



March 9, 2010

TO: Francis S. Collins, M.D., Ph.D.
Director
National Institutes of Health

FROM: /Lori S. Pilcher/
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SUBJECT: National Institute of Environmental Health Sciences: Internal Control Review of the Process for Awarding American Recovery and Reinvestment Act Funds (A-04-09-01065)

The attached final report provides the results of our review of internal controls over the process for awarding American Recovery and Reinvestment Act of 2009, P.L. No. 111-5 (Recovery Act), funds at the National Institute of Environmental Health Sciences. This review was part of the Office of Inspector General's assessment of whether the Department of Health & Human Services is using Recovery Act funds in accordance with legal and administrative requirements and is meeting the accountability objectives defined by the Office of Management and Budget.

The Recovery Act was signed into law by President Obama on February 17, 2009. The Recovery Act includes measures to modernize our nation's infrastructure, enhance energy independence, expand educational opportunities, preserve and improve affordable health care, provide tax relief, and protect those in greatest need.

At the President's direction, Federal agencies are taking critical steps to carry out the Recovery Act effectively. All Federal agencies and departments receiving Recovery Act funds must maintain strong internal controls and implement oversight mechanisms and other approaches to meet the accountability objectives of the Recovery Act.

Our objective was to assess the internal controls NIEHS has in place over the grant-award process used to award Recovery Act funds and to determine whether the controls have been suitably designed.

The internal controls for awarding Recovery Act funds to grantees, as described by management, are suitably designed to provide reasonable assurance that the specified internal control objectives would be achieved if the described internal controls were complied with satisfactorily and applied as designed. However, we did not perform procedures to determine the operating effectiveness of these internal controls. Accordingly, we express no opinion on the operating

effectiveness of any aspects of NIEHS's controls for awarding Recovery Act funds, individually or in the aggregate.

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, Office of Inspector General reports generally are made available to the public to the extent that information in the report is not subject to exemptions in the Act. Accordingly, the final report will be posted on the Internet at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to contact me at (202) 619-1175 or through email at Lori.Pilcher@oig.hhs.gov. Please refer to report number A-04-09-01065 in all correspondence.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NATIONAL INSTITUTE OF
ENVIRONMENTAL HEALTH
SCIENCES: INTERNAL CONTROL
REVIEW OF THE PROCESS FOR
AWARDING AMERICAN
RECOVERY AND REINVESTMENT
ACT FUNDS**



Daniel R. Levinson
Inspector General

March 2010
A-04-09-01065

Office of Inspector General

<http://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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

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

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The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

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Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

The American Recovery and Reinvestment Act of 2009, P.L. No. 111-5 (Recovery Act), was signed into law by President Obama on February 17, 2009. The Recovery Act includes measures to modernize our nation's infrastructure, enhance energy independence, expand educational opportunities, preserve and improve affordable health care, provide tax relief, and protect those in greatest need.

Every taxpayer dollar spent on the economic recovery must be subject to unprecedented levels of transparency and accountability. The five crucial objectives for Department of Health and Human Services and its agencies are:

- Recovery Act funds are awarded and distributed in a prompt, fair, and reasonable manner.
- Recovery Act funds are transparent to the public, and the public benefits of these funds are reported clearly, accurately, and in a timely manner.
- Recovery Act funds are used for authorized purposes and every step is taken to prevent instances of fraud, error, and abuse.
- Projects funded under the Recovery Act avoid unnecessary delays and cost overruns.
- Projects funded under the Recovery Act ensure program goals are achieved, including specific program outcomes and improved results on broader economic indicators.

At the President's direction, Federal agencies are taking critical steps to carry out the Recovery Act effectively. An Office of Management and Budget memorandum (April 3, 2009) updated initial implementing Recovery Act guidance (February 18, 2009) and required that all Federal agencies and departments receiving Recovery Act funds must maintain strong internal controls implement appropriate oversight mechanisms and other approaches to meet the accountability objectives of the Recovery Act.

Recovery Act Funding for National Institute of Environmental Health Sciences Research

The Recovery Act provides \$8.2 billion to the National Institutes of Health (NIH), Office of the Director, to help stimulate the economy through the support and advancement of scientific research. Of the \$8.2 billion, \$7.4 billion is to be allocated proportionally to the NIH Institutes and Centers and \$800 million to the Office of the Director. In addition, the Recovery Act provides \$400 million for comparative effectiveness research and \$300 million for shared instrumentation. The Recovery Act funds will remain available for obligation until September 30, 2010. The National Institute of Environmental Health Sciences (NIEHS) is to receive approximately \$168 million as its proportional share, as well as a portion of the \$800 million from the Office of Director for funding extramural research.

The NIH Recovery Act Web site indicated that while NIH has broad flexibility to invest in many types of grant programs, it will follow the spirit of the Recovery Act by funding projects that will stimulate the economy, will create or retain jobs, and have the potential for making scientific progress within 2 years. NIEHS expects to:

- select recently peer-reviewed, highly meritorious research grant applications that can be accomplished in 2 years or less;
- fund new research applications;
- accelerate the tempo of ongoing science through targeted supplements to current grants;
- support new types of activities, such as the NIH Challenge Grant program, that meet the goals of the Recovery Act; and
- use other funding mechanisms as appropriate.

Research funds will be used to award grants and cooperative agreements to research entities including nonprofit and for-profit organizations, universities, hospitals, research foundations, governments and their agencies, and individuals.

OBJECTIVE

Our objective was to assess the internal controls NIEHS has in place over the grant-award process used to award Recovery Act funds and to determine whether the controls have been suitably designed.

RESULTS OF REVIEW

The internal controls over the grant-award process used to award Recovery Act funds, as described by NIEHS and NIH management, are suitably designed to provide reasonable assurance that the specified internal control objectives would be achieved if the described internal controls were complied with satisfactorily and applied as designed. However, we did not perform procedures to determine the operating effectiveness of these internal controls. Accordingly, we express no opinion on the operating effectiveness of any aspect of NIEHS's internal controls over the grant-award process used to award Recovery Act funds, individually or in the aggregate.

This report is intended to provide a sufficient understanding of NIEHS's grant process for awarding Recovery Act funds to grantees as it pertains to internal control objectives in the following internal control areas: authorization and approval; accuracy, completeness, and validity; physical safeguards and security; error handling; and segregation of duties.

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INTRODUCTION

BACKGROUND

Recovery Act Requirements

The American Recovery and Reinvestment Act of 2009, P.L. No. 111-5 (Recovery Act), was signed into law by President Obama on February 17, 2009. The Recovery Act includes measures to modernize our nation's infrastructure, enhance energy independence, expand educational opportunities, preserve and improve affordable health care, provide tax relief, and protect those in greatest need.

According to the Department of Health and Human Services (HHS) Recovery Act Web site,¹ every taxpayer dollar spent on our economic recovery must be subject to unprecedented levels of transparency and accountability. The five crucial objectives for HHS and its agencies are:

- Recovery Act funds are awarded and distributed in a prompt, fair, and reasonable manner.
- Recovery Act funds are transparent to the public, and the public benefits of these funds are reported clearly, accurately, and in a timely manner.
- Recovery Act funds are used for authorized purposes and every step is taken to prevent instances of fraud, error, and abuse.
- Projects funded under the Recovery Act avoid unnecessary delays and cost overruns.
- Projects funded under the Recovery Act ensure program goals are achieved, including specific program outcomes and improved results on broader economic indicators.

At the President's direction, Federal agencies are taking critical steps to carry out the Recovery Act effectively. An Office of Management and Budget (OMB) memorandum (April 3, 2009) updated initial implementing Recovery Act guidance (February 18, 2009) and requires that all Federal agencies and departments receiving Recovery Act funds must maintain strong internal controls and implement appropriate oversight mechanisms and other approaches to meet the accountability objectives of the Recovery Act.

National Institutes of Health and National Institute of Environmental Health Sciences

The National Institutes of Health (NIH) is the steward of medical and behavioral research for the nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.

¹Available online at <http://www.hhs.gov/recovery/reports/index.html>. Accessed on September 5, 2009.

The National Institute of Environmental Health Sciences (NIEHS) is one of the 27 Institutes and Centers included in the NIH organization and is located in Research Triangle Park, North Carolina. NIEHS's mission is to reduce the burden of human illness and disability by understanding how the environment influences the development and progression of human disease.

NIEHS grants and cooperative agreements are awarded as discretionary grants. NIEHS has the authority through NIH to determine the recipient of the grant and/or cooperative agreement and the amount awarded. NIH programs are legislatively authorized by Congress, which also issues legislative mandates regarding the use of congressional appropriations and statutory provisions that limit the use of funds on NIH programs. The head of each agency is required by law to prescribe by regulation a system of administrative controls to ensure that obligations and expenditures are limited to the amount of the appropriation. The system of controls is also designed to allow the agency head to fix responsibility for the creation of any obligation or the making of any expenditure in excess of an appropriation.

National Institutes of Health and National Institute of Environmental Health Sciences Research

The Recovery Act provides \$8.2 billion to the NIH Office of the Director to help stimulate the economy through the support and advancement of scientific research. Of the \$8.2 billion, \$7.4 billion is to be allocated proportionally to the NIH Institutes and Centers and \$800 million to the Office of the Director. In addition, the Recovery Act provides \$400 million for comparative effectiveness research and \$300 million for shared instrumentation. The Recovery Act funds will remain available for obligation until September 30, 2010. NIEHS is to receive approximately \$168 million as its proportional share, as well as a portion of the \$800 million from the Office of Director for funding extramural research.

The NIH Recovery Act Web site stated that while the NIH has broad flexibility to invest in many types of grant programs, it will follow the spirit of the Recovery Act by funding projects that will stimulate the economy, will create or retain jobs, and have the potential for making scientific progress within 2 years. NIEHS expects to:

- select recently peer-reviewed, highly meritorious research grant applications that can be accomplished in 2 years or less;
- fund new research applications;
- accelerate the tempo of ongoing science through targeted supplements to current grants;

- support new types of activities, such as the NIH Challenge Grant program,² that meet the goals of the Recovery Act; and
- use other funding mechanisms as appropriate.

Research funds will be used to award grants and cooperative agreements to research entities including nonprofit and for-profit organizations, universities, hospitals, research foundations, governments and their agencies, and individuals.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to assess the internal controls NIEHS has in place over the grant-award process used to award Recovery Act funds and to determine whether the controls have been suitably designed.

Scope

We assessed NIEHS's internal controls, and NIH's internal controls when appropriate, over the grant-award process used to award Recovery Act funds for scientific research. Our assessment was limited to determining whether existing controls adequately achieved the internal control objectives for: (1) authorization; (2) accuracy, completeness, and validity; (3) physical safeguards and security; (4) error handling; and (5) segregation of duties. We did not perform procedures to determine the operating effectiveness of these controls. Accordingly, we express no opinion on the operating effectiveness of any aspects of NIEHS's internal controls over the grant-award process used to award Recovery Act funds, individually or in the aggregate.

We performed fieldwork at NIEHS offices in Research Triangle Park, North Carolina, from May through September 2009.

Methodology

The internal control environment represents the collective effect of a number of elements in establishing, enhancing, or mitigating the effectiveness of specific policies and procedures. To gain an understanding of NIEHS's internal control environment, we:

- reviewed relevant Federal laws and regulations, including Recovery Act guidance that NIEHS must follow for awarding grants;

²Challenge grants address specific scientific and health research challenges, defined by NIH, in biomedical and behavioral research that will benefit from significant 2-year jumpstart funds.

- reviewed NIH and NIEHS's organizational structure, including segregations of functional responsibilities and policy statements;
- interviewed NIEHS management and other personnel responsible for developing and applying internal controls; and
- reviewed the grant-award process for four grants funded with Recovery Act funds.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

RESULTS OF REVIEW

The internal controls over the grant-award process used to award Recovery Act funds, as described by NIEHS and NIH management, are suitably designed to provide reasonable assurance that the specified internal control objectives would be achieved if the described internal controls were complied with satisfactorily and applied as designed.

This report provides a sufficient understanding of NIEHS's grant process for awarding Recovery Act funds to grantees as it pertains to internal control objectives in the following internal control areas:

- authorization and approval: transactions and other significant events should be authorized and executed only by persons acting within the scope of their authority;
- accuracy, completeness, and validity: all transactions should be consistent with the originating data and fairly represent the economic events that actually occurred, and no valid transactions should be omitted;
- physical safeguards and security: physical controls need to be established to secure and safeguard vulnerable assets and to limit access to resources and records to authorized individuals;
- error handling: errors detected at any stage of processing should receive prompt corrective action and be reported to the appropriate level of management; and
- segregation of duties: key duties and responsibilities need to be divided or segregated among different people to reduce the risk of error or fraud.

AUTHORIZATION AND APPROVAL

Internal Control Objective 1: Internal Controls Provide Reasonable Assurance That Grant Eligibility Requirements Are in Accordance With Laws, Regulations, Recovery Act Guidance, and Agency Policy

- NIEHS's policy is to look for grant proposals of high scientific caliber that are relevant to public health needs and are within NIEHS's priorities. Each type of NIEHS grant program has its own set of eligibility requirements. Applicants can find eligibility information in section III of each funding opportunity announcement (FOA). Eligibility requirements are primarily based on the experience of the applicant.
- NIH policy is intended to ensure that grant applications are evaluated on the basis of a process that is fair, equitable, timely, and bias-free. The NIH dual peer review system³ is mandated by statute (section 492 of the Public Health Service Act) and Federal regulations (42 CFR part 52h).
- NIH policy is to include the NIH Grants Policy Statement in all Notice of Awards as a term and condition of the award. The NIH Grants Policy Statement provides that NIH grant awards are for the reimbursement of actual and allowable costs incurred, and are subject to Federal cost principles. The cost principles are set forth in OMB Circulars A-21, A-87, and A-122; 45 CFR § 74, appendix E; and 48 CFR § 31.2 and incorporated by reference in 45 CFR §§ 74.27 and 92.22. (The notice of award terms and conditions incorporate 45 CFR parts 74 and 92, as applicable.) The cost principles address four tests to determine the allowability of costs: reasonableness, allocability, consistency, and conformance. The NIH Grants Policy Statement also includes administrative and other remedies the Federal Government may use if a grantee does not comply with requirements.

Internal Control Objective 2: Internal Controls Provide Reasonable Assurance That Information and Methods Used To Publicize the Program Are in Accordance With Laws, Regulations, Recovery Act Guidance, and Agency Policy

- OMB implementation guidance for the Recovery Act requires Federal agencies to provide information on the funding notifications made for all award types on Recovery.gov with a link to the agency's Web site. The funding notifications stem from public announcements on the amount of funds available to entities outside of the Federal Government. The notifications include funds available immediately through formula or block grants, through the solicitation of applications or proposals for award in the future, or through any other public notification. Grants, contracts, loans, loan guarantees,

³The dual peer review system used by NIH has two levels of review. The first level, the initial peer review, provides a judgment of scientific merit. The second level assesses the quality of the initial peer review, sets program priorities, and makes funding recommendations.

cooperative agreements, and other forms of assistance are all subject to this reporting requirement.

- NIEHS posts the grant eligibility requirements and research objectives on its own Web site and Grants.gov using an FOA. NIEHS's Web site is linked to Recovery.gov. FOAs are a new requirement and result in the submission of grant applications through Grants.gov. FOAs are requests for applications and are issued to invite grant applications in a well-defined scientific area and stimulate activity in the NIEHS's programmatic priority areas.
- NIH policy is to make new grantees aware of financial management system requirements through the Welcome Wagon Letter posted on the NIH Office of Extramural Research Web site and as part of the award negotiation, if applicable. NIEHS posts a link entitled "Information for New Grantees" on its Web site, which transfers users to the NIH Welcome Wagon Letter located on the NIH Web site. The Welcome Wagon Letter informs grantees that they must follow the procedures found in laws, regulations, policies, and Facilities & Administrative rate negotiations. Facilities & Administrative rate negotiation information is provided on the NIH Office of Extramural Research Web site, and NIEHS's Web site provides a link to that information as well.
- The NIH Office of Extramural Research Web site provides a multitude of resource materials that educate grantees about the cost principles and other applicable regulations and policies governing the administration of grants. NIEHS posts a link to this Web site entitled "Getting Started at NIH."

Internal Control Objective 3: Internal Controls Provide Reasonable Assurance That Grant Application Processing Procedures Are Established and in Accordance With Laws, Regulations, Recovery Act Guidance, and Agency Policy

- NIH policy is to evaluate submitted grant applications in a fair, equitable, timely, and bias-free manner. The NIH dual peer review system is mandated by statute (section 492 of the Public Health Service Act) and Federal regulations (42 CFR part 52h).
- As required, applications are processed through two levels of review and assigned a numerical ranking. The initial peer review⁴ assesses each application's scientific and technical merit. Using established criteria, the initial peer review group prepares an evaluation and gives the application a score (or ranking). The second level of review is performed by the National Environmental Health Sciences Council (Council). The Council approves grant applications that meet the NIEHS's goals, ranks the applications from the most meritorious to the least, and recommends a funding amount. The results of

⁴Depending on the grant assignment, initial peer review meetings are administered by either the Center for Scientific Review or by NIEHS.

the initial peer review and the council are recorded in the NIH Information for Management, Planning, Analysis, and Coordination (IMPAC) II system.⁵

- The NIH Grants Cycle Memorandum states that before awarding a grant, Grants Management staff will use a checklist to ensure that administrative requirements have been addressed. The Grants Management staff will also determine whether the grant was funded in rank order. For all new and competing continuation awards, Congress must be alerted at least 72 hours before the grant is awarded. The Grants Management Officer, an NIEHS employee, approves the Notice of Grant Award, which is sent to the grantee.

Internal Control Objective 4: Internal Controls Provide Reasonable Assurance That Grantee Procedures for Control, Use, and Reporting of Grant-Funded Operations Are in Accordance With Laws, Regulations, Recovery Act Guidance, and Agency Policy

- NIEHS requires grantees to meet the standards and requirements for financial management systems set forth or referenced in 45 CFR §§ 74.21 or 92.20, as applicable. Requirements for grantees' financial and administrative systems are included in the NIH Grants Policy Statement. NIEHS grant-award terms and conditions are included in 45 CFR parts 74 and 92, as well as in the NIH Grants Policy Statement by reference.
- NIEHS may impose corrective actions and/or include special conditions on awards or may suspend, terminate, or withhold support.

Internal Control Objective 5: Internal Controls Provide Reasonable Assurance That Grant Requirements Are Noted and in Place

- The Authorized Organization Representative's signature on the grant application is to ensure that the applicant organization will be accountable both for the appropriate use of funds awarded and for the performance of the grant-supported project or other activities resulting from the application. The Authorized Organization Representative is also responsible to NIEHS for ensuring that the organization complies with the terms and conditions of individual awards and organizationwide requirements, such as those concerning financial management and property management.
- A grantee acknowledges and accepts an NIEHS award and its associated terms and conditions by drawing down or requesting funds made by the Notice of Award. Once the award is accepted by the grantee, the terms and conditions of the Notice of Award are binding.

⁵IMPAC is a computer database system developed and maintained by the Office of Extramural Research for information concerning extramural programs. IMPAC II is the successor to NIH's original IMPAC information management system.

ACCURACY, COMPLETENESS, AND VALIDITY

Internal Control Objective 1: Internal Controls Provide Reasonable Assurance That Program Objectives Are Achieved in an Economical and Efficient Manner

- The Council reviews applications not only for appropriate initial peer review recommendations but also for relevance to the NIEHS's programs, priorities, and funding. The Council may concur with the results of the initial peer review and approve the grant award or return the grant application to the initial peer review group for further review.

Internal Control Objective 2: Internal Controls Provide Reasonable Assurance That Procedures Used To Process and Approve Grant Applications and Related Transactions Are Efficient

- NIH is replacing paper grant applications with electronic applications and has begun the transition for requiring electronic submission of grant applications via the online portal of Grants.gov.
- NIH requires that submitted applications undergo checks at Grants.gov and at NIH. The Grants.gov checks ensure that no viruses are attached to the application and the Date Universal Numbering System (DUNS) number is correct.⁶ At NIH, the application is checked against an application evaluation checklist. If there are no errors, NIH assembles the entire application in the NIH eRA Commons.
- NIH provides the submitting organization's business official (the signing official) and the principal investigator 2 days to view the application before it goes to the Division of Receipt and Referral for processing.

Internal Control Objective 3: Internal Controls Provide Reasonable Assurance That the Agency Has Mechanisms in Place To Timely Award Grant and Contract Funds

- From the Recovery Act funds, NIEHS will try to fund grant applications that were approved in fiscal year 2008 but not funded. Recovery Act grants must be awarded in short timeframes and obligated within 2 years.

⁶The DUNS is a unique nine-digit number assigned by Dun and Bradstreet Information Services. It is the universal standard for identifying and keeping track of more than 92 million businesses worldwide. Grants.gov requires a DUNS number for registration. For applicants, the DUNS number in the application must match the DUNS number in the Institutional Profile in the Electronic Research Administration (eRA) Commons. The eRA Commons is a secure meeting place on the Web where research organizations and grantees electronically receive and transmit information about the administration of biomedical and behavioral research grants. The eRA Commons allows applicants to access the status of their applications; grantees can access the status of their awards, submit reports, and make requests electronically.

Internal Control Objective 4: Internal Controls Provide Reasonable Assurance That Only Those Grant Requests That Meet the Eligibility Requirements Are Approved

- NIH policy states that organizations and individuals that are suspended, debarred, or voluntarily excluded from eligibility cannot receive NIH grants or be paid from NIH grant funds. It specifies that charges made to NIH grants for such individuals are unallowable. It also requires that grants management staff verify whether the applicant, proposed Principal Investigator, or other key personnel are debarred or suspended from participation in Federal assistance programs before issuing a grant.
- NIH policy requires the Grants Management Officer to certify that all applicable requirements for an independent, competitive review have been carried out before funding the grant application.
- NIH grants policy states that, before awarding the grant, the Grants Management Office should review the application for indication of inadequate administrative systems and to ensure that applications have been approved. When necessary, particularly for new organizations, grants management staff should request and review grantee administrative policies and financial statements.

Internal Control Objective 5: Internal Controls Provide Reasonable Assurance That Grantee Records Are Periodically Substantiated and Evaluated

- Pursuant to OMB Circular A-133 and 45 CFR § 74.26, grantees that expend more than \$500,000 in a fiscal year are required to obtain audits of their organizations' operations annually from private accounting firms.
- NIH Grants Policy Statement says that Grants Management Officers and Program Officials will use reports, correspondence from the grantee, site visits, and other available information to monitor costs and performance results and to identify areas where technical assistance or enforcement action may be necessary.

PHYSICAL SAFEGUARDS AND SECURITY

Internal Control Objective 1: Internal Controls Provide Reasonable Assurance That Access to Grant and Accounting Records, Critical Forms, Processing Areas, and Processing Procedures Are Permitted Only in Accordance With Policy

- NIH maintains an agencywide security program to safeguard and secure access to records. The "NIH Fiscal Year 2008 Improper Payments Information Act Risk Assessment" (risk assessment) noted that security policies were updated to align with new OMB, National Institute of Standards and Technology, and HHS policies and guidance. The risk assessment also noted that the Enterprise Master Information Technology Security Plan, which implements relevant Federal laws, regulations, and policies, was recently revised. Finally, the risk assessment noted the revision of the information technology security language for contracts and acquisitions compliance with

the Federal Information Security Management Act (FISMA) and contractor security oversight.

Internal Control Objective 2: Internal Controls Provide Reasonable Assurance That Valuable Assets and Information Are Safeguarded From Unauthorized Access or Use

- NIH officials told us that NIH has actively addressed security issues by providing frequent training to staff. NIH has worked with HHS to develop role-based training for personnel with significant security responsibilities to comply with OMB requirements. NIH also recently updated its security awareness course, which is an annual requirement for all personnel who use information systems.
- NIH has a number of internal controls in place to ensure the safeguarding and security of data. NIH maintains an offsite server to provide backup and recovery of data. It implemented an automated Web-based application called NIH Certification and Accreditation Tool that it uses for managing and tracking the inventory of information systems. The certification and accreditation is to be performed for 100 percent of FISMA systems, including systems that are critical infrastructure. Certification and accreditation ensures that safeguards are implemented effectively and commensurate with risks. NIH also implemented the HHS Security & Privacy Online Reporting Tool for tracking FISMA information.

ERROR HANDLING

Internal Control Objective 1: Internal Controls Provide Reasonable Assurance That the National Institutes of Health Accurately and Promptly Classifies, Summarizes, and Reports Adjustments to Grant Application Information and Records

- NIH allows applicants the opportunity to correct errors identified during the application process and submit the corrected information through [Grants.gov](https://www.grants.gov) within a specified timeframe.
- When NIH identifies an error, its policy is for the application process to immediately stop. The applicant is either notified of the error or given a warning. A warning alerts the applicant to the less-than-ideal condition. Correcting the error allows an application to proceed.

SEGREGATION OF DUTIES

Internal Control Objective 1: Internal Controls Provide Reasonable Assurance That Opportunities for an Individual To Both Cause and Conceal Errors Are Reduced

- Scientific Review Administrators provide both the scientific review experience and scientific expertise for the competitive review process.

- Grants Management Officers serve as the receipt and distribution point for prior approval requests, progress reports, and other reports required by the terms and conditions of the Notice of Grant Award.
- Program Officials establish or participate in the establishment of goals for new programs and plans of action for implementation.
- Program Officials evaluate the submissions for appropriateness to solicitation topics, and the Grants Management Officer determines compliance with policy, regulations, and guidelines.