. We stress the importance of timely and complete applications, specifically citing the areas of human subjects and animal assurances as well as financial status reports, since those areas are identified as the most common missing elements in type 5 progress reports.
- NIH plans further development and refinement of electronic systems to assist grantees with submitting complete and timely applications:
 - Email reminders are sent to Principal Investigators 2 months before a type 5 progress report is due. A similar email reminder is in development for business officials.
 - Email reminders are automatically generated when a type 5 progress report is more than 15 days late.
 - Grantees can access a Web site to obtain a listing of all noncompeting progress reports (type 5) for their institution and their due dates (http://era.nih.gov/userreports/pr_due.cfm).
 - Many grantees can now submit selected type 5 progress reports electronically through the NIH Commons in an expanded pilot program to all institutions participating in the Federal Demonstration Partnership. NIH has seen a dramatic increase in the volume of type 5 progress reports submitted electronically, from a cumulative total of 778 in January 2004 to 1,012 at the end of February 2004. The expanded pilot program should further accelerate use of this system. We anticipate that this system will be open to all Commons-registered institutions in FY2005. In addition, expansion of electronic receipt to accommodate all progress reports is also planned for FY2005.
 - All grantees can submit Financial Status Reports electronically through the NIH Commons.

NIH also has taken steps to improve its internal processes. For example, Program Officers have the capability to document their review of type 5 progress reports electronically, an improvement that will help streamline the type 5 award process. We have also recently developed a monitoring tool to assist IC grants management offices with tracking the award process to help ensure timely awards. This will also be a useful management tool for NIH because it will provide data by IC as well as aggregate data for all ICs.

Further, the NIH grants management community has voted to unanimously support establishing a central receipt point for scanning type 5 progress reports received in hard copy. These will also be indexed and uploaded into the IMPAC II system, NIH's enterprise database. After receiving final approval, NIH plans to establish this central receipt point by October 1, 2004, so it will be fully functional for FY2005 type 5 progress reports, that is, for type 5 progress reports with budget start dates after October 1, 2004. Having all progress reports stored and accessible in an electronic repository will allow for significant changes in the process with an ultimate goal of improving the time needed for processing prior to award.

A major achievement for NIH is the creation of the Division of Extramural Activities Support (DEAS) that will serve as the central office to receive and track paper type 5 progress reports. This organization will also be responsible for quality control of type 5 progress reports and ensuring that they are complete. As necessary, DEAS staff will follow-up with applicants on information missing from grant applications. NIH Institute and Center (IC) grants management offices will no longer perform these functions. We would like to note that although the report correctly stated that five ICs did not have operating procedures specific to type 5 applications or awards at the time of the review, this is now a moot point because of the responsibilities of DEAS in this area.

In support of DEAS, standard operating procedures are being developed. We believe that these will have a positive effect on work flow issues by standardizing and improving the type 5 award process. DEAS will provide efficiencies by optimizing consistent processing of type 5 progress reports and providing more reliable data on which to base analysis. More consistent, and therefore reliable, data will provide NIH with the means for identifying grantee institutions that consistently submit late or incomplete type 5 progress reports so that appropriate actions can be taken at an institutional level.

The report stated that a small percentage of the awards studied were late due to "process delays at NIH," and cited sizeable workload and inadequate staffing as contributing factors affecting the timeliness of awards. While NIH recognizes these issues as factors, it should be acknowledged that awards may also be late for appropriate reasons. For example, a type 5 award could be deliberately delayed while grants management staff addresses issues of concern (e.g., adverse event or Investigational New Drug (IND) issues, compliance issues, administrative issues, etc.). Often, these issues require multiple rounds of communication between the grantee institution and NIH grants management and program staff to satisfy the concern. NIH strongly believes that such

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delays are justified to ensure an appropriate level of oversight and to provide responsible stewardship of Federal grant funds.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Mark R. Yessian, Ph.D., Regional Inspector General for Evaluation and Inspections in the Boston Regional Office, and Joyce M. Greenleaf, MBA, Assistant Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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▶ E N D N O T E S

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. Twenty-four institutes have grant-making authority.

⁵ NIH distinguishes grants by type. A type 1 award refers to funding for a new project, which must first undergo peer review. A type 2 award is an extension of a project that was scheduled to expire, and must also undergo peer review. Type 3 and type 4 awards allow for changes in either the budget or scope of research for a project that NIH is currently funding. Type 7 and type 9 awards reflect changes in either the grantee institution at which the research is taking place or the NIH institute overseeing the grant.

⁶ These are the most common funding mechanisms among single project, multiple project, and cooperative agreement awards, respectively.

⁷ NIH Grants Policy Statement, March 2001, p. 117.

⁸ NIH Manual, 5003 - Issuance and Recording of Grant Award Obligations, Release Date 7/1/89.

⁹ NIH Grants Policy Statement, March 2001, p. 96. Preaward spending is part of NIH's expanded authorities.