

GAO

Report to the Ranking Member,  
Committee on Finance, U.S. Senate

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September 2009

# NATIONAL INSTITUTES OF HEALTH

## Completion of Comprehensive Risk Management Program Essential to Effective Oversight



GAO

Accountability \* Integrity \* Reliability

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Highlights of [GAO-09-687](#), a report to the Ranking Member, Committee on Finance, U.S. Senate

## Why GAO Did This Study

The National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS), is the primary federal agency for supporting medical research. The Office of the Director (OD) is the central NIH office responsible for setting policy and overseeing NIH's 27 institutes and centers (IC). Allegations involving one institute raised questions about areas of oversight by the OD. In light of these questions, GAO examined (1) how NIH makes extramural research funding decisions and OD monitoring of this process, (2) the design of selected internal controls over NIH's travel and personnel appointment processes, and (3) the design of NIH's new risk management program and the program it is replacing. To address these objectives, GAO reviewed relevant NIH policies, procedures, and supporting documentation. GAO also selected 3 institutes that varied in size for in-depth reviews.

## What GAO Recommends

To help improve oversight, GAO made three recommendations to the Director of NIH: (1) monitor the extent to which IC directors use discretion in funding decisions, (2) add key components to the Enterprise Risk Management Program, and (3) ensure implementation of the program. HHS disagreed with the first recommendation, partially concurred with the second recommendation, and identified a final date for implementation of the program.

[View GAO-09-687](#) or [key components](#). For more information, contact Linda T. Kohn at (202) 512-7114 or [kohnl@gao.gov](mailto:kohnl@gao.gov) or Susan Ragland at (202) 512-8486 or [raglands@gao.gov](mailto:raglands@gao.gov).

# NATIONAL INSTITUTES OF HEALTH

## Completion of Comprehensive Risk Management Program Essential to Effective Oversight

### What GAO Found

NIH is required by law to make its extramural research funding decisions—funding provided to scientists external to NIH such as those at universities—using a dual peer review system. During the first level, initial peer review groups assess applications and assign a score to them based on their scientific merit. During the second level, advisory councils review the applications and their scores and, on the basis of this review, recommend to the ICs certain applications for funding consideration. IC directors can use their discretion and choose to fund applications based on factors in addition to scientific merit, “skipping” over applications with higher scores or making “exceptions” to fund applications with lower scores. GAO found that in fiscal year 2007, IC directors funded about 19 percent of NIH's applications for a common type of grant based on factors in addition to scientific merit. However, the NIH OD does not monitor the extent to which IC directors use such discretion when making extramural funding decisions—an action that would be consistent with federal internal control standards.

The NIH OD has established policies and procedures that incorporate key internal controls into the travel and personnel appointment processes. For example, the processes require multiple levels of review and approval. However, there is not an NIH-wide process for risk-based monitoring of the effectiveness of controls. Without monitoring actual implementation of controls based on assessed risk levels, NIH does not have adequate assurance that controls are operating as intended within those areas that have been identified as posing risks to the agency's ability to achieve its mission.

NIH's Management Control Program, a risk management program updated in 2004, did not comprehensively address risks to the agency's overall operations and resulted in a lack of sufficient information for effective oversight and agencywide risk management. Recognizing this, in 2006, NIH began designing a new risk management program, the Enterprise Risk Management Program. Although an improvement over the earlier program, the design of the new program does not fully address the components identified in GAO's framework for effective risk management. For example, the design does not incorporate strategic goals and objectives as a precondition for risk management, the evaluation of alternative responses to address identified risks, or documentation of the rationale for selecting a risk response. Further, NIH's new program is not yet fully implemented, despite an over 3-year effort. According to NIH officials, NIH has experienced delays because of a change in contractors, balancing staff resources with competing demands, and underestimating time needed for implementation.

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# Contents

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## Letter

Background	5
NIH Is Required to Use a Peer Review System to Make Extramural Funding Decisions; NIH's OD Does Not Monitor Key Decisions in which IC Directors Exercise Their Discretion Over Funding	9
Design of NIH's Travel and Personnel Appointment Processes Includes Key Control Activities and Some Monitoring Activities but Lacks Systemic Risk-Based Monitoring	15
NIH's Management Control Program and Enterprise Risk Management Program Do Not Fully Address Key Components of Effective Risk Management	17
Conclusions	25
Recommendations for Executive Action	26
Agency Comments and Our Evaluation	27

---

<b>Appendix I</b>	<b>Scope and Methodology</b>	34
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<b>Appendix II</b>	<b>NIH Organization and Mission</b>	39
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<b>Appendix III</b>	<b>Comments from the National Institutes of Health</b>	45
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<b>Appendix IV</b>	<b>GAO Contacts and Staff Acknowledgments</b>	62
--------------------	---	----

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## Tables

Table 1: Extramural Research R01 Grant Applications Funded in Fiscal Years 2003 through 2007	13
Table 2: GAO's Risk Management Framework	19
Table 3: Overview of ICs Including Establishment Date, Mission, and Fiscal Year 2008 Appropriation	42

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## Figures

Figure 1: Relationship of the Risk Management Framework Components	8
Figure 2: National Cancer Institute's Fiscal Year 2007 Payline for R01 Grant Applications	12
Figure 3: Organizational Structure of NIH	40

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## Abbreviations

CSR	Center for Scientific Review
COSO	Committee of Sponsoring Organizations
GPRA	Government Performance and Results Act
HHS	Department of Health and Human Services
IC	institutes and centers
NCI	National Cancer Institute
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
OD	Office of the Director
OMB	Office of Management and Budget

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United States Government Accountability Office  
Washington, DC 20548

September 11, 2009

The Honorable Charles E. Grassley  
Ranking Member  
Committee on Finance  
United States Senate

Dear Senator Grassley:

The National Institutes of Health (NIH) is the primary federal agency for supporting medical research in the United States. In fiscal year 2008, NIH provided \$24.4 billion—83 percent of its \$29.5 billion budget—in extramural research funding, which supports scientists and research personnel working at universities, medical schools, and other research institutions.<sup>1</sup> NIH's extramural research funding efforts reflect its large, decentralized organization. NIH comprises 27 institutes and centers (IC) and an Office of the Director (OD). Each of the ICs has its own budget, mission, and staff and focuses on particular diseases or research areas, such as cancer or aging issues. Twenty-four of the 27 ICs fund extramural research, each with a separate appropriation,<sup>2</sup> and these ICs make final decisions on which extramural research projects to fund following a standard process defined by law and NIH policy. As the central office at NIH, the OD establishes NIH policy and is responsible for overseeing the ICs, including their research funding efforts and their various administrative functions, such as hiring personnel and approving personnel travel. The OD's oversight responsibilities have grown over the years. Between 1985 and 2000, 7 of the 27 ICs were created—and these additions have helped to increase the overall complexity of overseeing the ICs. More recently, under the American Recovery and Reinvestment Act of 2009, NIH received \$10.4 billion that NIH plans to use in 2009 and 2010 to fund extramural and other research and support the construction, renovation, and repair of certain research facilities.

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<sup>1</sup>NIH also supports intramural research, which is performed by NIH scientists in NIH laboratories.

<sup>2</sup>The three centers that do not fund extramural research and do not receive separate appropriations (Center for Scientific Review, Center for Information Technology, and the Clinical Center) are funded through the NIH Management Fund, which is funded using a portion of other NIH appropriations. See 42 U.S.C. § 290.

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We and others have raised questions about the OD's ability to effectively oversee IC activities. For example, in April 2007, we reported that NIH had not established clear policies related to managing conflicts of interest among senior NIH employees who have decision-making responsibilities for NIH's research efforts,<sup>3</sup> which include NIH's extramural research funding. We noted that such policies are part of NIH's framework for ensuring the integrity of NIH-funded research and recommended that NIH clarify them. NIH agreed with our recommendation. In mid-2007 you raised questions over allegations of improper travel, personnel appointments, and extramural research funding decisions involving the director of one of NIH's ICs, the National Institute of Environmental Health Sciences (NIEHS), which supports research on environmental influences on the development and progression of human disease. Similar questions prompted the House Committee on Appropriations to request that NIH conduct a management review of NIEHS, which found management and operational problems at the Institute.<sup>4</sup>

The above issues focus on how NIH makes extramural funding decisions and the quality of its internal control over administrative functions such as travel arrangements and personnel appointments. Internal control can include the establishment of safeguards, such as supervisory reviews, that are incorporated into agency work processes. According to federal standards, effectively designed and implemented internal control provides reasonable assurance that an agency's operations are effective and efficient, its financial reporting reliable, and that the agency complies with applicable laws and regulations.<sup>5</sup> The issues at NIH also raise broader questions about NIH's risk management, the process whereby an agency or organization systematically identifies risks associated with achieving its mission or objectives; assesses the magnitude of those risks; puts in place, when necessary, mitigating actions to address those risks; and then monitors the effectiveness of those actions. During our review, NIH was in the process of implementing its Enterprise Risk Management Program, a new risk management program that is replacing the NIH Management Control Program—the agency's previous risk management program.

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<sup>3</sup>GAO, *NIH Conflict of Interest: Recusal Policies for Senior Employees Need Clarification*, [GAO-07-319](#) (Washington, D.C.: Apr. 30, 2007).

<sup>4</sup>H.R. Rep. No. 110-231, at 161-62 (2007); NIH Office of Management Assessment, *Management Review: National Institute of Environmental Health Sciences* (Apr. 9, 2008).

<sup>5</sup>GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999).

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You asked us to examine NIH's oversight of the ICs. Specifically, we agreed to provide information on NIH's extramural research funding decisions, employee travel arrangements and hiring practices for certain employees, and NIH's process for identifying and addressing potential risks to its operations. In this report we

1. describe how NIH makes extramural research funding decisions and the extent to which the NIH's OD monitors this process,
2. review the design of selected internal controls over NIH's travel and personnel appointment processes, and
3. review the design of the NIH Management Control Program and the Enterprise Risk Management Program to determine if they contain key components of an effective risk management program.

To address these objectives, we reviewed relevant NIH policies, procedures, and supporting documentation on (1) the process used across NIH for making extramural research funding decisions and efforts by the OD to monitor this process, (2) the design of key internal controls for employee travel and Title 42 personnel appointments<sup>6</sup>—specifically, control and monitoring activities—and (3) the design of the NIH Management Control Program and the Enterprise Risk Management Program. We also selected 3 ICs—the National Cancer Institute (NCI), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and National Institute on Alcohol Abuse and Alcoholism (NIAAA)—for more in-depth reviews of the process used across NIH for making extramural research funding decisions and for more in-depth reviews of the design of the ICs' control and monitoring activities for travel and Title 42 personnel appointment processes. We selected these 3 ICs because they vary in size and focus on different disease-specific research missions. We interviewed officials from the NIH OD and the selected ICs to clarify our understanding of the process used for making extramural research funding decisions and the OD's monitoring of this process. We also collected data

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<sup>6</sup>Under two provisions of title 42 United States Code, NIH has additional hiring flexibilities not permitted under title 5 authorities related to the general schedule and senior executive service. These flexibilities are referred to as "title 42" personnel appointments. Specifically, title 42 authorities allow NIH to hire scientists at salary levels comparable to those outside of the federal government. In 2008, under these authorities, NIH could hire scientists with salary levels up to \$250,000. However, maximum pay for the general schedule was \$149,000 and for the senior executive service was \$172,200 in 2008. See 42 U.S.C. § 209 (f), (g).

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on funding decisions for each of the 24 ICs that fund extramural research.<sup>7</sup> We performed walkthroughs<sup>8</sup> at the 3 selected ICs and interviewed officials from the NIH OD and the selected ICs to clarify our understanding of the design of the ICs' control and monitoring activities for travel and Title 42 personnel appointment processes. We also interviewed officials from the NIH OD to further our understanding of the NIH Management Control Program and the Enterprise Risk Management Program.

As part of our review, we compared the OD's monitoring of the process used for making extramural research funding decisions and the design of the control and monitoring activities at the three selected ICs to GAO's *Standards for Internal Control in the Federal Government*.<sup>9</sup> In reviewing the design of the NIH Management Control Program and the Enterprise Risk Management Program, we compared these designs to our framework for effective risk management.<sup>10</sup> The scope of our audit did not include testing the implementation of internal control over travel and Title 42 personnel appointments. Furthermore, we did not review the implementation of either the NIH Management Control Program or the Enterprise Risk Management Program because, at the time of our review, NIH did not plan to continue the Management Control program and the Enterprise Risk Management Program was not yet fully implemented.

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<sup>7</sup>Specifically, we reviewed funding decisions made for R01 grants, the original grant mechanism used by NIH, which is a common type of grant awarded to organizations of all types (universities, colleges, small businesses, for-profit, foreign and domestic, etc.) to support a discrete, specified project to be performed by a specific investigator or group of investigators.

<sup>8</sup>A walkthrough is a method used to develop an understanding of key processes and controls in which an auditor traces a transaction through the organization's procedures.

<sup>9</sup>See [GAO/AIMD-00-21.3.1](#).

<sup>10</sup>See table 2 for GAO's framework for effective risk management. GAO developed the framework based on authoritative literature and standards, as well as previous GAO reports and testimonies. We consulted the Government Performance and Results Act (GPRA) of 1993; the Government Auditing Standards, 2003 Revision; GAO's *Standards for Internal Control in the Federal Government* (November 1999); guidance from the Office of Management and Budget (OMB); the work of the President's Commission on Risk Management; consulting papers; and the enterprise risk management approach of the Committee of Sponsoring Organizations (COSO) of the Treadway Commission. We reviewed numerous frameworks from industry, government, and academic sources. GAO, "Appendix I: A Risk Management Framework" of *Risk Management: Further Refinements Needed to Assess Risks and Prioritize Protective Measures at Ports and Other Critical Infrastructure*, [GAO-06-91](#) (Washington, D.C.: Dec. 15, 2005).



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Appendix I includes additional details on our scope and methodology. We conducted this performance audit from March 2008 to September 2009, 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 objectives.

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## Background

As the primary federal agency for supporting medical research in the United States, NIH's 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." NIH is headed by a Director who is supported by staff and program offices within the OD and 27 ICs. Each of the ICs has its own director and staff. Each IC director reports to the OD.<sup>11</sup> Appendix II provides more information about NIH's organizational structure.

NIH's ICs were created over time, with each having an explicit mission focused on a particular disease, organ system, stage of development, or cross-cutting mission, such as providing scientists and researchers with the tools they need to understand, detect, treat, and prevent a wide range of diseases. The first institute, NCI, was created in 1937, and the newest institute, National Institute of Biomedical Imaging and Bioengineering, was created in 2000.

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## Internal Control

Internal control is an integral part of managing an agency.<sup>12</sup> It comprises the plans, methods, and procedures used to meet missions, goals, and objectives. Effectively designed and implemented internal control provides management with reasonable assurance that the following objectives are being achieved: (1) effectiveness and efficiency of operations, (2) reliability of financial reporting, and (3) compliance with

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<sup>11</sup>The Director of NIH is appointed by the President, with Senate confirmation. The President also appoints the director of NCI, while the Secretary of the Department of Health and Human Services (HHS) appoints the other IC directors.

<sup>12</sup>See [GAO/AIMD-00-21.3.1](#).

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applicable laws and regulations.<sup>13</sup> Internal control serves as the first line of defense in preventing and detecting errors and fraud. The following five elements of internal control provide the basis against which internal control is evaluated.

- **Control Environment**—Sets the tone for an organization and is the foundation for all other standards. Management and employees should establish and maintain an environment throughout the organization that sets a positive and supportive attitude toward internal control and conscientious management. Among others, control environment includes management’s integrity and ethical values, commitment to competence, philosophy and operating style, and organizational structure.
- **Risk Assessment**—The identification and analysis of relevant risks associated with achieving the objectives and forming a basis for determining how risks should be managed. This standard includes an assessment of the risks the agency faces from both external and internal sources.
- **Control Activities**—The policies, procedures, techniques, and mechanisms that enforce management’s directives. Control activities occur at all levels and functions of the agency and include a wide range of diverse activities such as approvals, authorizations, verifications, and reconciliations.
- **Information and Communication**—Information should be recorded and communicated to management and others within the entity who need it and in a form and within a time frame that enables them to carry out their internal control and other responsibilities. In addition to internal communications, management should ensure there are adequate means of communicating with, and obtaining information from, external stakeholders that may have a significant impact on the agency achieving its goals.
- **Monitoring**—Includes ongoing monitoring in the course of normal operations (e.g., regular management and supervisory activities, comparisons, and reconciliations) and risk-based monitoring that includes separate evaluations of controls’ effectiveness whose scope and frequency depends primarily on the assessment of risks and effectiveness of ongoing monitoring procedures.

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<sup>13</sup>See 31 U.S.C. § 3512(c).

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## Risk Management

One way to help ensure that internal control is continuously monitored and improved is through risk management. Risk management helps agencies to identify the most significant areas in which to place or enhance controls.<sup>14</sup> Additionally, based on the assessment of risk that is performed as part of an overall risk management program, agencies can determine the scope and frequency of control evaluations. Risk management is a continuous process whereby an organization systematically identifies risks associated with achieving its objectives; assesses the magnitude of those risks; puts in place, when necessary, mitigating actions to address those risks; and then monitors the effectiveness of those actions taken. In addition, because governmental, economic, industry, regulatory, and operating conditions continually change, risk management provides a mechanism to identify and deal with any special risks prompted by such changes. While risk management programs do not provide absolute assurance regarding the achievement of an agency's objectives, an effective risk management program can be particularly useful in a decentralized organization to help top management identify potential problems and allocate limited resources using a reasonable basis (such as risk).

In 2005, GAO identified risk management as an area of increasing concern, particularly with regard to the need for the completion of threat and risk assessments in a variety of areas.<sup>15</sup> To help address the concern, GAO developed a framework for effective risk management activities in the federal government based on best practices and authoritative literature.<sup>16</sup> This framework includes five components that define a risk management

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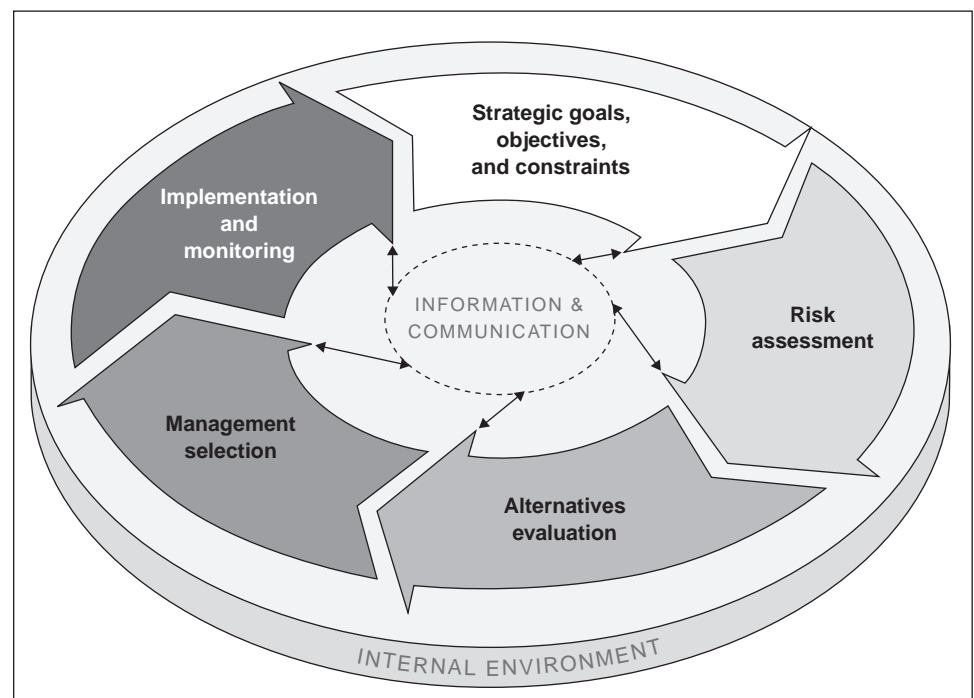
<sup>14</sup>Risk management does not replace, but rather incorporates and expands on internal control. Thus, risk management provides a more robust and extensive focus to effectively identify, assess, and manage risk.

<sup>15</sup>GAO, *High-Risk Series: An Update*, [GAO-05-207](#) (Washington, D.C.: January 2005).

<sup>16</sup>See table 2. GAO developed the framework based on authoritative literature and standards, as well as previous GAO reports and testimonies. We consulted the Government Performance and Results Act (GPRA) of 1993; the Government Auditing Standards, 2003 Revision; GAO's *Standards for Internal Control in the Federal Government* (November 1999); guidance from the Office of Management and Budget (OMB); the work of the President's Commission on Risk Management; consulting papers; and the enterprise risk management approach of the Committee of Sponsoring Organizations (COSO) of the Treadway Commission. We reviewed numerous frameworks from industry, government, and academic sources. GAO, "Appendix I: A Risk Management Framework" of *Risk Management: Further Refinements Needed to Assess Risks and Prioritize Protective Measures at Ports and Other Critical Infrastructure*, [GAO-06-91](#) (Washington, D.C.: Dec. 15, 2005).

program for federal agencies: strategic goals, objectives, and constraints; risk assessment; alternatives evaluation; management selection; and implementation and monitoring. For the purposes of our analysis of NIH's program, we also considered two additional components, internal environment and information and communications, based on guidance and standards on risk management and internal controls.<sup>17</sup> Figure 1 illustrates the interrelationship of these seven components. The components of the framework should operate within an internal environment that supports the other components, and pertinent information should be communicated between and among internal and external stakeholders as well as personnel responsible for carrying out the duties associated with each of the components.

**Figure 1: Relationship of the Risk Management Framework Components**



Source: GAO.

<sup>17</sup>The Committee of Sponsoring Organizations of the Treadway Commission, *Enterprise Risk Management—Integrated Framework* (Jersey City, N.J.: American Institute of Certified Public Accountants, September 2004) and [GAO/AIMD-00-21.3.1](#).

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## NIH Is Required to Use a Peer Review System to Make Extramural Funding Decisions; NIH's OD Does Not Monitor Key Decisions in which IC Directors Exercise Their Discretion Over Funding

NIH is required by law to use a peer review system in its process for making extramural research funding decisions. NIH's dual peer review system is designed to help ensure the objective evaluation of the scientific merit of applications for extramural funding. After NIH's peer review process is concluded, IC directors have discretion when making final extramural funding decisions and are not required to fund applications based strictly on the scores resulting from the evaluation of their scientific merit. We found that in fiscal year 2007 IC directors decided to fund about 19 percent of NIH's applications for RO1 grants, a common type of grant, based on factors in addition to these scores. However, NIH's OD does not monitor extramural funding decisions in which the IC Directors exercise their discretion.

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## By Law, NIH Must Use a Dual Peer Review System Designed to Evaluate Scientific Merit of Extramural Funding Applications

NIH is required by law to use a peer review system in its process for making extramural research funding decisions. This system comprises two sequential levels of peer review by panels of experts in various fields of research who help NIH identify the most promising extramural grant applications to fund, as defined primarily by an assessment of the applications' technical and scientific merit.<sup>18</sup> According to NIH, compared to a single level of peer review, the dual peer review system allows for multiple reviews and therefore a more objective evaluation of the scientific merit of grant applications.

Applications for NIH's extramural funding are received by NIH's Center for Scientific Review (CSR), which is responsible for assigning each application to the first level of peer review. The first level of peer review is conducted by what are known as initial peer review groups, to which CSR assigns applications for review, based on the applications' proposed area of research and the initial peer review groups' area of expertise. These initial peer review groups specialize in various research areas such as cancer or digestive disorders and are composed of scientists, who are

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<sup>18</sup>See 42 U.S.C. §§ 282(b)(9); 289a(a); 289a-1(a)(2). The Secretary of HHS promulgated regulations expanding on the use of peer review by groups appointed by the Director of NIH and the directors of the national research institutes.

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often recognized as experts in their field.<sup>19</sup> Each group meets three times per fiscal year to review grant applications.

The initial peer review groups are responsible for identifying the most promising applications for funding, based on an assessment of the applications' scientific merit.<sup>20</sup> The groups review the applications assigned to them and assess their scientific merit, using criteria that require reviewers to examine such components as a grant application's design and methodology, innovation, and scientific significance.<sup>21</sup> Using these criteria, the initial peer review groups assign a priority score to the applications they reviewed, which are used to rank the applications from among those in the cohort of applications. After the applications are scored and ranked, the information is forwarded to the appropriate IC—based on the applications' proposed area of research—for the second level of peer review.

Each IC that funds extramural research has its own advisory council, which conducts the second level of peer review.<sup>22</sup> Advisory councils consist of no more than 18 voting members, two-thirds of whom are scientists in the research areas of the IC and one-third of whom are leaders of non-science fields.<sup>23</sup> Advisory councils meet at least three times

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<sup>19</sup>The composition of the initial peer review groups is specified in 42 C.F.R. § 52h.4 (2008). Based on these criteria, NIH staff select the initial peer reviewers, who generally agree to participate for 4 years.

<sup>20</sup>See 42 C.F.R. § 52h.7 (2008).

<sup>21</sup>42 C.F.R. § 52h.8 (2008) directs peer review groups to assess each proposed research project taking into account the following criteria, among other pertinent factors: (a) its significance, (b) the adequacy of its approach and methodology, (c) its innovativeness and originality, (d) the qualifications and experience of its principal investigator and staff, (e) the scientific environment and reasonable availability of resources for it, (f) the adequacy of its plans to include both genders, minorities, children, and special populations as appropriate for its scientific goals, (g) the reasonableness of its budget and duration, and (h) the adequacy of its protections for humans, animals, and the environment.

<sup>22</sup>42 U.S.C. § 284a. Although the law setting forth the requirements for advisory councils is specific to institutes, each center that funds extramural research has an advisory council substantially similar to those of the institutes. See 42 U.S.C. §§ 287a (National Center for Research Resources), 287c-21(b) (National Center for Complementary and Alternative Medicine), 287c-31(j) (National Center on Minority Health and Health Disparities).

<sup>23</sup>Advisory councils also include ex officio members, who are nonvoting. Voting members generally serve 4-year terms. At the NCI, the President appoints voting advisory council members, and the members serve 6-year terms. For all other advisory councils, the Secretary of HHS appoints voting members.

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per fiscal year.<sup>24</sup> Under law and NIH policy, the advisory councils are responsible for reviewing the applications and their priority scores and, on the basis of this review, recommending to the ICs certain applications for funding consideration. The advisory council may ask for applications to be scored a second time, such as if they have questions about whether the scientific criteria were applied appropriately. NIH advisory council members we interviewed noted that councils only have time to discuss a few applications individually, so they consider many applications in large groups, particularly in cases when no concerns are apparent about the applications or their priority scores. Based on data we reviewed, we found that from fiscal year 2003 to 2007, in most cases, only a small number of applications were not recommended by advisory councils for funding consideration. The advisory councils' recommendations conclude NIH's peer review process.

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### IC Directors Have Discretion to Make Final Extramural Funding Decisions, but NIH's OD Does Not Monitor Decisions in Which IC Directors Exercise This Discretion

After NIH's peer review process has been concluded, the director of each IC is responsible for making final extramural funding decisions. In deciding which applications to fund, the IC directors choose applications from among those recommended for funding consideration by the advisory council.<sup>25</sup> In general, IC directors select applications for funding based on their priority scores, which reflect the evaluation of the applications' scientific merit by NIH's peer review process. For each fiscal year, each IC establishes a funding line—known as the payline—which roughly corresponds with the number of extramural grant applications the IC will be able to fund that year. The payline for any given year is based on projections of the total funding available at the IC that year for grants, the average dollar amount expected to be awarded per application, and the number of applications received by the IC. For example, as shown in figure 2, based on the amount of funding available for extramural grants, NCI set its payline for R01 grants<sup>26</sup>—the most common grant category—at

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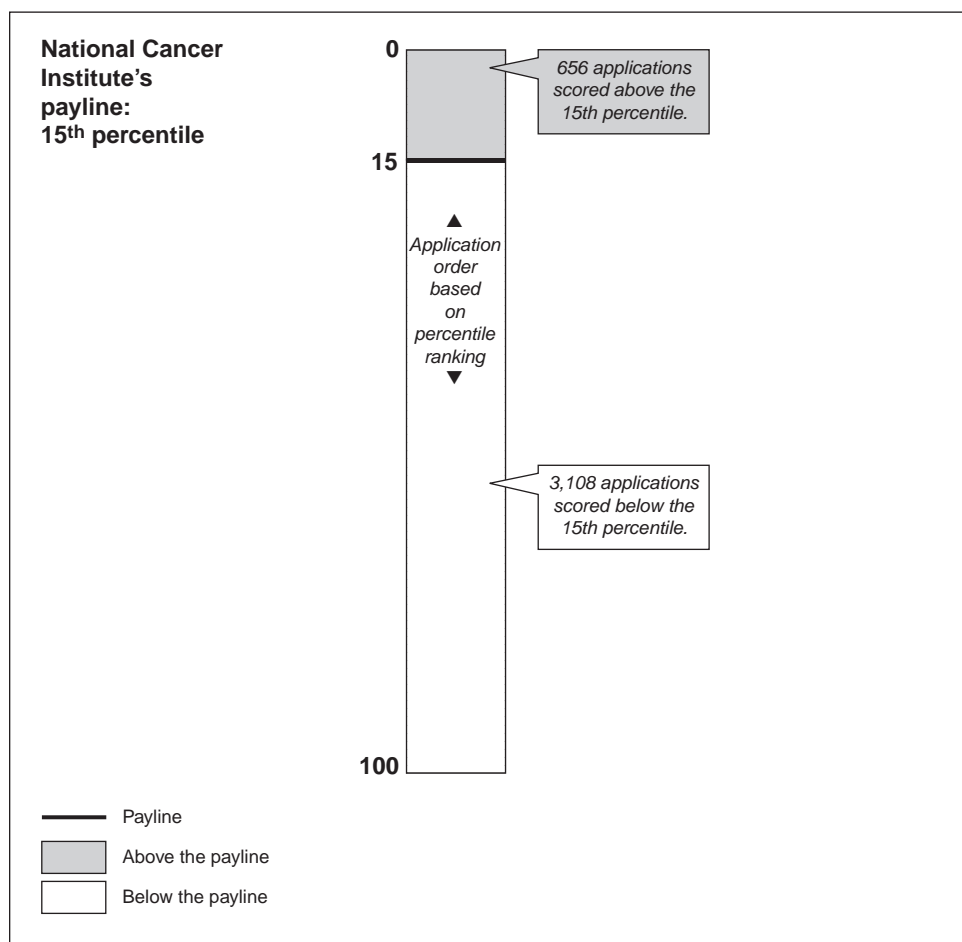
<sup>24</sup>By law, the advisory councils for NCI and the National Heart, Lung, and Blood Institute must meet at least four times per fiscal year. 42 U.S.C. § 284a(h)(2).

<sup>25</sup>NIH may not approve or fund any application unless it has been recommended for approval by a majority of the members of the initial peer review group and a majority of the voting members of the advisory council. The initial peer review groups recommend applications for approval via the scoring system. 42 U.S.C. § 289a-1(a)(2).

<sup>26</sup>The R01 grant is the original grant mechanism used by NIH. This type of grant is awarded to organizations of all types (universities, colleges, small businesses, for-profit, foreign and domestic, etc.) to support a discrete, specified project to be performed by a named investigator or investigators.

the 15th percentile for fiscal year 2007. This means that NCI expected to have sufficient funding at a minimum for all of the applications with scores in the top 15 percent. In general, IC directors fund only those applications with priority scores above the fiscal year's payline.

**Figure 2: National Cancer Institute's Fiscal Year 2007 Payline for R01 Grant Applications**



Source: GAO.

Note: Figure includes only applications that were recommended for funding consideration by an initial peer review group and the advisory council. The portion of applications that scored above the payline appears to be greater than 15 percent because applications that were considered for funding multiple times during the year and scored below the 15th percentile each time are only counted in this data once.



While the IC directors only fund projects recommended by their advisory councils and typically work within the paylines, ultimately they have discretion to make final extramural funding decisions. In particular, directors are not required to fund applications based strictly on the applications' priority scores or the payline. In some instances, IC directors decide not to fund applications that scored above the fiscal year's payline, such as when the applications duplicate research that has already received IC funding. These applications are called "skips." For example, of the 656 applications that scored above NCI's payline in fiscal year 2007, 3 applications were skipped. Similarly, though the IC directors typically do not decide to fund applications with priority scores that fall below the fiscal year's payline, in some cases they do. These applications are known as "exceptions." For example, of the 3,108 applications that scored below NCI's payline in 2007, 137 were funded as exceptions. In the case of exceptions, the IC directors may exercise their discretion and choose to fund these applications based on factors in addition to the applications' priority scores. These factors can include efforts to support the IC or NIH's research priorities. When skipping applications or funding applications as exceptions, IC directors are required under NIH policy to document the corresponding rationale used.

In reviewing the IC data, we found that 18.5 percent of NIH's funded R01 grant applications were funded as exceptions in fiscal year 2007, as shown in table 1. These applications had scientific merit scores that were below the payline for their respective ICs and thus were funded based on factors in addition to their scientific merit scores. This represents a substantial increase from 9.7 percent of funded applications that were exceptions in fiscal year 2003.

**Table 1: Extramural Research R01 Grant Applications Funded in Fiscal Years 2003 through 2007**

<b>Fiscal year</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>
Total number of applications funded	6,461	6,167	5,731	5,408	5,715
Number of applications funded above the payline	5,836	5,639	5,159	4,788	4,656
Number of applications funded below the payline – exceptions	625	528	572	620	1,059
Percentage of applications funded below the payline – exceptions	9.7	8.6	10.0	11.5	18.5

Source: GAO analysis of NIH grants data.

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Documentation that we reviewed from three of the ICs—NCI, NIDDK, and NIAAA—showed that IC directors funded applications as exceptions for various reasons. For example, IC officials cited the NIH-wide initiative to fund new investigators as one of the most frequent reasons for making the exceptions. In addition, IC officials told us that they funded applications as exceptions in order to maintain a diverse portfolio of research topics.

NIH's OD collects information on some aspects of the extramural research process. For example, the NIH OD collects information on the number of extramural grants funded by each IC; the percentage of applications that receive funding; and the priority rankings, by percentile, of funded applications. The NIH OD also targets some of these collection efforts towards specific types of extramural grants. For example, as part of its effort to support new investigators, the NIH OD has been collecting data on the number of extramural grants awarded to new investigators.

Although NIH's OD collects some information on the extramural research process, it does not monitor key funding decisions made by IC directors—specifically, the instances in which IC directors exercise their discretion to make skips or exceptions to the funding payline. Skips and exceptions represent an area of potential risk because IC directors have latitude in making these decisions; monitoring these decisions would be consistent with federal internal control standards.<sup>27</sup> Although ICs are required to document the rationales used when skipping applications or funding applications as exceptions, the ICs are not required to provide the NIH OD with this documentation, and the NIH OD does not collect it. As a result, NIH's OD does not have information on the number of applications skipped or funded as exceptions and the reasons for these decisions.

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<sup>27</sup>See GAO, [GAO/AIMD-00-21.3.1](#). The Department of Health and Human Services, of which NIH is a component, is required to establish and maintain an effective system of internal control, consistent with the standards prescribed by the Comptroller General. 31 U.S.C. § 3512(c), (d).

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## Design of NIH's Travel and Personnel Appointment Processes Includes Key Control Activities and Some Monitoring Activities but Lacks Systemic Risk-Based Monitoring

With regard to the design of NIH-wide travel processes, NIH OD has established policies and procedures to help ensure that federal travel regulations are followed with regard to issues such as premium class travel, per diem expenses, and travel paid by third parties. The key control and monitoring activities for travel include reviews and approvals which take place during two stages—authorization and voucher—of the process. During the authorization stage, the traveler receives approval to travel based on the supervisor's approval of the mission-relatedness of the trip and an administrative official's approval of the method of transportation used, the cost estimates set forth for travel expenses, and the availability of funds for reimbursement to the traveler. During the voucher stage, the traveler's voucher for reimbursement of travel expenses is approved based on an administrative official's review of the voucher package which includes the traveler's certification of the voucher and required receipts for travel expenses.

The NIH OD has also established policies and procedures to help ensure that Title 42 personnel appointment decisions are appropriate. The design of NIH-wide key control activities for Title 42 personnel appointments includes reviews and approvals which take place during three stages—resource determination, appointment selection, and compensation—of the process. During the resource determination stage, the IC's selecting official identifies a hiring need and the administrative official determines whether necessary resources are available to meet the hiring need. During the appointment selection stage, the IC completes the recruitment including receiving applications, conducting candidate interviews, and making a tentative selection. For some positions, the NIH Offices of Human Resources, Intramural Research, and Extramural Research also play a role in preparing the recruitment and approving the selected candidate.<sup>28</sup> During the compensation stage, final approval for the appointment and compensation is given depending upon the position and salary level for the candidate. Specifically, if the proposed compensation is below the lowest third of a given position's salary range, then the IC director makes the final approval; if the proposed compensation is above the lowest third of a given position's salary range but still within the range, then the IC director makes the final approval based on a recommendation from an IC committee; and if the proposed compensation is above the

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<sup>28</sup>Examples of positions that would require more involvement from the NIH-level offices include senior-level employees such as tenure-track investigators, senior investigators, senior scientists, and senior clinicians.

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salary range or other specified limits, then the NIH director makes the final approval based on recommendations from an IC committee, the IC director, and an NIH-wide committee.

Overall, we found that the design of the controls included in the NIH-wide processes over travel and Title 42 personnel appointments included key controls necessary to help ensure these activities were being carried out appropriately, except in one key area related to the lack of requirements for risk-based monitoring. While controls may appear adequate based on written policies and procedures, without monitoring actual implementation based on the assessed risk levels, NIH does not have adequate assurance that controls are operating as intended within those areas that pose risk. NIH policy did not require the ICs to perform monitoring that includes risk-based control evaluations. Further, although NIH policy required a flexible plan for NIH-wide control evaluations that would generally target high- and medium-risk areas for review, according to NIH OD officials, such reviews have not been performed for over 3 years because they do not have staff to perform these reviews.

At NIH OD and two of the three ICs we reviewed—NCI and NIAAA—we found that some monitoring activities were performed over travel and Title 42 personnel appointments. However, these monitoring activities were either not part of systemic risk assessment efforts that lead to subsequent monitoring based on assessed risk or not performed on a consistent and ongoing basis. Specifically,

- Because of travel issues previously identified by GAO,<sup>29</sup> HHS requires each of its operating divisions, which includes NIH, to perform quarterly control evaluations of travel cards.<sup>30</sup> As a result of this requirement, each quarter the NIH OD selected a sample of travel transactions from across the ICs and tested compliance with federal travel regulations and NIH policies and procedures. For example, during each of the first 2 quarters of fiscal year 2008, the NIH OD found problems with about 20 percent of the 100 sample items it tested. During the third quarter, the NIH OD found problems with about 30 percent of the 75 sample items it tested. Some of the problems found during these quarters included over- or underpayment to travelers,

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<sup>29</sup>GAO, *Department of Health and Human Services: Controls Over Travel Program Are Generally Effective, but Some Improvements Are Needed*, [GAO-03-334](#) (Washington, D.C.: Feb. 21, 2003).

<sup>30</sup>Travel cards are a type of charge card used for official travel-related expenses.

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failure of travelers to take advantage of lodging tax exemptions, and misuse of travel cards. The NIH OD required follow-up actions such as reimbursement of overpayment amounts and issuing additional guidance. However, these travel control evaluations were not part of a systemic process for assessing risk over operations and subsequently monitoring or evaluating controls based on assessed risk levels.

- In 2008, NCI and NIAAA performed control evaluations over travel, and NCI performed a control evaluation of personnel appointments (including those under Title 42). These control evaluations were performed in response to prior audit findings, to prepare for upcoming audits or reviews, or to address concerns regarding process inefficiencies. However, they were not incorporated into the design of the processes and therefore were not performed on a consistent and ongoing basis.

One of the three ICs we reviewed—NIDDK—had adopted its own risk-based program which consisted of assessing the risks over operational areas, including travel and personnel appointments, and subsequently monitoring the controls over those operational areas. The frequency of monitoring depended upon the risk level, and high-risk activities at NIDDK were scheduled to be monitored more frequently than low- or medium-risk activities. The design of NIDDK’s program represents a positive step towards an effective risk management program. Further details on a framework for an effective risk management program are discussed in the next section.

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## NIH’s Management Control Program and Enterprise Risk Management Program Do Not Fully Address Key Components of Effective Risk Management

The design of the Management Control Program provided NIH with a limited ability to identify and address risks to the agency’s overall operations. Recognizing the need for improvement, in 2006, the NIH OD began redesigning its program. However, while an improvement over the Management Control Program, the new Enterprise Risk Management Program does not fully address all of the components of GAO’s framework for effective risk management. Further, NIH’s Enterprise Risk Management Program has not been fully implemented, despite an over 3-year effort, and NIH had not yet established milestones for its full implementation.

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## NIH's Management Control Program Had Weaknesses

NIH's Management Control Program was initially implemented in 1999 and updated in 2004. Under the design of this program, risk assessments are performed that relate to specific management control areas, such as functional areas, systems, or processes (e.g., intramural research programs) without relating those areas to potential systemic or agencywide risks. If weaknesses are identified within the particular area being reviewed, the Management Control Program appropriately requires that corrective action plans be developed and implemented to correct the weakness and that such actions be monitored after implementation to ensure that the weakness has been corrected.

As designed, NIH's Management Control Program did not address several of the components and related key elements included in GAO's framework for an effective risk management program. An effective risk management program should enable management to proactively identify, assess, and mitigate risks. Table 2 outlines the seven components of the risk management framework and the key elements within each of these components.

**Table 2: GAO’s Risk Management Framework**

Risk management component	Description	Key elements
Strategic goals, objectives, and constraints	Addresses what the strategic goals and objectives are attempting to achieve and the steps needed to attain these results, and considers the constraints under which an agency operates such as statute, higher level policy, budget, or other factors beyond management’s control that may affect an agency’s risk management plans.	<p>An agency’s risk management program should:</p> <ul style="list-style-type: none"> <li>• Require mission-based strategic goals and objectives, that are clearly articulated and measurable, to be set as a pre-condition for effective risk management. Without clearly identified strategic goals and objectives, an agency cannot effectively identify and address potential risks to its mission, prioritize risk, or identify criteria against which to measure performance.</li> <li>• Require agencies to identify constraints (e.g., legislative requirements or resources) that may limit effective risk management.</li> </ul>
Risk assessment	Addresses the identification and evaluation of potential risks to an agency’s ability to achieve its goals and objectives so that management can design and implement responses to prevent or mitigate identified risks.	<p>An agency’s risk management program should:</p> <ul style="list-style-type: none"> <li>• Identify potential events which may adversely affect the agency, called risks, and evaluate the events based on likelihood of occurrence and impact. For example, an agency may identify and evaluate potential risks associated with economic and legislative changes, natural disasters, and criminal or terrorist activities.</li> <li>• Require continuous identification and evaluation of potential risks since governmental, economic, industry, legislative, and operating conditions continually change.</li> </ul>
Alternatives evaluation	Addresses the identification and evaluation of alternative ways in which the agency can act to alter either the likelihood of occurrence or the impact of a potential risk.	<p>An agency’s risk management program should:</p> <ul style="list-style-type: none"> <li>• Identify alternative ways the agency can respond to prevent or mitigate an identified risk. For example, to comply with new legislation, an agency may need to revise existing policy and procedures or develop new policies and procedures.</li> <li>• Evaluate the alternatives identified to consider the effect on likelihood of occurrence and impact of a potential risk.</li> <li>• Evaluate the alternatives identified to consider the costs and benefits.</li> </ul>
Management selection	Addresses the selection of a response to mitigate an identified risk based on the alternatives evaluated and management priorities, such as management’s attitude towards risk and how limited resources will be targeted.	<p>An agency’s risk management program should:</p> <ul style="list-style-type: none"> <li>• Require management to select and document an alternative, such as revising or creating a policy or procedure, for addressing an identified risk.</li> <li>• Require management to document the rationale for selecting the alternative.</li> </ul>

Risk management component	Description	Key elements
Implementation and monitoring	Addresses how risk responses will be applied and assessed to improve efficiency and effectiveness. In addition, addresses how the risk management program will be assessed to determine whether changes are needed to improve efficiency and effectiveness.	<p>An agency's risk management program should:</p> <ul style="list-style-type: none"> <li>• Implement management's selected alternative to address risk.</li> <li>• Periodically assess management's selected alternative to address risk.</li> <li>• Periodically assess the efficiency and effectiveness of the entire risk management program.</li> </ul>
Internal environment	Addresses how management will establish and maintain a positive environment that sets the tone throughout the agency and is the foundation upon which all other components of risk management operate.	<p>An agency's risk management program should:</p> <ul style="list-style-type: none"> <li>• Include an agency's risk management philosophy to help position the agency so that it can effectively recognize and manage risk.</li> <li>• Require oversight by a high-level senior body within the agency.</li> <li>• Incorporate the importance of integrity and ethical values to increase the effectiveness of the risk management program since the program and its results depend upon the personnel who carry out risk activities.</li> <li>• Include the way management assigns authority and responsibility to help ensure that risk responsibilities are carried out.</li> <li>• Hold managers accountable for their assigned duties in the risk management program.</li> <li>• Require management to organize its risk structure to provide a framework for the agency to plan, execute, control, and monitor risk activities.</li> <li>• Require management to initially train its personnel to help ensure that they have the necessary knowledge and skills to perform their assigned tasks.</li> <li>• Ensure management maintains competence of the agency's personnel by providing for continuous training to update personnel on risk management practices and techniques.</li> </ul>
Information and communication	Addresses the need to identify and communicate pertinent information in a form and timeframe that allows personnel to carry out their risk management responsibilities.	<p>An agency's risk management program should:</p> <ul style="list-style-type: none"> <li>• Require pertinent information to be collected from and disseminated to relevant internal stakeholders in a form and timeframe consistent with the agency's risk management needs.</li> <li>• Require pertinent information to be collected from and disseminated to relevant external stakeholders in a form and timeframe consistent with the agency's risk management needs.</li> </ul>

Sources: [GAO-06-91](#); The Committee of Sponsoring Organizations of the Treadway Commission, *Enterprise Risk Management—Integrated Framework* (Jersey City, N.J.: American Institute of Certified Public Accountants, September 2004); and [GAO/AIMD-00-21.3.1](#).



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The three components of the framework that the Management Control Program did not address are strategic goals, objectives, and constraints; risk assessment; and information and communication. Specifically, the program did not do the following.

- Link the identification of potential risks with the agency's strategic goals and objectives. The design of the Management Control Program did not require strategic goals and objectives to be set as a precondition for risk management. Without clearly identified strategic goals and objectives, an agency is limited in its ability to effectively identify and address potential risks to its mission, prioritize risk, or identify criteria against which to measure performance.
- Require risk assessments be performed to identify and evaluate potential risks that could adversely affect NIH's ability to achieve its objectives. The design of the Management Control Program called for evaluating the risks within specific functional areas, systems, or processes rather than assessing the risks that could adversely affect the agency as a whole.
- Require pertinent information to be collected from and disseminated to relevant internal and external stakeholders in a form and time frame consistent with the agency's overall risk management needs. The design of the Management Control Program allowed for inconsistent and incomparable information from the ICs, which can prevent management from effectively using the information to help ensure that agency objectives are met.

For a number of years, NIH OD officials recognized that weaknesses existed in the agency's Management Control Program, which resulted in a lack of sufficient information for effective oversight and agencywide risk management. For example, according to NIH OD officials, the program (1) did not hold managers responsible for their assigned duties in the risk management program, (2) did not require the ICs to communicate information in a form that allows NIH to effectively identify and manage risk across the agency, and (3) was not overseen by a high-level senior body, such as the Steering Committee.<sup>31</sup> The three weaknesses NIH officials identified in the agency's Management Control Program

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<sup>31</sup>The Steering Committee, which is chaired by the NIH director and composed of 10 IC directors who serve on a rotating basis, is NIH's most senior-level governing body. The Steering Committee is responsible for addressing NIH-wide issues, other than those that relate to science.

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correspond to the following key components of our framework for effective risk management: 1) internal environment, 2) information and communication, and 3) internal environment, respectively. As a result of acknowledged shortcomings, in 2006 NIH began redesigning its risk management efforts. According to NIH OD officials, the new risk management program will improve the ability of the NIH OD to proactively identify and mitigate risks before they become obstacles to the NIH mission. However, as discussed later, NIH has not fully implemented the new Enterprise Risk Management Program and has encountered several obstacles in implementing initial phases of the program.

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**NIH's Enterprise Risk Management Program, while Improved, Does Not Fully Address Several Key Components of Effective Risk Management**

NIH began developing a new risk management program in 2006. The new program is designed to consist of a formal six-step methodology for managing risks.<sup>32</sup> The six steps include:

- Organize – Identify and train those charged with carrying out risk management activities, and define the risk management structure.<sup>33</sup>
- Identify and Score<sup>34</sup> – Identify and score risks, review risks for quality and accuracy, and develop the risk baseline.
- Assess – Document, analyze, and test processes and controls.
- Remediate – Develop, review, approve, and execute corrective action plans.
- Monitor – Monitor the risk baseline.
- Report – Report risk information and results.

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<sup>32</sup>NIH Office of Management Assessment, *NIH Enterprise Risk Management Program, Enterprise Risk Management Guidebook: A Step-By-Step Guide* (March 2009, Draft).

<sup>33</sup>Risk management structure is a segmentation of discrete, mission-oriented subsets of an organization to facilitate risk management activities at the lower level.

<sup>34</sup>Scoring risks includes assessing the risk based on likelihood of occurrence and impact. Based on the assessment, risks are assigned a points value, which allows for quantitative comparison and ranking of risks across NIH.

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The design of the Enterprise Risk Management Program represents an improvement over the 2004 NIH Management Control Program in several key areas. Specifically, the new program will allow for improved identification, assessment, and mitigation of risks agencywide because it includes the following:

- Risk assessments: The new program requires the identification of potential events that could adversely affect the agency and the evaluation of those events based on likelihood of occurrence and impact.
- Oversight by a high-level senior body: The design requires the Steering Committee to oversee the new risk management program.
- Information and communication: The design requires that pertinent information be collected from and disseminated to relevant internal stakeholders in a form and time frame consistent with NIH's risk management needs. For example, the program requires a consistent methodology for identifying, assessing, and communicating risks across NIH, which will allow for consistent, comparable information from each of the ICs.

However, the Enterprise Risk Management Program still does not fully address all of the components that we have identified for an effective risk management framework. As discussed below, further consideration of the risk management framework could significantly improve the design of NIH's new risk management program, which, if effectively implemented, could assist management in maintaining effective control over the agency's decentralized and diverse activities.

Strategic Goals, Objectives, and Constraints. The Enterprise Risk Management Program does not require the NIH OD or ICs to set mission-based strategic goals and objectives as a precondition for risk management. This is a critical shortcoming because although the risk design requires risks to be assessed on the basis of their impact on NIH's mission, there is not an NIH-wide strategic plan against which to assess risks. Further, while some ICs and NIH OD offices have strategic plans for their organizations, the risk management program as designed does not call for risks to be assessed on the basis of their impact on IC- or NIH OD office-level missions.

Alternatives Evaluation. Although the Enterprise Risk Management Program identifies four different responses the agency can select to prevent or mitigate identified risks (creating a new policy, procedure, or

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control; revising an existing policy, procedure, or control; streamlining or automating an existing policy, procedure, or control; or redesigning the process), the program does not require management to evaluate the risk responses identified to consider (1) the effect on the likelihood of occurrence and impact of a potential risk and (2) the costs and benefits. These types of evaluations could assist management in making an informed decision within an environment that includes constrained resources.

Management Selection. The design of the Enterprise Risk Management Program does not require management to document the rationale for selecting a particular risk response. Such documentation could help improve accountability and facilitate analysis of the effectiveness of actions taken.

Implementation and Monitoring. Although the design of the Enterprise Risk Management Program requires periodic assessments of the overall efficiency and effectiveness of the risk management program, it does not offer any detail regarding how these assessments will be performed. For example, the program does not provide details such as the frequency, scope, or methodology for these reviews. Further, the design does not require periodic assessments of implemented risk responses. These types of monitoring activities are critical in helping management to identify problems with the overall risk management program and to determine whether risk responses are preventing or mitigating risks and operating as intended.

Internal Environment. The Enterprise Risk Management Program includes many of the elements that define this component. However, the design could be improved by (1) incorporating the importance of ethical values into the risk management program and (2) ensuring management maintains the competence of its personnel by providing for continuous training to update personnel on risk management practices and techniques.

Information and Communication. The design of NIH's Enterprise Risk Management Program does not require the collection and dissemination of pertinent information to relevant external stakeholders in a form and time frame consistent with NIH's risk management needs. For example, although the design requires annual reporting, in aggregate, to HHS on the adequacy of internal control, it does not require communication with other external stakeholders, such as congressional oversight committees.

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## Implementation of the Enterprise Risk Management Program Has Been Hampered by Lack of Milestones

The design and implementation of NIH's new risk management program is not yet completed, despite an over 3-year effort. Without a sound risk management program NIH cannot be reasonably assured that it will be able to effectively and proactively identify, assess, and mitigate risks before they become problems that affect NIH's ability to achieve its mission. During fiscal year 2008, the NIH OD implemented the first two steps of the six steps in its new risk management program. NIH had (1) organized the risk structure at the NIH OD and ICs, and identified and trained personnel responsible for managing risks within NIH OD, and (2) identified and scored risk at the NIH OD. NIH OD officials said they planned to complete the IC-level implementation of these two steps by the end of fiscal year 2009.

The NIH OD is responsible for the design and implementation of the new program, and it has developed a time line with milestones for implementing some steps of the program. However, the timeline's milestones are not firm, and the NIH OD has revised the timeline to accommodate delays. According to NIH OD officials, they have experienced delays in designing and implementing the new program because of a change in contractors, balancing limited staff resources with competing demands, and underestimating the amount of time necessary for implementing specific steps of the program. As of the completion of our draft report, the NIH OD had not set a date for fully implementing the program agencywide. However, in providing written comments on a draft of this report, HHS indicated that the Enterprise Risk Management Program at NIH was scheduled for full implementation throughout NIH by June 2010. (See agency comments and our evaluation for additional details.)

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## Conclusions

While NIH's decentralized structure allows NIH to address a wide range of research areas, it also creates significant oversight challenges. The ICs operate largely independently—each with its own budget, mission, and staff—making it vitally important that NIH and especially the OD have the means to ensure that all the ICs operate in accordance with NIH's policies and mission. With an annual budget of nearly \$30 billion, plus an additional \$10 billion in funding available in 2009 and 2010 through the American Recovery and Reinvestment Act of 2009, the financial stakes are high.

We found gaps in NIH's ability to monitor key aspects of its extramural funding process. Specifically, NIH's OD does not monitor extramural funding decisions in which IC directors exercise their discretion to skip

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applications and make exceptions, even though information on these decisions is collected at the IC level. Without routine monitoring, which is consistent with federal internal control standards, NIH does not have the information to be reasonably assured that these decisions are appropriate and support the agency's mission. Appropriate funding decisions are critical to ensuring an effective use of taxpayer dollars and supporting NIH's reputation as the premier federal medical research agency in the United States. In reviewing selected administrative operations, we also found a key weakness in the design of the controls the NIH OD has established for oversight of travel and Title 42 personnel appointments. Without internal controls that include risk-based monitoring of the controls' actual implementation, NIH cannot be reasonably assured that these controls are effective and operating as intended in areas identified as posing potential risks to NIH.

Given these issues, a comprehensive risk management program could help ensure that such monitoring gaps are identified and addressed. NIH has recognized the importance of risk management to its organization and has taken steps towards implementing its new Enterprise Risk Management Program. Specifically, NIH has organized the risk structure at the NIH OD and ICs, identified and trained personnel responsible for managing risks within the NIH OD, and made progress in identifying and scoring risks at both the NIH OD and the ICs, which represent important steps. However, the design of the Enterprise Risk Management Program lacks several key components identified in our framework as necessary for effective risk management and the program has not yet been fully implemented throughout NIH.

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## Recommendations for Executive Action

To ensure effective oversight of extramural funding decisions, we recommend that the Director of NIH establish a process for routine monitoring of the extramural funding decisions in which the IC directors use their discretion to skip applications or fund applications as exceptions.

To help ensure that NIH has a comprehensive program to effectively address potential risks to the agency's mission, including those related to the monitoring of extramural research funding decisions, travel, and personnel appointments, we recommend that the Director of NIH take two actions to complete the design and implementation of NIH's Enterprise Risk Management Program:

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- Add key components and related elements needed to achieve comprehensive and effective agencywide risk management to the design of NIH's Enterprise Risk Management Program, including:
    - mission-based strategic goals and objectives as a precondition for risk management and risks to be assessed on the basis of their impact on the achievement of these goals and objectives;
    - the evaluation of risk responses to consider the effect on the likelihood of occurrence and impact of a potential risk and the costs and benefits;
    - the documentation of the rationale for selecting risk responses;
    - additional detail regarding how the assessments of the overall efficiency and effectiveness of the risk management program will be performed;
    - periodic assessments of implemented risk responses;
    - the importance of ethical values;
    - continuous training to maintain the competence of personnel carrying out risk management duties; and
    - communication with relevant external stakeholders.
  - Identify major milestones, including a final implementation date, to help ensure that NIH completes and implements the Enterprise Risk Management Program in a reasonable time frame.

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## Agency Comments and Our Evaluation

The Department of Health and Human Services provided written comments on a draft of this report, which are reprinted in appendix III. In responding to our draft report, HHS disagreed with the first recommendation and partially concurred with the second recommendation. In response to the third recommendation, HHS provided new information. The following sections summarize HHS's comments on each of our three major findings and related recommendations and provide our responses.

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## OD Oversight of Extramural Funding Decisions

HHS disagreed with our recommendation that the Director of NIH should establish a process for routine monitoring of the extramural funding decisions in which the IC directors use their discretion to skip applications or fund applications as exceptions. In its written comments, HHS stated that we implied an inappropriate role for the NIH OD. Specifically, HHS said that the OD's role was not to provide input on the scientific reasoning for making skips and exceptions, which should be left to the judgment of the scientific officials who understand the current trends in science and the institute research portfolios. HHS further stressed that the ICs are required to document the reasons for these decisions and that the documents are available for review by the OD upon request.

Our work shows there would be benefit for the Office of the Director of NIH, as part of its responsibility to oversee IC operations, to routinely monitor the extent to which IC directors use their discretion to skip applications and fund applications as exceptions. This monitoring can be consistent with NIH's stated reliance on scientific reasoning and the judgment of the scientific officials in making these decisions. As we noted in our draft report, when IC directors decide to skip applications and fund applications as exceptions, they do so by considering factors other than the science-based priority scores originally assigned to each application by NIH's initial peer review groups and advisory councils. There can be good reasons for the decision to skip an application or fund an application as an exception, such as the desire to maintain a diverse portfolio of work. Routinely monitoring the extent to which IC directors use their discretion to skip applications and fund applications as exceptions would position the Director of NIH to help ensure that these decisions are consistent with NIH policy goals and are therefore appropriate. Such routine monitoring would also enable the Director of NIH to identify instances in which further review by appropriate officials may be desirable. Further, the routine monitoring we recommended is consistent with other efforts by the OD to monitor extramural funding decisions. As we noted in our draft report, the NIH OD already collects certain information related to extramural funding decisions, such as the priority rankings of funded applications and the number of extramural grants awarded to new investigators in response to an NIH-wide initiative. Finally, NIH OD monitoring activities would be consistent with federal internal control standards.

In related comments, HHS drew attention to our finding that the share of RO1 grants awarded outside the payline (as exceptions) increased substantially from fiscal year 2003 through fiscal year 2007, and noted that this increase resulted largely from a corresponding increase in the number



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of RO1 grants awarded to new investigators. We agree with HHS, and noted in our draft report that our analysis of NIH's records showed that the NIH-wide initiative to fund new investigators was one of the most frequently cited reasons for funding an application as an exception. HHS further stated that it would like to review our methods for quantifying the number of extramural grants funded as exceptions. As we indicated in the scope and methodology section of our draft report, we based our analysis on data provided by NIH. We noted that NIH provided us with information about the payline established by each of the 24 ICs for each fiscal year from 2003 through 2007, and the number of RO1 grant applications funded relative to each IC's payline for each year.

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### Design of Controls Over NIH's Travel and Personnel Appointment Processes

HHS concurred with our finding that the design of NIH's Title 42 personnel appointment process included key control activities and some monitoring but lacked systematic risk-based monitoring. HHS said that it intends to incorporate risk-based monitoring into the Title 42 personnel appointment process. HHS also commented that NIH has identified and scored the agency travel process within its Enterprise Risk Management Program (discussed in the next section) but that it will reassess the travel risk levels to ensure that they are appropriate.

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### Design of NIH's Management Control Program and Enterprise Risk Management Program

In response to our recommendation that NIH add key components to the design of its Enterprise Risk Management Program to achieve comprehensive and effective agencywide risk management, HHS agreed with some of our specific recommendations and disagreed with others. We identified eight specific items in this area; HHS agreed with four, partially agreed with one, and disagreed with three.

- HHS agreed that the design of NIH's Enterprise Risk Management Program should be modified to include the evaluation of risk responses to consider the effect on the likelihood of occurrence and impact of a potential risk and the costs and benefits. HHS noted that NIH will modify its Enterprise Risk Management Guidebook to reflect this recommendation.
- HHS agreed that the design of NIH's Enterprise Risk Management Program should be modified to include documentation of the rationale for selecting risk responses. HHS noted that it appreciated the feedback and has incorporated this element into NIH's processes and amended the NIH Enterprise Risk Management Guidebook.

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- HHS agreed that the design of NIH's Enterprise Risk Management Program should be modified to include periodic assessment of implemented risk responses.
  - HHS agreed that the design of NIH's Enterprise Risk Management Program should be modified to include additional detail regarding how the assessments of the overall efficiency and effectiveness of the risk management program will be performed. However, HHS noted that the NIH Enterprise Risk Management Program has already undergone incremental evaluation during implementation. HHS also noted that NIH plans to develop a program evaluation process and conduct periodic reviews of the program in fiscal year 2011.
  - HHS partially agreed that the design of NIH's Enterprise Risk Management Program should be modified to include communication with relevant external stakeholders. HHS noted that NIH promptly responds to all requests for information from external stakeholders. However, HHS also noted that the Enterprise Risk Management Program will include external communications as it matures.
  - HHS did not agree that the design of NIH's Enterprise Risk Management Program should be modified to include mission-based strategic goals and objectives as a precondition for risk management and to assess risks on the basis of their impact on the achievement of these goals and objectives. HHS said that NIH's Enterprise Risk Management Program is designed to identify and manage risks before they become obstacles to the NIH mission and noted that the ICs establish their own strategic goals and objectives. As we noted in the draft report, the design of the program does not require the NIH OD or ICs to set mission-based strategic goals and objectives as a precondition for risk management, nor does the design call for risks to be assessed on the basis of their impact on IC- or NIH OD-level missions. We continue to believe that a clear and explicit link to strategic goals and objectives would help ensure that risks are routinely assessed based on their potential impact to achieving NIH's mission and would identify criteria against which to measure performance.
  - HHS did not agree that the design of NIH's Enterprise Risk Management Program should be modified to include the importance of ethical values. HHS said that NIH's risk management program already operates within the context of a positive environment in which integrity and ethical values play a key role. However, HHS said that NIH would modify the design of the Enterprise Risk Management Program as we recommended, by amending the Enterprise Risk Management Guidebook to include specific language addressing the importance of ethics at NIH.

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- HHS did not agree that the design of NIH’s Enterprise Risk Management Program should be modified to include continuous training to maintain the competence of personnel carrying out risk management duties. Nevertheless, HHS stated that NIH has provided training to over 400 individuals who hold significant risk management roles and noted that NIH plans to develop continuous training for all employees on risk management. Moreover, HHS said that NIH will modify the design of the Enterprise Risk Management Program as we recommended, by modifying the Enterprise Risk Management training plan to incorporate ongoing training such as training updates and refreshers.

In response to our recommendation that the Director of NIH should identify major milestones, including a final implementation date, to help ensure timely implementation of the Enterprise Risk Management Program, HHS identified a final implementation date of June 2010. Although HHS asserted that NIH’s Enterprise Risk Management Program is fully functional because NIH has implemented all six steps of the program at some level, as we noted in our draft report and as HHS confirmed in its written comments, several elements of the program have not been implemented across all of NIH. For example, HHS stated that steps one and two (identify and score risks) have been implemented across all of NIH—including the OD and the ICs—but that steps three and four (assess and remediate risks) have been implemented at the OD level but not across the ICs. If NIH proceeds with the actions and time frames outlined in HHS’s comments, it should meet the intent of our recommendation.

HHS stated that the prior risk management program—which our draft referred to as the “current” program—was discontinued in 2006. This statement is not consistent with the information we gathered during the time of our review nor with the policy manual posted on the NIH Web site, which states that the Management Control Program was “temporarily rescinded effective June 24, 2009,”—1 day after HHS received our report for review and comment—and that replacement guidance has not been issued. If the prior program has been discontinued and the final implementation date for the new program is scheduled for June 2010, NIH may have been operating without a fully functioning risk assessment program in place, which is a key element of a system of internal control. Although we believe our draft report correctly characterized the status of NIH’s Management Control Program and Enterprise Risk Management Program at the time of our review, in response to HHS’s comments we revised the wording in our report to more clearly distinguish between the

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new Enterprise Risk Management Program and the Management Control Program it is replacing.

In commenting on our evaluation of the NIH Enterprise Risk Management Program, HHS questioned the criteria we used in our evaluation. HHS stated that it defines risk management as synonymous with internal control and that the NIH Enterprise Risk Management Program was developed based on the *Standards for Internal Control in the Federal Government* and the Office of Management and Budget (OMB) Circular A-123. Thus, HHS suggested that we should revise our report using different criteria. We believe that our criteria are appropriate for the evaluation. As noted in the draft report, GAO developed the framework based on authoritative literature and standards, as well as previous GAO reports and testimonies. We consulted the Government Performance and Results Act (GPRA) of 1993; the *Government Auditing Standards, 2003 Revision*; GAO's *Standards for Internal Control in the Federal Government* (November 1999); guidance from OMB; the work of the President's Commission on Risk Management; consulting papers; and the enterprise risk management approach of the Committee of Sponsoring Organizations (COSO) of the Treadway Commission. We also reviewed numerous risk management frameworks from industry, government, and academic sources.

Furthermore, our draft report noted the relationship between internal control and risk management. Specifically, risk management is a continuous process through which an organization identifies, assesses, and mitigates risks, and through risk management, an organization can identify the most significant areas in which to place or enhance internal control. Systems of internal control may help an organization prevent or reduce risks, such as fraud, waste, abuse, or mismanagement. Internal control standards, therefore, provide an important tool for use in risk management. For example, in response to our draft report, NIH pointed out a variety of management oversight mechanisms, as discussed below. Those mechanisms could be considered part of NIH's internal controls, but are not part of its risk management program. We believe that the framework we used to evaluate NIH's risk management program was appropriate.

In addition, HHS commented that our report implied that the risk management program is the sole management oversight mechanism at NIH and that we failed to acknowledge other oversight bodies and functions. We agree that NIH has many mechanisms for managerial oversight and accountability and we cited some of the mechanisms HHS

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specified in the draft report, such as oversight of travel and Title 42 personnel appointments. However, it was beyond the scope of our report to evaluate the full spectrum of NIH's oversight and accountability mechanisms. Further, regardless of the number or type of the other oversight mechanisms in place at NIH, these do not in any way diminish NIH's need to make its risk management program fully functioning, comprehensive, and effective.

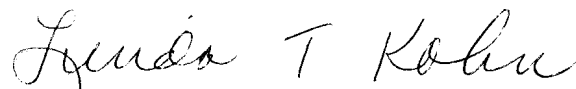
HHS also provided us with technical comments, which we incorporated as appropriate.

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As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies of this report to other interested congressional committees, the Secretary of HHS, and the Director of NIH. This report will also be available on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions regarding this report, please contact Linda T. Kohn at (202) 512-7114 or [kohnl@gao.gov](mailto:kohnl@gao.gov) or Susan Ragland at (202) 512-8486 or [raglands@gao.gov](mailto:raglands@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix IV.

Sincerely yours,



Linda T. Kohn, Director  
Health Care



Susan Ragland, Director  
Financial Management and Assurance

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# Appendix I: Scope and Methodology

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To gain an understanding of the process used to make extramural research funding decisions, we reviewed the laws and regulations governing the funding process and National Institutes of Health (NIH) policies related to each stage of the process. We also interviewed NIH officials with responsibility for establishing these policies and overseeing the institutes and centers' (IC) implementation of this process. In addition, to develop a detailed understanding of how the 24 ICs that fund extramural research implement the process, we selected 3 of the 24 ICs for a more detailed review: the National Cancer Institute (NCI), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). These ICs were chosen because they vary in budget size and focus on different disease-specific research missions. We also included the Center for Scientific Review (CSR), which does not fund extramural research but is responsible for implementing the initial steps in the extramural research funding process, including receipt of all grant applications.

At the IC level, we reviewed IC policies and guidance for implementing the extramural research funding process and interviewed officials at each of the 3 selected ICs plus CSR about their roles in receiving applications, facilitating peer review of the applications, and making final funding decisions. We also interviewed members of the NCI, NIAAA, and NIDDK advisory councils about their role in reviewing and making recommendations regarding extramural grant applications. In addition, we analyzed selected data from the 24 ICs that fund extramural research regarding funding decisions for grants in NIH's R01 category, which is the most common of NIH's various grant categories. The R01 grant is the original and historically oldest grant mechanism used by NIH. This type of grant is awarded to organizations of all types (universities, colleges, small businesses, for-profit, foreign and domestic, etc.) to support a discrete, specified project to be performed by a named investigator or investigators. Specifically, we requested information about the paylines each of the 24 ICs established during fiscal years 2003 through 2007 to be used when making funding decisions. (The payline roughly corresponds with the number of extramural grant applications an IC will be able to fund each year and is based on projections of the total funding available for grants at the IC that year, the average dollar amount expected to be awarded per application, and the number of applications coming to an IC.) We also requested data about the number of R01 grant applications received, scored, and recommended by the peer review groups; the total number of grant applications funded; and the number of grant applications funded relative to each IC's payline that year. We used the data to analyze trends in funding decisions over the 5-year period. In order to analyze the reasons

the ICs cited when funding applications as exceptions to the payline for R01 grants, we collected IC documentation for fiscal years 2006 and 2007 from NCI, NIAAA, and NIDDK. Because the total number of exception decisions made by NCI and NIDDK were large during this time frame, we analyzed documents for a random sample of the grants awarded as exceptions to the main payline. We also reviewed IC documentation related to applications with priority scores above the main payline that were not funded by NCI and NIDDK. NIAAA did not choose to skip any applications during these fiscal years.

To ensure that the IC data were sufficiently reliable for our analyses, we conducted detailed data reliability assessments of the data that we used. We assessed the reliability of the IC data by reviewing existing information about the data and the system that produced them and interviewing agency officials knowledgeable about the data. We determined that the data were sufficiently reliable for the purposes of this report.

To gain an understanding of the design of control and monitoring activities over travel and Title 42 personnel appointments, we reviewed relevant NIH policies and guidance.<sup>1</sup> To further our understanding of control and monitoring activities, we also performed walkthroughs of the travel and Title 42 personnel appointment processes at three ICs—NCI, NIDDK, and NIAAA; these were the three ICs selected for our review of the extramural research funding process.

During our walkthroughs of the travel process, we reviewed authorizations, vouchers, and supporting receipts for travel transactions at each of the selected ICs. During our walkthroughs of the Title 42 personnel appointment process, we reviewed checklists showing documents included in the appointment packages, routing slips showing who received the appointment packages, and memos documenting approvals for Title 42 personnel appointments at each of the selected ICs. We interviewed key officials from the NIH OD and the ICs, including the:

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<sup>1</sup>For travel, we reviewed NIH manual chapters *1500-01: Introduction to Official Government Travel* (Jan. 5, 2004), *1500-02: Traveler Responsibilities* (May 13, 2008), and *1500-08: Acceptance of Payment from a Nonfederal Source to Cover Travel Expenses [Sponsored Travel]* (Jan. 23, 2006). For Title 42 personnel appointments, we reviewed *Title 42 Pay Model—NIH* (Dec. 21, 2004) and NIH manual chapter *2300-575-2: Title 42 Recruitment and Retention Incentives* (May 4, 2000).

- NIH Deputy Director and the NIH Deputy Director for Management to clarify our understanding of the differences between the roles of the NIH OD and the ICs in the travel and personnel appointment processes and the associated control and monitoring activities;
- NIH Director of Financial Management and the NIH Director and Deputy Director of the Office of Human Resources to gain an understanding of the control and monitoring activities that the NIH OD performs over travel and Title 42 personnel appointments; and
- IC Executive Officers (the highest level officials at the ICs that oversee administrative activities) and other specialists within the ICs to clarify our understanding of control and monitoring activities in the travel and Title 42 personnel appointments at the IC level.

We compared the design of the processes to GAO's *Standards for Internal Control in the Federal Government*<sup>2</sup> to determine if the processes as designed included appropriate control and monitoring activities. While the design of control activities is based on NIH-wide policies and procedures, monitoring activities vary at the individual ICs. Therefore, our review of monitoring activities for travel and Title 42 personnel appointments at these selected ICs cannot be generalized to the other ICs. The scope of our audit did not include testing the implementation of controls over travel and Title 42 personnel appointments.

To gain an understanding of the design of the NIH Management Control Program, we reviewed relevant NIH policy and supporting documentation. Specifically, we reviewed relevant NIH policies<sup>3</sup> and the NIH OD's fiscal year 2008 guidance to the ICs on reporting risk management activities. To gain an understanding of the design of the Enterprise Risk Management Program we reviewed NIH draft guidance.<sup>4</sup> We also reviewed the time lines for implementing the Enterprise Risk Management Program to determine the estimated implementation dates. We interviewed key officials from the NIH OD including the:

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<sup>2</sup>GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999).

<sup>3</sup>*NIH Manual Chapter 1750 – Management Control Program* (Nov. 15, 2004).

<sup>4</sup>NIH Office of Management Assessment, *NIH Enterprise Risk Management Program, Enterprise Risk Management Guidebook: A Step-By-Step Guide* (March 2009, Draft).



- NIH Deputy Director and the NIH Deputy Director for Management to gain a high-level understanding of how the Enterprise Risk Management Program will address recent oversight issues at NIEHS and help NIH to better manage its decentralized organization;
- NIH Director of Financial Management to understand the risk activities NIH performed for fiscal year 2008 as part of the NIH Management Control Program; and
- NIH Director for the Office of Management Assessment—the office with primary responsibility for designing and implementing the new risk management program—to understand current risk activities at NIH, to clarify the design of the new risk management program, and to further our understanding of the implementation time line for the new risk management program as well as the cause for delays in implementation.

We compared elements of the NIH Management Control Program and the Enterprise Risk Management Program to our risk management framework<sup>5</sup> to determine if the designs contain the key components of an effective risk management program. We did not review the implementation of either the NIH Management Control Program or the Enterprise Risk Management Program because, at the time of our review, NIH did not plan to continue the Management Control Program and the Enterprise Risk Management Program was not yet fully implemented.

We conducted this performance audit from March 2008 to September 2009, 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

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<sup>5</sup>See table 2. GAO developed the framework based on authoritative literature and standards, as well as previous GAO reports and testimonies. We consulted the Government Performance and Results Act (GPRA) of 1993; the *Government Auditing Standards, 2003 Revision*; GAO's *Standards for Internal Control in the Federal Government* (November 1999); guidance from the Office of Management and Budget (OMB); the work of the President's Commission on Risk Management; consulting papers; and the enterprise risk management approach of the Committee of Sponsoring Organizations (COSO) of the Treadway Commission. We reviewed numerous frameworks from industry, government, and academic sources. GAO, "Appendix I: A Risk Management Framework" of *Risk Management: Further Refinements Needed to Assess Risks and Prioritize Protective Measures at Ports and Other Critical Infrastructure*, [GAO-06-91](#) (Washington, D.C.: Dec. 15, 2005).

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the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

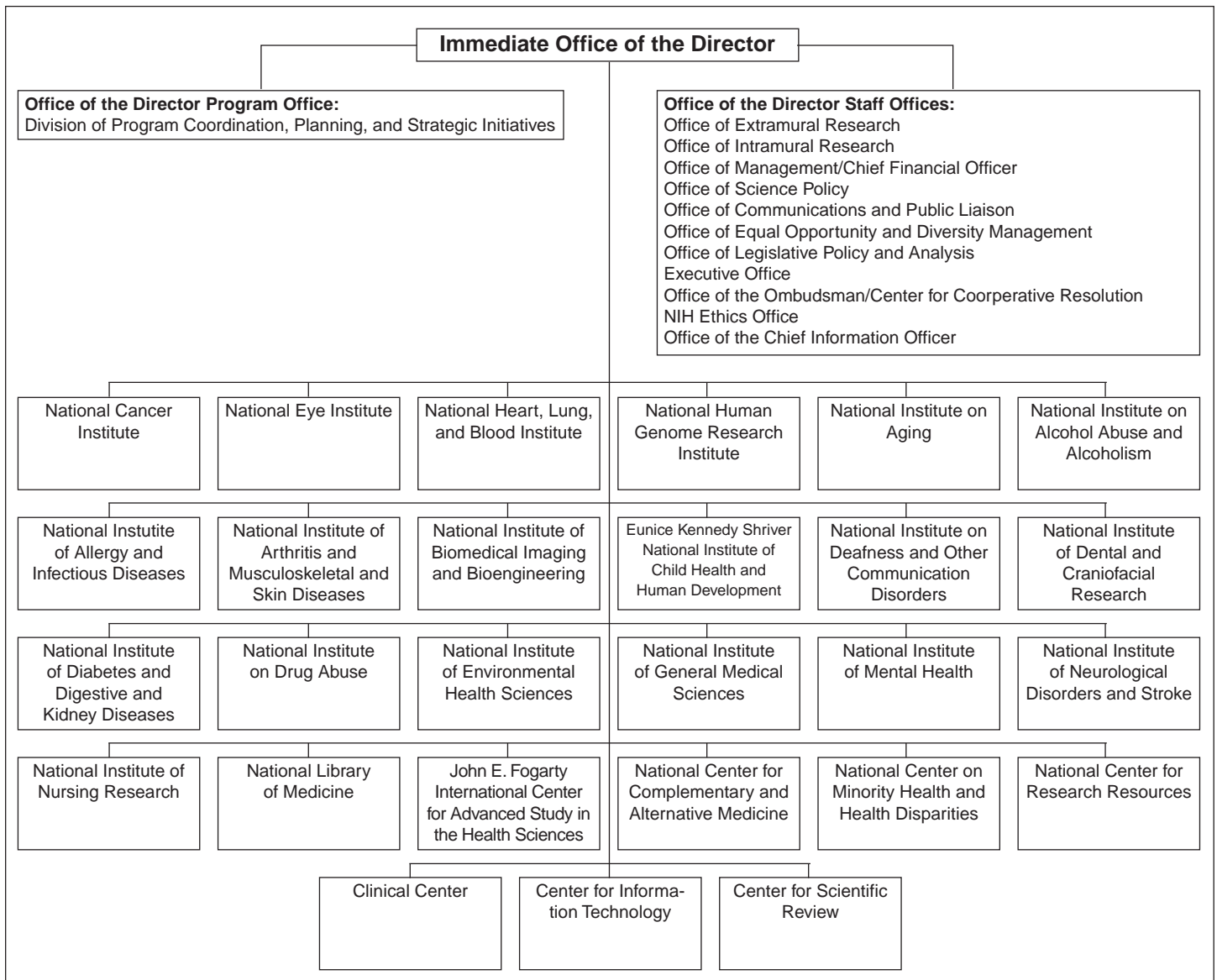
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# Appendix II: NIH Organization and Mission

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As the primary federal agency for supporting medical research in the United States, the National Institutes of Health's (NIH) 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". NIH is headed by a Director who is supported by 11 staff offices and 1 program office within the NIH Office of the Director (OD) and 27 institutes and centers (IC). Figure 3 depicts the organizational structure of NIH.

Figure 3: Organizational Structure of NIH



Source: NIH.

The ICs, which were established over time, each have an explicit mission focused on a particular disease or organ system, an area of human health and development, or aspects of research support.<sup>1</sup> The first institute, the National Cancer Institute, was established in 1937, and the newest institute, the National Institute of Biomedical Imaging and Bioengineering, was established in 2000. Research funded by NIH can be conducted by scientists in NIH laboratories and Clinical Center—called intramural research—or by nonfederal scientists at universities, academic health centers, hospitals, and independent research institutions—called extramural research. Table 3 depicts a time line of the establishment of the 27 ICs and their respective missions and fiscal year 2008 appropriations.

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<sup>1</sup>Prior to 1985, Congress either created ICs itself or gave others (e.g., the Surgeon General or the Secretary of HHS) the authority to create ICs through individual laws. Since 1985, the Secretary of HHS has had the authority to establish, reorganize, or abolish ICs. Pub. L. No. 99-158, 99 Stat. 820 (1985).

Table 3: Overview of ICs Including Establishment Date, Mission, and Fiscal Year 2008 Appropriation

IC	Year established	Mission	FY 2008 appropriation (in 000s)
National Cancer Institute	1937	Conducts and supports research that will lead to a future in which we can prevent cancer, identify cancers that do develop at the earliest stage, eliminate cancers through innovative treatment interventions, and biologically control those cancers that we cannot eliminate so they become manageable, chronic diseases.	\$4,830,647
Center for Scientific Review	1946	Conducts initial peer reviews of the majority of research and research-training applications submitted to NIH.	N/A <sup>a</sup>
National Institute of Allergy and Infectious Diseases	1948	Leads research that strives to understand, treat, and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives.	4,583,344
National Heart, Lung, and Blood Institute	1948	Provides leadership for a national program in diseases of the heart, blood vessels, lung, and blood; blood resources; and sleep disorders.	2,937,654
National Institute of Dental and Craniofacial Research	1948	Provides leadership for a national research program designed to understand, treat, and ultimately prevent the infectious and inherited craniofacial-oral-dental diseases and disorders that compromise millions of human lives.	392,233
National Institute of Mental Health	1949	Provides national leadership dedicated to understanding, treating, and preventing mental illnesses through basic research on the brain and behavior, and through clinical, epidemiological, and services research.	1,412,951
National Institute of Diabetes and Digestive and Kidney Diseases	1950	Conducts and supports basic and applied research and provides leadership for a national program in diabetes, endocrinology, and metabolic diseases; digestive diseases and nutrition; and kidney, urologic, and hematologic diseases.	1,715,761
National Institute of Neurological Disorders and Stroke	1950	Seeks to reduce the burden of neurological diseases by supporting and conducting research, both basic and clinical, on the normal and diseased nervous system, fostering the training of investigators in the basic and clinical neurosciences, and seeking better understanding, diagnosis, treatment, and prevention of neurological disorders.	1,552,113
Clinical Center	1953	Provides the patient care, services, and environment needed to initiate and support the highest quality conduct of and training in clinical research.	N/A <sup>a</sup>
National Library of Medicine	1956	Collects, organizes, and makes available biomedical science information to scientists, health professionals, and the public.	322,212
National Institute of General Medical Sciences	1962	Supports basic biomedical research that is not targeted to specific diseases but rather funds studies on genes, proteins, and cells, as well as on fundamental processes like communication within and between cells, how our bodies use energy, and how we respond to medicines.	1,946,104

**Appendix II: NIH Organization and Mission**

<b>IC</b>	<b>Year established</b>	<b>Mission</b>	<b>FY 2008 appropriation (in 000s)</b>
Eunice Kennedy Shriver National Institute of Child Health and Human Development	1962	Leads research on fertility, pregnancy, growth, development, and medical rehabilitation that strives to ensure that every child is born healthy and wanted and grows up free from disease and disability.	1,261,381
National Center for Research Resources	1962	Provides laboratory scientists and clinical researchers with the environments and tools they need to understand, detect, treat, and prevent a wide range of diseases.	1,155,560
Center for Information Technology	1964	Incorporates the power of modern computers into the biomedical programs and administrative procedures of NIH by focusing on three primary activities: conducting-computational biosciences research, developing computer systems, and providing computer facilities.	N/A <sup>a</sup>
National Eye Institute	1968	Conducts and supports research that helps prevent and treat eye diseases and other disorders of vision.	670,664
John E. Fogarty International Center for Advanced Study in the Health Sciences	1968	Promotes and supports scientific research and training internationally to reduce disparities in global health.	66,912
National Institute of Environmental Health Sciences	1969	Reduces the burden of human illness and dysfunction from environmental causes by, defining how environmental exposures, genetic susceptibility, and age interact to affect an individual's health.	645,669
National Institute on Alcohol Abuse and Alcoholism	1970	Conducts research focused on improving the treatment and prevention of alcoholism and alcohol-related problems to reduce the enormous health, social, and economic consequences of this disease.	438,579
National Institute on Drug Abuse	1973	Supports and conducts research across a broad range of disciplines and rapid and effective dissemination of results of that research to improve drug abuse and addiction prevention, treatment, and policy.	1,006,022
National Institute on Aging	1974	Leads a national program of research on the biomedical, social, and behavioral aspects of the aging process; the prevention of age-related diseases and disabilities; and the promotion of a better quality of life for all older Americans.	1,052,830
National Institute of Arthritis and Musculoskeletal and Skin Diseases	1986	Supports research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases, the training of basic and clinical scientists to carry out this research, and the dissemination of information on research progress in these diseases.	511,291
National Institute of Nursing Research	1986	Supports clinical and basic research to establish a scientific basis for the care of individuals across the life span—including managing patients during illness and recovery to reducing risks for disease and disability; promoting healthy lifestyles; promoting quality of life in those with chronic illness; and caring for individuals at the end of life.	138,207

**Appendix II: NIH Organization and Mission**

<b>IC</b>	<b>Year established</b>	<b>Mission</b>	<b>FY 2008 appropriation (in 000s)</b>
National Institute on Deafness and Other Communication Disorders	1988	Conducts and supports biomedical research and research training on normal and disordered processes of hearing, balance, smell, taste, voice, speech, and language that affect 46 million Americans.	396,234
National Human Genome Research Institute	1989	Supports the NIH component of the Human Genome Project, a worldwide research effort designed to analyze the structure of human DNA and determine the location of the estimated 30,000 to 40,000 human genes.	489,368
National Center on Minority Health and Health Disparities	1993	Promotes minority health and leads, coordinates, supports, and assesses NIH efforts to reduce and ultimately eliminate health disparities among minority and other medically underserved communities. Conducts and supports basic, clinical, social, and behavioral research; promotes research infrastructure and training; fosters emerging programs; disseminates information; and reaches out to minority and other medically underserved communities.	200,630
National Center for Complementary and Alternative Medicine	1999	Explores complementary and alternative medical practices in the context of rigorous science; trains researchers; and disseminates authoritative information.	122,224
National Institute of Biomedical Imaging and Bioengineering	2000	Improves health by promoting fundamental discoveries, design and development, and translation and assessment of technological capabilities in biomedical imaging and bioengineering.	300,233

Source: NIH.

<sup>a</sup>The IC does not fund research and does not receive a separate appropriation but rather is funded through the NIH Management Fund.



# Appendix III: Comments from the National Institutes of Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

JUL 31 2009

Linda T. Kohn  
Director, Health Care  
U.S. Government Accountability Office  
441 G Street N.W.  
Washington, DC 20548

Dear Ms. Kohn:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: NATIONAL INSTITUTES OF HEALTH: Completion of Comprehensive Risk Management Program Essential to Effective Oversight (GAO-09-687).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Barbara Pisaro Clark".

Barbara Pisaro Clark  
Acting Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "NATIONAL INSTITUTES OF HEALTH: COMPLETION OF COMPREHENSIVE RISK MANAGEMENT PROGRAM ESSENTIAL TO EFFECTIVE OVERSIGHT" (GAO-09-687)**

The National Institutes of Health (NIH) appreciates the review conducted by GAO and the opportunity to provide clarifications, corrections, and additional supporting documentation on this draft report. NIH respectfully submits the following general comments. Technical comments are included as a separate attachment.

***GAO's Overall Conclusion: Completion of Comprehensive Risk Management Program Essential to Effective Oversight***

GAO's draft report implies that the NIH Enterprise Risk Management Program is the sole management oversight mechanism at NIH and fails to acknowledge other management, governance, and oversight bodies and functions.

As emphasized by the title of the report, it appears that GAO equates the NIH Risk Management Program with overall governance and management of the agency. This is a false assumption. NIH offers the following clarification.

While the risk management program at NIH is an important tool used by managers NIH-wide for decision-making, it is only one of many mechanisms available to the Office of the Director (OD) for effective oversight and accountability over the agency's 27 Institutes and Centers (IC).

OD is responsible for a number of programs that manage risk, reasonably ensure internal control, provide governance, and drive performance for the agency. As an Attachment to this response, NIH has enumerated many, but not all, of the oversight functions of NIH-wide activities that OD performs. For example, the NIH Steering Committee, chaired by the NIH Director and composed of 10 IC Directors, works as an efficient and transparent forum for trans-NIH governance and streamlined decision-making. Further, standing working groups provide recommendations to the NIH Steering Committee on issues such as intramural and extramural research, facilities, budget, and information technology.

Another example of an OD oversight mechanism is the NIH Ethics Advisory Committee that provides centralized, consistent, and rigorous reviews of requests to engage in outside activities and awards that bestow gifts over \$2,500. The Office of Extramural Research manages the Peer Review process, promotes scientific integrity, and manages research risks to patients. Likewise, the Office of Intramural Research manages the Institutional Review Board process for intramural research performed by NIH scientists.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "NATIONAL INSTITUTES OF HEALTH: COMPLETION OF COMPREHENSIVE RISK MANAGEMENT PROGRAM ESSENTIAL TO EFFECTIVE OVERSIGHT" (GAO-09-687)**

*GAO Finding: NIH's Current and Proposed Risk Management Programs Do Not Fully Address Key Components of Effective Risk Management (p.19)*

**1. Clarification: NIH's Enterprise Risk Management Program is based on widely-accepted Federal Government internal control standards.**

On page 19, GAO states that the program "does not fully address all of the components of GAO's framework for effective risk management." GAO's report relies on a comparison of the NIH Enterprise Risk Management Program with a risk management process published in an appendix to a report entitled, *Risk Management: Further Refinements Needed to Assess Risks and Prioritize Protective Measures at Ports and Other Critical Infrastructure* (GAO-06-91, Dec. 2005).

In a footnote on page 7 of the report, GAO states that "risk management does not replace, but rather incorporates and expands on internal control." However, NIH defines risk management as synonymous with internal control. The title "Risk Management" was used to distinguish the new internal control program from the former internal control program, which ended in 2006. NIH believed that the Risk Management Program would bring new enthusiasm to the internal control program from the scientific and management communities at NIH. NIH suggests deleting the footnote.

The criteria to which GAO compared the NIH Enterprise Risk Management Program are not the same criteria that NIH used in developing its Risk Management Program. Specifically, NIH used the *Standards for Internal Control in the Federal Government*; the Office of Management and Budget (OMB) Circular A-123, *Management's Responsibility for Internal Control*; the GAO *Internal Control and Management Evaluation Tool*; and the *Guidance Manual for OMB circular A-123 Assessments* published by the Department of Health and Human Services. We believe that these frameworks provide robust guidance to effectively manage risk and reasonably ensure internal control. Although there is some overlap between the guidance GAO used and the guidance NIH used, NIH chose its criteria because it meets the OMB and HHS standards for an internal control program.

While the fundamentals of the NIH Risk Management Program adhere to the above frameworks, NIH tailored the content and approach of the Program to have it work effectively in a scientific research environment. NIH strongly believes that these adaptations are critically important to the Program's success. For example, the NIH Program has developed a set of standardized criteria to evaluate and prioritize risks. Development of these criteria included input from a wide array of scientific and management personnel at NIH to make the criteria applicable to a wide range of risks at the agency. NIH suggests that GAO revise its report accordingly.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "NATIONAL INSTITUTES OF HEALTH: COMPLETION OF COMPREHENSIVE RISK MANAGEMENT PROGRAM ESSENTIAL TO EFFECTIVE OVERSIGHT" (GAO-09-687)**

2. **Correction:** GAO's draft report refers to a "current program" that is in fact a retired risk management program that has not been used in two years. The "proposed program" cited in the draft report is the NIH Enterprise Risk Management Program currently operating at NIH.

On page 19, GAO indicates that NIH implemented its "current" program in 1999 and updated it in 2004. This statement is incorrect.

The "current" program that was in place in 1999 and 2004 and was retired by NIH in 2006. All references to the "current" program in GAO's report correspond to the outdated program and are neither timely nor relevant to the activities currently being conducted and implemented as part of the NIH Enterprise Risk Management Program. The program identified by GAO as "proposed" is in fact the current program that is in operation at NIH.

NIH recommends that GAO correctly refer to the retired program as well as the Enterprise Risk Management Program that is currently being implemented and operated at NIH. In addition, NIH recommends that GAO move all references to the retired program (pages 19-23), including related findings, to a background section or remove them entirely from the report. NIH has provided technical comments on each reference made to the retired program so that GAO may appropriately correct this error.

3. **NIH does not concur with GAO's finding that the NIH Enterprise Risk Management Program "does not require NIH OD or ICs to set mission-based strategic goals and objectives as a pre-condition for risk management;" the report fails to acknowledge that all 27 NIH ICs have strategic plans and that the Program is designed to "support the research mission and vision of NIH."**<sup>1</sup>

On page 24 of the Strategic Goals, Objectives, and Constraints section of the draft report, GAO states that the program "does not require NIH OD or ICs to set mission-based strategic goals and objectives as a pre-condition for risk management." NIH recommends that GAO delete this finding and the associated recommendation.

The NIH Enterprise Risk Management Program "is designed to proactively identify and manage risks before they become obstacles to the NIH mission."<sup>2</sup> The NIH Enterprise Risk Management Program provides explicit guidance for all Program stakeholders to "Think strategically. Consider the goals, objectives and mission of the organization. Any event or condition that could prevent or inhibit the accomplishment of the organization's goals, objectives or mission should be documented as a risk."<sup>3</sup>

The ICs establish their own scientific research strategic goals and objectives. IC-level goals and objectives do not contradict each other, are relevant to the broader NIH-wide mission, and include measurement criteria. However, there is a direct link between each IC's operational strategies and those of NIH as a whole. NIH is the steward of medical and behavioral research for the nation. One of the four

<sup>1</sup> NIH Enterprise Risk Management Guidebook, page 6.

<sup>2</sup> Ibid.

<sup>3</sup> NIH Enterprise Risk Management Guidebook, page 25.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "NATIONAL INSTITUTES OF HEALTH: COMPLETION OF COMPREHENSIVE RISK MANAGEMENT PROGRAM ESSENTIAL TO EFFECTIVE OVERSIGHT" (GAO-09-687)**

goals of the agency is to "exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science."<sup>4</sup> In realizing this goal, the NIH Deputy Director for Management provides leadership and direction to programs such as the Enterprise Risk Management Program.

The Program is part of a management strategy to support the scientific research mission of NIH. The NIH Deputy Director for Management's (DDM) Strategic Plan includes four goals:

- Goal 1 – Improving Human Capital Planning and Management
- Goal 2 – Leveraging Information for Data Driven Decision-Making to achieve Performance Excellence
- Goal 3 – Employing Proactive Risk Management to Enhance Program Performance
- Goal 4 – Enhancing Internal Communications

The mission of the management community is to enable NIH to pursue its biomedical research mission of scientific discovery and advancement of knowledge by serving as a valued partner that provides timely, high quality, and responsive programs and services in a manner that reflects a commitment to excellence and the preservation of public trust.

**4. NIH concurs with GAO's finding and corresponding recommendation regarding alternatives evaluation, including evaluation of risk responses.**

On page 25 under the Alternatives Evaluation section of the draft report, GAO states that the program "does not require management to evaluate the risk responses identified to consider (1) the effect on the likelihood of occurrence and impact of a potential risk and (2) the costs and benefits."

We appreciate this valuable feedback to improve our Program. As a result of GAO's review, findings and recommendations, NIH will update the Enterprise Risk Management Guidebook to reflect this recommendation. The proposed risk response should be reviewed by the Program and discussed during the Remediate phase to determine appropriateness. The resulting assignment of the risk response will consider alternatives based upon various factors, including cost and benefits.

NIH is in the process of updating its policy regarding enterprise risk management and internal controls found in Manual Chapter 1750. Revisions to the policy will be reflected in updates to its Enterprise Risk Management Guidebook to address ongoing monitoring of risk strategies and potential alternatives.

**5. NIH concurs with GAO's finding and corresponding recommendation regarding documentation of management selection.**

On page 25 under the Management Selection section of the draft report, GAO states that the program does "not require management to document the rationale for selecting a particular risk response." We

<sup>4</sup> NIH website, [www.nih.gov/about](http://www.nih.gov/about)

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "NATIONAL INSTITUTES OF HEALTH: COMPLETION OF COMPREHENSIVE RISK MANAGEMENT PROGRAM ESSENTIAL TO EFFECTIVE OVERSIGHT" (GAO-09-687)**

appreciate this feedback and have incorporated this element into our processes and amended the Enterprise Risk Management Guidebook.

**6. NIH concurs with GAO's Implementation and Monitoring finding regarding how the assessments of the overall effectiveness of the risk management program should be performed. However, NIH offers the following clarifications.**

On page 25, within the Implementation and Monitoring section of the draft report, GAO states that the program "does not offer any detail regarding how assessments will be performed" and "the design does not require periodic assessments of implemented risk responses."

The NIH Enterprise Risk Management Program has already undergone several incremental evaluations. First, upon completion of the pilot, the Program conducted an evaluation to gather stakeholder feedback. This feedback was used to further refine the NIH risk management methodology and the tools that support it. Results of the pilot evaluation are documented in a pilot test report that was completed at the conclusion of pilot test activities.

In addition, after the completion of the risk identification and scoring steps in the first phase of implementation with the NIH OD, the Program conducted an internal evaluation. Program staff evaluated the process and outcomes and developed lessons learned and recommendations for improvement to guide the Program in the implementation of Phase 2 with the NIH ICs. Results of this evaluation are documented in the OD Baseline Report.

An additional staff evaluation, documentation of lessons learned and development of recommendations for further Program improvements is currently underway and is expected to be finalized by August 15, 2009.

A more formal evaluation of the Program is being planned and will likely include a follow-up of the Risk Culture Survey that was conducted during the HHS audit in 2006. The Risk Culture Survey examines potential strengths and weakness in the risk management and control environment. It measures the impact of the Program on the internal control environment at NIH, focusing on Leadership and Strategy, Accountability and Reinforcement, People and Communication, Risk Management and Infrastructure. These four areas include sub-components that include ethics, tone at the top, and training.

NIH has identified target milestone periods for ongoing evaluation in the Risk Management portion of the NIH Deputy Director for Management's Administrative Management Strategic Plan. This includes developing a program evaluation process and conducting periodic reviews. NIH anticipates that by June 30, 2010, NIH will conduct a follow-up Risk Culture Survey and will develop a program evaluation process, to include determining the frequency, scope and methodology for the reviews. In FY 2011, NIH will conduct reviews of the overall efficiency and effectiveness of the NIH Enterprise Risk Management Program.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "NATIONAL INSTITUTES OF HEALTH: COMPLETION OF COMPREHENSIVE RISK MANAGEMENT PROGRAM ESSENTIAL TO EFFECTIVE OVERSIGHT" (GAO-09-687)**

7. NIH does not concur with the finding and corresponding recommendation regarding the Program's internal environment. NIH does incorporate the importance of ethical values into the Program and maintains the competence of its risk management personnel by providing training.

NIH operates within an environment in which ethical values play a key role

On page 25, GAO states that the Risk Management Program could be improved by "incorporating the importance of ethical values." The Program already operates within the context of a positive environment in which integrity and ethical values play a key role. NIH has a formal code of conduct; senior management has established an ethical tone and consistently models and enforces conscientious and competent leadership; management takes disciplinary action whenever appropriate or necessary and NIH has an extensive set of guidance on ethics. The NIH Ethics Office, within the OD, works in tandem with each individual IC Ethics Program to provide mandatory ethics training—both for new and current employees—that exceeds federal requirements. The importance of ethical values is being reinforced constantly through other means and in other ways that more directly affect internal controls.

Furthermore, the report does not provide any evidence to support this statement and does not state how this would be achieved. We ask that the finding and recommendation be deleted from the report. Nevertheless, NIH will amend the Enterprise Risk Management Guidebook to include specific language addressing the importance of ethics at NIH.

NIH maintains the competence of its risk management personnel by providing training

On page 25, GAO states that the program could be improved by "ensuring management maintains the competence of its personnel by providing for continuous training to update personnel on risk management practices and techniques." It should be highlighted that NIH provided GAO with documentation about training given to OD and IC staff who hold significant risk management roles, as well as the completion dates of training. The information shows that NIH does ensure the competence of staff working in risk management and does not support GAO's conclusion about the lack of training on risk management practices and techniques. NIH does not understand how GAO reached this conclusion, and the report does not provide an explanation or supporting evidence for this finding.

To date, the NIH Enterprise Risk Management Program has provided training to over 400 individuals who hold significant risk management roles. This includes training specifically tailored for all OD Office Directors and IC Executive Officers. In addition, specific training focusing on the methodology and the identification of risks was provided to OD Office staff and IC leadership staff identified by OD Office Directors and IC Executive Officers as having important risk management roles. Additional training data is available to GAO upon request.

The number of individuals trained to date is a result of the NIH Enterprise Risk Management training plan, which establishes targets for continuous training. NIH has also developed a formal risk management training course that is available to all NIH employees through the NIH Training Center and is developing training for NIH Administrative Officers. Furthermore, the DDM Strategic Plan includes a strategy for developing role-based and general awareness risk management training to reinforce a culture of risk awareness among leadership and staff. The training, as well as risk management communications,

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "NATIONAL INSTITUTES OF HEALTH: COMPLETION OF COMPREHENSIVE RISK MANAGEMENT PROGRAM ESSENTIAL TO EFFECTIVE OVERSIGHT" (GAO-09-687)**

help ensure that all employees understand their role in conducting operations in a manner that manages risk. NIH has not provided training updates and refreshers because the program first began reaching personnel in 2008 and 2009. However, the NIH Enterprise Risk Management training plan will incorporate these as the Program continues. Therefore, NIH recommends that GAO change its finding and revise its recommendation for NIH to "fully implement its plan for ongoing training."

**8. NIH partially concurs with GAO's finding that the NIH Enterprise Risk Management Program should "require the collection and dissemination of pertinent information to relevant external stakeholders."**

On page 26 within the Information and Communication component, GAO states that "the program does not require the collection and dissemination of pertinent information to relevant external stakeholders in a form and timeframe consistent with NIH's risk management needs." NIH offers the following clarification. GAO places emphasis on the communications with internal stakeholders cited in the GAO framework, *Risk Management: Further Refinements Needed to Assess Risks and Prioritize Protective Measures at Ports and Other Critical Infrastructure* (GAO-06-91).

NIH promptly responds to all requests for information from external stakeholders, including those related to internal controls and risk management. The Risk Management Program provides NIH and HHS internal stakeholders with timely and accurate risk management data. For example, the Program provides the NIH Risk Management Council and NIH Risk Management Senior Assessment Team with risk management reports, program status updates, and updates on emerging risk management issues such as the Recovery Act. Another example of internal risk management communications is the Program's delivery to HHS of the NIH annual Federal Managers' Financial Integrity Act (FMFIA) statement of assurance attesting that NIH federal programs have effective and efficient controls in place that meet the objectives of the FMFIA and OMB Circular A-123.

The Program will include external communications and exchanges as it matures.

**9. NIH does not concur with GAO's finding that the Enterprise Risk Management Program has been hampered by a lack of milestones. Although the Program has encountered some delays, the Program maintains a schedule of milestones.**

NIH has implemented all six steps of the Enterprise Risk Management methodology.

On pages 19 and 26, the GAO report states that the NIH program has "not yet [been] fully implemented despite an over 3-year effort." This statement is incorrect.

During the field work phase of its audit, GAO inquired about whether the risk management methodology had been implemented NIH-wide. NIH stated that as of November 19, 2008, the new risk management methodology had not been fully implemented across NIH.

However, since November 2008, NIH has implemented steps 1 and 2 (Organize and Identify and Score) of the methodology across all 27 ICs, as well as steps 3 and 4 (Assess and Remediate) of the methodology



**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "NATIONAL INSTITUTES OF HEALTH: COMPLETION OF COMPREHENSIVE RISK MANAGEMENT PROGRAM ESSENTIAL TO EFFECTIVE OVERSIGHT" (GAO-09-687)**

across OD. The creation of a comprehensive NIH enterprise baseline risk inventory is a result of the agency's implementation of the Identify and Score steps of the methodology across NIH. Furthermore, On May 7, 2009, NIH hosted the first Risk Management Council (RMC) meeting. The RMC provides guidance on program implementation and operations, has oversight over the completion of risk management activities, and reports results to the NIH Risk Management Senior Assessment Team. Because these two risk management governance structures are operational, NIH executed Steps 5 and 6 (Monitor and Report) of the methodology. Therefore, NIH believes that it has executed all six steps of its Enterprise Risk Management Program for a fully functioning Program.

NIH began developing the Enterprise Risk Management Program in August 2007. In just two years, NIH has designed and executed its Enterprise Risk Management Program to conform to GAO, OMB, and HHS guidance. This represents extraordinary progress. NIH recognizes the need for continued progress to fully implement and continuously improve the Program. NIH defines full implementation as an initial completion of the Program's first two steps (Organize and Identify and Score) and the continuous operation of the remaining four steps: Assess, Remediate, Monitor and Report. The NIH Enterprise Risk Management Program is scheduled for full implementation by June 2010.

The Program maintains a schedule of milestones

On pages 19 and 26, GAO's draft report indicates that the NIH program has "been hampered by a lack of milestones." This statement is also incorrect.

According to the GAO document, *Performance Measurement and Evaluation*, GAO/GGD-98-26, page 3, a "program may be any activity, project, function, or policy that has an identifiable purpose or set of objectives." The NIH Enterprise Risk Management Program maintains a schedule of milestones and defines the Program's goals and objectives in the NIH Management Strategic Plan discussed in Response #4 of this document. During the fieldwork phase of GAO's audit, NIH provided GAO with a Work Breakdown Structure document that contained significant milestones such as the following:

- Complete a pilot of the Enterprise Risk Management Program methodology
- Implement steps 1 through 4 of the methodology across OD
- Implement steps 1 and 2 of the methodology across all 27 ICs
- Conduct risk management training to individuals who hold significant risk management roles
- Implement both risk management governance structures: the Risk Management Council and the Risk Management Senior Assessment Team

The development and implementation of the Program demonstrates the remarkable level of effort and commitment NIH has invested over the past two years.

GAO does not provide agencies with an standard timeline for fully implementing a Risk Management Program

On page 29, GAO recommends that NIH complete and implement its program in a reasonable timeframe. GAO does not define what constitutes a "reasonable" timeframe. NIH offers the following clarification.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "NATIONAL INSTITUTES OF HEALTH: COMPLETION OF COMPREHENSIVE RISK MANAGEMENT PROGRAM ESSENTIAL TO EFFECTIVE OVERSIGHT" (GAO-09-687)**

In the December 2005 report, *Risk Management: Further Refinements Needed to Assess Risks and Prioritize Protective Measures at Ports and Other Critical Infrastructure* (GAO-06-91), pages 99 and 101, GAO acknowledges that the "[GAO] risk management framework has been used to evaluate activities related to security and combating terrorism" and "is intended to be a starting point for risk management activities and will likely evolve as processes mature and lessons are learned." While the framework is a valuable tool for establishing a "full cycle of related activities from strategic planning through implementation and monitoring" and is used to "inform agency officials and decision makers of the basic components of a risk management system," it does not provide agencies with a standard timeline for fully implementing a risk management program.

NIH would like to know the criteria GAO used as a basis for its conclusion and asks that this finding be modified in the report.

***GAO Finding: NIH Is Required to Use a Peer Review System to Make Extramural Funding Decisions; NIH's OD Does Not Monitor Key Decisions In Which IC Directors Exercise Their Discretion Over Funding Decisions (p.9)***

**1. NIH does not concur with the recommendation that would require an oversight role for the OD that is inconsistent with the IC Director's authority to make grant award decisions.**

GAO states that IC directors can use their discretion and choose to fund applications on the basis of factors other than scientific merit, "skipping" over applications with higher scores or making "exceptions" to fund applications with lower scores. NIH stresses that while IC directors authorize these actions, their decisions are not made in isolation or without consultation, and review. The NIH OD ensures that there is a process in place that documents these decisions and that these documents are available upon request, should questions arise.

ICs are required to document the rationales used when skipping applications or funding applications as exceptions. While the ICs are not required to routinely provide the NIH OD with this documentation, these data are available, upon request, for analysis by the NIH OD for assessing compliance or for other purposes. The GAO recommendation should be revised accordingly to recognize that the role of the NIH OD for this activity is to ensure that documentation procedures are in place, not to have input about the specific scientific reasoning about skipping applications or funding applications as exceptions.

GAO implies a role for the OD that is not scientifically appropriate. Specific reasons for skips and exceptions must and should rely on the judgment of scientific officials who understand the current trends in science, as well as the portfolios of the institute.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "NATIONAL INSTITUTES OF HEALTH: COMPLETION OF COMPREHENSIVE RISK MANAGEMENT PROGRAM ESSENTIAL TO EFFECTIVE OVERSIGHT" (GAO-09-687)**

2. In response to Page 15, Table 1, "Extramural Research R01 Grant Applications Funded in FY03 –FY07", NIH would like to highlight that R01 grants awarded outside the payline from FY03 through FY07 were in fact a result of the increase in the number of R01 grants awarded to new investigators.

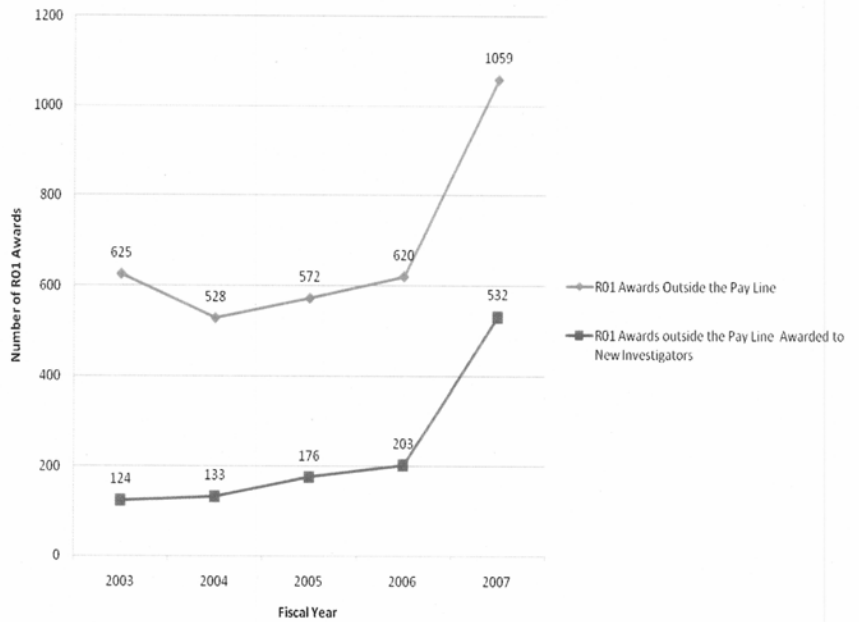
Maintaining a viable research workforce is considered essential to the vitality of health-related research. That means new investigators must enter the pool of NIH funded Principal Investigators at a reasonable rate to replace those who choose to leave or leave because their applications are no longer competitive. In some cases, an adequate supply of new investigators is dependent on funding applications that receive review scores outside the normal funding range, as shown in the chart below. It should be pointed out that these applications are still well within the range of scores that are considered to be highly meritorious. In order to protect the viability of the extramural workforce the NIH reaches for additional applications from New Investigators.

During FY07 through FY 2009, the OD designed and implemented policies to support new investigators. The policies were designed to reverse the steady decline in the number of new investigators that started in FY03. Annually, OD has presented guidelines to the Institute Directors. Those guidelines are available at [http://grants.nih.gov/grants/new\\_investigators/index.htm](http://grants.nih.gov/grants/new_investigators/index.htm). Each year the OD sets New Investigator targets for the ICs and then tracks awards to New Investigators during the course of the year. Over the past three fiscal years the NIH has reached the established targets. The importance of new investigators to the continued success of the NIH extramural programs is well understood. This information has been clearly articulated in notices that have appeared in the *NIH Guide for Grants and Contracts* and in other NIH publications and presentations.

NIH created the graph below to illustrate the increase in the raise-to-pay awards as a result of the increase in R01 awards to new investigators.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "NATIONAL INSTITUTES OF HEALTH: COMPLETION OF COMPREHENSIVE RISK MANAGEMENT PROGRAM ESSENTIAL TO EFFECTIVE OVERSIGHT" (GAO-09-687)**

**NIH R01 Awards Outside the Pay Line  
Awarded to New Investigators**



3. NIH would like to review GAO's method and approach for quantifying out of order funding.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "NATIONAL INSTITUTES OF HEALTH: COMPLETION OF COMPREHENSIVE RISK MANAGEMENT PROGRAM ESSENTIAL TO EFFECTIVE OVERSIGHT" (GAO-09-687)**

*GAO Finding: Design of NIH's Travel and Personnel Appointment Processes Include Key Control Activities and Some Monitoring Activities but Lacks Systemic Risk-Based Monitoring (p.16)*

**1. NIH concurs with the finding that the design of NIH's Title 42 personnel appointment process includes key control activities and some monitoring but lacks systemic risk-based monitoring.**

On page 16, GAO states: "The NIH OD has also established policies and procedures to help ensure that Title 42 personnel appointment decisions are appropriate." The report continues on page 17 to say that "the design of the controls included in the NIH-wide processes over travel and Title 42 personnel appointments included key controls necessary to help ensure these activities were being carried out appropriately, except in one key area related to the lack of requirements for risk-based management." This key area was identified as systemic monitoring that "includes risk-based control evaluations." Further the report states that while some monitoring was going on, it was neither a part of a systemic risk assessment plan and was not performed on an on-going basis.

In regard to the Title 42 personnel appointment process, NIH agrees with the GAO finding that at the present, NIH does not have in place a systemic monitoring program for risk-based evaluations. While evaluations are done, as the report notes, they do not meet the test of being part of a "systemic risk assessment plan" or are not performed on a consistent and on-going basis. NIH will incorporate risk-based monitoring into the Title 42 personnel appointment process. In addition, NIH will add the Title 42 personnel appointment process as a risk area within the NIH Enterprise Risk Management Program to ensure that the risk is monitored and assessed.

NIH identified and scored the agency travel process as a risk area within the NIH Enterprise Risk Management Program. Therefore, travel risks are being monitored. NIH will reassess the travel risk levels to ensure that they are appropriate.

**Appendix III: Comments from the National Institutes of Health**

Attachment

The National Institutes of Health Inventory of OH Oversight Mechanisms for the GAO Government and Oversight Review					
#	OD Organization Responsible for the Oversight	OD Oversight Mechanism Currently In Place	Purpose of the OD Oversight Mechanism	How the OD Oversight Mechanism Operates	Frequency
1	IMOD	NIH Steering Committee	Committee chaired by the NIH Director and composed of ten IC Directors works to streamline, harmonize and better coordinate decisions that affect the entire agency	Makes decisions on NIH-wide policies and operational issues that will be disseminated and carried out NIH-wide	Other
2	IMOD	Institute and Center Directors Meetings	Chaired by the NIH Director and composed of Directors from all the NIH Institutes and Centers, this body provides oversight on matters of scientific priority.	Addresses NIH-wide issues concerning scientific prioritization and provides recommendations to the NIH Director	Bi-weekly
3	IMOD	NIH Steering Committee Working Groups	Working Groups on Management and Budget, Intramural Research, Extramural Research, Facilities, and Information Technology work to streamline, harmonize and better coordinate decisions in these areas for better cross-agency coordination	Provides oversight on issues in the purview of each Working group and makes decisions or raises issues to the level of the NIH Steering Committee, when appropriate.	Other
4	NEO	NIH Ethics Advisory Committee	To provide a centralized, consistent, and rigorous review of requests to engage in outside activities with pharmaceutical and biotech companies, awards that bestow gifts over \$2500, and senior officials' outside activity requests	Conducts central review by knowledgeable scientific peers (with the aid of ethics officials and legal staff) of requests for approval to engage in certain outside activities and to accept certain gifts associated with bona fide awards	Bi-weekly
5	OALM	Annual Trans-NIH Asset Inventory	To provide a mechanism to track property over time to reconcile losses and non-declared items, and to provide IC reports that determines if equipment is used for its planned lifecycle or turned in early.	NIH/OALM/OA/OD/IS/ Property Branch conducts a rolling 100% inventory of all accountable property to ensure that it is either declared or will be declared. Discrepancies are provided to the ICs for use in property reports of survey.	Annually
6	OALM	Delegated Acquisition Reviews	To ensure that IC delegated procurement areas are in compliance with simplified acquisition policies/procedures established by FAR, HHS, and NIH guidelines. The reviews are conducted to prevent fraud, waste and abuse as well as a tool to evaluate the effectiveness of the NIH Simplified Acquisition Delegated Training provided to employees.	Periodic reviews of approvers and buyers in the delegated offices where a sampling of previous actions within a timeframe are examined for compliance	Continuously
7	OALM	Acquisition Management Reviews	To ensure that acquisitions across NIH are in compliance with current OMB, FAR, HHS, and NIH regulations.	Performs periodic reviews of the various NIH acquisition mechanisms by forming a team of acquisition officials to assess the overall acquisition process at NIH	Other
8	OALM	Purchase Card Reviews	To ensure that IC purchase cards are being used appropriately and are within established HHS, NIH and FAR guidelines. The reviews are conducted to prevent fraud, waste and abuse and to train employees.	Periodic desk to desk audits of cardholders, and monthly compliance reviews (review of all monthly purchases) are being conducted continuously.	Continuously
9	OALM	Review & negotiation of indirect cost rates	To ensure that the award and reimbursement of indirect costs charged to NIH contracts and grants by commercial organizations are reasonable, allowable and allocable.	Commercial organizations submit annual indirect cost rate proposals to the Division of Financial Advisory Services, OALM, for review and negotiation of provisional and final rates; rate agreements are posted on a secure database for use by awarding components. (Awardee submiss proposals annually)	Annually
10	OALM	Resolution of audit findings of NIH grantees	To ensure that unallowable costs charged to NIH awards are refunded to the government and that awardees' non-compliant practices are corrected.	Awardees' audit reports (from annual Single Audits and OHG audits) that contain findings related to NIH awards are forwarded to DFAS, OALM, for resolution. The DHHS OIG maintains a tracking database (AIMS) to ensure that all findings have been resolved.	Annually
11	OALM	Delinquent audit follow-up	To ensure that awardees subject to the Single Audit Act have had their required audit performed by an outside CPA firm, and that they have submitted required audit reports to the Federal Audit Clearinghouse for review and further action.	The Department matches awardee expenditures with audit reports received and forwards an annual list of delinquent organizations to each OPDIV for follow-up. DFAS and OALM performs the follow-up function for NIH. DFAS reports the status of delinquent audit follow-up to the Department on a quarterly basis.	Quarterly
12	OALM	Board of Contract Awards financial reviews	To ensure that the financial aspects of acquisitions are in accordance with policies and procedures.	A sample of proposed contract award files are forwarded to DAPE, OALM for review. DFAS, OALM performs the financial part of the review	Multiple times per year
13	OALM	Board of Contract Award Reviews	To ensure compliance with the HHS Acquisition Regulation which requires the NIH Head of the Contracting Activity to establish review and approval procedures for proposed contract actions.	Each of the 10 Offices of Acquisition is required to submit a percentage of files for review each fiscal year.	Continuously
14	OALM	Contracting Officer's Warrant Review	To ensure that warrant holders have met the refresher training requirements, that the office still has a need for them to have that authority and that the warrant should remain valid.	Delegated to the Acquisition Career Manager (ACM), who works with Office of Acquisition Directors to verify warrant information.	Continuously
15	OALM	Review of Noncompetitive Contract Actions Exceeding \$550,000	To provide an additional level of review for actions required by HHS to be approved by the NIH Competition Advocates.	The Division of Acquisition Policy and Evaluation/OALM reviews and recommends approval, as appropriate, of noncompetitive actions exceeding \$550,000 prior to the HHS required review by the NIH Head of the Contracting Activity	Continuously
16	OAR	Portfolio Assessment	To ensure NIH AIDS research dollars are used to support the current highest scientific priorities in AIDS research.	Using the ARIS database, OAR senior scientific staff identify projects that are eligible for recompetition during the Strategic Plan year that are no longer aligned with the current scientific priorities. ICs are informed of the projects that should no longer be supported with AIDS funds.	Annually

Page 1

**Appendix III: Comments from the National Institutes of Health**

Attachment

The National Institutes of Health Inventory of OD Oversight Mechanisms for the GAO Governance and Oversight Review					
#	OD Organization Responsible for the Oversight	OD Oversight Mechanism Currently In Place	Purpose of the OD Oversight Mechanism	How the OD Oversight Mechanism Operates	Frequency
17	OB	Reprogramming	Reprogramming is the process of shifting funds within an appropriation during the budget execution phase. Justification and documentation procedures are disseminated annually by OB to assist ICs in determining whether an alternate distribution of enacted budget authority is warranted based on their operating plan and Congressional reprogramming thresholds.	OB issues guidance to the ICs that reaffirms under what circumstances reprogramming is allowed. The IC's reprogramming requests indicate where funds will be used and from where they would be taken with a narrative of the reasons. OB validates the accuracy and checks for potential variances of each reprogramming request to ensure it conforms to the law and NIH policy. OB forwards the reprogramming requests to Congress through HHS and OMB consistent with statutory requirements	Annually
18	OCIO	Information Technology Management Committee (ITMC)	IC advisory committee to the CIO, chaired by the NIH CIO and composed of IC CIOs and other key IT leaders, works to streamline, harmonize and better coordinate IT activities and decisions that affect the entire agency	Advises the NIH CIO on NIH-wide IT issues that will affect all of NIH	Monthly
19	OCIO	Information Systems Security Officers (ISSO)	IC advisory committee to the CISO, chaired by the NIH Senior ISSO and composed of IC ISSOs and other IT security team members, works to streamline, harmonize and better coordinate IT security activities and decisions that affect the entire agency	Advises the NIH CISO on NIH-wide IT issues that will affect all of NIH	Monthly
20	OEP	NIH Guide Publishing System Integrity Monitoring	To provide a state-of-the-art centralized repository for grant documents using a SharePoint system developed within the OD. This technical support system provides document storage and easy access Trans-NIH, as well as other Federal Agencies, for rigorous review of each document by 8-10 senior staff, of policies and procedures pertaining to grant documents published in <i>The NIH Guide for Grants and Contracts</i> . The NIH Guide Publishing System provides oversight, accountability, monitoring, and quality control for over 1,000 FOAs, Notices, Contracts, and grant documents for the 27 NIH Institutes and Centers, as well as other Federal Agency subscribers.	The first of two oversight mechanisms for publications in <i>The NIH Guide</i> : ensures adherence to policy and policy integrity, the NIH Guide Director and staff continuously monitor, edit, and correct documents submitted to the NIH Guide Publishing System used by 27 NIH Institutes and Centers, and other Federal Agency subscribers, before clearance for publication in <i>The NIH Guide</i> . Daily meetings are conducted with Trans-NIH constituents and contracted SharePoint support staff, to monitor communication and decision making regarding overall system issues, set priorities, reformulate policy, evaluate and monitor NIH Guide Publishing System effectiveness, and identify technical issues for study or discussion. Makes recommendations to the NIH Extramural Community.	Continuously
21	OEP	NIH Review Policy Officer (RPO)	Oversees the establishment, consistent interpretation, oversight, and implementation of all NIH-wide review policies including receipt and referral, conduct of reviews, reports of review proceedings (summary statements), conflicts of interest, and confidentiality. This includes policies and procedures for the initial (study section) level of peer review, the second (Advisory Council/Board) level of peer review, and other types of review such as non-FACA meetings and review of RAID proposals.	The NIH Review Policy Officer is responsible for the establishment, consistent application, and oversight of review policy across all ICs; is the final authority on the contents of the NIH Grants Administration Manual on the Peer Review Process and the Manual Chapter on Advisory Council Procedures; makes recommendations to the DDER on waivers of conflicts of interest and NIH policy; works with the OFACP on implementation of FACA for review committees and Advisory Councils/Boards; and advises the DDER on all issues pertaining to peer review policy. The decisions of the DDER are final.	Continuously
22	OEP	Research Misconduct Allegation Review	The NIH Agency Extramural Research Integrity Officer (AERIO) is the designated NIH official responsible for handling allegations of research misconduct that involve extramural NIH funding or NIH-supported research. The AERIO resides in OER, and currently is the Acting DDER. In addition, the Extramural Research Integrity Liaison Officer(s) (ERILOs) reside in OEP.	The AERIO and ERILOs are responsible for receiving all allegations of research misconduct from the ICs, performing initial reviews of all allegations, forwarding them to the Office of Research Integrity (DHHS) or other offices as appropriate, and communicating with IC staff concerning allegations in their IC. They are responsible also for coordinating all communications concerning allegations between the ORI and NIH, and for providing annual training to NIH extramural staff and IC Research Integrity Officers.	Continuously
23	OER	Waivers in Peer Review Policy	To provide a centralized, consistent, and rigorous review of any relationships or procedures that deviate from peer review policy regarding: Conflicts of Interest that result from Professional Relationships; Practices that differ from NIH policy; Committee composition	Conducts central review and makes decisions about whether a waiver is justified.	Continuously
24	OER	Approval of IC awards that are recused	To provide review of Institute spending plans that include awards to institutions/organizations where the IC Director is recused	Conducts central review to ensure that the peer review process was followed and that no perceived or real bias is introduced in the award selection process.	Continuously
25	OER	Extramural-OD Title 42 Committee	The Extramural Title 42 (T) Committee is responsible for advising the Director of NIH on matters regarding the effective administration of the Extramural-OD Title 42 (T) Model, and to ensure that extramural-OD Title 42 appointments are made in compliance with governing laws, regulations and policies.	The ETFC reviews overall policy issues as well as the procedures and processes associated with extramural-OD Title 42 appointments; sets priorities and formulates review principles; reviews all extramural Title 42 position proposals submitted for consideration by ICs; and monitors effectiveness, equity and consistency in the application of the Title 42 Model. The Committee identifies areas and issues for specific study or discussion and makes recommendations to the Director of NIH.	Bi-Weekly
26	OER	OLAW Division of Assurances	Provides centralized review of animal welfare concerns identified during peer review of grants pending award; ensures resolution prior to award	Conducts central review to ensure that P.L. 99-158 is appropriately followed and grants are not awarded without animal welfare concerns resolved.	Continuously
27	OER	OLAW Division of Compliance Oversight	Provides centralized review concerning noncompliance with PHS animal welfare policy and provides guidance to IC grants management staff concerning when terms and conditions of award are in question	Conducts central review and ensures P.L. 99-158 is appropriately followed.	Continuously

Page 2

**Appendix III: Comments from the National Institutes of Health**

Attachment

The National Institutes of Health Inventory of OD Oversight Mechanisms for the LACU Governance and Oversight Review					
#	OD Organization Responsible for the Oversight	OD Oversight Mechanism Currently in Place	Purpose of the OD Oversight Mechanism	How the OD Oversight Mechanism Operates	Frequency
28	OER	OLAW Division of Assurances	Provides centralized review and tracking of grants where due to end of year funding, restricted terms and conditions are in place when Animal Welfare Assurances or verification of IACUC approval are lacking.	Conducts central review, tracking and audits to ensure restrictions on grants are resolved in keeping with P.L. 99-158.	Continuously
29	OER	Financial Conflict of Interest (FCOI) compliance oversight	To provide oversight of grantee institutions' compliance with 42 CFR Part 50 Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought.	Work with grantee institutions to address questions/concerns regarding particular or potential investigator FCOI by requesting pertinent information, including how conflicts were identified and managed, reduced, or eliminated. Evaluate if institutional policies and procedures are compliant with regulation and work with institutions to correct identified deficiencies. Also provide oversight of grantee institution reporting and NIH extramural staff evaluation of FCOIs.	Continuously
30	OER	Management Control Compliance Model	To ensure that IC grants management staff are complying with NIH/OER grants policy.	Conducts risk assessment and conducts internal control testing to assess IC compliance with policy. Provides feedback to IC staff and requires corrective actions, as necessary.	Continuously
31	OER	Grantee Compliance with Terms and Conditions of Award	On behalf of IC grants management, coordinate large cases of institutional noncompliance to ensure issues are addressed through corrective actions and any funds due NIH are recovered.	Work with grantee institutional officials to address instances of noncompliance. Also collaborate with US Department of Justice, Offices of Inspector General, and the HHS Office of the General Counsel.	Continuously
32	OER	Human Subjects Concerns Reconciliation	To provide a centralized, consistent, and rigorous review of all proposed NIH grants that have a bar to funding due to human subjects concerns identified in the peer review process. The NIH Extramural Human Research Protection Officers are responsible for reviewing and changing codes to lift the bar to funding by ensuring that all regulatory requirements have been met.	Human Research Protection Officers review all grant documents to ensure that human subjects are protected throughout research, and work with IC (and applicant institution) to address concerns and bring research into compliance with OHRP/DHHS policy and regulation.	Continuously
33	OFACP	NIH Advisory Committee Office and Service Center Reviews/Audits	To ensure that federal advisory committees at NIH are managed according to federal statutes, regulations, and HHS/NIH policies.	OFACP Specialist visits IC Committee Management Offices performs audit, followed by a written report.	Other
34	OFM	Travel Voucher/Travel Card Review	To provide a centralized, random sampling review of completed travel vouchers to assess compliance with the Federal Travel Regulation (FTR) and GSA travel card use.	Conducts central review by knowledgeable FTR functional experts.	Quarterly
35	OFM	Corporate Travel Management Committee	Committee chaired by the Deputy Director for Management and composed of the two other Deputy Directors (Intramural and Extramural), the Director, Office of Financial Management (OFM) and the Director, Fogarty International Center.	Makes decisions on NIH-wide Travel policies for compliance with FTR and HHS regulations/policies and oversees trans-NIH travel to largely attended conferences, travel medical waivers, IC Director travel, sponsored travel and international travel.	Continuously
36	OHR	NIH Performance Review Board (PRB) and SES ERB	Reviews all SES appointments, and initial performance ratings and recognition recommendations and make recommendations to the NIH Director.	Boards are convened of senior NIH management officials as needed to review cases.	Continuously
37	OHR	NIH Clinical Compensation Panel (NCCP)	Reviews all request for appointment or conversion to the Title 42(D) Clinical Track.	Standing committees comprised of senior NIH management officials review cases.	Continuously
38	OHR	NIH Compensation Committee (NCC)	Reviews all actions requiring central approval to facilitate equitable and consistent pay setting for similarly qualified scientists performing similar work at NIH.	Standing committees comprised of senior NIH management officials review cases for technical compliance.	Bi-weekly
39	OHR	Employee Relations oversees disciplinary actions	Review and concur on disciplinary actions to ensure consistency.	Proposed disciplinary actions reviewed prior to issuance to employees.	Continuously
40	OIR	Annual Management Control Questionnaire	The series of questions posed to the Scientific Directors and their staff gathers information on the application of risk mitigation processes and reminds the SDs of their responsibilities in these areas.	Responses are received in the OIR and analyzed by the Management Liaison Director; responses are reviewed with the SDs collectively and individually for remediation.	Annually
41	OIR	NIH Animal Research Advisory Committee	The NIH ARAC meets regularly to review policies and operations of the NIH Animal Care and Use program with Animal Care and Use Committee Chairs as well as Animal Program Directors and coordinators. ARAC reviews all incidents reported to the NIH Office of Laboratory Animal Welfare in order to educate the community and avoid recurrence.	The ARAC advises the NIH Institutional Official (the Deputy Director for Intramural Research) on policy and other matters; it recommends actions to maintain an accredited animal care and use program at NIH.	Monthly
42	OIR	NIH Boards of Scientific Counselors	The DDR and the OIR oversee the outcomes of the IC Boards of Scientific Counselors at their individual sessions during the year, as well as review the overall operations of the BSCs annually with the Chairs of the IC BSCs.	The DDR or designated representatives of the OIR attend all outbriefings of the BSC site visits and full BSC meetings to hear the results of the reviews. An annual meeting of the BSC chairs is led by the DDR; the Director of NIH has opportunity to address the Chairs as well, and possible improvements to the BSC process are discussed.	Annually
43	OIR	Intramural Clinical Research Steering Committee	This high-level committee was established mainly to oversee the streamlining of clinical research at the NIH and to address the efficient operation of clinical research review.	The committee is chaired by the Deputy Director for Intramural Clinical Research in the OIR; it includes IC Directors, Scientific Directors, Clinical Directors.	Monthly
44	OIR	NIH Technology Transfer Policy Board	The Board recommends and oversees technology transfer policies at NIH, including the development and use of CRADAs, MTAs, etc.	The Board is chaired by the DDR with representation by the technology transfer coordinators in the ICs.	Monthly
45	OIR	Human Subjects Research Advisory Committee	The NIH HSRAC meets regularly to review policies and operations of the NIH Human Subjects Protections Program with IRB Chairs and coordinators. HSRAC is responsible for reviewing all Standard Operating Procedures of the IRBs.	HSRAC draws on the expertise of active IRB chairs to review and recommend on human research protection policies to the DDR who also serves as the NIH Institutional Official on the mandated Federal-wide assurance.	Monthly

Page 3



**Appendix III: Comments from the National Institutes of Health**

Attachment

The National Institutes of Health Inventory of OD Oversight Mechanisms for the GAO Governance and Oversight Review					
#	OD Organization Responsible for the Oversight	OD Oversight Mechanism Currently In Place	Purpose of the OD Oversight Mechanism	How the OD Oversight Mechanism Operates	Frequency
46	OIR	Committee on Scientific Conduct and Ethics	The CSCE develops and/or refines existing guidelines for the conduct of research, effective mechanisms for research ethics training for the NIH scientific community, and policies and mechanisms to deal rapidly and fairly with allegations of scientific misconduct, or disputes related to authorship practices, sharing of data or reagents, mentoring or supervision, or comparable issues. The CSCE has also developed a course to train principal investigators in leadership, mentoring, and handling of conflict skills.	All policies and guidelines are presented to the SDs and the DDR for final approval.	Monthly
47	OMA	Risk Management Senior Assessment Team	Committee chaired by the NIH Principal Deputy Director and composed of senior NIH officials provides oversight and accountability for the NIH Enterprise Risk Management program and reports program issues to the NIH Steering Committee	Continuously monitors the status of the NIH Enterprise Risk Management program and makes decisions on ERM policy and the overall direction of the program	Quarterly
48	OMA	OIG/GAO Liaison	Provide oversight and coordination for all OIG/GAO audits conducted at NIH	Coordinate with auditors to ensure that complete and accurate information and documentation is provided and provide centralized comments to draft audit reports on behalf of NIH	Continuously
49	OMA	Review of allegations	Review allegations of misuse of NIH Grant and Contract funds and improper conduct by NIH employees	OMA is responsible for reviewing allegations of misuse of NIH grant and contract funds, NIH grantee and contractor conflict of interest, improper employee conduct, violations of HHS grant or contract regulations or policy that are not directly tied to misuse of funds, and issues referred to OMA by the OIG when prosecutive or civil action has been declined or when the OIG plans no further investigation	Continuously
50	ORF	National Environmental Policy Act (NEPA) Designated Official	Consistent with Delegation of Authorities Number 19, the Director of ORF is the designated official for carrying out the requirements pertaining to NIH of Federal environmental laws, Executive Orders and regulations. Specifically included is the authority to conduct environmental assessments on NIH actions and to publish a finding of No Adverse Environmental Impact when this is the case.	ORF, with support by OGC, conducts environmental reviews in order to ensure that construction projects, equipment grants and research grants are executed in accordance with NEPA.	Continuously
51	ORS	NIH Radiation Safety Committee	To provide oversight and policy direction to the NIH Radiation Safety Program conducted by the Division of Radiation Safety, Office of Research Services. Ensures that the NIH operates in compliance with all regulations pertaining to the safe use of radioactive materials and radiation producing machinery and the radiation exposures to NIH employees, research subjects, visitors and the public are as low as reasonably achievable.	Advises the DRS on program, policy and enforcement issues. Reviews and approves clinical research protocols for research subject that involve radiation exposure to ensure guidelines are met and that proper informed consent is conducted.	Monthly
52	ORS	COOP: IC Crisis Response Team Assessments and Emergency Operations Command Center (EOCC) Connectivity	To ensure the NIH has the capability to coordinate, manage and recover its essential functions following a crisis or disaster	Conducts individual assessments with IC Emergency Coordinators to monitor the developmental progress of their emergency management programs. ORS staff test the connectivity of all network and telephone connections and equipment to ensure connectivity in all EOCCs.	Annually

Page 4

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# Appendix IV: GAO Contacts and Staff Acknowledgments

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## GAO Contacts

Linda T. Kohn (202) 512-7114 or kohnl@gao.gov  
Susan Ragland (202) 512-8486 or raglands@gao.gov

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