




SEP 21 2009

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

FROM: Joseph E. Vengrin 
Deputy Inspector General for Audit Services

SUBJECT: National Institutes of Health—Internal Control Review of the Process for Awarding American Recovery and Reinvestment Act Funds (A-05-09-00064)

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 Institutes of Health. This review was part of the Office of Inspector General's assessment of whether the Department of Health and 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 NIH has in place over the grants-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 NIH's internal 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 call me or your staff may contact Lori S. Pilcher, Assistant Inspector for Grants, Internal Activities, and Information Technology Audits at (202) 619-1175 or through email at Lori.Pilcher@oig.hhs.gov. Please refer to report number A-05-09-00064 in all correspondence.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NATIONAL INSTITUTES OF
HEALTH—INTERNAL CONTROL
REVIEW OF THE PROCESS FOR
AWARDING AMERICAN
RECOVERY AND REINVESTMENT
ACT FUNDS**



Daniel R. Levinson
Inspector General

September 2009
A-05-09-00064

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:

Office of Audit Services

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.

Office of Evaluation and Inspections

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.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

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.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <http://oig.hhs.gov>

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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 the 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 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 Scientific 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.

- 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 the NIH Certification and Accreditation Tool that it uses for managing and tracking the inventory of information systems. The certification and accreditation is 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 resubmit the corrected information through [Grants.gov](https://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 the 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 reception 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 are required by NIH to evaluate the submissions for appropriateness to solicitation topics, and the Grants Management Officer determines compliance with policy, regulations, and guidelines.

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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. NIH 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 occasionally individuals. The application, review, and award process is similar for grants supported under the Scientific Research, Comparative Effectiveness Research, and Shared Instrumentation programs.

OBJECTIVE

Our objective was to assess the internal controls NIH has in place over the grants-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 grants-award process used to award Recovery Act funds, as described by 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 NIH's internal controls over the grants-award process used to award Recovery Act funds, individually or in the aggregate.

This report is intended to provide a sufficient understanding of NIH'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 the 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.
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- Recovery Act funds are used for authorized purposes and every step is taken to prevent instances of fraud, error, and abuse.
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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

¹<http://www.hhs.gov/recovery/reports/index.html>, accessed June 25, 2009.

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 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. NIH 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 occasionally individuals. The application, review, and award process is similar for grants supported under the Scientific Research, Comparative Effectiveness Research, and Shared Instrumentation programs.

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. Research supported through the issuance of grants and cooperative agreements enables NIH to fulfill its mission. The NIH organization includes Institutes and Centers, each with its own mission and functions, separate appropriations, and statutory authorities.

Office of Policy for Extramural Research Administration

The NIH Office of Policy for Extramural Research Administration provides guidance relating to the laws, regulations, and policies pertinent to the administration of NIH grants. The Institutes and Centers are expected to comply with these grant requirements and, because of research specifications, may implement additional requirements.

²Challenge grants address specific scientific and health research challenges, as defined by NIH, in biomedical and behavioral research that will benefit from a significant 2-year jump start to funding.

The NIH “Grants Narrative Process Cycle Memorandum” states that NIH is to make awards to organizations that are competently managed, responsible, and committed to achieving the objectives of awarded grants. Grants management officials, including staff from the Office of Policy for Extramural Research Administration, are responsible for recognizing at-risk (high-risk) organizations, determining the appropriateness of issuing awards to such organizations, and safeguarding grant funds made to these grantees by instituting special award conditions, as appropriate.

Grants and Cooperative Agreements

NIH grants and cooperative agreements are awarded as discretionary grants. NIH has the authority to determine the recipient of the grant and/or cooperative agreement and the amount awarded. NIH programs are legislatively authorized by Congress, which also defines, for example, their purpose and policy, authorization of appropriations, allotment of funds, and limitation on assistance.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

We assessed NIH’s internal controls over the grants award process used to award Recovery Act funds for scientific research, shared instrumentation, and comparative effectiveness research. Our assessment was limited to determining whether existing internal 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 performed fieldwork at NIH offices in Bethesda, Maryland, from May through July 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 NIH’s internal control environment, we:

- reviewed relevant Federal laws and regulations, including Recovery Act guidance issued by the Office of Management and Budget, that NIH must follow for awarding grants;
- reviewed NIH’s organizational structure, including segregations of functional responsibilities, policy statements, operating manuals, and personnel policies;

- interviewed NIH management as well as operations, administrative, and other personnel responsible for developing, assuring adherence to, and applying internal controls; and
- reviewed the grant-award process for three 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 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 NIH's internal controls over the grant-award process used to award Recovery Act funds, individually or in the aggregate.

This report provides a sufficient understanding of NIH'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.

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

- NIH's policy is to look for grant proposals of high scientific caliber that are relevant to public health needs and are within NIH Institutes' and Centers' priorities. Each type of NIH 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 believes it evaluates grant applications by 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 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, cooperative agreements, and other forms of assistance are all subject to this reporting requirement.
- NIH requires each Institute and Center to post the grant eligibility requirements and research objectives on its own Web site and Grants.gov using a FOA. Each 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 NIH Institutes' or Centers' 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, through NIH education and outreach activities, and as part of the award negotiation, if applicable. The Welcome Wagon Letter informs grantees that they must follow the procedures authorized in accordance with laws, regulations, policies, and

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.

Facilities & Administrative rate negotiations. Facilities & Administrative rate negotiation information is provided on the NIH Office of Extramural Research Web site.

- 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. NIH staff also provide policy interpretation and consultation to the grantee community.

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's policy is to evaluate 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 advisory council of the potential awarding Institute or Center. The advisory council approves grant applications that meet the Institute's or Center's goals, ranks the applications from the most meritorious to the least, and recommends a funding amount. The results of the initial peer review and the advisory council review are recorded in the NIH IMPAC II system.⁵
- Before awarding a grant, NIH requires Grants Management staff to use a checklist to ensure that administrative requirements have been addressed, including 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 Specialist, an NIH 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

- NIH 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.

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

⁵Information for Management, Planning, Analysis, and Coordination (IMPAC) 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.

Requirements for grantees' financial and administrative systems are included in the NIH Grants Policy Statement and posted on the Grants Management Infonet as a resource for Grants Management staff.

- NIH may impose corrective actions and/or include special conditions on awards or suspend, terminate, or withhold support. Questionnaires are posted on the Grants Management Infonet as a resource for Grants Management staff to use when evaluating the grantee's financial and administrative systems.

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 NIH for ensuring that the organization complies with the terms and conditions of individual awards and organization-wide requirements, such as those concerning financial management and property management.
- A grantee acknowledges and accepts an NIH 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.

ACCURACY, COMPLETENESS AND VALIDITY

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

- NIH requires that advisory councils review applications not only for appropriate initial peer review recommendations but also for relevance to the Institutes' or Centers' programs, priorities, and funding. The advisory 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 through [Grants.gov](https://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 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

- NIH intends to use some of its Recovery Act funds for 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. NIH officials told us it will allocate additional staff as needed to address the increased number of grant applications.

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

- NIH policy requires that grants management staff review the HHS National External Audit Resources alert listing and the General Services Administration Listing of Parties Excluded From Federal Procurement and Non-Procurement 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.
- Before awarding the grant, NIH requires its Grants Management staff to review the application for indication of inadequate administrative systems in the applicant and to ensure that applications have been approved. When necessary, particularly for new organizations, grants management staff will request and review grantee administrative policies and financial statements.

⁶Date Universal Numbering System (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 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 organization's operations annually from private accounting firms. Additionally, NIH conducts technical site visits and educational outreach seminars to educate staff and to enhance administrative oversight of sponsored research.
- NIH Grants Management Officers and Program Officials use reports, correspondence from the grantee, audit reports, site visits, and other available information to monitor cost and performance results, identify potential problems, and identify areas where technical assistance or enforcement action may be necessary.
- The Office of Management Assessment reviews allegations concerning misspending of NIH grant funds and reports its findings to NIH management officials, including those in the Office of Extramural Research. Office of Management Assessment reports usually contain an assessment of internal controls in effect at the grantee organization, with recommendations for system improvements.

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 agency-wide 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 that the information technology security language for contracts and acquisitions compliance with the Federal Information Security Management Act (FISMA) and contractor security oversight was also revised.

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 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 the NIH Certification and Accreditation Tool that it uses for managing and tracking the inventory of information systems. The certification and accreditation is 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 resubmit the corrected information through [Grants.gov](https://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 the 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 reception 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 are required by NIH to evaluate the submissions for appropriateness to solicitation topics, and the Grants Management Officer determines compliance with policy, regulations, and guidelines.