Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE DID NOT FULLY COMPLY WITH FEDERAL REQUIREMENTS FOR OTHER TRANSACTIONS

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Office of Inspector General

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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: April 2021
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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

The National Heart, Lung, and Blood Institute Did Not Fully Comply With Federal Requirements for Other Transactions

Why OIG Did This Audit

The National Institutes of Health's (NIH) use of "other transactions" (OTs), which are special award instruments that are generally not subject to Federal laws and regulations that apply to traditional award instruments, increased by $314 million from 2016 to 2019. The Federal Government generally uses OTs for high-risk, high-reward research and development projects. Although OTs are subject to fewer restrictions than contracts, grants, or cooperative agreements, they must be awarded and administered in a way that ensures proper stewardship of Federal funds.

From October 1, 2016, through September 30, 2019 (audit period), the NIH National Heart, Lung, and Blood Institute (NHLBI) awarded $84.3 million in Federal funds under 29 OTs.

Our objective was to determine whether NHLBI complied with applicable Federal requirements for awarding and administering OTs.

How OIG Did This Audit

Our audit covered a judgmental sample of 12 OTs totaling $71.9 million that NHLBI awarded and administered during the audit period.

Our audit procedures focused on whether NHLBI documentation for the sampled OTs provided evidence of compliance with Federal requirements. This audit is responsive to a U.S. Office of Special Counsel complaint referral.

What OIG Found

NHLBI did not fully comply with Federal requirements for awarding and administering OTs during our audit period. For the 12 OTs in our sample, NHLBI did not adequately document: (1) its justifications for using OTs rather than traditional award instruments; (2) that awarded amounts were fair and reasonable and incurred costs were allowable; or (3) that it complied with Federal requirements for obligating annual appropriations.

NHLBI did not adequately document its compliance with applicable Federal requirements because its internal controls for awarding and administering OTs were ineffective. As a result, NHLBI could not ensure the proper stewardship of Federal funds used to award OTs, including the $71.9 million we reviewed.

What OIG Recommends and NIH Comments

We recommend that NHLBI strengthen its internal controls for OTs by updating its policies and procedures to properly document its justifications for using OTs instead of traditional award instruments and to determine fairness and reasonableness of award amounts, allowability of costs, and compliance with Federal funding requirements.

In written comments on our draft report, NIH concurred with our recommendations and said that it would update its policies and procedures by November 15, 2021, to reflect our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

Congress has granted 11 Federal agencies including the Department of Health and Human Services (HHS) statutory authority to award Federal funds under transactions other than contracts, grants, or cooperative agreements. Such transactions, commonly known in the Federal Government as "other transactions" (OTs[1]), are generally not subject to the Federal laws and regulations that apply to traditional award instruments. OTs are considered to be higher risk than traditional awards and should generally only be used when the objectives of a federally funded project cannot be accomplished under a traditional Federal award. Accordingly, the Federal Government generally uses OTs for high-risk, high-reward research and development projects.

Only four components within HHS have OT authority, including certain Institutes, Centers, and Offices (ICOs) of the National Institutes of Health (NIH).[2] NIH's use of OTs increased from $34 million in fiscal year (FY) 2016 to more than $348 million in FY 2019. Within NIH, the National Heart, Lung, and Blood Institute (NHLBI) has had OT authority longer than any other HHS component.[3] From October 1, 2016, through September 30, 2019 (audit period), NHLBI awarded $84.3 million in Federal funds for 29 OTs.[4]

OBJECTIVE

Our objective was to determine whether NHLBI complied with applicable Federal requirements for awarding and administering OTs**.**

BACKGROUND

Other Transactions

Distinct from traditional authorities, Congress established "other transaction authority" for certain agencies. Under OT authority, agencies may develop agreements that are not required to: (1) follow a standard format or (2) include terms and conditions that are typically required when using traditional mechanisms. Agreements entered into using traditional mechanisms,

[1] Throughout this report, we use the term "OT" to refer to an award mechanism that is not a contract, grant, or cooperative agreement.

[2] HHS components with OT authority include the Biomedical Advanced Research and Development Authority, the NIH Office of the Director, the National Center for Advancing Translational Sciences, and the National Heart, Lung, and Blood Institute.

[3] NHLBI's OT authority began in 1972.

[4] The 29 OTs include two that NHLBI cofunded under an agreement with the NIH Office of the Director.

such as a contract, grant, cooperative agreement, or cooperative research and development agreement, contain terms and conditions to ensure compliance with statutory requirements applicable to those mechanisms. Agreements entered into using OT authority, conversely, are not generally subject to these requirements, and the terms and conditions of each individual OT agreement may be tailored to meet the specific situation. This flexibility can help agencies attract and partner with entities that have not done business with Federal agencies because of concerns about Government requirements applicable to contracts and grants.

Although OT authority offers benefits to Federal agencies and entities, its use also carries risks. The Government Accountability Office (GAO) and others have previously reported that agencies' use of OT authority has resulted in reduced accountability and transparency, in part because OT agreements may be exempt from the Federal Acquisition Regulation (FAR) and government cost accounting standards.[5] GAO has also reported on the challenges Federal agencies face in creating and administering OT agreements because the agreements do not have a standard structure based on regulatory guidelines.[6]

National Heart, Lung, and Blood Institute

NHLBI, located in Bethesda, Maryland, is 1 of NIH's 28 ICOs and is the leading funder of research to advance the prevention and treatment of heart, lung, blood, and sleep disorders in the country. NHLBI uses a variety of instruments to fund research projects and to procure goods and services that advance its mission, including grants, cooperative agreements, contracts, and OTs.

National Heart, Lung, and Blood Institute's Other Transactions

OT authority provides NHLBI the flexibility to negotiate terms and conditions appropriate to fund research projects and to procure goods and services. NHLBI's Director must approve all OT initiatives. Once approved, NHLBI executes OTs through legally binding, bilaterally signed agreements (OT agreements) between NHLBI and the awardee. OT Agreements Officers are the only individuals at NIH with the delegated authority to negotiate and legally commit the Government to an OT agreement, to execute modifications to existing OT agreements, and to

[5] GAO, Federal Acquisitions: Use of "Other Transaction" Agreements Limited and Mostly for Research and Development Activities, GAO-16-209 (Washington, D.C.: Jan. 7, 2016); GAO, Defense Acquisitions: DOD Has Implemented Section 845 Recommendations but Reporting Can be Enhanced, GAO-03-150 (Washington, D.C.: Oct. 9, 2002); Congressional Research Service, Other Transaction (OT) Authority, RL34760 (Washington, D.C.: Jan. 4, 2012); and National Aeronautics and Space Administration's Office of Inspector General, NASA's Use of Space Act Agreements, IG-14-020 (Washington, D.C.: June 5, 2014).

[6] GAO-16-209; GAO, Department of Homeland Security: Improvements Could Further Enhance Ability to Acquire Innovative Technologies Using Other Transaction Authority, GAO-08-1088 (Washington, D.C.: Sept. 23, 2008).

commit (obligate) funds for OTs.[7] These individuals are also responsible for the administrative and financial aspects of OT awards. NHLBI also uses NIH's "Notice of Award" documents, customarily used for NIH grants and cooperative agreements, to obligate Federal funds for OT awards.[8]

Since FY 2017, NHLBI has entered into OT agreements with universities, nonprofit organizations, and for-profit organizations for initiatives related to curing sickle cell disease, increasing access to NHLBI datasets, and streamlining data use through partnerships with commercial cloud service providers. Although they are a small fraction of its awards overall, NHLBI considers the use of OTs to fund some of its highest risk, most innovative biomedical research initiatives to be critical in its support of research to advance the prevention and treatment of heart, lung, blood, and sleep disorders.

Federal Requirements

Federal law permits NHLBI to enter into OTs as necessary under policies established by the Director of NIH.[9] In May 2017, NIH issued the *NIH "Other Transactions" (OT) Policy Guide* (Policy Guide), which establishes policies on OTs. According to the Policy Guide, OTs are subject to fewer restrictions than other types of awards; however, ICOs must still award and administer OTs in a way that ensures proper stewardship of Federal funds. The Policy Guide states that ICOs have the authority to include additional requirements on OT awardees and to provide further guidance on specific issues other than what is provided in the Policy Guide; however, all ICO-specific policies and procedures must be documented and implemented consistently among all OTs issued by the ICO for a particular program and must comply with Policy Guide requirements.[10]

HOW WE CONDUCTED THIS AUDIT

Our audit covered a judgmental sample of 12 NHLBI OTs totaling $71.9 million (representing more than 85 percent of dollars awarded under NHLBI OTs) executed during our audit period.[11] We focused on whether NHLBI documentation for the sampled OTs provided evidence of compliance with Federal requirements, including requirements that NHLBI: (1) justify the appropriate use of its OT authority, (2) award OTs in amounts that are fair and reasonable, (3)

[7] NIH OT Agreements Officers must have either a Level III Federal Acquisition Certification for Contracting Officer Representative or a Level III HHS/NIH Grants Management Certification (or equivalent government grants management certification).

[8] The term "OT award" refers to the document used to obligate OT funding in the NIH accounting system.

[9] 42 U.S.C. § 285b–3(b)(3).

[10] Policy Guide, "Introduction" and §§ II.Q.1 and 2.

[11] We selected for our sample OTs that had relatively high dollar values or that had other potentially high-risk characteristics such as those with cofunding arrangements.

ensure that OT awardees claim only allowable costs, and (4) fund OTs in accordance with applicable Federal requirements.

The U.S. Office of Special Counsel provided HHS with a complaint referral regarding OTs that HHS delegated to the Office of Inspector General. This audit is responsive to that referral.

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 scope and methodology, Appendix B details Federal requirements and NIH guidance, and Appendix C contains a summary of our sample results.

FINDINGS

NHLBI did not fully comply with Federal requirements for awarding and administering OTs during our audit period. For the 12 OTs in our sample, NHLBI did not adequately document: (1) its justifications for using OTs rather than traditional award instruments; (2) that awarded amounts were fair and reasonable and incurred costs were allowable; or (3) that it complied with Federal requirements for obligating annual appropriations. See Table 1 and Appendix C.

Table 1: Summary of Documentation Issues by Topic

Justifications to Use OTs		Amounts/Costs		Federal Funding Requirements	
Inadequately Documented Prior to Award	**Inadequately Documented Throughout Award**	**Fairness and Reasonableness of Costs Inadequately Documented**	**Allowability of Costs Incurred Inadequately Documented**	**Inadequately Documented Work Requirements**	**Bona Fide Needs Arose After Award**
12	8 (of 8*)	12†	8 (of 8*)	10	2

* Determinations for continued use of OT authority or allowable costs were only applicable for eight OTs.

† NHLBI had not documented its review of the fairness and reasonableness of cost estimates for at least 1 "funding action" under all 12 OTs. (A "funding action" is the obligation of Federal funds for either a new or existing OT agreement.)

NHLBI did not adequately document its compliance with applicable Federal requirements because its internal controls for awarding and administering OTs were ineffective.

As a result, NHLBI could not ensure the proper stewardship of Federal funds used to award OTs, including the $71.9 million we reviewed.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE DID NOT ALWAYS ADEQUATELY DOCUMENT JUSTIFICATIONS FOR USING OTHER TRANSACTION AUTHORITY

For all 12 sampled OTs, NHLBI did not adequately document, prior to award issuance and, when applicable, throughout the life of the awards, its justifications for using OTs instead of traditional award instruments, as required by NIH policy.[12]

Justifications Not Adequately Documented for Using Other Transaction Authority Prior to Award

The Policy Guide states that justifications for using OTs, as opposed to conventional funding instruments, must be documented prior to OT award issuance. Examples of justifications cited in the Policy Guide include using OTs when there is a need for: (1) fluid implementation of a program, (2) nontraditional review and award management practices because the science is expected to be highly evolving, or (3) collaborative involvement by the Government in the technical direction and oversight of the research.[13]

In May 2019, NHLBI issued guidance (NHLBI Guidance) on its OT authority stating that OTs are generally considered funding mechanisms of last resort that should be reserved for use when neither contracts nor grants are likely to accomplish NHLBI objectives.[14] The guidance also lists circumstances under which it is appropriate for NHLBI to use its OT authority.[15]

[12] During the audit period, determinations for continuing to use OT authority were applicable for 8 of the 12 sampled OTs. For the remaining four sampled OTs, determinations for continuing to use OT authority would not have been needed until after the end of the audit period and, thus, they fell outside of our audit scope.

[13] Policy Guide § II.A.4.

[14] *NHLBI Standard Operating Procedure (SOP): Guidance for Other Transactions Authority* (NHLBI Guidance) § 3.1.

[15] These include, for example, when: NHLBI needs to engage nontraditional partners; a large-scale initiative cuts across a number of disciplines and specialties at NHLBI; specific requirements may not yet exist and science is rapidly evolving; or substantial and continuous modification of terms, budget, and scope are needed to meet changing needs of program objectives.

For the 12 OTs in our sample, NHLBI's documented justification for using its OT authority was generally consistent with NHLBI guidance[16] or the Policy Guide.[17]

However, NHLBI did not always clearly document the extent to which it analyzed whether traditional award instruments could have been used instead of OTs. Specifically:

- In all 12 sampled OTs, the OT awardees[18] had been recipients of numerous Federal grants or contracts, including NIH grants or contracts, before receiving the NHLBI OT awards.[19] NHLBI's documentation did not address justifications for using OTs with these current or former NIH grant or contract recipients.

- In 10 of the 12 sampled OTs, NHLBI did not clearly indicate why grants or contracts could not be used or how traditional award instruments were otherwise not appropriate for the contemplated programs. Specifically:

    - NHLBI used what it called a "consortium approach" in the performance of each of the programs for these 10 OTs. NHLBI described this approach as a nimble consortium of awardees that offered a diversity of scientific or functional expertise and capabilities to address a problem that no single awardee working alone could effectively solve. We noted, however, that NIH also had a grant mechanism for consortiums, under which a grantee performs a substantive role in a research project alongside other organizations.[20] It was not clear from NHLBI's documentation that it assessed whether the grant mechanism for consortiums may have been appropriate in these cases.

    - NHLBI's documentation stated that the associated programs required awardees to have partnership roles rather than direct servicing roles for 6 of these 10 OTs. However, it was not clear that NHLBI considered whether cooperative agreement awards—awards used at NIH when there will be substantial Federal scientific or

[16] For awards issued after the NHLBI Guidance was issued.

[17] Specifically, for nine OTs, NHLBI documented the need to negotiate milestones, objectives, and deliverables for programs based on the needs and progress of OT awardee efforts. It also cited that collaborative and flexible strategies were needed because it was unknown which scientific strategies would work at the start of the programs. For the remaining three OTs, NHLBI or the NIH Deputy Director anticipated that working with non-traditional NIH partners and changing the scope or terms of the agreements would require the use of the OT mechanism.

[18] Our sample included two OTs associated with one awardee.

[19] The Policy Guide does not prohibit ICOs from awarding OTs to organizations that have received Federal grants or contracts.

[20] Per the NIH Grants Policy Statement, consortium agreements are formalized agreements under which a research project is carried out by a grantee and one or more other organizations that are separate legal entities.

programmatic involvement[21] in the project—would have been appropriate for such programs.

Additionally, for 10 of the 12 sampled OTs, memos used by NHLBI to document its justifications for using OT authority were not signed or dated. Further, the memos did not indicate who had written them, when they were prepared, or whether they were reviewed and approved prior to award issuance.[22, 23]

Signed and dated justification memos that included input and approval of OT Agreements Officers and that clearly explained the extent to which traditional award instruments had been evaluated and ruled out, would have provided additional assurance that NHLBI had fully complied with NIH policies.

Justifications Not Adequately Documented Throughout the Life of Other Transaction Agreements

The Policy Guide requires ICOs to track circumstances throughout the life of OT agreements to ensure that the use of OT authority continues to be appropriate for a program. Similarly, NHLBI Guidance states that OT Agreements Officers should periodically reconsider the original justification for using OT authority and, if a reasonable basis for using OT authority no longer exists, NHLBI should aim to transition the OT agreements to traditional funding mechanisms if a formal relationship with the awardee is still required.[24]

Eight OTs in our sample spanned multiple years during our audit period, and for those eight OTs, NHLBI did not adequately document that the continued use of OT authority was appropriate. NHLBI used memos for work planning activities and to approve follow-on funding for these OT agreements. However, these memos did not reflect that NHLBI analyzed whether the continued use of OTs was appropriate or considered whether the associated work should be transitioned to a traditional award instrument.

[21] Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

[22] In some cases, the memos were used in conjunction with other documents maintained in an electronic system that NHLBI used to track and approve OT administrative actions, including approvals by the NHLBI Director. However, we were unable to verify that the memos were included in that system prior to award issuance.

[23] OT Agreements Officer involvement was also not evident.

[24] NHLBI Guidance § 4.3.6.

Internal Controls for Documenting Justifications for Using Other Transactions Were Ineffective and Resulted in a Potential Lack of Proper Stewardship of Funds

NHLBI's internal controls for documenting its justifications to use OTs rather than traditional award instruments prior to issuing OT awards were ineffective.

Until May 2019, NHLBI did not have any written procedures for OTs.[25, 26] In May 2019, it issued NHLBI Guidance, which included written procedures that required legal justification memos to be part of NHLBI's OT approval process to document the justification for the proposed use of an OT and to ensure that the use of an OT was consistent with NHLBI's legal authorities. However, the procedures did not specifically require that memos include the reasons why NHLBI could not have used a traditional award instrument. The procedures also stated that OT Agreements Officers were to "periodically reconsider the original justification for use of OT," but the procedures neither required OT Agreements Officers to document this reconsideration nor defined the term "periodically."

Because OTs are generally considered a higher risk instrument than traditional award instruments, NHLBI's ineffective internal controls for justifying the use of OTs increased the risks that NHLBI may not have ensured proper stewardship of Federal funds.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE DID NOT ADEQUATELY DOCUMENT THAT AWARD AMOUNTS WERE FAIR AND REASONABLE OR THAT COSTS WERE ALLOWABLE

For all 12 sampled OTs, NHLBI did not adequately document how it determined that OT award amounts were fair and reasonable or that costs were allowable.

NHLBI Did Not Always Adequately Document That Award Amounts Were Fair and Reasonable

The Policy Guide requires that ICOs determine that award amounts associated with OTs are fair and reasonable and that internal documentation address the reasonableness of anticipated costs of OTs. Internal documentation should also address the fairness and reasonableness of OT cost estimates.[27]

[25] The NIH Policy Guide represented the only written policies and procedures that NHLBI had for awarding and administering OTs prior to May 2019.

[26] Internal controls include the policies and procedures used to fulfill the mission, strategic plan, goals, and objectives of an entity (*Standards for Internal Control in the Federal Government* § OV1.03).

[27] Policy Guide §§ II.A and F.

According to NHLBI, it based finalized OT award amounts on funding availability, awardee budget proposals,[28] and final negotiated award terms and conditions. However, we found that NHLBI did not always maintain adequate documentation to support its determinations that specific OT award amounts were fair and reasonable. Our sample of 12 OTs included 23 funding actions that NHLBI took during the audit period. NHLBI provided written assessments of the fairness and reasonableness of costs for 4 of the 23 actions.[29] For the remaining 19 funding actions, NHLBI did not provide documentation that such assessments were performed.

Further, NHLBI did not always maintain specific, underlying cost information to justify the finalized award amounts that sometimes varied significantly from the applicants' submitted budget proposals. For two funding actions, award applicants submitted budget proposals that were significantly lower than their finalized OT award amounts.[30] For example, one applicant submitted a budget proposal totaling $2.1 million for a 180-day period; however, the finalized award amount was $5.85 million for a 1-year period. For 14 funding actions, award applicants submitted budget proposals that were significantly higher than their finalized OT award amounts. For example, one applicant submitted a budget proposal totaling $8.5 million for an 18-month period; however, the finalized award amount was $1.7 million for a 24-month period.

Lastly, for three other funding actions in our sample for which the final award amount equaled the applicant's budget proposal, NHLBI did not document its assessment of the fairness and reasonableness of the award amount.[31]

NHLBI Did Not Adequately Document Whether Awardees' Incurred Costs Were Allowable

The Policy Guide states that OT agreements should include a clause that documents the basis for determining interim or actual costs, what constitutes direct versus indirect costs, and the basis for allocating indirect costs.[32] However, neither the Policy Guide nor NHLBI Guidance includes any requirements for reviewing awardees' costs prior to reimbursement, including any processes for reviewing invoices, vouchers, or other documentation for allowability.

[28] NHLBI required that OT award applicants submit budget proposal cost estimates prior to the execution of a new OT agreement or prior to a supplemental award under an existing OT agreement. Some budget proposals contained cost estimates for broad categories including, for example, personnel, travel, and other costs, while other proposals only showed overall cost estimates for various project phases and did not contain categorical cost details.

[29] These assessments were performed by NHLBI OT Agreements Officers.

[30] NHLBI stated that costs were based on the awardees' 180-day proposals, extrapolated over a longer period, and adjusted to account for specific technical use cases.

[31] For one of the four funding actions, NHLBI stated that the awardee had submitted a revised proposal prior to award that matched the finalized award amount; however, NHLBI did not provide this document.

[32] Policy Guide § II.H.3.1.

Each of the 12 OT agreements in our sample contained a clause regarding costs and provided for either the reimbursement of awardees' costs or payments for services rendered; however, NHLBI's documentation did not indicate that it reviewed the costs being reimbursed or determined that services had been rendered. During our audit period, OT awardees for 8 of the 12 OT agreements reported disbursements of OT funds. The disbursements were reflected on Federal cash transaction reports and on some awardees' quarterly progress reports. However, NHLBI's documentation did not reflect whether it used these documents or other potential sources of information to determine the allowability of costs incurred by the OT awardees.

Internal Controls for Determining Fair and Reasonable Award Amounts and Allowable Costs Were Ineffective and Resulted in a Potential Lack of Proper Stewardship of Funds

NHLBI internal controls for determining fair and reasonable award amounts and allowable costs were ineffective. Specifically, NHLBI did not have policies and procedures for: (1) documenting its determinations that OT award amounts were fair and reasonable or (2) determining and documenting that costs were allowable in accordance with OT agreement terms and conditions.[33]

Without adequate documentation reflecting the basis of award amounts and cost allowability determinations, NHLBI could not ensure that it always maintained proper stewardship of Federal funds awarded under its OT agreements.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE DID NOT ADEQUATELY DOCUMENT COMPLIANCE WITH FEDERAL FUNDING REQUIREMENTS

NHLBI did not adequately document its compliance with Federal funding requirements, including the Antideficiency Act.[34]

For 10 of the 12 sampled OTs, NHLBI obligated funds without adequately documenting work requirements[35] before the OT agreements were bilaterally executed. For the remaining two sampled OTs, work requirements arose (or were expected to arise) in a future fiscal year and had not yet arisen in the fiscal year in which the obligation of funds had occurred.

[33] A principle of internal control is that management designs control activities in response to an entity's objectives and risks to achieve an effective internal control system. Clearly documenting all transactions in a manner that allows the documentation to be readily available for examination, properly managed, and maintained is a common control activity (*Standards for Internal Control in the Federal Government* §§ 10.01 through 10.03).

[34] Codified at 31 U.S.C. § 1341(a), with additional provisions also found in §§ 1342 and 1517(a).

[35] Statements of Objectives and Milestones are the provisions in NHLBI OT agreements that form the basis for the obligation of Federal funds.

Work Requirements Were Not Adequately Documented in Executed Agreements

The Policy Guide states that Federal funding requirements, including the Antideficiency Act, are applicable to OTs. The Antideficiency Act prohibits an agency from obligating or expending funds in advance of or in excess of an appropriation unless specifically authorized by law (31 U.S.C. § 1341(a)(1)). The Recording Statute requires that an amount be recorded as an obligation of the Federal Government when supported by, among other things, documentary evidence of a binding agreement between an agency and another person (including an agency) that is in writing, used for specific work or services to be provided, and executed before the end of the period of availability for obligation of the appropriation (31 U.S.C. §§ 1501 (a)(1)(A) and (B)).[36]

For funding actions under 10 of the 12 sampled OTs, NHLBI obligated funds for executed OT agreements without adequately documenting associated work requirements. For these 10 OTs, obligations were not supported by OT agreements that described specific work to be provided at the time of award.

For four sampled OT agreements,[37] NHLBI did not establish work requirements until the fiscal year following its obligation and awarding of funds. For example, in September 2017, NHLBI obligated FY 2017 appropriations totaling $2.85 million to fund an OT agreement with a 1-year period of performance. However, work requirements of the OT were not documented until the following FY (2018) after NHLBI required the awardee to submit a revised proposal.[38] At that time, the parties agreed to include a new section of the OT agreement called "work activities" that included things like enhancing usability of NHLBI data and tools for users and providing user training and engagement. NHLBI modified the original OT agreement to include those activities. Because the OT agreement executed in September 2017 did not include any work activities, NHLBI had not adequately defined or properly documented work requirements to justify obligating the $2.85 million in FY 2017 funds.

There were other issues with NHLBI inadequately documenting work requirements for six other OTs. Specifically:

[36] The GAO has held that any authorization to record an obligation for an amount less than the full amount of the government's contractual obligation must be explicitly stated. (*Authority to Rent Space in District of Columbia*, B-195260, July 11, 1979; the Federal Emergency Management Agency had authority to enter into multiple-year leases but must obligate the rental charges for the full term of the lease because it lacked statutory authority to do otherwise).

[37] These OTs sought to integrate heart, lung, blood, and sleep data sets with other NIH data.

[38] NHLBI advised the awardee that budgets were strictly limited to the total dollar of the OT award and instructed the awardee to describe its activities, milestones, deliverables, and budgets. The awardee's revised proposal had a new 1-year performance period and a budget totaling $2.84 million.

- For two OT agreements, NHLBI obligated $3 million and $4 million from the FY 2018 annual appropriation. However, execution of the OT agreements, which contained the OT work requirements, occurred in FY 2019.[39] In accordance with the Recording Statute, the obligation of the funds should have occurred in the same fiscal year that the agreements were executed.

- For one OT agreement, NHLBI obligated $800,000 more than what was in the awardee's original budget proposal without documenting any additional work requirements justifying the need for the additional funds.[40] Further, in a separate funding action, NHLBI obligated an additional $2.1 million for this agreement without documenting any additional work requirements.

- For one OT agreement, NHLBI obligated $3.3 million with a 4-year period of performance but did not specify any work requirements to be performed beyond an initial 6-month period in the executed agreement.

- For two OT agreements, NHLBI obligated $2.2 million and $1 million without documenting any work requirements in the executed OT agreements associated with those amounts.[41]

If NHLBI had required its OT agreements to contain specific work requirements—even if the requirements were later revised—it could have maintained the flexibilities that OTs provide while also documenting that bona fide needs were fully established at the time of the OT award and obligation of funds. Furthermore, in accordance with the Recording Statute and NHLBI's own practices, NHLBI should have obligated funds only after bilateral execution of the OT agreements occurred.[42]

Documentation Did Not Support Funding of Multi-Year Other Transaction Agreements Because Bona Fide Needs Arose After Expiration of Fund Availability

The Policy Guide states that Federal funding requirements, including the Antideficiency Act, are applicable to OTs. The Antideficiency Act (31 U.S.C. § 1341(a)(1)) prohibits an agency from

[39] The obligations of $3 million and $4 million of FY 2018 appropriations occurred on September 24, 2018, while bilateral execution of the OT agreements occurred on October 2, 2018 and October 1, 2018, respectively.

[40] NHLBI stated that it used an updated budget proposal to determine the amount but did not provide that document.

[41] These awards were unique arrangements in which NIH provided funding through "Intra-NIH Direct Citation Agreements" under OT agreements for cloud-computing services between the OT awardees and the NIH Office of the Director; however, the direct citation agreements also lacked specific work requirements.

[42] NIH and NHLBI policies did not explicitly require bilaterally signed agreements; however, NHLBI used this practice in all 12 OTs in our sample.

obligating or expending funds in advance of or in excess of an appropriation unless specifically authorized by law. A fiscal year appropriation may be obligated only to meet a bona fide or legitimate need arising in, or in some cases arising before but continuing to exist in, the appropriation's period of availability (31 U.S.C. § 1502(a)). This is referred to as the bona fide needs rule.

For 2 of the 12 sampled OTs, NHLBI obligated annual appropriations for performance periods that spanned multiple fiscal years. NHLBI's documentation (the OT agreements, the awardee proposals, and other documents) showed that the bona fide needs for certain work requirements were expected to only arise in years subsequent to the first year of the award, that is, after the period of availability of the annual appropriation had expired. However, NHLBI obligated funds for these OTs in amounts that were anticipated to cover the entire performance periods. Thus, NHLBI obligated current-year funds to cover future-year needs without documenting why these actions were appropriate.

In addition, NHLBI's justifications for using OTs for these projects and the other OTs in our sample showed that the work requirements had uncertainties and were subject to change over time.[43] Because of those uncertainties, NHLBI should have limited its awards to 1-year increments to ensure that it established bona fide needs in each funded year of the agreements.

NHLBI maintained that it had satisfied Federal funding requirements because: (1) it needed only to show that a bona fide need existed in the year that it obligated funds, (2) it was not necessary for the bona fide need to be tied to a concrete set of milestones or tasks, and (3) broadly applied, the bona fide need was to provide financial assistance to solve scientific problems so that awardees could experiment with potential solutions and approaches. However, we disagreed with NHLBI's analysis.

We also noted that other NIH programs with OT authority had practices to reduce the risk of noncompliance with Federal funding requirements. For example, policy guides for these programs[44] state that, generally, a single award covering an entire period of support should be used only if the total planned period of support would be less than 18 months. The guides also state that budget periods are usually 12 months long; however, shorter or longer budget periods may be established for "compelling programmatic or administrative reasons."

[43] Uncertainties were reflected in justifications discussed previously in this report. For nine OTs, justifications showed that it was unknown which scientific strategies would work at the start of the contemplated programs. For the other 3 OTs, changes in the scopes or terms of the agreements were specifically anticipated.

[44] Policy guides for OT projects under NIH's Precision Medicine Initiative and its Stimulating Peripheral Activity to Relieve Conditions (SPARC) programs state that OTs are to be programmatically approved for support in their entirety but funded in increments called budget periods (*Other Transaction Award Policy Guide for the NIH Precision Medicine Initiative Research Programs* and *NIH Other Transaction Award Policy Guide for the SPARC Program*).

Internal Controls for Complying With Federal Funding Requirements Were Ineffective and Resulted in Potential Violations of Federal Law

NHLBI's internal controls for complying with Federal funding requirements were ineffective.

Prior to May 2019, NHLBI had not adopted any written policies and procedures for complying with Federal funding requirements, including any policies and procedures addressing the establishment of specific work requirements in OT agreements and the bona fide needs rule. NHLBI guidance adopted in May 2019, provided only that, within an OT agreement, the "statement of objectives and milestones" established the basis for obligating Federal funds;[45] however, it did not provide any further guidance with regard to the proper obligation of Federal funds, complying with the bona fide needs rule, or complying with other related Federal funding requirements, including the Recording Statute and the Antideficiency Act.

Without documenting its compliance with Federal funding requirements, NHLBI could not be sure that it used OT funding in a manner that ensured the proper stewardship of OT funds. Further, it may have violated the bona fide needs rule and, consequently, the Antideficiency Act. Although OTs provide unique flexibilities to renegotiate milestones, objectives, and deliverables after an initial award based on changing project needs; properly establishing and documenting bona fide needs of the OT award, including specific work requirements, prior to obligating annual appropriations should be considered a key control activity for ensuring compliance with the Antideficiency Act and ensuring proper stewardship of Federal funds.

RECOMMENDATIONS

We recommend that the National Heart, Lung, and Blood Institute strengthen its internal controls for OTs by updating its policies and procedures to:

- require that OT justification memos:
    - be signed, dated, and written or developed with involvement from appropriate parties, including OT Agreements Officers, and
    - include explicit statements as to why a traditional award instrument could not be used for a project;
- require that justifications for the continued use of OT authority be documented throughout the life of OT agreements with reconsideration required at a defined frequency; and

[45] NHLBI Guidance § 4.3.5.2.

- specify requirements for determining and documenting:

    - the fairness and reasonableness of award amounts or cost estimates provided by OT award applicants;

    - the allowability of costs charged to OT awards; and

    - its compliance with Federal funding requirements including the proper establishment of bona fide needs through specific work requirements prior to the obligation of OT funds.

NATIONAL INSTITUTES OF HEALTH COMMENTS

In written comments on our draft report, NIH concurred with our recommendations and said that it would update its policies and procedures by November 15, 2021, to reflect our recommendations. NIH's comments are included in their entirety as Appendix D.

NIH also provided technical comments on our draft report, which we considered.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 12 OT agreements totaling $71.9 million awarded by NHLBI from October 1, 2016, though September 30, 2019 (audit period).

The U.S. Office of Special Counsel provided HHS with a complaint referral regarding OTs that HHS delegated to the Office of Inspector General. This audit is responsive to that referral.

We performed fieldwork at NHLBI offices located in Bethesda, Maryland.

METHODOLOGY

To accomplish our audit objective, we:

- reviewed legislation authorizing OTs, Federal fiscal laws, and other applicable Federal requirements;

- reviewed organizational charts, position descriptions, and personnel requirements, relevant to NHLBI OT awards including training and warrant information for NHLBI OT Agreements Officers;

- interviewed personnel responsible for awarding, monitoring, managing, and overseeing the administration of NHLBI OTs;

- reviewed NIH and NHLBI policies and procedures, including policy guides, to identify applicable requirements associated with awarding, administering, and overseeing OTs;

- selected a judgmental sample of 12 NHLBI OTs awarded during our audit period and reviewed NHLBI's OT files to assess whether NHLBI had:

    - justified its use of OT authority prior to OT award and that using its OT authority continued to be appropriate throughout the life of applicable OTs;

    - determined that OT award amounts were fair and reasonable and that costs charged by OT awardees were allowable; and

    - funded OT agreements in accordance with applicable Federal fiscal laws and related requirements; and

- discussed the results of our audit with NHLBI officials.

Our audit objective required that we obtain an understanding of internal controls. Of the five components of internal control,[46] control environment, control activities, and the following underlying principles were significant to our audit objective:

- management should establish an organizational structure, assign responsibility, and delegate authority to achieve the entity's objectives;

- management should demonstrate a commitment to recruit, develop, and retain competent individuals;

- management should design control activities to achieve objectives and respond to risks; and

- management should implement control activities through policies.

We assessed the design, implementation, and operational effectiveness of the internal controls we identified as significant to our audit objective.

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.

[46] *Standards for Internal Control in the Federal Government* (GAO-14-704G), section OV2.09, Figure 3.

APPENDIX B: FEDERAL REQUIREMENTS AND NIH GUIDANCE

FEDERAL REQUIREMENTS

> [T]he Director of the Institute, under policies established by the Director of NIH . . . may enter into such contracts, leases, cooperative agreements, or other transactions, as may be necessary in the conduct of the Director's functions, with any public agency, or with any person, firm, association, corporation, or educational institutions (42 U.S.C. § 285b–3(b)(3)).
>
> [A]n officer or employee of the United States Government . . . may not . . . make or authorize an expenditure or obligation exceeding an amount available in an appropriation or fund for the expenditure or obligation . . . [or] involve either government in a contract or obligation for the payment of money before an appropriation is made unless authorized by law (31 U.S.C. § 1341. (a)(1)(A) and (B)).
>
> An amount shall be recorded as an obligation . . . only when supported by documentary evidence of . . . a binding agreement between an agency and another person (including an agency) that is . . . in writing, in a way and form, and for a purpose authorized by law; and . . . executed before the end of the period of availability for obligation of the appropriation or fund used for specific goods to be delivered, real property to be bought or leased, or work or service to be provided (31 U.S.C. § 1501 (a)(1)(A) and (B)).
>
> The balance of an appropriation or fund limited for obligation to a definite period is available only for payment of expenses properly incurred during the period of availability or to complete contracts properly made within that period of availability and obligated consistent with section 1501 of this title. However, the appropriation or fund is not available for expenditure for a period beyond the period otherwise authorized by law (31 U.S.C. § 1502 (a)).

NATIONAL INSTITUTES OF HEALTH: *OTHER TRANSACTIONS (OT) POLICY GUIDE*

> While OTs come with fewer restrictions than other types of awards, they still must be awarded in a manner that ensures proper stewardship of Federal funds and comply with requirements applicable to all Federal funding (regardless of funding mechanism). For this reason, [NIH] ICOs must be sure that their OT requirements are fully documented and consistently applied. They also must comply with the policy requirements discussed throughout this document, as appropriate ("Introduction").
>
> Prior to issuing an [OT] agreement, an ICO must document its rationale for using an OT, as opposed to a conventional funding instrument, and track

circumstances throughout the life of the agreement to ensure the use of OT authority continues to be appropriate . . . . The documentation should address project-specific risks, such as fairness and reasonableness of cost estimates, but may also rely on broader risk management policies to inform overarching issues . . . . [T]he ICO's internal documentation must also address the reasonableness of the anticipated cost and applicable terms and conditions (section II.A.4).

The government must be able to determine that the amount of the agreement is fair and reasonable (section II.F).

ICOs retain the authority to include additional requirements on OT [agreement] awardees and to provide further guidance on specific issues than what is provided in this Policy Guide . . . . All ICO-specific policies and procedures must be fully documented and implemented consistently among all OT [agreement] awards issued by the ICO for a particular program and must comply with the requirements of this Policy Guide (sections II.Q.1 and 2).

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE *STANDARD OPERATING PROCEDURE (SOP): GUIDANCE FOR OTHER TRANSACTIONS AUTHORITY*

OT is generally considered a mechanism of last resort that should be reserved for use when neither a contract nor a grant is likely to accomplish the objectives of an initiative of the NHLBI (section 3.1).

[T]he [statement of objectives and milestones] that is incorporated into the OT agreement . . . forms the basis for the obligation of [F]ederal funds (section 4.3.5.2).

[T]he [OT] Agreements Officer should periodically reconsider the original justification for the use of OT[s] . . . [, and,] if a reasonable basis for OT authority no longer exists and a formal relationship with the awardee is still required, the Institute should aim to transition the OT agreement to a traditional NIH mechanism (section 4.3.6).

APPENDIX C: RESULTS OF SAMPLE ITEMS REVIEWED

Table 2: Areas of Compliance Reviewed by Sample Item

					Areas of Compliance		
Sample Item	Agreement Number	Award Date	Award Amount	Number of Funding Actions	Justifications for OT Use	Award Amounts and Costs	Funding / Bona Fide Needs
1	142478-01	9/26/2017	$2,850,000	1	a	c	e
1	142478-01S1	9/24/2018	1,885,000	1	b	c	e
1	142478-01S2	9/26/2019	2,500,000	1	b	c	e
2	142479-01	9/26/2017	1,200,000	1	a	c	e
2	142479-01S1	7/16/2018	213,708	1	b	c	e
2	142479-01S2	9/24/2018	1,731,818	1	b	c	e
2	142479-01S3	9/26/2019	2,000,000	1	b	c	e
3	142480-01	9/26/2017	1,100,000	1	a	c	e
3	142480-01S1	9/27/2018	3,880,788	1	b	c	e
3	142480-01S2	9/27/2019	1,000,000	1	b	c	e
4	142481-01	9/26/2017	5,850,000	1	a	c	e
4	142481-01S1	9/24/2018	2,607,065	1	b	c	e
4	142481-01S2	9/28/2019	7,700,000	1	b	c	e
5	147154-01	8/13/2018	5,798,287	1	a	c	g
5	147154-01S1	9/26/2019	5,681,776	1	b	c	g
6	142340-01	9/26/2017	4,697,455	1	a	c	e
6	142340-01S1	9/17/2019	2,073,176	1	b	c	e
7	147741-01	9/24/2018	3,000,000	1	a	c	f
8	147810-01	9/24/2018	4,000,000	1	a	c	f
9	152448-01	9/7/2019	3,301,289	1	a	d	e
10	152932-01	9/27/2019	5,641,200	1	a	d	g
11	027060-01S1	9/18/2019	2,200,000	1	a	d	e
12	027852-01S1	9/19/2019	1,000,000	1	a	d	e
Totals			**$71,911,562**	**23**			

Key:

a	Documentation of justifications to use OTs did not show: (1) that reasons were approved prior to OT award issuance or (2) the extent of any analysis performed to justify using OTs over traditional award mechanisms.
b	Justifications for continued use of OT authority were not documented.
c	Fairness and reasonableness of award amounts or allowability of costs was not documented.
d	Fairness and reasonableness of award amounts was not documented.
e	Work requirements were not adequately documented.
f	Work requirements were not adequately documented, and the OT agreement was bilaterally executed after obligation of funds occurred.
g	Documentation did not support funding of multi-year OT agreements because *bona fide* needs arose after expiration of fund availability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

DATE: March 17, 2021

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

FROM: Principal Deputy Director, National Institutes of Health

SUBJECT: NIH Comments on OIG Draft Report, "The National Heart, Lung, and Blood Institute Did Not Fully Comply With Federal Requirements for Other Transactions" (A-04-20-04078)

Attached are the National Institutes of Health's (NIH) comments on the draft Office of Inspector General's (OIG) report, "The National Heart, Lung, and Blood Institute Did Not Fully Comply With Federal Requirements for Other Transactions" (A-04-20-04078).

NIH appreciates the review conducted by the OIG and the opportunity to provide clarifications on the draft report. If you have questions or concerns, please contact Meredith Stein in the Office of Management Assessment at 301-402-8482.

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

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

Attachments

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 HEART, LUNG, AND BLOOD INSTITUTE DID NOT FULLY COMPLY WITH FEDERAL REQUIREMENTS FOR OTHER TRANSCATIONS" (A-04-20-04078)

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. Technical comments are provided under separate cover.

NIH and its component National Heart, Lung and Blood Institute (NHLBI) remain committed to the appropriate use of Other Transaction (OTs) to meet its research requirements and mission needs in a manner that minimizes potential risk, with the understanding that OTs are not subject to the Federal Acquisition Regulation.

NIH is pleased that the OIG identified neither fraud, waste, or abuse, nor violations of laws or regulations. NIH is pleased to note the OIG's positive recognition of the controls NHLBI had in place for documenting the justification for using its OT authority that was generally consistent with prevailing NIH and NHLBI policies.

NIH understands that OTs must be awarded in a manner that ensures proper stewardship of federal funds and complies with requirements applicable to all federal funding. NIH believes that NHLBI meets the requirements of Sections 1502 and 1501 of Title 31, U.S. Code. NIH further believes that the specific examples cited in the OIG's draft report are not violations of law.

The draft report contained three recommendations, with which NIH and NHLBI concur.

OIG Recommendation 1:
NHLBI should update its policies and procedures to require (a) that OT justification memos be signed, dated, and written or developed with involvement from appropriate parties, including OT Agreements Officers, and (b) include explicit statements as to why a traditional award instrument could not be used for a project.

NIH Response:
NHLBI concurs with OIG's recommendation. NHLBI will update its policies and procedures by November 15, 2021 to reflect OIG's recommendation.

OIG Recommendation 2:
NHLBI should update its policies and procedures to require that justifications for the continued use of OT authority be documented throughout the life of OT agreements with reconsideration required at a defined frequency.

NIH Response:
NHLBI concurs with OIG's recommendation. NHLBI will update its policies and procedures by November 15, 2021 to reflect OIG's recommendation.

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 HEART, LUNG, AND BLOOD INSTITUTE DID NOT FULLY COMPLY WITH FEDERAL REQUIREMENTS FOR OTHER TRANSCATIONS" (A-04-20-04078)

OIG Recommendation 3:
NHLBI should update its policies and procedures to specify requirements for determining and documenting: (a) the fairness and reasonableness of award amounts or cost estimates provided by OT award applicants, (b) the allowability of costs charged to OT awards, and (c) its compliance with Federal funding requirements including the proper establishment of bona fide needs through specific work requirements prior to the obligation of OT funds.

NIH Response:
NHLBI concurs with OIG's recommendation. NHLBI will update its policies and procedures by November 15, 2021 to reflect OIG's recommendation.