

May 2000

NIH RESEARCH**Improvements Needed
in Monitoring
Extramural Grants****G A O****Accountability * Integrity * Reliability**

Contents

Letter		3
Appendixes		
	Appendix I: Scope and Methodology	30
	Appendix II: Unaudited Fiscal Year 1999 and 2000 NIH Appropriations	33
	Appendix III: Comments From the Department of Health and Human Services	34
	Appendix IV: GAO Contacts and Staff Acknowledgments	41
Related GAO Products		42
Tables		
	Table 1: Unaudited Fiscal Year 1998-99 NIH Appropriations	22
	Table 2: Unaudited Fiscal Year 1998-99 Changes in Funding for NIH Extramural Research Grants	24

Abbreviations

CAS	central accounting system
HHS	Department of Health and Human Services
IMPAC II	information for management, planning, and coordination
IPA	independent public accountant
NIH	National Institutes of Health
OER	Office of Extramural Research
OFM	Office of Financial Management
OIG	Office of Inspector General
OMB	Office of Management and Budget
PHS	Public Health Service
PMS	payment management system



United States General Accounting Office
Washington, D.C. 20548

**Health, Education, and
Human Services Division**

B-282900

May 31, 2000

The Honorable Tom Bliley
Chairman, Committee on Commerce
House of Representatives

The Honorable Fred Upton
Chairman, Subcommittee on Oversight
and Investigations
Committee on Commerce
House of Representatives

In each of the past 2 years, the Congress has increased the appropriations for the National Institutes of Health (NIH) by 15 percent. This has put the Congress on track for doubling NIH's appropriations from fiscal year 1998 levels by fiscal year 2003 as urged by some congressional leaders. NIH, an operating division of the Department of Health and Human Services (HHS), is made up of 25 institutes and centers with a combined fiscal year 2000 appropriation of \$17.8 billion—the largest of all federal agencies engaged in nondefense research.¹ Its appropriations account for nearly 40 percent of all federal nondefense research and development dollars.

More than 80 percent of the appropriations, about \$13 billion in fiscal year 1999, go toward extramural research that supports scientists in more than 2,000 institutions—universities, medical schools, hospitals, small businesses, and research institutions—throughout the country and abroad. Principal investigators, who are scientists at these institutions, compete for extramural NIH grants. While project periods under these grants average 4 years in duration, the institutes and centers provide funding for only a single year at a time. The continuation of funding each year after the first is primarily contingent upon the awarding entity's determination that the scientific progress of the research is satisfactory.

¹HHS has 13 component organizations called operating divisions.

Given the level of funding disbursed and the importance of the research it supports, the oversight and monitoring of NIH grantees are critical. In accordance with Office of Management and Budget (OMB) guidance, NIH places the primary responsibility for ensuring compliance with federal requirements on the grantees.² Recipients of NIH extramural grant funds are asked to certify to NIH that they comply with federal requirements related to the funding. These certifications cover a wide range of topics, including having procedures for investigating allegations of scientific misconduct, ensuring that recipients of a grant are not delinquent in their payment of federal debt, and ensuring that research meets federal requirements for protecting the rights and welfare of human and animal subjects.

Because of your concern about oversight and monitoring, you asked us to report on three areas related to NIH's use of extramural grant funds: (1) how NIH monitors the scientific progress of extramural research, (2) whether NIH has controls to ensure the effective financial management of extramural research grants, and (3) how NIH used the increased funds from its fiscal year 1999 appropriations to support extramural research.

To assess how NIH monitors scientific progress, we reviewed its policy on administering research grants, interviewed NIH officials, and randomly selected and reviewed 116 research project grants and program project grants that were active in fiscal year 1997 at six institutes.³ By selecting grants active in fiscal year 1997, we were able to ensure that our sample included grants with at least one assessment of scientific progress and grants where the project period was completed. To assess NIH's financial management of extramural grants, we selected a statistical sample of 78 grants that were active in fiscal year 1999. The 1999 sample, awarded by 15 institutes, allowed us to examine the financial controls currently in place. To determine NIH's use of its increased appropriations, we compared the NIH fiscal year 1998 appropriations that NIH allocated to extramural research grants with its fiscal year 1999 allocations. We conducted our

²See OMB Circular A-110, *Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations* (Washington, D.C.: Aug. 29, 1997).

³Institutes and centers award the majority of extramural research funds through research project grants and program project grants. In general, the research project grant funds a single project with an individual principal investigator while the program project grant funds a group of multidisciplinary projects conducted by several investigators working on different aspects of a specific research objective or theme.

work between May 1999 and April 2000 in accordance with generally accepted government auditing standards. (See appendix I for details on our scope and methodology.)

Results in Brief

Assessing scientific progress and ensuring effective financial management are critical elements in managing NIH's extramural grant programs. NIH has developed policies and procedures to carry out these important functions, but we found that its system of internal controls could be strengthened. Institutes and grantees have flexibility in implementing NIH's policies and procedures for administering grants. Although the processes for assessing scientific progress varied at the six institutes we reviewed, each contained similar key aspects. These included annual reviews of the scientific progress and budgetary aspects of the research as well as assessments of compliance with administrative requirements. However, we found that some grant files lacked documentation of these reviews. In addition, some institutes lacked written procedures for documenting the reviews. Furthermore, some files in five of the six institutes lacked required reports for appropriately closing completed grants. As a result, NIH lacked important information on scientific progress and inventions developed in a grant's last year as well as on unobligated funds that could be recovered for rebudgeting within the federal government.

Regarding controls over financial management, we identified areas in the oversight and monitoring of grantees that could be strengthened. For example, NIH did not always receive and use single audit reports as OMB required.⁴ A single audit is an organizationwide audit of a grantee that focuses on internal controls and compliance with laws and regulations over federal grant funds. The reports resulting from these audits are a key tool for financial management oversight. However, NIH awarded grant funds to several grantees that had not submitted single audit reports. While NIH generally maintained adequate documentation for the financial monitoring

⁴OMB's Circular A-133, *Audits of States, Local Governments, and Non-Profit Organizations* (Washington, D.C.: June 24, 1997), stipulates specific reporting requirements for nonfederal agencies. It currently requires that audits be completed and necessary documentation be submitted to the federal clearinghouse that OMB has designated, within 30 days after the receipt of the auditor's report by the auditee or 9 months after the end of the audit period, whichever is earlier. For fiscal years beginning on or before June 30, 1998, the circular requires that audits be completed and supporting documentation be submitted 30 days after receipt of the auditor's report or 13 months after the end of the audit period, whichever is earlier.

of its grantees, we identified other areas in internal controls that could be strengthened. For example, we found discrepancies between grant award amounts reported in key NIH systems, which increases the risk of inaccuracies and improper authorization of grant funds. In its fiscal year 1999 audit report on internal controls, the independent public accountant (IPA) responsible for the financial audit of NIH identified a material weakness in the analysis and development of financial statements that included a weakness related to the financial management of grants. Resolving these issues would provide NIH and HHS assurance that grant funds are being awarded to eligible recipients only, that these funds are properly used, and that funds available for future use are accurately accounted for and reported.

Regarding NIH's use of fiscal year 1999 appropriations, NIH allocated about the same percentage of funds to extramural research as it did in fiscal year 1998. Appropriations allocated for extramural research grants accounted for about \$1.4 billion of the nearly \$2 billion increase in NIH's appropriations, or 70 percent. About 41 percent of the increase for extramural grants was used to expand by 978 the number of competitive grants and to increase the average amount awarded for each competitive grant by 15 percent over fiscal year 1998 levels. The remaining funds were used to provide outyear commitments to more than 20,000 ongoing grants, support for extramural research centers, and other extramural research activities.

HHS generally agreed with our recommendations for improving internal controls over extramural grants. It did not concur with our recommendation to perform an analysis of the status of fiscal year 1998 single audit reports, maintaining that to further collapse the time for identifying delinquent single audit reports would not be worthwhile. However, HHS has misinterpreted the intent of our recommendation. We believe it would be worthwhile to begin analyzing the reports without waiting until all have been submitted.

Background

NIH, the nation's leader in conducting and sponsoring biomedical research, is made up of 25 institutes and centers. Most of them have separate appropriations and are charged with specific missions. Their missions generally focus on a given disease, like cancer or arthritis; a particular organ, like the heart or eye; or a stage of development, like childhood or old age. Fiscal year 2000 appropriations range from the \$43 million for the Fogarty International Center for Advanced Study in the Health Sciences to

the \$3.3 billion for the National Cancer Institute. (See appendix II for fiscal year 2000 appropriations.)

NIH institutes and centers accomplish their missions chiefly through intramural and extramural research. Intramural research, accounting for \$1.6 billion in fiscal year 1999, entails government scientists conducting research in the institutes' and centers' own laboratories and clinics. Extramural research entails scientists conducting research in research institutions, and it amounted to about \$13 billion in fiscal year 1999. Principal investigators compete for extramural grants. After the first year of funding, they must submit noncompetitive continuation grant applications for continued funding. These applications include annual progress reports, budget information, and invention statements. While grantees are responsible for managing the day-to-day grant activities in accordance with NIH requirements, an institute or center awarding a grant has overall responsibility for the grant and for deciding whether to continue funding it. At the end of a grant's multiyear project period, principal investigators may apply for renewal of funding through the competitive process. Upon completion of research and termination of funding, grantees are required to submit a final financial status report, a statement identifying inventions developed under the grant, and a final report on scientific progress.

NIH's management is responsible for ensuring that adequate systems of internal controls are developed and implemented for the proper oversight and monitoring of research institutions. An adequate system of internal controls, as defined by the Comptroller General's *Standards for Internal Control in the Federal Government*, which is issued pursuant to the Federal Managers' Financial Integrity Act of 1982, should provide reasonable assurance that an agency is effectively and efficiently using resources, producing reliable reports, and complying with applicable laws and regulations. The standards also state that internal control monitoring should assess the quality of performance over time and ensure that the findings of audits and other reviews are promptly resolved. Accordingly, cost-effective internal controls should be designed to provide reasonable assurance regarding the prevention or prompt detection of unauthorized acquisition, use, or disposition of federal funds.

Generally, activities such as site visits and reviews of progress and financial reports that grantees file are controls that federal officials use to oversee and monitor grant programs. An additional key control for the oversight and monitoring of NIH grants available to NIH management is the single

audit. A single audit is an organizationwide audit of a grantee that focuses on internal controls and the recipients' compliance with laws and regulations governing the funds received from federal grants. OMB's June 1997 Circular A-133 established policies to guide the implementation of the Single Audit Act Amendments of 1996 and provided an administrative foundation for uniform audit requirements for nonfederal entities that administer federal awards. These audit requirements apply to nonfederal entities that spend \$300,000 or more in federal awards.

The Institutes' Process for Reviewing Scientific Progress

Under the general direction of NIH, institutes monitor the scientific progress of the extramural grants they award. In the six institutes we reviewed, program staff, who are scientists with expertise in the fields of research sponsored by their institutes, assessed the scientific progress of research annually primarily by reviewing documents such as progress reports the grantees submitted. They also said they monitor scientific progress throughout the year through such means as reviewing publications. In addition, grants management staff contributed to monitoring scientific progress by reviewing budget information submitted by grantees to determine whether the pace of expenditures is consistent with the expected progress of the research.

NIH Provides Overall Guidance

Through its Office of Extramural Research (OER), NIH gives institutes general guidance for monitoring the scientific progress of extramural grants. Building upon the Public Health Service's (PHS) Grants Policy Statement, first issued in 1965, OER developed the NIH Grants Policy Statement for monitoring extramural grants in 1998. The policy incorporates statutory requirements and OMB and HHS requirements. It also provides guidance for the institutes' monitoring of scientific progress and other aspects of grantee performance. Institutes and grantees have flexibility in implementing the guidance.

OER requires an institute to determine that the principal investigator has made satisfactory scientific progress before providing subsequent funding on an ongoing grant. OER also requires that institutes review grantee reports of scientific progress annually. These reports are to contain specific research aims, results of studies the principal investigator conducted, a statement of the potential significance of findings to the scientific field and their potential effect on health, and a list of related publications by the principal investigator, including manuscripts submitted or accepted for publication.

Beginning in 1995, OER required new program staff to attend 7 days of basic training in order to give the staff a uniform base of information and knowledge for monitoring research grants. The training includes information on NIH, the extramural program and grant process, responsibilities of program staff, relationships between grants and contracts management staff, and relevant regulations, policies, and procedures. Experienced program staff are required to attend two training activities annually to maintain current knowledge of extramural policies and procedures. Program and grants management staff we spoke with also emphasized the importance of working closely with and being mentored by more experienced staff. Mentoring assignments could last up to 2 years for the more complex grants.

Program Staff at the Six Institutes Primarily Used Progress Reports to Monitor Scientific Progress

The six institutes we visited generally followed NIH policy in monitoring the scientific progress of the extramural grants that the institutes awarded.⁵ Program staff in these institutes determined whether progress was satisfactory by comparing the accomplishments in the principal investigator's annual progress report with the stated aims and objectives of the research proposal. They also reviewed the annual progress report to see whether there were any changes in the scope and objectives of the research and whether the principal investigator encountered any problems while doing the research. Program staff also considered the number and quality of investigator-authored publications as another indication of scientific progress.

In addition to reviewing grantee annual progress reports as required by policy, program staff told us they monitored scientific progress throughout the year. For example, program staff reviewed published papers and unpublished manuscripts that the principal investigator submitted to them and that were related to research performed under the grant. They also frequently communicated with principal investigators. This interaction was facilitated by attendance at scientific conferences and professional meetings. One program officer said that because of frequent contact with principal investigators, she was generally alerted to problems in their research before receiving annual progress reports.

⁵The six institutes were the National Cancer Institute; National Heart, Lung, and Blood Institute; National Institute on Alcohol Abuse and Alcoholism; National Institute of Child Health and Human Development; National Institute of Dental and Craniofacial Research; and National Institute of Neurological Disorders and Stroke.

Program staff explained that they were able to anticipate some problems affecting scientific progress because during the initial competitive award process, external reviewers documented issues that could interfere with accomplishing the principal investigator's research aims. For example, if these reviewers considered a particular research strategy to be risky and thought the principal investigator might encounter difficulties in accomplishing the specific aims and objectives, this concern would be expressed in the reviewers' summary statement. Summary statements are included in the grant files and are thus available to the program staff for monitoring purposes.

The number of progress reports each staff member reviewed varied among institutes and even within a single institute. Among the institutes we visited, the average number of progress reports reviewed annually by each program staff varied from a high of 125 at one institute to a low of 40 at another. Although the number of grants reviewed varied among staff members, the workload, based on the type or complexity of grants, was about the same, according to NIH officials. Staff whose portfolios included more complex grants, such as program project grants and clinical trials, reviewed a smaller number of progress reports than staff whose portfolios included less complex research project grants.

Because there is no separate job series for staff responsible for monitoring scientific progress, precise staffing figures for this function are not readily available. However, at the end of fiscal year 1999, NIH had 1,088 full-time-equivalent employees in the job series that includes program staff and their supervisors. The six institutes we visited employed 370 of these staff, ranging from 21 full-time-equivalent employees in one institute to 160 in another. For the six institutes, this staffing level was about a 16 percent increase from fiscal year 1997 levels.

Grants Management Staff at the Six Institutes Contributed to Monitoring Scientific Progress

Grants management staff, who are responsible for the financial management of grants and for ensuring grantee compliance with statutes, regulations, and guidelines, also contributed to the monitoring of scientific progress at the six institutes we reviewed. They did this by examining required budgetary information submitted by grantees. For example, grants management staff assessed this information for large unobligated balances to determine whether the pace of expenditures corresponded with the anticipated progress of the research. Large unobligated balances could result from the failure to purchase necessary equipment or hire key personnel as planned. In clinical research, the slow recruitment of human

subjects can also lead to large unobligated balances. In reviewing three such files, we found two in which the institutes reduced funds and required interim progress reports.⁶ At four of the institutes we reviewed, grants management staff also verified that program staff had assessed the principal investigator's scientific progress.

The specific budget information available to grants management staff varied, depending on whether the grant was a research project grant or a program project grant. For research project grants, the grants management staff assessed information annually on changes in financial support for key personnel, significant rebudgeting of funds, changes in the level of effort of key personnel, and estimates of expected and large unobligated balances.⁷ For program project grants, the staff had access to all this information as well as detailed budget information, a budget justification, and an annual report on expenditures.

The Documentation of Scientific Progress Was Not Always Available

Each of the six institutes we visited required program staff to document their assessment of scientific progress by completing a checklist. The institutes' checklists varied in detail, but all had a section devoted to the same purpose: assessing scientific progress. For example, one institute used a checklist that, in addition to a box to check indicating adequate scientific progress, included items on the involvement of human subjects or vertebrate animals in the research, the need for biohazard protections, changes in research scope and objectives, scientific overlap with other research, substantial changes in foreign involvement, additional questions if the grant is a cooperative agreement, and space for nearly a full page of narrative comments. Other institutes required much less detail in documenting their assessment.

Of the 116 grants we reviewed, 98 files contained evidence that the program staff had assessed scientific progress for each year that the research was funded. For the remaining 18 files, in one or more years that

⁶The three files come from a sample of problem cases that the institutes we visited identified.

⁷In 1995, NIH implemented the Streamlined Noncompeting Award Process for research project grants and certain other types of grants to expedite the processing of noncompetitive continuation awards. For awards under this process, grantees are no longer required to submit annual budget information with a budget justification and the expenditure report is required only at the end of the grant period.

the research was funded, there was no documentation to indicate whether scientific progress had been assessed. About 6 percent of the time there was no evidence whether scientific progress was assessed.⁸

We noted wide variation in the level of documentation of scientific progress on checklists among and within the institutes. Some program staff checked the appropriate box on the progress report review checklist to indicate satisfactory progress. Others also wrote one or two paragraphs, and still others wrote up to two pages. We were told that the additional written documentation was used to highlight the results of the research. Although individual institutes may require more written documentation, an OER official said that he expected narrative comments on the checklists only when problems with scientific progress had surfaced. However, in its comments for management consideration, the IPA responsible for the financial audit of NIH noted that many of the institutes and centers did not have written procedures on how they prepare checklists, progress review forms, and grants management worksheets. When standard forms were used in the process, the information captured was consistent.

While most files indicated that scientific progress was assessed in conjunction with annual decisions on continuation funding, we found much less documentation to support ongoing monitoring. Although program staff told us they monitored grants throughout the year, they generally did not document their efforts in the grant files.

Some Grant Files Lacked Documentation of Closeouts for Completed Grants

Grants management staff are responsible for ensuring that a grantee submit a complete closeout package within 90 days after the end of the grant's multiyear project period. Closeout documents are to include a final financial status report, a final scientific progress report, and a final statement on inventions developed under the grant. A final financial status report is needed to ensure proper accounting for the use of grant funds. A final scientific progress report provides a summary of progress toward the achievement of the specified aims, a list of significant results, and a list of publications for the grant. A final invention statement provides information on all inventions that were conceived or first used under the grant, even if previously reported.

⁸The 116 grants in our sample should have been assessed a total of 369 times when applications were submitted annually for noncompetitive continuation of funding.

In our review of the six institutes, we found that grantees did not always comply with closeout requirements. For example, at one institute we visited, grantees of 628 of the 736 grants were delinquent in providing complete closeout packages in fiscal year 1998. NIH staff in several institutes told us that ensuring grantee compliance with closeout requirements was not a high priority, especially in relation to monitoring active grants. Among grants we reviewed, about 20 percent were no longer funded in late 1999. We found that a little less than half of those—11 grants from five institutes—did not submit all the required reports. Three of the 11 were more than 2 years overdue.

Five of the grants did not include final financial status reports. Four of these were research project grants and one was a program project grant. As a result, NIH lacked information on how much of the grant funds had not been spent and therefore should have been recovered for rebudgeting within the federal government. The absence of final financial status reports for the research project grants meant that NIH lacked financial information from these projects for the entire duration of the grants. For program project grants, however, financial status reports are submitted annually. Consequently, the absence of the final financial status report for the program project grant meant that financial information was missing only for the final grant year.

In addition, of the 11 grants, 10 did not include the final progress report and 9 did not include the final invention statement in their files. Progress reports from previous award years of a grant would have been submitted as part of the annual noncompetitive application, so that the absence of this information means that NIH did not know what progress was made in the final year of the grant. Similarly, the absence of a final invention statement means that NIH did not know of inventions developed in the final year of the grant.

By law, a grantee that wants to retain title and profit from inventions it created under federally funded research projects must disclose inventions, acknowledge the government's royalty-free right to the inventions, and record the government's interest on any patent filed on the invention. Grantees are required under the Bayh-Dole Act and Executive Order 12591 to report inventions created under federally sponsored projects within 60

days of the date the inventor reports them to the grantee.⁹ However, in 1994, the HHS Office of Inspector General (OIG) reported that NIH had no system for determining whether documents were submitted in a timely fashion. OIG concluded that NIH did not have procedures to detect grantee noncompliance with requirements related to inventions developed using federal funds, including requirements of the Bayh-Dole Act, and recommended that NIH use a database to track grantees for timely compliance.¹⁰

As a result, NIH developed I-Edison, an interactive database for tracking inventions developed with federal funds. Grantees can submit invention reports to I-Edison electronically, but they are not required to do so. Instead, they may submit paper documentation to NIH. Regardless, NIH's policy is to have this information in the grant file. According to officials in OER, the absence of the final invention statement in the grant file does not necessarily mean that NIH did not know of any inventions that occurred on the projects. NIH officials said that ensuring that final invention statements and other closeout documents appeared in grant files has not been a high priority for institutes, despite NIH's policy. Instead, institutes have placed a higher priority on monitoring compliance from grantees with active research grants.

On February 16, 2000, OER issued final guidance to institutes on procedures for obtaining closeout documents and imposing sanctions on grantees if such documents are not received. Sanctions can include withholding funds for a specific grant or for an entire grantee institution.

⁹See *Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision* (GAO/RCED-99-242, Aug. 12, 1999), in which we noted that organizations did not always disclose or document the government's rights as required.

¹⁰See HHS, OIG, *NIH Oversight of Extramural Research Inventions*, Report OEI-03-91-00930 (Washington, D.C.: May 1994).

Internal Controls Over the Financial Management of Grants Need to Be Strengthened

We identified areas in internal controls related to the oversight and monitoring of grant recipients that need to be strengthened. For example, NIH did not always receive single audit reports from recipients in accordance with OMB's reporting requirements and did not effectively use the results of single audit reports for deciding on grantees' eligibility for grant funds and determining financial management systems' capabilities. In its fiscal year 1999 financial audit report on internal controls, the IPA identified a material weakness in the analysis and development of financial statements that included a weakness related to the financial management of grants. We also identified discrepancies between the data in the information for management, planning, and coordination (IMPAC II) system, the central accounting system (CAS), and the payment management system (PMS) that affect the accuracy of grant award amounts.¹¹ In some instances, the "paylist," which identifies grant applications that were selected for funding, was not always properly authorized. These deficiencies could result in NIH's erroneously awarding grants to ineligible grant recipients and in funds being used for improper purposes.

The Use of Single Audit Results Could Enhance the Oversight of Grantees

NIH did not always receive single audit reports from grant recipients in accordance with OMB's reporting requirements, and it did not effectively use the results of single audit reports to oversee and monitor program recipients. One of the objectives of the Single Audit Act is to ensure that federal departments and agencies rely on and use audit work performed pursuant to the act. Federal agencies are required to ensure that audits are performed on a timely basis and to monitor the reports to ensure that findings are identified and resolved. The Comptroller General's *Standards for Internal Control in the Federal Government* states that monitoring internal controls should include policies and procedures for ensuring that the findings of audits and other reviews are promptly resolved. To comply with the standards, NIH should (1) promptly evaluate findings from audits and other reviews, including those showing deficiencies and

¹¹IMPAC II, the NIH grants system, is an online computer-based information system that contains application and award information on extramural grants. CAS is the central system that accumulates all NIH's accounting records and is designed to meet NIH's specific financial needs. PMS serves as a fiscal intermediary between agencies that award grants and recipients of grants and contracts. Among other functions, it expedites the flow of cash between the federal government and recipients, transmits recipient disbursement data back to the awarding agencies, and maintains cash advances sent to the grant recipients.

recommendations reported by auditors and others who evaluate agencies' operations; (2) determine proper actions in response to findings and recommendations from audits and reviews; and (3) complete, within established time periods, all actions that correct or otherwise resolve the matters brought to its attention. As discussed in our June 1994 report, the Single Audit Act of 1984 encouraged recipients of federal funds to review and revise their financial management practices.¹² This resulted in state and local governments' institutionalizing fundamental reforms, such as (1) strengthening internal controls, (2) installing new accounting systems or enhancing old ones, (3) improving systems for tracking federal funds, and (4) resolving audit findings. Single audit reports contain meaningful information on entities' financial status and management of federal funds and can indicate where the entities have additional problems that need further audit or investigation. Entities' financial statements can contain information indicating problems of concern to the federal government, such as possible overcharges or a failure to reimburse the federal government.

In audit reports covering fiscal years 1996 and 1997, the IPA responsible for the financial audit of NIH reported that NIH did not have an adequate system to ensure that all single audit reports were received. In reports covering fiscal years 1998 and 1999, this issue was reported as a comment for management's consideration. The IPA recommended that HHS and its operating divisions, including NIH, develop a system to track the submission of single audit reports by grantees and identify those that are delinquent or noncompliant with the Single Audit Act. The IPA also recommended that procedures be developed for early identification, reporting, and followup of grantees that are delinquent in the submission of the reports.

HHS, which establishes guidance for its operating divisions, has acknowledged that improved oversight in filing single audit reports is needed. In response to the IPA's recommendation, HHS established a process to identify and follow up with grantees that had not submitted an audit report when required. Under this process, HHS and NIH identified reports that had not been submitted for fiscal years 1995, 1996, and 1997. As of December 1999, 2 of the grantees had not submitted single audit

¹²See *Single Audit: Refinements Can Improve Usefulness* (GAO/AIMD-94-133, June 21, 1994). The 1984 act was superseded by the Single Audit Act Amendments of 1996 (31 U.S.C. 7501) to improve coverage, effectiveness, and reporting.

reports for fiscal year 1995 and 29 had not submitted the reports for fiscal year 1996. For fiscal year 1997, 351 of 915 NIH grantees that should have submitted a single audit report had not done so as of February 2000. HHS had not completed the followup and resolution of these delinquent reports. In addition, as of January 2000, about 6 months after the fiscal year 1998 single audit reports should have been received, HHS had not begun analysis of these reports. Based on information from HHS' single audit reports database, about 40 percent of these reports would have been due by July 1999. However, HHS and its operating divisions had not identified the recipients that were delinquent in submitting the reports.

Although NIH's top 100 recipients, which account for more than 75 percent of its grant funds, have submitted single audit reports for fiscal year 1997, proper oversight of the remaining 25 percent is still needed. NIH has continued to award current funds to some of the grantees that had not submitted single audit reports. For example, in fiscal year 1999, NIH awarded funds to 15 of the 31 grantees that had not submitted fiscal year 1995 and 1996 single audit reports. Together, the grants related to the 15 grantees amounted to about \$73 million as of December 1999.¹³ Lack of timely receipt and effective use of the results of single audit reports hinders NIH's ability to determine whether grantees were eligible to receive grant funds or properly accounted for these funds.

In a single audit, auditors review internal controls of an entity's financial management systems. Thus, timely receipt and analysis of single audit reports can assist NIH in assessing the financial management capabilities of its grantees' systems. However, NIH did not routinely review single audit reports to assess the grantees' financial management systems' capabilities. According to NIH grant policy, grants management staff may review the financial and business management systems of its grantees to determine the adequacy of the systems to support the expenditure of and accountability for NIH funds. At 11 of the 15 institutes we visited, financial management systems were not reviewed for all grantees but, rather, were reviewed case by case, depending on whether the grantee had received a grant in previous years from NIH or was considered a high-risk grantee, such as a small business. If NIH does not use the results of single audit

¹³In commenting on the draft of this report, HHS provided updated information. As of May 2000, eight grantees have not submitted fiscal year 1995 or 1996 single audit reports. HHS said that NIH made grant awards in fiscal year 1999 to three of these grantees totaling about \$15.4 million.

reports to assess the adequacy of the grantees' systems to expend and account for NIH funds, it could be awarding grants to recipients with inadequate financial management systems that could result in the mismanagement of grant funds.

As mentioned earlier, HHS has acknowledged that improved oversight in filing single audit reports is needed. In accordance with OMB's guidance, HHS required its operating divisions, including NIH, to apply sanctions to grantees considered delinquent for submission of a single audit report. The HHS operating division providing the majority of financial assistance should apply the sanctions to recipients found to be delinquent in submission of their single audit report. These sanctions include (1) withholding further grant payments on current funds, (2) withholding additional support for the grant, (3) withholding a percentage of federal awards until the audit is satisfactorily completed, and (4) suspending federal awards until the audit is conducted or terminating the federal award. Because these sanctions had not been fully implemented at the time of our review, we were not able to assess them.

Adequate Documentation Was Maintained but Other Controls Need Strengthening

From our review of 78 grant files, we found that NIH generally maintained adequate documentation for the financial monitoring of its grants. This documentation included a signed grant application, approved Notice of Grant Award, financial status reports, where applicable, and progress reports.¹⁴ For example, for 76 of the 78 grants we reviewed, we found that the dollar amount of the award and the document number—the common identifier of grants—could be tracked and verified through three key financial management systems. However, in one instance, we found that the amount reported in IMPAC II did not agree with the amount in PMS. Grant award data in IMPAC II, CAS, and PMS should agree.¹⁵ We also found that a grant award amount was incorrectly posted to the wrong grantee in PMS. While NIH officials could not document what caused this error, they told us that the principal investigator moved from the university to a

¹⁴The Notice of Grant Award is a legally binding document that notifies the grantee and others that an award has been made. It contains or references all terms and conditions of the award and its dollar amount.

¹⁵Each institute transmits grant award data from IMPAC II to the Office of Financial Management (OFM). These data include the dollar amount of the grant award, document number, and the common account number. OFM transmits this information to NIH's CAS, which in turn transmits valid transactions to PMS.

federal agency in the fourth year of the grant. The related grant award data in IMPAC II and CAS reflected the federal agency as the new recipient of the funds. However, PMS continued to reflect the university as the grantee. As a result, funds appropriated for year four of the grant were incorrectly made available in PMS for the university's use. At the time of our review, the university had not drawn down these funds. However, this error could have resulted in an improper payment of grant funds. In another instance, the award amount on the Notice of Grant Award did not agree with the amount in IMPAC II, CAS, or PMS. The amount on the Notice of Grant Award was \$195,000, compared with the \$69,000 reported in the three key systems. As a result, the correct award amount was not available to the grantee. NIH officials could not explain how this error occurred and were not aware of either of these errors until we brought them to their attention.

The Comptroller General's *Standards for Internal Control in the Federal Government* states that ongoing monitoring activities should include comparisons and reconciliations to identify inaccuracies or exceptions that alert management to any internal problems. The IPA's internal control report covering fiscal year 1999 reported a material weakness in controls over the analysis and development of financial statements. The IPA reported that in the review of NIH's synchronization report, deficiencies in the reconciliation of data between CAS and PMS were not resolved in a timely manner.¹⁶ A significant number of the discrepancies between the two systems were more than a year old and included such items as incorrect posting of expenditures in CAS, duplicate posting of grant obligations in CAS, or duplicate transmittals of payment authority to PMS. In one instance, the IPA noted that a document that had a \$200,000 authorization in PMS could not be supported by data contained in CAS or IMPAC II. Timely resolution of these items reduces the risk of overpayment to grantees and could help ensure the accuracy of funds available for grantees' future use.

In addition, we found areas in which internal controls over award authorization needed strengthening. For example, the "paylist," which is a list of competing grant applications selected for funding, was not always properly approved by authorized officials. The Comptroller General's *Standards for Internal Control in the Federal Government* states that transactions and other significant events should be authorized and executed only by persons acting within the scope of their authority.

¹⁶The synchronization report identifies inconsistencies in grant data between CAS and PMS.

According to the standards, this is the principal means of ensuring that only valid transactions to exchange, transfer, use, or commit resources and other events are initiated or entered into. Authorizations should be clearly communicated to managers and employees. When an application is submitted, it is initially reviewed for scientific merit and budget reasonableness. Following the initial review, a second-level review is performed by Advisory Council members who should have knowledge of the institute's programmatic areas, familiarity with the institute's priorities and procedures, and knowledge of the institute's mission. Immediately following the second-level review, the institute's director is provided a "ranking list" or "paylist" of competing applications to review for payment. The approved grant applications are ranked in percentile or priority score order from most meritorious to least, and an amount is recommended. After review and discussion with the institute's division director, the institute's program director indicates on the ranking list the applications that have been selected for funding. According to NIH officials, the institute's Associate Director of the Division of Extramural Activities and the Chief Grants Management Officer should sign the paylist as the authorization to issue the Notice of Grant Award to prevent incorrect and unauthorized grant awards.

However, we found that the paylist at one of the institutes was signed by only one NIH official and another paylist at a different institute was unsigned and maintained on the Intranet, an internal network. While we found only one instance in which the paylist was not signed, 38 grants on this list amounted to about \$10 million.¹⁷ Lack of proper authorization of grant award documents increases the risk of inaccuracies and improper authorizations of grant funds awarded to grantees.

On another matter, in reviewing NIH's instructions for completing grant applications, we noted an inconsistency between NIH's Grants Policy Statement and PHS' instructions. Grant applicants must make a certification on their grant application that covers various topics, including nondelinquency of federal debt as defined by the agency. According to OMB Memorandum M-87-32, "Certification of Nondelinquency by Applicants for Federal Assistance," the certification is seen as an important step toward ensuring that recipients of federal grant funds are not delinquent on federal debt.

¹⁷Of the 38 grants on the paylist, 1 was included in our sample of 78 grants.

NIH's policy statement and PHS' instructions each refer to the Federal Debt Collection Procedures Act, which provides that a debtor is ineligible to receive a federal grant that is financed directly or indirectly by the United States if there is a judgment lien against the debtor's property for a debt to the United States (28 U.S.C. 3201 (e)). NIH's and PHS' position is that a debtor with such a lien may not receive grant funds either directly as a grant award or indirectly as payment for participating in an NIH grant awarded to someone else. Consistent with that position, NIH's policy statement and PHS' instructions clearly provide that costs charged to awards that provide funds to individuals who are in violation of the act will be disallowed.

NIH's policy statement and PHS' instructions, however, are not similarly consistent on the scope of the certification regarding nondelinquency of federal debt. The PHS instructions make clear that the certification applies only to the applicant organization. The PHS instructions state that in accordance with OMB Memorandum M-87-32, the applicant organization must certify that it is not delinquent on the repayment of any federal debt before a grant award can be made. The PHS instructions also state that the certification "applies to the applicant organization, not to the person signing the application as the authorized representative nor to the principal investigator." In contrast, the NIH policy statement provides that before a grant can be awarded, the applicant organization must certify that the applicant organization is not delinquent in repaying any federal debt and "any person to be paid from grant funds" is also not delinquent in repaying such debt. During our review, we discussed the apparent inconsistency with NIH officials. As we were completing our review, NIH received a legal opinion from its Office of General Counsel that concluded that an inconsistency exists and that in interpreting the certification on the grant application, the PHS instructions take precedence over the NIH policy statement. The legal opinion provided options to NIH on changing its Grants Policy Statement in light of the inconsistency.

Fiscal Year 1999 Funding Increases Expanded Extramural Research

In fiscal year 1999, the Congress increased NIH appropriations nearly \$2 billion over fiscal year 1998 levels. The proportion of funds that the Congress appropriated to each NIH component remained about the same. (See table 1.)

Table 1: Unaudited Fiscal Year 1998-99 NIH Appropriations

	1998	Percent of total	1999	Percent of total	Percent change 1998-99
National Cancer Institute	\$2,528 ^a	18.5%	\$2,892 ^a	18.5%	14.4%
National Heart, Lung, and Blood Institute	1,571	11.5	1,775	11.4	13.0
National Institute of Allergy and Infectious Diseases	1,359	9.9	1,571	10.0	15.6
National Institute of General Medical Sciences	1,062	7.8	1,203	7.7	13.3
National Institute of Diabetes and Digestive and Kidney Diseases	900	6.6	1,021	6.5	13.4
National Institute of Neurological Disorders and Stroke	775	5.7	897	5.7	15.8
National Institute of Mental Health	743	5.4	854	5.5	14.9
National Institute of Child Health and Human Development	675	4.9	752	4.8	11.5
National Institute on Drug Abuse	541	4.0	617	3.9	14.0
National Institute on Aging	520	3.8	600	3.8	15.3
National Center for Research Resources	452	3.3	561	3.6	24.0
National Eye Institute	355	2.6	396	2.5	11.3
National Institute of Environmental Health Sciences	341	2.5	388	2.5	13.6
National Institute of Arthritis and Musculoskeletal and Skin Diseases	273	2.0	306	2.0	12.1
National Institute on Alcohol Abuse and Alcoholism	226	1.7	259	1.7	14.7
National Human Genome Research Institute	223	1.6	284	1.8	27.4
National Institute of Dental and Craniofacial Research	214	1.6	238	1.5	11.2
National Institute on Deafness and Other Communication Disorders	201	1.5	231	1.5	14.7
National Library of Medicine	161	1.2	182	1.2	13.2
National Institute of Nursing Research	64	0.5	70	0.4	9.9
National Center for Complementary and Alternative Medicine ^b	20	0.1	51	0.3	158.5
John E. Fogarty International Center for Advanced Study in the Health Sciences	28	0.2	35	0.2	24.7
Office of the Director ^b	221	1.6	256	1.6	15.7
Buildings and facilities	207	1.5	197	1.3	-4.4
Total	\$13,659	100.0%	\$15,633	100.0%	14.5%

Note: Totals may not add because of rounding. NIH consists of 25 institutes and centers. In fiscal year 2000, NIH received 24 appropriations—for 22 institutes and centers, the Office of the Director, and buildings and facilities. The three centers not listed in this table—the Warren Grant Magnuson Clinical Center, the Center for Scientific Review, and the Center for Information Technology—received no separate appropriation.

^aDollars in millions.

^bNational Center for Complementary and Alternative Medicine received its first direct appropriation in fiscal year 2000. This table presents the amounts allocated to its predecessor, the Office of Alternative Medicine, from the Office of Director appropriation. The Office of Director amounts have been adjusted accordingly.

Source: HHS, NIH, *Fiscal Year 2000 Justification of Estimates for Appropriations Committees*, Vol. 1 (Washington, D.C.: 1999), p. 26, and *Fiscal Year 2001 Justification of Estimates for Appropriations Committees*, Vol. 1 (Washington, D.C.: 2000), p. 36.

NIH allocated about 70 percent, or nearly \$1.4 billion, of the fiscal year 1999 increase to extramural research grants. The proportion of extramural funding allocated to project grants, research center grants, and other research grants for fiscal year 1999 remained about the same as it was in fiscal year 1998.

About 41 percent of the nearly \$1.4 billion increase was used to expand the number of competitive project grants awarded. (See table 2.) As a result, 978 more grants were funded than in fiscal year 1998, bringing the total number of competitive grants awarded to 8,565 grants in fiscal year 1999. At the same time, the average amount awarded for competitive project grants increased by 15 percent from an average of about \$255,900 in fiscal year 1998 to about \$293,600 in fiscal year 1999. This 15 percent increase resulted in part from NIH's attempt to award amounts closer to those recommended by external reviewers. Previously, some institutes we visited had been making across-the-board reductions to the recommended amounts, ranging from 5 to 25 percent, in order to fund more grants. NIH officials told us that they did not augment funding for the approximately 20,000 ongoing grants awarded in previous years except as previously committed. These increases accounted for about 27 percent of the extramural research increase. Research centers' grants and other research grants received 29 percent, about \$390 million of the nearly \$1.4 billion increase in funding for extramural research grants. Research centers' grants included infrastructure support for clinical research, biotechnology, and comparative medicine. Other research grants included funds for research career development, cooperative clinical research, and biomedical research support. The remaining 3 percent, about \$50 million, went for small business research technology transfer.

Table 2: Unaudited Fiscal Year 1998-99 Changes in Funding for NIH Extramural Research Grants

Extramural research grants	Funding ^a		Increase ^a	Percent increase
	1998	1999		
Project grants				
Competitive grants	\$1,941	\$2,515	\$574	41.4%
Noncompetitive grants	5,617	5,988	371	26.8
SBIR and STTR ^b	269	315	46	3.3
Subtotal	\$7,827	\$8,818	\$991	71.5%
Research center grants				
Specialized and comprehensive centers	844	1,002	158	11.4
Clinical research	170	202	32	2.3
Biotechnology	58	71	13	0.9
Comparative medicine	64	76	12	0.9
Centers in minority institutions	32	34	2	0.1
Subtotal	\$1,168	\$1,385	\$217	15.7%
Other research grants				
Research careers	226	271	45	3.2
Cancer education	14	17	3	0.2
Cooperative clinical research	197	246	49	3.5
Biomedical research support	26	38	12	0.9
Minority biomedical research support	54	66	12	0.9
Other	115	171	56	4.0
Subtotal	\$632	\$809	\$177	12.8%
Total	\$9,627	\$11,012	\$1,385	100.0%

Note: Excludes about \$2 billion in fiscal year 1999 extramural research funding for Training, Research and Development Contracts, construction, a portion of the funding for Cancer Prevention and Control, and the National Library of Medicine. Totals may not add because of rounding.

^aDollars in millions.

^bSBIR = Small Business Innovation Research. STTR = Small Business Technology Transfer.

Source: HHS, NIH, *Fiscal Year 2000 Justification of Estimates for Appropriations Committees*, Vol. 1 (Washington, D.C.: 1999), p. 30, and *Fiscal Year 2001 Justification of Estimates for Appropriations Committees*, Vol. 1 (Washington, D.C.: 2000), p. 40.

Conclusions

Monitoring the scientific progress and financial management of research grants is important because these activities help ensure that the NIH extramural research program, the largest component of NIH's budget, is soundly managed. Implementing appropriate internal controls is a key factor in ensuring the accountability of federal funds. Although NIH has

developed processes to ensure the proper oversight of its extramural research program, its system of internal controls is not always followed or documented. Internal control problems related to scientific progress include inconsistencies in documenting assessments of progress before awarding continued funding and in ensuring the timely closeout of completed grants. Internal control problems related to financial management include weaknesses in ensuring that single audits are conducted, submitted on a timely basis, and used in considering grant awards. Furthermore, another internal control problem involves the accuracy of grant data maintained in key financial systems. As a result, scientific monitoring and financial management functions need to be improved.

Recommendations

To improve internal controls, we recommend that the Secretary of HHS direct the Assistant Secretary for Management and Budget to refine and implement the procedures that have been developed to identify, report, and follow up on grantees that are delinquent in submitting single audit reports by ensuring the (1) completion of the followup and resolution of delinquent reports from fiscal years 1995, 1996, and 1997; (2) performance of the analysis to determine the status of the fiscal year 1998 single audit reports; and (3) reinforcement of the use of sanctions against delinquent grantees.

To improve internal controls at NIH, we recommend that the Secretary of HHS direct the Acting Director of NIH to

- require that the institutes document their assessments of grantees' scientific progress before awarding continued funding by ensuring that progress report review forms are properly filled out and problems with scientific progress are documented;
- ensure that institutes properly close out completed grant files in a timely manner;
- follow up and resolve delinquent single audit reports on a timely basis after HHS has identified delinquent grantees and, in particular, complete the followup and resolution of delinquent reports for fiscal years 1995, 1996, and 1997;
- establish and implement a process to ensure that single audit reports are reviewed to identify significant problems related to NIH's grants and use this process as a management tool for ensuring that significant problems are resolved and considered in the oversight and monitoring of grant recipients; and

- ensure the accuracy of grant data in the three key financial management systems, IMPAC II, CAS, and PMS, by (1) resolving discrepancies resulting from the reconciliation between CAS and PMS on a timely basis and (2) performing periodic detailed reviews of transactions, specifically the grant award amount, within IMPAC II, CAS, and PMS.

Agency Comments and Our Evaluation

In written comments (reprinted in appendix III) on a draft of this report, HHS generally agreed with our recommendations for improving internal controls over extramural grants. It did not concur with our recommendation to perform an analysis of the status of fiscal year 1998 single audit reports. In its comments, HHS reaffirmed its commitment to an effective grants monitoring process.

HHS concurred with our recommendation that the Assistant Secretary for Management and Budget complete the followup and resolution of delinquent reports from fiscal years 1995, 1996, and 1997. It noted that HHS instituted a system 3 years ago for identifying grantees and the federal dollars at risk and has consistently pursued the identification and collection of outstanding audit reports. In addition, HHS noted that the financial audits by independent public accounting firms for HHS and NIH no longer cite an internal control weakness in this area. While the single audit issue was not reported in the IPA's internal control report in fiscal year 1999, it was cited as an internal control weakness for management's consideration in fiscal years 1998 and 1999.

HHS did not concur with our recommendation that it perform an analysis to determine the status of the fiscal year 1998 single audit reports, stating that to further collapse the time for identifying delinquent audits would not be worthwhile. However, we did not recommend that HHS further collapse the time for identifying delinquent audits; our recommendation was that HHS perform the analysis to determine the status of the fiscal year 1998 single audit reports. To the extent that single audit reports are not analyzed until all reports for a particular fiscal year are due, the risk increases that grants will be awarded to ineligible grantees or to grantees that have not submitted prior years' single audit reports.

HHS concurred with our recommendation to reinforce the use of sanctions against delinquent grantees. HHS said that it will use sanctions where appropriate.

HHS concurred with our recommendation that NIH document assessments of grantees' scientific progress. It noted that NIH has reinforced its policy that requires documentation and plans to develop a standard checklist for all awarding units to use for these assessments and stated that NIH expects a written narrative when progress is not acceptable. These actions should help ensure that scientific progress is documented. Without a completed checklist, it is not possible to know whether scientific progress was assessed. A narrative addition to the checklist is an appropriate and needed way to document problems.

HHS also concurred with our recommendation that NIH ensure adequate documentation of closeouts of completed grants. It said that existing policy provides clear guidance to grantees for submitting final reports. HHS acknowledged that closeout activity has not been a priority for the institutes. HHS stated that it would need to apply sanctions to grantees to foster their compliance and that doing so would be difficult and resource intensive. However, as we note in the report, in February 2000 OER issued guidance to the institutes recommending steps—including sanctions—for the institutes to take to ensure grantee compliance. We believe that NIH should appropriately implement requirements regarding closeout documentation. Although HHS concurred with this recommendation, it did not specify any actions to implement it.

HHS concurred in principle with our recommendation that NIH follow up and resolve delinquent single audit reports in a timely manner after HHS has identified delinquent grantees and, in particular, complete the followup and resolution of delinquent reports for fiscal years 1995, 1996, and 1997. HHS noted that some of the data cited in our draft report as related to single audits were either out of date or not correct. NIH provided the information and it was correct as of December 1999. We have included data HHS provided that were current as of May 2000.

HHS concurred in principle with our recommendation that NIH establish and implement a process to ensure that single audit reports are reviewed to identify significant problems related to its grants and use this process as a management tool for ensuring that significant problems are resolved and considered in the oversight and monitoring of grant recipients. It noted that NIH's Special Reviews Branch of the Division of Financial Advisory Services of the Office of Contracts Management is responsible for resolving single audit findings and for maintaining all audit reports that have been forwarded to NIH for audit resolution for use by NIH staff. In addition, HHS noted that NIH established a work group in November 1998 to determine

whether all required single audit reports had been received and to follow up with recipients that were delinquent in submitting the reports and impose sanctions where appropriate. We support these efforts. However, HHS did not specify how it will use the results of single audit reports as a management tool for overseeing and monitoring grant recipients.

HHS concurred with our recommendation that NIH ensure the accuracy of grant data in the three key financial management systems, IMPAC II, CAS, and PMS. It noted that NIH has devoted more staff to improve the timeliness and accuracy of the reconciliation between CAS and PMS. In addition, to improve the quality of the reconciliation process, NIH has plans to implement a new NIH business system.

Finally, HHS stated that in general NIH provides appropriate oversight and monitoring in accordance with federal requirements. As we note in this report, NIH has developed policies and procedures to assess scientific progress and provide financial management for its grants. However, we found that these policies and procedures were not consistently implemented by the institutes. Our recommendations are intended to help ensure that NIH's internal control processes are effectively carried out, thereby helping to ensure that its objectives are accomplished.

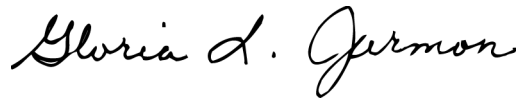
HHS also provided technical comments, which we incorporated, where appropriate.

As we agreed with your offices, unless you publicly announce the report's contents earlier, we plan no further distribution of it until 30 days from the date of this letter. We will then send copies to other interested congressional committees; the Honorable Donna Shalala, Secretary of the Department of Health and Human Services; Dr. Ruth Kirschstein, Acting Director of the National Institutes of Health; the Honorable Jacob J. Lew, Director of the Office of Management and Budget; and others who are interested. We will also make copies available to others on request. If you or your staff have any questions or need additional information, please

call Janet Heinrich at (202) 512-7119 or Gloria L. Jarmon at (202) 512-4476. GAO contacts and staff acknowledgments are listed in appendix IV.

A handwritten signature in black ink that reads "Janet Heinrich". The script is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Janet Heinrich
Associate Director, Health Financing and Public Health Issues
Health, Education, and Human Services Division

A handwritten signature in black ink that reads "Gloria L. Jarmon". The script is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Gloria L. Jarmon
Director, Health, Education, and Human Services
Accounting and Financial Management Issues
Accounting and Information Management Division

Scope and Methodology

We identified the process the National Institutes of Health (NIH) uses to monitor scientific progress in extramural grants, its financial management of these grants, and its use of additional funding in fiscal year 1999. We did not examine its competitive process for making awards, but we did examine its oversight of research that it has already decided to support. In this appendix, we give details on the methodology we used in examining each aspect of your request.

Monitoring Scientific Progress

To ascertain how NIH monitors scientific progress in extramural grants, we obtained and reviewed NIH grant administration policy and interviewed NIH staff at the Office of Extramural Programs and the Office of Policy for Extramural Research Administration. In addition, we examined a sample of files from extramural grants that were active in fiscal year 1997.

We first stratified the NIH institutes into large, medium, and small institutes, based on their estimated number of active grants. Specifically, we defined large institutes as those that monitored more than 2,000 grants, medium institutes as those that monitored between 1,000 and 2,000 grants, and small institutes as those that monitored fewer than 1,000 grants in 1997. We then selected two institutes from each group, ensuring that each institute supported a diverse mix of research, including basic, applied, clinical, and population-based research. We visited the National Cancer Institute and the National Heart, Lung, and Blood Institute, each of which monitors more than 2,000 such grants annually; the National Institute of Neurological Disorders and Stroke and the National Institute of Child Health and Human Development, each of which monitors 1,000 to 2,000 grants; and the National Institute on Alcohol Abuse and Alcoholism and the National Institute of Dental and Craniofacial Research, each of which monitors fewer than 1,000 grants.

Using a list of active grants that NIH provided us, we selected a random sample of 15 research project grants from each of these six institutes. We also randomly selected 5 program project grants from 5 of the 6 institutes. In the remaining institute, only a single program project grant was active in fiscal year 1997, which we reviewed. We focused on research project grants and program project grants because they constituted about 87 percent of the extramural research funding for research grants. Other types of extramural funding included awards for small businesses, research and development contracts, cooperative agreements, training grants, and fellowships.

We reviewed each sample file to ascertain the extent of institutes' monitoring of scientific progress. This included (1) obtaining an overall grant history; (2) reviewing evidence that institutes had reviewed the adequacy of scientific progress, changes in research scope and objectives, and significant budgetary information; (3) identifying evidence that institutes had approved the grants for continued funding; and (4) where appropriate, determining whether the files included documents required in closing out the grants.

To ensure that each grant would have at least one annual progress report reviewed by NIH for noncompetitive continuation funding, we selected grants that were active in fiscal year 1997. Since funding for some grants that were active in fiscal year 1997 would likely have ended by the time of our data collection in 1999, selecting this period also allowed us to review the institutes' procedures for closing out grants. Furthermore, we asked officials at each institute to identify two grants that had problems, and we reviewed the files to understand the difficulties and ascertain how they were resolved. In addition, at each of the six institutes we reviewed the files of grants that were terminated or withdrawn in fiscal year 1997 according to the information for management, planning, and coordination (IMPAC II) database. We cannot generalize from the results of our sample review to other institutes or NIH as a whole.

The Financial Management of Grants

To determine whether NIH has controls to ensure the effective financial management of its extramural research grants, we obtained an understanding of the grants control environment by reviewing and analyzing related grants policies and procedures and interviewing NIH officials. We held discussions with and coordinated our work with the independent public accountant (IPA) responsible for performing the fiscal year 1999 financial audit of NIH and reviewed fiscal year 1998 and 1999 workpapers related to grants monitoring.

We selected a statistical sample of 78 research project grants and program project grants that were active in fiscal year 1999 from the IMPAC II system. These 78 grants were awarded by 15 NIH institutes. The 15 institutes were the National Institute on Alcohol Abuse and Alcoholism; National Institute on Aging; National Institute of Allergy and Infectious Diseases; National Institute of Arthritis and Musculoskeletal and Skin Diseases; National Cancer Institute; National Institute on Drug Abuse; National Institute on Deafness and other Communication Disorders; National Institute of Diabetes and Digestive and Kidney Diseases; National

Institute of Environmental Health Sciences; National Eye Institute; National Institute of General Medical Sciences; National Institute of Child Health and Human Development; National Heart, Lung, and Blood Institute; National Institute of Mental Health; and National Institute of Neurological Disorders and Stroke. We interviewed grants management staff at these 15 institutes and reviewed the grantee files related to the 78 grants to determine whether key financial monitoring documentation was maintained, such as signed grant applications, approved Notice of Grant Awards, and financial status reports. We traced the 78 grants to the payment management system and to the NIH accounting system to determine whether they were properly accounted for and reported. To understand a research institution's management of grants, we interviewed officials at one of NIH's top ten recipients of extramural grant funds. To determine whether NIH's grantees complied with the Single Audit Act requirements, we analyzed fiscal year 1997 data from the Department of Health and Human Services' (HHS) single audit report database. We also reviewed HHS' policies and procedures on the Single Audit Act and interviewed agency officials.

The Use of Fiscal Year 1999 Funding for Extramural Research

To ascertain how NIH used its increased fiscal year 1999 appropriation for extramural research, which accounted for the largest percentage of the nearly \$2 billion increase in funding for fiscal year 1999, we compared the NIH fiscal year 1998 and 1999 appropriations allocated to extramural research. Additionally, we examined the increase in the average cost per research grant awarded in fiscal year 1999. For this comparison, we obtained the data from the HHS budget justification to appropriations committees for fiscal years 2000 and 2001 and did not independently verify the information. In the course of this work, we also interviewed officials from NIH's Office of Budget.

We performed our work at NIH's Washington, D.C., area offices and the HHS headquarters in Washington, D.C., from May 1999 through April 2000. We conducted our work in accordance with generally accepted government auditing standards.

Unaudited Fiscal Year 1999 and 2000 NIH Appropriations

	1999	2000
National Cancer Institute	\$2,892	\$3,312
National Heart, Lung, and Blood Institute	1,775	2,026
National Institute of Allergy and Infectious Diseases	1,571	1,797
National Institute of General Medical Sciences	1,203	1,354
National Institute of Diabetes and Digestive and Kidney Diseases	1,021	1,141
National Institute of Neurological Disorders and Stroke	897	1,030
National Institute of Mental Health	854	975
National Institute of Child Health and Human Development	752	859
National Institute on Drug Abuse	617	687
National Institute on Aging	600	688
National Center for Research Resources	561	675
National Eye Institute	396	450
National Institute of Environmental Health Sciences	388	443
National Institute of Arthritis and Musculoskeletal and Skin Diseases	306	349
National Human Genome Research Institute	284	336
National Institute on Alcohol Abuse and Alcoholism	259	293
National Institute of Dental and Craniofacial Research	238	269
National Institute on Deafness and Other Communication Disorders	231	264
National Library of Medicine	182	215
National Institute of Nursing Research	70	90
National Center for Complementary and Alternative Medicine ^a	51	69
John E. Fogarty International Center for Advanced Study in the Health Sciences	35	43
Office of the Director ^a	256	282
Buildings and facilities	197	165
Total	\$15,633	\$17,813

Note: Dollars in millions. Totals may not add because of rounding.

^aNational Center for Complementary and Alternative Medicine received its first direct appropriation in fiscal year 2000. Fiscal year 1999 amounts were allocated to its predecessor, the Office of Alternative Medicine, from the Office of Director appropriation. The Office of Director amounts have been adjusted accordingly.

Source: HHS, NIH, *Fiscal Year 2001 Justification of Estimates for Appropriations Committees*, Vol. 1 (Washington, D.C.: 2000), p. 36.

Comments From the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

MAY 8 2000

Ms. Janet Heinrich
Associate Director, Health Care Financing
and Public Health Issues
United States General
Accounting Office
Washington, D.C. 20548

Dear Ms. Heinrich:

Enclosed are the Department's comments on your draft report, "NIH Research: Improvements Needed in Monitoring Extramural Grants." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department also provided extensive technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

Michael Mangano
for June Gibbs Brown
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

Comments of the Department of Health and Human Services
on the General Accounting Office Draft Report "NIH Research: Improvements
Needed in Monitoring Extramural Grants" GAO/HEHS/AIMD-00-139

General Comments

The Department of Health and Human Services (Department) appreciates the opportunity to comment on the General Accounting Office's (GAO) draft report. In general, we concur with two of the three recommendations made to the Department regarding the Department's Assistant Secretary for Management and Budget. The Department does not concur with GAO's recommendation relating to the analysis of Fiscal Year (FY) 1998 single audit reports. The Department agrees in principle with the five recommendations concerning the Department's National Institutes of Health (NIH). Each of the areas where GAO has made a recommendation concerning NIH is an area where GAO's report provides evidence that NIH has well-established and effective policies and procedures for monitoring extramural grants. Furthermore, it is evident that, in general, NIH provides appropriate oversight and monitoring in accordance with Federal requirements.

The Department provided extensive technical comments to GAO that encompass virtually the entire report. The Department's ongoing and planned activities, reflected in the comments below as well as those previously provided, reflect our and NIH's commitment to an effective grants monitoring process.

GAO Recommendation

To improve internal controls, we recommend that the Secretary of HHS direct the Assistant Secretary for Management and Budget to refine and implement the procedures that have been developed to identify, report, and follow up on grantees that are delinquent in submitting single audit reports by ensuring the

1) completion of the followup and resolution of delinquent reports from fiscal years 1995, 1996, and 1997;

Department Comment

We concur. The Department was proceeding with these activities prior to the GAO review. The Department instituted a system 3 years ago for identifying grantees and the Federal dollars at risk and has consistently pursued identification and collection of outstanding audit reports. The financial audits by independent public accounting firms for the Department and NIH no longer cite an internal control weakness in this area.

**Appendix III
Comments From the Department of Health
and Human Services**

GAO Recommendation

2) performance of the analysis to determine the status of the fiscal year 1998 single audit reports; and

Department Comment

We do not concur and do not agree that further collapsing the time for identifying delinquent audits would be worthwhile. The due date for an audit is dependent on the end of the fiscal year for the audited organization. The Department's process begins as soon as all audits for a particular Federal fiscal year are due. The Department's Office of Inspector General (OIG) generates an initial list of organizations from the OIG's audit tracking system matched against the Department's Payment Management System (PMS). This initial list contains many organizations that have already submitted audits or are not required to submit Office of Management and Budget (OMB) A-133 audits. An A-133 audit is a financial audit that is required of nonfederal entities which receive total Federal assistance of \$300,000 or more. Some time is taken to contact all these entities to improve the accuracy of a revised list. The Single Audit Act Amendments of 1996 (Amendments) require audits to be sent to the Single Audit Act Clearinghouse which adds an additional time delay for the Department. Finally, the Amendments accelerate the submission of audits by 4 months beginning with audit reports required for fiscal years beginning after June 30, 1998.

GAO Recommendation

3) reinforcement of the use of sanctions against delinquent grantees.

Department Comment

We concur. The Department's new oversight efforts are directed at addressing the new time tables provided for in the Amendments and will utilize sanctions, where appropriate, against delinquent grantees.

GAO Recommendation

To improve internal controls at NIH, we recommend that the Secretary of HHS direct the Acting Director of NIH to

require that the institutes document their assessments of grantees' scientific progress before awarding continued funding by ensuring that progress report review forms are properly filled out and problems with scientific progress are documented;

Now page 11.

Department Comment

We concur. The NIH policy and procedures require that an assessment of scientific progress be made prior to issuing the next funding increment. Page 10 of the draft GAO report acknowledges that each of the six institutes visited required program staff to document their assessment of scientific progress by completing a checklist. This policy and procedure was recently reinforced with grants management staff as part of a policy and procedure announcement entitled, "Determination of Funding Level for NIH Assistance Awards." We acknowledge the variation in the checklists and will establish a standard document to be used by all awarding units.

GAO Recommendation

ensure that institutes properly close out completed grant files in a timely manner;

Department Comment

We concur. The NIH Grants Policy Statement provides clear guidance to grantees for the close out of terminated grants. In addition, an Institute/center (I/C) places a footnote on an award notice for the terminal year reminding investigators and grantees of the requirement for submitting final reports. While most I/Cs devote effort to closing grant records, we acknowledge that this activity is not a priority. The limited resources in I/C grant offices require that priority be given to active and pending grants rather than closing terminated records. In addition, the grantee community does not view final reports as a priority and without a "big stick" to encourage compliance, enormous amounts of staff time are required to assure that final reports (particularly progress reports) are received. The ability to apply sanctions to delinquent grantees would require a centralized database to assure that I/Cs have the most current data before sanctioning a particular grantee. Additional staff and computer resources would be required in order to bring this activity into full compliance.

GAO Recommendation

follow up and resolve delinquent single audit reports on a timely basis after HHS has identified delinquent grantees and, in particular, complete the followup and resolution of delinquent reports for fiscal years 1995, 1996, and 1997;

Department Comment

Now pages 16-17.

We concur in principle but believe that some data (pages 16 and 17) cited in the GAO draft report are either out-of-date or not correct. Some of the information that NIH provided to GAO was preliminary because follow-up activities were still in process. We offer the following specific comments concerning the draft report:

Two organizations have requested relief from the provisions of A-133 audit requirements for FY 1995. Both organizations have submitted the required audit report to the National

Appendix III
Comments From the Department of Health
and Human Services

External Audit Review Center (NEAR), but only one report, with no findings, has been released to NIH. The NIH is awaiting the review and processing of the other audit report by NEAR. With these two pending exceptions, NIH has completed follow-up action on all 47 of the FY 1995 delinquent recipients. The two organizations that have requested relief represent \$284,249 in FY 1995 grant awards.

There were 73 delinquent recipients representing approximately \$51.8 million referred to NIH for follow-up action for FY 1996. The NIH has completed follow-up action on 65 of the delinquent recipients. Two organizations are involved with other pending actions affecting NIH follow-up activities. The remaining six organizations have received a letter stating that sanctions will be imposed, in accordance with Department policy, if the required audit report is not submitted by a specified date.

For FY 1997, the total Department listing of potential nonmatches consisted of 1,082 organizations and of those, 351 organizations had funding attributed to NIH. Preliminary work by a Department working group has determined that many of the 351 organizations were in fact already in compliance with A-133 requirements (that is, the audit reports were filed under another name or the awardee was included under the audit of another organization), received no NIH funds in FY 1997, or were exempt from the provisions of A-133 (for example, Government Owned, Contractor Operated for profit hospitals). As a result, NIH may be required to follow up on only 38 of the 351 organizations delinquent in submitting a FY 1997 audit report. Follow-up activities for FY 1997 delinquent recipients will begin as soon as final data has been received from the Department. The Department has received responses to their inquiries from many of the FY 1997 potential delinquent recipients, and follow-up on these responses may reduce the list of potential delinquent recipients referred to NIH even further.

The GAO draft report states that the Department has not begun analysis on data for FY 1998 single audit reports. Because FY 1998 single audit reports may have been due as late as February 2000, the computer match had not been completed at the time of the GAO audit. The match process is very time consuming and efficient use of resources warrants the implementation of the most inclusive match date. It should be noted that both the Department and NIH have representatives on an OMB working group tasked with the revision of the Federal Single Audit Act Clearinghouse data collection form. Improvements to the form, and ultimately the Single Audit Act Database, will simplify future computer matches.

In summary, there are eight grantees that have not submitted FY 1995 or FY 1996 single audit reports. In FY 1999, NIH made awards to three of the eight grantees. Together, the grants related to the three grantees amounted to approximately \$15.4 million. We do not believe that GAO correctly calculated FY 1999 award data to arrive at the \$73 million figure cited on page 17 of the report. Of the \$15.4 million awarded in FY 1999, \$12 million is associated with a grantee that has been designated as high risk and is on a restricted payment plan. This grantee's FY 1996 audit has been completed but not finalized because of legal proceedings involving the grantee organization, a CPA firm, and the Department of Justice. In addition, \$2.9 million is associated with a grantee that

Appendix III
Comments From the Department of Health
and Human Services

has Defense Contract Audit Agency (DCAA) resident auditors at the grantee's location providing continual audit coverage. The DCAA has completed their incurred cost audit and the grantee is awaiting finalization of their financial statement audit by the CPA firm. The remaining \$0.5 million relates to a grantee that requested relief from A-133 audit requirements. A subsequent audit was submitted and there were no reported findings.

GAO Recommendation

establish and implement a process to ensure that single audit reports are reviewed to identify significant problems related to NIH's grants and use this process as a management tool for ensuring that significant problems are resolved and considered in the oversight and monitoring of grant recipient; and

Department Comment

We concur in principle. In addition to our comments in response to recommendation 1, we would like to provide the following comments. There are two aspects with respect to single audit reports; audit resolution and tracking receipt of annual reports.

Audit Resolution

The Special Reviews Branch of the Division of Financial Advisory Services (DFAS), Office of Contracts Management, NIH, is responsible for the resolution of audit findings reported by the OIG as a result of audits of NIH contractors and grantees, including audits performed under the provisions of OMB A-133.

During the audit resolution process, DFAS reviews each assigned finding and discusses the contents of the audit report with officials of the auditee organization, auditors, cognizant NIH grants and contracts management staff, and staff and representatives of other awarding agencies as warranted. The DFAS evaluates corrective action plans and reviews related supporting documentation. All audit reports that have been forwarded to NIH for audit resolution are maintained by DFAS for use by NIH staff.

To assist with prompt and thorough audit resolution, the OIG issues monthly reports to each of the Department's operating division's resolution offices. The DFAS uses these monthly reports to verify receipt of all audit reports with findings coded for NIH resolution, to track any outstanding findings and to verify that the proper information has been transmitted to the OIG.

The NIH is in full compliance with the Department's audit resolution policy. As a further measure to ensure the integrity of the audit resolution process, formal reconciliation of the audit resolution information is required for all monetary findings twice a year.

Appendix III
Comments From the Department of Health
and Human Services

Tracking of Single Audit Reports

The NIH is also in full compliance with the Department's policy for ensuring that grant recipients are in compliance with Single Audit Act requirements. In direct response to the findings in NIH's FY 1996 and FY 1997 financial audit reports, NIH established a work group in November 1998 regarding A-133 delinquent recipients to determine if all required A-133 audit reports had been received and to follow up with recipients that are delinquent or noncompliant and impose sanctions, as appropriate.

GAO Recommendation

ensure the accuracy of grant data in the three key financial management systems, IMPAC II, CAS, and PMS, by (1) resolving discrepancies resulting from the reconciliation between CAS and PMS on a timely basis and (2) performing periodic detailed reviews of transactions, specifically the grant award amount, within IMPAC II, CAS, and PMS.

Department Comment

We concur. The NIH has devoted more staff to improve the timeliness and accuracy of this reconciliation. The implementation of a new NIH business system (NBS) will also improve the quality of this process. The NBS is the result of a study of the business options available to update NIH's administrative computing systems. Several options are being entertained based on a 6-month study that began in September 1999 involving almost 200 people from all parts of the NIH administrative and business communities. Two choices have emerged: buy a system on the commercial market known as an Enterprise Resource Planning package, or develop a customized application such as the Administrative Data Base (ADB), already in use at NIH. Through work groups and under the guidance of a steering committee chaired by the Deputy Director of Management, NIH (including executive officers, the scientific community, the Office of the Director, and functional managers), a process was crafted to identify the requirements of a new system to replace the current ADB. Numerous demonstrations have taken place. It is anticipated that a decision will be made shortly. The final product will imbed many best practices from the commercial community into a comprehensive system that will reflect potentially new ways of doing business.

GAO Contacts and Staff Acknowledgments

GAO Contacts	Bruce D. Layton, 202-512-6837 Chinero N. Nwaigwe, 202-512-5472
Staff Acknowledgments	David W. Bieritz, Bertha Dong, Harrison E. Greene, Jr., Rosa R. Harris, and Paul T. Wagner, Jr., also made key contributions to this report.

Related GAO Products

Financial Management: National Institutes of Health Research Invention Licenses and Royalties (GAO/AIMD-00-44R, Nov. 22, 1999).

Financial Management: Increased Attention Needed to Prevent Billions in Improper Payments (GAO/AIMD-00-10, Oct. 29, 1999).

NIH Clinical Trials: Various Factors Affect Patient Participation (GAO/HEHS-99-182, Sept. 30, 1999).

Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision (GAO/RCED-99-242, Aug. 12, 1999).

Technology Transfer: Number and Characteristics of Inventions Licensed by Six Federal Agencies (GAO/RCED-99-173, June 18, 1999).

Single Audit: Efforts Underway to Implement 1996 Refinements (GAO/T-AIMD-99-177, May 13, 1999).

Single Audit: Refinements Can Improve Usefulness (GAO/AIMD-94-133, June 21, 1994).

NIH Extramural Clinical Research: Internal Controls Are Key to Safeguarding Phase III Trials Against Misconduct (GAO/HEHS-96-117, July 11, 1996).

Ordering Information

The first copy of each GAO report is free. Additional copies of reports are \$2 each. A check or money order should be made out to the Superintendent of Documents. VISA and MasterCard credit cards are accepted, also.

Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

Orders by mail:

U.S. General Accounting Office
P.O. Box 37050
Washington, DC 20013

Orders by visiting:

Room 1100
700 4th St. NW (corner of 4th and G Sts. NW)
U.S. General Accounting Office
Washington, DC

Orders by phone:

(202) 512-6000
fax: (202) 512-6061
TDD (202) 512-2537

Each day, GAO issues a list of newly available reports and testimony. To receive facsimile copies of the daily list or any list from the past 30 days, please call (202) 512-6000 using a touchtone phone. A recorded menu will provide information on how to obtain these lists.

Orders by Internet:

For information on how to access GAO reports on the Internet, send an e-mail message with "info" in the body to:

info@www.gao.gov

or visit GAO's World Wide Web home page at:

<http://www.gao.gov>

To Report Fraud, Waste, or Abuse in Federal Programs

Contact one:

- Web site: <http://www.gao.gov/fraudnet/fraudnet.htm>
- e-mail: fraudnet@gao.gov
- 1-800-424-5454 (automated answering system)

**United States
General Accounting Office
Washington, D.C. 20548-0001**

**Official Business
Penalty for Private Use \$300**

Address Correction Requested

<p>Bulk Rate Postage & Fees Paid GAO Permit No. GI00</p>

