Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE NATIONAL HUMAN GENOME RESEARCH INSTITUTE SHOULD STRENGTHEN PROCEDURES IN ITS PRE-AWARD PROCESS TO ASSESS RISK FOR CERTAIN FOREIGN AND HIGHER RISK APPLICANTS

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Amy J. Frontz
Deputy Inspector General
for Audit Services

August 2021
A-05-20-00026

Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

Report in Brief

Date: August 2021
Report No. A-05-20-00026

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Why OIG Did This Audit

The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act 2019, P.L. No. 115-245, directed OIG to examine the efforts of the National Institutes of Health (NIH) to ensure the integrity of its grant application evaluation and recipient selection processes. This audit is part of OIG's response to this directive. Previous OIG audits evaluated the pre-award risk assessment process at NIH's National Eye Institute and National Cancer Institute.

Our objective was to determine whether the National Human Genome Research Institute (NHGRI) had adequate policies and procedures in its pre-award process for assessing risk when awarding grant funds.

How OIG Did This Audit

We obtained a list of all 557 grant awards, totaling $468.2 million, that NHGRI made in fiscal year 2019. We interviewed NIH and NHGRI officials familiar with the grant pre-award process. We obtained and reviewed NHGRI policies and procedures covering its grant pre-award process.

To review the grant pre-award risk assessment process for different types of recipients and awards, we selected a non-statistical sample of 32 grant awards, totaling $107.9 million, intended to cover a mix of the types of research awards that NHGRI funds.

The National Human Genome Research Institute Should Strengthen Procedures in Its Pre-Award Process To Assess Risk for Certain Foreign and Higher Risk Applicants

What OIG Found

NHGRI generally had adequate policies and procedures in place for assessing risk in its grant pre-award process when awarding grant funds. However, we determined that NHGRI had inadequate policies and procedures as they relate to assessing the risk to NHGRI grant programs presented by foreign applicants and mitigating potential risk associated with applicants demonstrating higher risk factors. As a result, some risks associated with foreign applicants and applicants demonstrating higher risk factors may not have been identified and mitigated before grant funds were awarded.

What OIG Recommends and National Institutes of Health Comments

We recommend that NIH direct NHGRI to: (1) improve its policies and procedures to ensure Grants Specialists monitor whether required audit reports are submitted for foreign applicants; (2) clarify existing procedures to specify when Grants Specialists should take additional steps, including the imposition of specific award conditions, to mitigate risk for new grantees; and (3) update policies and procedures for Grants Specialists to require that they review available Internal Revenue Service (IRS) Form 990s regarding grant applicants' risk factors before awarding grant funds.

In written comments on our draft report, NIH concurred with our first and third recommendations and considered our second recommendation to be closed and implemented. With regards to the first recommendation, NIH stated that it plans to issue enhanced guidance to monitor whether required audit reports are submitted for all applicants, not limited to foreign entities. With regards to the second recommendation, NIH stated that it takes appropriate steps to mitigate risk for new recipients and has provided guidance that specifically addresses new grantee risk reviews and appropriate consideration of specific award conditions. We revised the second recommendation to specifically address the need to clarify when special award conditions should be imposed. With regards to the third recommendation, NIH stated that it will review its pre-award risk assessment policies and procedures and integrate the review of available IRS Form 990s where appropriate. NIH plans to complete this process by the summer of 2022.

The final report can be found at https://oig.hhs.gov/oas/reports/region5/52000026.asp.

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INTRODUCTION

WHY WE DID THIS AUDIT

The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, P.L. No. 115-245, directed the Office of Inspector General (OIG) to examine the efforts of the National Institutes of Health (NIH) to ensure the integrity of its grant application evaluation and recipient selection processes. This audit is part of OIG's response to this directive. Previous OIG audits[1] evaluated the pre-award risk assessment process at NIH's National Eye Institute and National Cancer Institute.

OBJECTIVE

Our objective was to determine whether the National Human Genome Research Institute (NHGRI) had adequate policies and procedures in its pre-award process for assessing risk when awarding grant funds.

BACKGROUND

NIH comprises 27 Institutes and Centers, each with a specific research agenda, often focusing on particular diseases or body systems. As a leading authority in the field of genomics, NHGRI's mission is to accelerate scientific and medical breakthroughs that improve human health by driving cutting-edge research, developing new technologies, and studying the impact of genomics on society. In fiscal year (FY) 2019, NHGRI made 557 awards totaling $468.2 million to universities and other institutions for research, fellowships, career development, and training.

The six major steps in NIH's grants selection process are summarized below.

- **Funding Announcement:** NIH publishes a funding opportunity announcement on Grants.gov and in the *NIH Guide for Grants and Contracts*.

- **Application for Grant Funding:** Applicants complete and submit an application.[2]

[1] *The National Eye Institute Generally Had Adequate Procedures To Assess an Applicant's Risk During the Pre-Award Process* (A-05-19-00017) and *The National Cancer Institute Needs To Strengthen Procedures in Its Pre-Award Process To Assess Risk for Higher Risk Applicants* (A-03-19-03004).

[2] The grant application asks where the proposed project will primarily be located and whether it involves activities outside the United States or in partnership with international collaborators. The Biographical Sketch within the application includes an area where the applicant can report other research support or affiliations.

- **Receipt & Referral:** NIH assigns applications to an Institute or Center.

- **Peer Review:** The first level of peer review is conducted by an initial review group or a scientific review group to evaluate scientific and technical merit. Applications recommended for further consideration receive a second level of review by the Institute or Center's National Advisory Council or Board for scientific and technical merit and relevance to the Institute or Center's programs and priorities.

- **Pre-Award and Award Process:** Following the peer review process, applications are reviewed for other considerations, including the project's budget, applicant eligibility, and an assessment of the applicant's management systems. NHGRI also uses "just-in-time" procedures for certain programs, which allow certain elements of an application (e.g., active and pending support for senior/key personnel) to be submitted later in the application process, once funding is under consideration. NHGRI conducts final administrative reviews, including pre-award risk assessments. Once an application is approved, successful applicants receive Notices of Award.

- **Post-Award Monitoring and Reporting:** NHGRI monitors the awarded grants; monitoring activities include, but are not limited to, corresponding with the recipient, reviewing audit reports, reviewing progress reports, and conducting site visits during the award period.

Before making a Federal award, NHGRI must comply with Federal regulations at 45 CFR § 75.205, which state that Federal awarding agencies are required to review the risks posed by applicants.[3] Even if NHGRI determines that a Federal award will be made, it may impose special conditions on the recipient that correspond to the degree of risk associated with making the Federal award. NHGRI cannot support research unless it has assurance that the grantee will use its funds appropriately, maintain adequate documentation of transactions, and safeguard assets.

HOW WE CONDUCTED THIS AUDIT

We obtained a list of all 557 grant awards, totaling $468.2 million, that NHGRI made in FY 2019. We interviewed NIH and NHGRI officials familiar with the grant pre-award process. We obtained and reviewed NHGRI policies and procedures covering its grant pre-award process. To review the grant pre-award risk assessment process for different types of recipients and

[3] These regulations permit Department of Health and Human Services (HHS) awarding agencies evaluating risks posed by applicants to consider factors such as financial stability, quality of management systems, ability to meet management standards, history of performance, reports and findings from audits, and ability to effectively meet requirements. The HHS *Grants Policy and Administration Manual* (GPAM) establishes HHS policies for the administration of grants and cooperative agreements. The GPAM provides all HHS grant-awarding agencies with a uniform set of minimum policy requirements that HHS staff must follow throughout a grant's life cycle.

awards, we selected a non-statistical sample of 32 grant awards, totaling $107.9 million, intended to cover a mix of the types of research awards that NHGRI funds (Table, below):

Table: Type of Recipients and Awards We Considered When Selecting Grants for Review

Type of Recipient	Type of Award
• New NHGRI awardee • Existing NHGRI awardee • Foreign organization • University • Small Business Innovation Research awardee	• High-dollar award[4] • Cooperative Agreement • Research projects

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

Appendix A contains the details of our audit scope and methodology.

FINDINGS

NHGRI generally had adequate policies and procedures in place for assessing risk in its grant pre-award process when awarding grant funds. However, we determined that NHGRI had inadequate policies and procedures as they relate to assessing the risk to NHGRI grant programs presented by foreign applicants and mitigating potential risk associated with applicants demonstrating higher risk factors. As a result, some risks associated with foreign applicants and applicants demonstrating higher risk factors may not have been identified and mitigated before grant funds were awarded.

THE NATIONAL HUMAN GENOME RESEARCH INSTITUTE GENERALLY HAD ADEQUATE PRE-AWARD POLICIES AND PROCEDURES TO ASSESS AN APPLICANT'S RISK

NHGRI generally had adequate policies and procedures in place for its pre-award process to assess an applicant's risk prior to awarding grant funds. NHGRI accesses a number of systems, programs, and internal checklists to identify and assess risk. A description of the sources NHGRI uses and how NHGRI uses them in the pre-award risk assessment is below.

[4] We defined high-dollar awards as those awards of at least $10 million.

- NHGRI uses electronic Research Administration (eRA),[5] an automated system that maintains all of the checklists and worksheets generated to document the application and review process. The checklist items vary based on many factors, including, but not limited to, whether the applicant is a new or an existing recipient; the type of research being conducted (including human, animal, clinical research, or biohazard); the type of application (including research grants, career development awards, or research training and fellowship program projects); and whether the applicant is foreign or domestic. In addition, for new or competing continuation grant awards made to a foreign organization or those with a foreign component,[6] NHGRI obtains the necessary clearances from the U.S. Department of State.[7]

- As part of the pre-award process, NHGRI uses two checklists maintained in eRA to assess the risk of grant applicants: the Grants Management checklist and the Program checklist. The Grants Management checklist covers topics that address administrative requirements to ensure completeness of an application, compliance with NIH and HHS policies, and compliance with other Federal regulations and requirements. The Grants Management checklist also prompts NHGRI staff to assess an applicant's financial management capabilities. The extent of this assessment is a matter of NHGRI staff judgment based on factors such as the applicant's previous experience in managing grant funds, experience with the applicant, the dollar amount of the grant, and the complexity of the grant. The Program checklist is used to verify compliance with programmatic requirements before the issuance of a competing award and to evaluate the scientific merit of the research.

  When completing the Grants Management checklist, NHGRI reviews information about an applicant's eligibility, financial integrity, and past performance.[8] Some sources NHGRI uses include:

  - *The General Services Administration System for Award Management (SAM)*. The SAM is an electronic, web-based system that is used to identify parties that are excluded from receiving Federal contracts and certain subcontracts and other types of Federal financial and non-financial assistance and benefits. Before making an award, NHGRI Grants Management Specialists (Grants Specialists) are required to

[5] eRA is an online interface where grant applicants, recipients, and Federal staff at NIH can access and share administration information related to research grants.

[6] A foreign component is defined as performance of any significant element or segment of the project outside the United States either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended (NIH Grants Policy Statement (GPS), section 16.2, October 1, 2018).

[7] NIH's Grants Narrative Process Cycle Memorandum, September 30, 2018.

[8] These risk factors are described at 45 CFR § 75.205.

check the SAM to determine whether the organization or individuals, or both, supported under the award are excluded or disqualified from participation.

- *The Federal Awardee Performance and Integrity Information System (FAPIIS)*. The FAPIIS provides publicly available information about an institution's integrity, business ethics, and past performance under financial assistance awards. Before making an award, the Grants Specialists are required to check the FAPIIS to determine whether an applicant is qualified to receive a Federal award.

- *National External Audit Review Center (NEAR) Alerts*. Certain recipients of Federal funds are required to conduct a Single Audit and to submit it to the Federal Audit Clearinghouse, which notifies NEAR of any audit findings related to an HHS award. NEAR Alerts are published monthly by the HHS OIG NEAR. Based on its review of an applicant's Single Audit, NEAR may issue an Alert for negative or potentially negative audit findings.[9] NIH staff compile and maintain a list of NEAR Alerts in a spreadsheet that is posted to its intranet website. Before making an award, the Grants Specialists are required to check the NEAR Alerts list to investigate the reasons for placement on the NEAR Alert list.

- Once the preparation of an award is complete, eRA generates the Award Worksheet, which summarizes the budget and the results from the Grants Management and Program checklists. NHGRI and NIH officials use the checklist results to evaluate an organization's risk and to determine whether issuing awards to an organization is appropriate.

- As part of completing the Grants Management and Program checklists, there are questions specific to foreign grants and grants with a foreign component. The questions on the checklists are used to ensure that data on each foreign grant or foreign component was entered into the Foreign Award and Component Tracking System (FACTS)[10] and that U.S. Department of State clearance was received. Additionally, one question is used to determine the viability of the project if U.S. Department of State clearance cannot be obtained.

[9] Non-Federal entities spending $750,000 or more during their FY in Federal awards are generally required to have a Single Audit conducted in accordance with 45 CFR § 75.514. Single Audits must be conducted in accordance with generally accepted government auditing standards and include an examination of the entity's financial records and financial statements, testing of the entity's internal controls, and a review of the entity's compliance with requirements related to expenditures of selected Federal awards. The final audit report contains comments from the recipient, including corrective actions planned or taken to address the findings.

[10] The FACTS is designed to meet NIH's need to accurately track and report NIH investments in research grants and contracts involving collaboration in foreign countries. The FACTS is also used to process requests for foreign collaborations that require U.S. Department of State clearance.

- Before NHGRI makes an award, it determines the best method to manage or mitigate any specific risks identified in the pre-award process. Possible methods include requiring cost reimbursement, or converting the award from a grant to a cooperative agreement to provide increased interaction between NHGRI and the grantee[11] to help ensure appropriate management of funds.

THE NATIONAL HUMAN GENOME RESEARCH INSTITUTE HAD INADEQUATE POLICIES AND PROCEDURES TO ENSURE FOREIGN APPLICANTS SUBMITTED REQUIRED AUDIT REPORTS

Federal Requirements

Foreign grantees are subject to the same audit requirements as for-profit grantees (NIH GPS, section 16.7.4, October 1, 2018). For-profit grantees spending $750,000 or more in HHS awards during their FY are required to submit an audit to HHS using one of two options, either: (1) a financial related audit of a particular award or a financial related audit of all HHS awards in accordance with Government Auditing Standards or (2) an audit that meets the requirements in 45 CFR § 75, Subpart F – Audit Requirements.[12]

The NIH GPS specifies that the audit must be completed and submitted to NEAR within 30 days after the receipt of the auditor's report or 9 months after the end of the audit period, whichever is earlier (NIH GPS, section 18.4.5, October 1, 2018). Federal regulations (45 CFR § 75.205(b-c)) require that HHS awarding agencies have a framework in place to review findings from audits in their pre-award process.

Inadequate Policies and Procedures To Ensure Audit Reports Were Submitted in Accordance With Federal Requirements

NHGRI did not have adequate policies and procedures in place to ensure that foreign applicants had submitted required audit reports to HHS, NIH, or NEAR. While NHGRI has policies and procedures that address the audit report resolution process, they do not address what should happen if a grant recipient fails to submit a required audit report.

Four of the twelve foreign applicants in our sample did not submit a required audit report to HHS, NIH, or NEAR. Each of the four applicants had been a grantee of NHGRI since at least FY 2015 and spent HHS funding each year in excess of the $750,000 threshold necessary to require an audit report. We contacted NEAR, NIH/NHGRI, the Centers for Disease Control and Prevention, and the HHS Assistant Secretary for Financial Resources and confirmed that the four foreign applicants had not submitted the required audit reports.

[11] A cooperative agreement differs from a grant in that the cooperative agreement provides for substantial interaction between the Federal awarding agency and the non-Federal entity in carrying out the activities covered by the Federal award.

[12] Requirements for commercial organizations are found at 45 CFR § 75.501(i)-(j).

Without having the required audit reports at the time of a new grant application or a grant renewal, the Grants Specialists did not have complete information regarding an applicant's financial position at the time they were considering the applicant for a new or renewal grant award.

THE NATIONAL HUMAN GENOME RESEARCH INSTITUTE HAD INADEQUATE POLICIES AND PROCEDURES TO MITIGATE POTENTIAL RISK BEFORE AWARDING GRANT FUNDS

Federal Requirements

Prior to making a Federal award, HHS awarding agencies are required to review information through any OMB-designated repositories of governmentwide eligibility qualification or financial integrity information as appropriate (45 CFR § 75.205(a)). Further, when evaluating risks posed by applicants, HHS awarding agencies may use a risk-based approach considering factors such as financial stability, quality of management systems, history of performance, reports and findings from audits, and the applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities (45 CFR § 75.205(c)). Last, the HHS awarding agency may impose specific award conditions as needed in accordance with 45 CFR § 75.207.

Inadequate Policies and Procedures To Mitigate Potential Risk Before Awarding Grant Funds

While NHGRI's policies and procedures address additional steps that can be taken in the pre-award process for grant applicants that have never received Federal funding and allow for specific award conditions to be added to a grant award in the event the applicant is of a higher risk, those policies and procedures rely on the Grants Specialists to use their discretion to identify instances where additional steps should be taken to mitigate potential risk. Further, NHGRI's policies and procedures do not require the Grants Specialists to use information found in Internal Revenue Service (IRS) Form 990s in the pre-award process.[13]

NHGRI did not take steps to fully mitigate risk factors before awarding grant funds for two of the grant awards we reviewed. In one instance, NHGRI awarded grant funds to a new organization with no known experience managing Federal funds. The organization's financial statements reported that the organization had no revenue for the year leading up to its NHGRI grant award. However, the Grants Specialists did not take appropriate steps to mitigate the risks posed by this organization's inexperience managing Federal funds. In another instance, NHGRI awarded grant funds to an established HHS grantee that self-reported on its IRS Form 990 that the organization had been subject to a diversion of assets that involved the theft of medical equipment, computer equipment, and cash payments in the 3 years leading up to its FY 2019 NHGRI grant award. NHGRI was not aware of the diversion of assets, which could

[13] The IRS generally requires tax-exempt organizations to submit IRS Form 990s to provide the IRS with financial information about an organization, among other things. The IRS Form 990 asks whether the organization was made aware of a significant diversion of assets during the year.

involve NHGRI or other HHS funding and did not place any specific award conditions on the grant.

For the applicant with no prior experience managing Federal funds, the Grants Specialists did not believe it was necessary to impose special award conditions because the organization's balance sheet reflected an acceptable debt-to-income ratio of 1:1.[14] For the applicant that sustained a diversion of assets, NHGRI was not previously made aware of the condition reported in the applicant's IRS Form 990. In response to our audit finding, NIH followed up with the organization to confirm that NIH funds were not involved in the identified issues stated on IRS Form 990 for FYs 2016−2018.

RECOMMENDATIONS

We recommend that the National Institutes of Health direct the National Human Genome Research Institute to:

- improve its policies and procedures to ensure Grants Specialists monitor whether required audit reports are submitted for foreign applicants;

- clarify existing procedures to specify when Grants Specialists should take additional steps, including the imposition of specific award conditions, to mitigate risk for new grantees; and

- update policies and procedures for Grants Specialists to require that they review available IRS Form 990s regarding grant applicants' risk factors before awarding grant funds.

NATIONAL INSTITUTES OF HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, NIH concurred with our first and third recommendations and considered our second recommendation to be closed and implemented. With regards to the first recommendation, NIH stated that it plans to issue enhanced guidance to monitor whether required audit reports are submitted for all applicants, not limited to foreign entities, by July 2021.[15] With regards to the third recommendation, NIH stated that it will review its pre-award risk assessment policies and procedures and integrate the review of available IRS Form 990s where appropriate. NIH plans to complete this process by the summer of 2022.

[14] The debt-to-income (DTI) ratio measures the amount of income a person or organization generates to service a debt. A high DTI ratio can signal that an individual or organization has too much debt for the amount of income earned each month.

[15] NIH issued enhanced financial review guidance on August 18, 2021.

With regards to the second recommendation, NIH stated that it takes appropriate steps to mitigate risk for new recipients and has provided guidance that specifically addresses new grantee risk reviews and appropriate consideration of specific award conditions. We agree that NIH currently has procedures in place regarding the imposition of special award conditions. However, we determined that such award conditions had not been imposed on an organization that was inexperienced in managing Federal funds and therefore revised the recommendation to specifically address the need to clarify when special award conditions should be imposed.

NIH's comments, excluding technical comments, which we addressed as appropriate, are included in their entirety as Appendix B.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed NHGRI policies and procedures related to its pre-award risk assessment process to determine whether they were adequate to assess risk before making an award. We obtained a list of 557 grant awards, totaling $468,234,976, that NHGRI awarded in FY 2019. We then selected a non-statistical sample of 32 of these awards, totaling $107,858,813, for detailed review.

We determined that internal control was significant to our audit objective. We assessed internal controls and compliance with laws and regulations necessary to satisfy the audit objective. In particular, we assessed the design, implementation, and operating effectiveness of NHGRI's internal controls as they related to the component's risk assessment and monitoring. As part of our internal control review, we evaluated NHGRI's policies and procedures for assessing risk before awarding grant funds. However, because our review was limited to these internal control components and underlying principles, it may not have disclosed all internal control deficiencies that may have existed at the time of this audit.

We conducted our fieldwork from April 2020 to April 2021, which included contacting NIH officials in Bethesda, Maryland.

METHODOLOGY

To accomplish our audit objective, we:

- reviewed applicable Federal and HHS regulations and policies,
- interviewed NIH and NHGRI personnel to obtain an understanding of NHGRI's pre-award risk assessment policies and procedures,
- obtained a list of all NHGRI grants awarded during FY 2019,
- selected a non-statistical sample of 32 NHGRI grant applicants to review the risk assessment process for those applications,
- determined whether the recipient's risk assessment was completed before the award date for the 32 NHGRI grant applicants in the non-statistical sample, and
- discussed the results of our review with NHGRI officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain

sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: NATIONAL INSTITUTES OF HEALTH COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

DATE: June 28, 2021

TO: Amy J. Frontz
Deputy Inspector General for Audit Services

FROM: Principal Deputy Director, National Institutes of Health

SUBJECT: NIH Comments on Draft Report, "*The National Human Genome Research Institute Should Strengthen Procedures in Its Pre-Award Process To Assess Risk for Certain Foreign and Higher Risk Applicants*" (A-05-20-00026)

Attached are the National Institutes of Health's (NIH) comments on the draft Office of Inspector General's (OIG) report, "*The National Human Genome Research Institute Should Strengthen Procedures in Its Pre-Award Process To Assess Risk for Certain Foreign and Higher Risk Applicants*" (A-05-20-00026).

NIH appreciates the review conducted by OIG and the opportunity to provide the clarifications on this draft report. If you have questions or concerns, please contact Tiffany Brown in the Office of Management Assessment at 301-496-2464.

/s/ Lawrence A. Tabak, D.D.S., Ph.D.

Lawrence A. Tabak, D.D.S., Ph.D.

Attachment

GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH (NIH) ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT ENTITLED: "THE NATIONAL HUMAN GENOME RESEARCH INSTITUTE SHOULD STRENGTHEN PROCEDURES IN ITS PRE-AWARD PROCESS TO ASSESS RISK FOR CERTAIN FOREIGN AND HIGHER RISK APPLICANTS" (A-05-20-00026)

The National Institutes of Health (NIH) appreciates the review conducted by Office of Inspector General (OIG) and the opportunity to provide clarifications on this draft report. NIH respectfully submits the following general comments.

OIG Recommendation 1:

We recommend that the National Institutes of Health direct the National Human Genome Research Institute to improve its policies and procedures to ensure Grants Specialists monitor whether required audit reports are submitted for foreign applicants.

NIH Response:

NIH concurs with OIG's recommendation and considers it open.

The Department of Health and Human Services' Audit Resolution Division is responsible for the receipt and tracking of timely foreign audit submissions. NIH grants management is responsible for the review of the most recent audit report as part of the pre-award process.

Based on this and other OIG audits of NIH's pre-award process, in August 2020, the NIH Office of Policy for Extramural Research Administration (OPERA) issued updated internal staff guidance entitled, "Pre-award Financial Capability Review Compliance Guidance," which included guidance on single audit reviews. NIH plans to further clarify this guidance to specifically address the need to review the most recent audit report for all NIH applicants including, but not limited to, foreign entities.

By July 2021, NIH plans to issue the enhanced guidance and will provide OIG a status update in the management decision.

OIG Recommendation 2:

We recommend that the National Institutes of Health direct the National Human Genome Research Institute to update procedures to ensure that Grants Specialists take appropriate steps to mitigate risk for new grantees, including the imposition of specific award conditions.

NIH Response:

NIH considers this recommendation closed-implemented.

In accordance with the NIH Grants Policy Statement, a term and condition of every NIH grant award, section 8.5.1, NIH may include specific award conditions in the grant award to require correction of identified financial or administrative deficiencies as a means of protecting NIH's interests and effecting positive change in a recipient's performance or compliance. When

specific conditions are imposed, the Grants Management Office (GMO) will notify the recipient in writing of the nature of the conditions, the reason why they are being imposed, the type of corrective action needed, the time allowed for completing corrective actions, and the method for requesting reconsideration of the condition.

NIH takes appropriate steps to mitigate risk for new recipients. Please refer to the "Pre-award Financial Capability Review Compliance Guidance" and its two appendices, dated August 2020. This guidance specifically addresses new grantee risk reviews and appropriate consideration of specific award conditions.

OIG Recommendation 3:

We recommend that the National Institutes of Health direct the National Human Genome Research Institute to update policies and procedures for Grants Specialists to require that they review available IRS form 990s regarding grant applicants' risk factors before awarding grant funds.

NIH Response:

NIH concurs with OIG's recommendation and considers it open.

To address this recommendation, NIH will review its pre-award risk assessment policies and procedures and integrate the review of available IRS form 990s where appropriate.

By Summer 2022, NIH anticipates completion of this recommendation and will provide OIG a status update in the management decision.