TO: The Secretary

           Through: DS _____

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FROM: Director, NIH

SUBJECT: Federal Managers' Financial Integrity Act (FMFIA) of 1982 – *Annual Assurances of Compliance* – INFORMATION

PURPOSE

The purpose of this memorandum is to provide the necessary assurances of and information on National Institutes of Health (NIH) compliance with the FMFIA (31 U.S.C. 3512). It is prepared in accordance with Office of Management and Budget (OMB) Fiscal Year (FY) 2003 reporting requirements and covers Section *2, Internal Controls,* and Section 4, *Financial Systems.*

I, Elias A. Zerhouni, NIH Director, state and assure that to the best of my knowledge:

(1)   The system of internal controls of this agency, except as indicated under (5), is functioning and provides reasonable assurance as to the efficiency and effectiveness of programs and operations; reliability of financial and performance information; and compliance with laws and regulations. These controls satisfy the requirements of the Federal Managers' Financial Integrity Act § 2.

(2)   The financial management systems of this agency, except as indicated under (5), provide reasonable assurances that obligations and costs are in compliance with applicable law; and performance data and proprietary and budgetary accounting transactions applicable to the agency are properly recorded and accounted for to permit the timely preparation of accounts and reliable performance information. The financial control at this agency satisfies the requirements of the Federal Managers' Financial Integrity Act § 4.

(3)   The system of internal controls of this agency that relates to the security of financial management systems and performance and other financial data, except as indicated under (5), provides protections commensurate with the risk and magnitude of harm resulting from loss, misuse, or unauthorized access and satisfies the requirements of § 5131 of the Clinger-Cohen Act of 1996, § 5 and 6 of the Computer Security Act, and §3533(D) (2) of the Government Information Security Reform Act.

(4)   The financial management systems of this agency, except as indicated under (5), provide this agency with reliable, timely, complete, and consistent performance and other financial information to make decisions and efficiently operate and evaluate programs and satisfy the requirements of the Federal Financial Management Improvement Act § 803(a), the Government Performance and Results Act, and *OMB Circular No. A-11 Preparation and Submission of Budget Estimates.* A remediation plan under FMFIA ( ) is (X) is not required.

(5)   I am monitoring and employing techniques that mitigate the material weaknesses, as follows:

Description of material weakness	Current status	Resolution Target date
Financial Reporting Systems	Corrections in process	2005 or completion of the NBRSS

ASSURANCE STATEMENT, SECTION 2

NIH is committed to ensuring effective management controls and clearly demonstrating and documenting them in its extramural, intramural, and administrative program areas. During FY 2003, we continued to successfully integrate management controls into program and administrative areas in support of our biomedical and behavioral research mission. We use a multifaceted approach to evaluate the efficacy of our management controls, which includes Management Control Reviews, Alternative Management Control Reviews, General Accounting Office (GAO) Reviews, Office of Inspector General Audits, Corrective Action Reviews, Corrective Action Plans, Program Evaluations, and Management Reviews conducted by both internal and external groups.

A total of 146 program reviews—16 intramural, 66 extramural, and 64 administrative— were ongoing or completed at NIH in FY 2003 (see enclosure E for an inventory of the reviews). In addition, we anticipate that the NIH Division of Program Integrity will open 82 new cases, review 87 cases that were opened in prior fiscal years, and close 62 cases. These reviews include an evaluation of systemic controls when related management

controls are found to be lacking or ineffective. Below are examples of proactive reviews that have improved or will enhance management controls for NIH's intramural, extramural, and administrative activities.

INTRAMURAL ACTIVITIES

Program Reviews

The Chairs of the NIH Boards of Scientific Counselors held their annual public meeting on November 30, 2002, to advise NIH Institutes and Centers on ways to improve the quality of intramural research. The Chairs' recommendations were transmitted to the NIH Scientific Directors for consideration. The NIH Deputy Director for Intramural Research chaired the meeting of this Federal advisory committee, which will hold its next meeting in the spring of 2004.

At the request of the NIH Director, the Deputy Director for Intramural Research also convened a clinical research blue-ribbon panel, from both inside and outside NIH, to make recommendations about the future of clinical research at NIH. The first meeting of the panel took place on August 6, 2003, with plans to convene at least two more times.

Blue-ribbon panels of experts will soon begin reviewing intramural programs at the National Institute of Child Health and Human Development and the National Institute of Diabetes and Digestive and Kidney Diseases. The names of proposed panel members have been submitted to the NIH Deputy Director for Intramural Research and to the Director of NIH. The reviews will begin as soon as the panels are approved.

Assessments of Management Controls

The Intramural Assessment of Management Controls is an ongoing process that requires the intramural community at each Institute or Center to carry out a self-assessment of its own management controls. NIH intramural staff are finalizing the Biennial Intramural Self-Assessment of Management Controls questionnaire and will be conducting assessments through the end of 2003.

Safety Activities

In response to recommendations from the Association for the Assessment and Accreditation of Laboratory Animal Care International, we have strengthened NIH mechanisms to prevent workers from contracting allergies from laboratory animals and to provide oversight of occupational safety and health programs associated with animal research. We created the Laboratory Animal Allergy Prevention Program, along with the associated occupational medicine support program, and developed educational brochures. Additionally, the NIH Animal Research Advisory Committee now assesses the entire occupational safety and health program for animal research activities annually.

The 2002 annual self-assessment of the Occupational Health and Safety component of the Office of Research Services found that the efficiency of laboratory audits could be improved. As a result, we tasked Council Rock Consulting with developing an electronic data collection and reporting system, which we are currently testing.

The Centers for Disease Control and Prevention inspected the NIH Bethesda campus in August 2003 for compliance with Select Agent Program requirements. The report has not been released, but no major deficiencies were cited at the exit briefing.

The Animal Plant Health Inspection Service of the U.S. Department of Agriculture inspected Building 41A in June 2003 for its suitability and safe use for research on highly pathogenic avian influenza virus. Final Department approval has not yet been received, but the State Veterinarian has given his approval.

Animal Care and Use

NIH has three new standing oversight committees in the Animal Research Advisory Committee that are chartered to review the scope and implementation of three trans-NIH programs: occupational safety and health, centralized training, and security and disaster preparedness. The committees are expected to issue a series of recommendations to strengthen some veterinary program shortcomings in one Institute and to improve practices at some of the Centers' and Institutes' Animal Care and Use Committees. The Association for the Assessment and Accreditation of Laboratory Animal Care International has given the NIH Intramural Research Programs continued full accreditation on condition that it receive descriptions of the recommendations. The committees are expected to issue their recommendations by year's end. The NIH Animal Care and Use Program received continued full accreditation in January 2003.

Animal Care and Use Committees oversee all intramural research involving animals and conduct semiannual in-depth reviews of all aspects of animal care and use programs. These reviews include not only the examination of facilities and animal procedures managed by the Institutes and Centers, but also the adequacy and interrelationship of support services, which include occupational safety and health and engineering services critical to the safe and efficient operation and maintenance of animal research facilities.

Graduate Medical Education

In December 2002, the Institutional Review Committee of the Accreditation Council for Graduate Medical Education informed the NIH Office of Education that the Graduate Medical Education Program had received a five-year institutional reaccreditation. NIH was commended for its commitment to graduate medical education by providing leadership and resources to achieve substantial compliance with the institutional requirements established by the Accreditation Council.

Continuing Medical Education

In July 2003, the Accreditation Council for Continuing Medical Education informed the NIH Office of Education that the National Institutes of Health/Foundation for Advanced Education in the Sciences Continuing Medical Education program had received a four-year accreditation.

Continuing Education

In April 2003, the Continuing Professional Education Committee of the American Psychological Association informed the Office of Education that the NIH Continuing Education program for psychologists had been approved for an additional five years.

Review of Human Subjects Research

The intramural program has created four working groups that are assessing the intramural clinical research program. The groups were the result of a clinical research retreat in March 2003 designed to examine successful examples of innovative clinical research, develop strategies to overcome barriers to optimal use of the new Clinical Research Center, and define the role of the Center as an integral part of the NIH clinical research effort. The intramural program has also completed an evaluation of the practices and procedures followed by its 14 Institutional Review Boards and has replaced Institute-based procedures with a single set of standard operating procedures to be followed by all the Boards.

Technology Transfer Activities

In October 2002, the NIH Office of Technology Transfer established a new integrated data system to resolve the material weakness that had been affecting the Office's electronic data system for several years and which resulted in NIH declaring a material weakness in its FMFIA report. We are continually assessing the new operating system and, as with any new data system, making adjustments and improvements on a continuing basis. Over the past year, the new system has successfully provided data and information that demonstrate that the former operational weaknesses (i.e., material weakness) have been corrected. In accordance with NIH policy, we will be conducting a corrective action review starting in November 2003 in order to validate the new system after one year of operation to see if any additional improvements are necessary.

EXTRAMURAL ACTIVITIES

Proactive Compliance Site Visits

The NIH Office of Extramural Research (OER) conducts proactive compliance site visits to minimize or eliminate incidences of noncompliance before problems arise, as well as

to reinvigorate the commitment to compliance and oversight in the extramural community. The site visits focus on assessing the level of understanding of Federal and NIH requirements through discussions of policies, procedures, and practices at recipient institutions. OER conducted proactive compliance site visits at five institutions in FY 2003: Ohio State University, Columbus Children's Research Institute, St. Louis University, Washington University, and George Washington University. Site visit plans for FY 2004 have not yet been finalized.

Areas discussed include: financial management of sponsored projects, financial conflict of interest, invention reporting/Bayh-Dole, data safety and monitoring, roles and responsibilities, and training and education. An education-outreach seminar, which has been an important component of the site visits, provides NIH officials with the opportunity to discuss at-risk issues with members of the biomedical research community.

Reduction of Regulatory Burden on the Grantee Community

In FY 2003, we extended for another year the Human Subjects Research Enhancements Program, which we created in 2002 to provide short-term support to institutions carrying out the vast majority of NIH-supported clinical research. Proposed enhancements have been in the areas of information technology, program efficiencies, and increased education for investigators.

In 2000, NIH initiated a study to minimize regulatory burdens on the grantee community and established the Regulatory Burden Working Group, as part of the Peer Review Oversight Group, to provide advice for future initiatives.

Grants Management Compliance Model and Grants Oversight Processes

The Office of Policy for Extramural Research Administration recently developed and implemented a Grants Management Compliance Model to provide oversight of NIH Manual Chapters related to grant management policies. The model will help ensure that NIH Institutes and Centers comply with all relevant Manual Chapters and grant administration policy. We are also completing an assessment of the relative risks associated with NIH-wide grant management policies. We will prioritize systematic reviews of Institute and Center compliance with individual policies based on the results of this risk assessment. In a related effort, OER has begun a review and assessment of the effectiveness and efficiency of all pertinent grant oversight processes in the areas of other support, grant close-out, prohibited research, and confidentiality of grant application reviews. Following review and analysis, we will consider implementing recommendations for improvements.

Improved National Research Service Awards Program and Payback Requirements

In 1999, the Office of Inspector General reviewed the NIH National Research Service Awards program and payback requirements and identified problems with the program's database. Specifically, we were unable to verify the current payback status of over 4,000 recipients. In response to the audit, we relocated the Payback Service Center from the National Institute of General Medical Sciences to the Office of the Director.

As of the end of FY 2003, the Payback Center was processing records for nearly all NIH Institutes and Centers, with the remaining ones expected to be included by the end of the calendar year.

Biomedical and Behavioral Scientists

OER has continued to work on adopting recommendations by the National Academy of Sciences 2000 report that suggested NIH address the problem of "unduly low" stipends and improve methods for tracking the careers of students and post-docs in the biomedical, behavioral, and clinical sciences. OER has identified National Research Service Awards stipend targets to be achieved through annual increases in 2001-06, and the Senate Appropriations Committee Report for FY 2003 endorsed this approach. We also are establishing a system to collect on-line professional profiles for all extramural investigators and trainees who have transactions with NIH. Information on post-training employment, publications, and honors will constitute a core set of career development data used to evaluate the effects of NIH research training programs.

Reporting of Patents and Inventions

In FY 2003, we continued to expand efforts to improve grantee/contractor patent and invention reporting compliance. We have hired additional data entry contractors to ensure timely acknowledgement of reports to NIH by extramural grantees and contractors. We have also expanded our outreach efforts; we held at least five training classes between April and October 2003.

Meanwhile, the Interagency Edison (iEdison) system continues to enhance our management controls by proactively providing electronic reminders to both grantees and internal agency management. iEdison is an Internet-based system created and deployed by OER in 1995 to meet statutory requirements for reporting inventions and patents. The system automatically sends e-mail notifications to grantees or agency officials of 15 different time-critical decisions that must be made regarding the reporting of intellectual property.

Benefits from iEdison were enhanced with the deployment in May 2003 of a new version of the system, which now provides the extramural grantee/contractor community state-of-the-art functionality, including, for the first time, the ability to submit all aspects of

reports electronically. Previously, several documents were required in hard copy.
Furthermore, additional agencies have joined iEdison; as of May 2003, extramural
grantees/contractors supported by any of 19 Federal agencies can report their subject
inventions to the cognizant agency through iEdison.

Electronic Research Administration

The Electronic Research Administration (eRA) project continues to implement new
electronic tools to facilitate and improve our management of extramural research grant
activities. All incoming competing applications are now scanned and stored in on-line
grant folders, which will ultimately replace traditional paper grant folders. In the fall,
eRA and Grants.gov will pilot a new system for receiving grant applications as XML
datastreams. These innovations will speed grant processing and improve oversight by
offering authorized staff immediate and concurrent access to grant files. eRA also
recently implemented several new modules to enhance grant management, including the
Internet-Assisted Review and the Financial Status Report Web Interface. A new program
module enables program officials to administer their portfolios using the paperless
business processes mandated by Congress.

In response to a recent GAO report that found deficiencies in NIH collection of data on
the inclusion of women and minorities in clinical research, eRA released a new
population tracking module. The Web-based grant closeout application, introduced in the
spring of 2002, enables users to identify terminating grants, track the collection of
documents required for closeout, and notify grantee institutions of missing items.
Finally, eRA is working on a new notification system to inform NIH staff and grantees
about changes, due dates, and other matters.

ASSURANCE STATEMENT - SECTION 4

NIH financial systems, as a whole, satisfy most policies and standards prescribed for
executive agencies in developing, operating, evaluating, and reporting on financial
management systems as defined in OMB Circular A-127, Financial Management
Systems, and OMB's *Implementation Guidance for the Federal Financial Management
Improvement Act (FFMIA) of 1996*.

There are instances, however, in which our financial systems, including the financial
portion of mixed systems, do not fully conform to all Government-wide standards. These
standards require that agency financial management systems comply with the following
requirements:

- Systems must use an agency-wide financial information classification structure.
- All financial and the financial portion of mixed systems must be integrated.

- Systems must use the U.S. Government Standard General Ledger at the transaction level.
- Systems must comply with applicable Federal accounting standards.
- Systems must meet all financial reporting requirements.
- Systems must capture and produce financial data to measure program performance.
- Systems must comply with the functional requirements of the Joint Financial Management Improvement Program.
- Systems must ensure that internal controls exist for all inputs, processing, and output functions.

Clifton Gunderson LLP reported in its FY 2002 *Report of Independent Auditors on Compliance with Laws and Regulations* that it performed tests to determine whether NIH financial management systems substantially comply with Federal financial management system requirements, applicable accounting standards, and the U.S. Standard General Ledger at the transaction level. The results of its tests disclosed instances in which NIH's financial management systems did not substantially comply with certain requirements.

As part of the FY 2003 Chief Financial Officer/Government Management Reform Act audit, we assessed our compliance with financial system requirements and with the Federal Financial Management Improvement Act and concluded that our financial systems, including mixed systems, do not fully conform to all Government-wide standards required by OMB Circular A-127. To address these issues, we have strengthened compensating controls and revised the accounting system closing process.

The NIH Central Accounting System uses most, but not all, U.S. Standard General Ledger accounts and processing rules at the transaction level. Some mixed systems do not provide financial transactions to the central system using consistent processing rules. In addition, some systems are not fully and seamlessly integrated but are otherwise linked with the system. For example, the property management information system does not comply with financial systems requirements. The NIH Chief Financial Officer five-year plan indicated that NIH did not fully comply with all financial systems requirements.

REMEDIATION PLAN

To address these issues, we

- contracted with Ernst and Young to help identify the applicable financial systems requirements;
- launched a review and assessment of how NIH transacts business among all internal activities and customers to identify system integration and accounting requirements; and
- awarded a contract for an NIH-wide business system, to include a Joint Financial Management Improvement Program-approved accounting system.

MAJOR REVIEWS

We initiated a review to address and resolve the material weaknesses cited in the audit of NIH's FY 2002 financial statements. The review included NIH and contract audit staff and focused on the methodology and discipline applied to our fiscal year closing process. As a result of these efforts, we have implemented numerous additional analyses and reconciliations; we have implemented a new, more disciplined and controlled process to prepare the trial balances from which our financial statements are prepared; and we have identified additional areas of potential improvement on which we have already begun work. Also, we plan to validate or change certain internal processes and provide significant training to staff. This effort will result in benefits to accounting operations and to the administrative operations of Institutes and Centers.

The Office of Financial Management, working with the NIH Center for Information Technology, has implemented a new Web-based tool that allows staff to analyze all general ledger accounts individually and by transaction codes on-line. This has allowed us to correct and compensate for some of the deficiencies noted by auditors. The information is more reliable and available in a timely manner for review and reporting.

<u>FMFIA REPORT</u>

The FMFIA report also includes the following documents and is available from Mr. David Holley, Division of Quality Management, Office of Management Assessment, Office of the Director. He can be reached at (301) 435-3343.

Enclosure *A - Statistical Summary of Performance*

Enclosure *B - Progress Report of High Risk Areas* (none)

Enclosure *C - Schedule of Corrective Actions for Pending Material Weaknesses* (none)

Enclosure *D - Schedule of Pending Material Non-Conformances (Section 4)* (none)

Enclosure *E - Inventory of FY 2003 Reviews*

/s/

Elias A. Zerhouni, M.D.