Department of Health and Human Services
Office of Inspector General
Office of Evaluation and Inspections

November 2025 | OEI-04-24-00140

Gaps in NIH's Oversight Put Millions in Funding for Other Transactions at Greater Risk of Fraud, Waste, or Abuse

HHS Office of Inspector General

REPORT HIGHLIGHTS

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Why OIG Did This Review

- Other Transactions (OTs) fund high-impact, cutting-edge, or urgent public health research. OTs are a higher-risk award mechanism than grants, contracts, and cooperative agreements due to fewer requirements. According to NIH, fewer requirements allow flexibility in negotiating intellectual property rights and attracting non-traditional recipients, among other benefits.
- NIH's use of OTs increased from just under $900 million in 2020 to $1.9 billion in 2024. This total includes both newly awarded OTs and continued funding of previously awarded OTs.

What OIG Found

By not consistently implementing required OT safeguards, NIH put millions of dollars in OT funding at greater risk of fraud, waste, and abuse. Each of the 15 OTs in our sample had issues in at least one area of our review:

NIH has fallen short in justifying its use of OTs. For 12 OTs in our sample, OT staff did not fully justify the use of OTs according to statutory and policy requirements, including why traditional, lower-risk funding mechanisms could not meet the purpose of the initiative.

NIH Institute, Centers, and Offices (ICOs) did not effectively manage the unique risks of each OT. For 12 of the OTs in our sample, OT staff conducted minimal risk management. Risk management helps protect OTs from the unique risks posed by the recipient and the proposed project.

Additionally, three of seven ICOs in our sample had no required OT internal control policies to ensure efficient and effective management of government resources to protect against fraud, waste, and abuse. Effective internal controls are important given the inherent risks of OTs. Also, despite the increasing use of OTs, few ICOs reported measuring the benefit of OTs as encouraged by NIH policy.

What OIG Recommends

OIG recommends that NIH:

1. Assess the benefits of OTs to inform future OT policies and use.
2. Strengthen justifications for using OTs.
3. More effectively manage the unique risks of all OTs.
4. Establish internal controls to protect OTs from mismanagement and fraud by both OT staff and recipients.

NIH concurred with all four recommendations.

TABLE OF CONTENTS

BACKGROUND

OBJECTIVES

1. To describe the National Institute of Health's (NIH) use of Other Transactions (OTs) during fiscal years (FY) 2022 and 2023.
2. To determine the extent to which and how NIH Institutes, Centers, and Offices (ICOs) documented required justifications, risk management, and internal controls for OTs.
3. To determine whether and how NIH established and tracked metrics to measure the benefits of OTs as recommended.

In 2024, NIH awarded over $1.9 billion in new and continued OTs. This amount represents an increase from just under $900 million in 2020.

OTs are, by definition, awards other than grants, contracts, or cooperative agreements.[1] OTs can be used to fund high-impact, cutting-edge research, or research in response to urgent public health situations.[2] Because they are not grants, contracts, or cooperative agreements, OTs are not subject to the Uniform Guidance or the Federal Acquisition Regulation. As such, OTs are considered to be higher risk and should generally be used only when the objectives of a Federally funded project cannot be accomplished under a traditional funding mechanism.

As an alternative to grants, contracts, and cooperative agreements, OTs provide some unique flexibilities to NIH that make them a more collaborative award mechanism. For example, OTs can allow for negotiation of terms and conditions for the work being funded, including who retains rights to the intellectual property resulting from the work.[3] NIH also views OTs as an important tool to attract recipients that have not received grants, contracts, or cooperative agreements from the Federal government (hereinafter referred to as non-traditional recipients).

While OTs come with fewer restrictions than other types of funding mechanisms, there are some required safeguards that protect these taxpayer funds from fraud, waste, and abuse. These safeguards include justifying the use of OTs, managing risks, and establishing OT internal control policies for ICOs that award OTs.

Other Transaction Authority at NIH

NIH is one of few Department of Health and Human Services (HHS) Operating Divisions with OT authority.[4] Only three ICOs within NIH have specific statutory authority to award an OT: the Office of the Director, the National Center for Advancing Translational Sciences, and the National Heart, Lung, and Blood Institute.[5] Additionally, the NIH Director, under the Public Health Service Act, may approve OT requests by other ICOs to

engage in OTs that carry out the Precision Medicine Initiative, the Common Fund, or high-impact cutting-edge research.[6, 7, 8]

NIH Roles and Responsibilities for Oversight and Management of OTs

Within NIH's Office of the Director, the Office of Policy for Extramural Research Administration (OPERA) is the central office responsible for policy and compliance related to NIH OTs. OPERA created NIH's OT Policy Guide (hereinafter referred to as the Policy Guide) that contains the requirements for all NIH OTs regardless of awarding ICO. Additionally, OPERA compiles an annual descriptive report on all OT initiatives operating under the broad NIH OT authorities. ICOs must ensure their OTs conform with the Policy Guide. Within ICOs, OT staff are responsible for the oversight and management of individual OTs.

Safeguards for Protecting NIH OTs from Fraud, Waste, and Abuse

Federal regulations and NIH's Policy Guide outline the requirements for all NIH OTs. These requirements are, in part, intended to protect Federal OT funds from fraud, waste, and abuse. The requirements include justifying the use of an OT, managing risks, and establishing internal controls to ensure efficient and effective management of government resources.

Justifying Each OT

ICOs must justify their use of OT authority for every OT to ensure each meets statutory requirements and is used only when traditional, lower-risk funding mechanisms cannot accomplish the initiative's purpose. There are three required justifications for NIH OTs.[9] ICOs must document all three of the following:

Bona fide need justification. ICOs must justify the bona fide need for an initial OT award and every modification that adds monies to the OT. An acceptable bona fide need justification supports that the obligation satisfies a need of the agency that arose during the period of fund availability (with certain limited exceptions) and meets the purpose and availability of funds established in the appropriation.[10]

Justification of why a traditional funding mechanism cannot meet the initiative's purpose. When justifying the use of OT authority, ICOs cannot simply state that they need to use an OT. They must explicitly describe why a traditional funding mechanism cannot meet the OT initiative's purpose. ICOs include this justification in their application for the use of OT authority prior to selecting recipients.

Statutory and scientific justification. ICOs must justify their use of OTs according to the statutory requirements for NIH, which require that OTs be for "high-impact cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, or treatment of diseases

and disorders, or research urgently required to respond to a public health threat."[11] ICOs must also provide a scientific justification for the research initiative by providing the background and rationale for the scientific need for the OT.

Managing the Unique Risks of Each OT

The Policy Guide requires ICOs to conduct risk management for all OTs. Risk management includes both risk analysis and risk mitigation.

A risk analysis should identify the unique risks of funding each potential OT recipient and project. There are no specific requirements for what a risk analysis should include, but the Policy Guide provides a list of possible components. This list includes checking Federal databases; conducting a strength, weakness, threat, and opportunity assessment; determining the fairness and reasonableness of anticipated costs; and reviewing the potential recipients' experience and performance history.

Although the Policy Guide requires ICOs to mitigate identified risks, ICOs have options for how they can do this. They can establish a risk management plan or establish terms and conditions of the award to mitigate risks. Terms and conditions set forth requirements for the OT to which both OT staff and the recipient must adhere. The terms and conditions in an OT agreement must protect the Federal government's interests.

Developing ICO-Specific OT Internal Controls

The Policy Guide also requires that ICOs document their process for OT internal controls within their OT Standard Operating Procedures (SOPs). Internal controls are "processes, designed and implemented, to provide reasonable assurance regarding effectiveness and efficiency of operations; reliability of reporting for internal and external use; compliance with applicable laws, regulations, and agency policy; and proper management of official records."

Internal controls are intended to prevent mismanagement and fraud by both NIH and OT recipients given the higher inherent risks of OTs. For example, requiring a supervisor to sign off on purchases prevents an employee from fraudulently making purchases without any oversight. ICOs establish their policies for OT internal controls to cover all OTs awarded by the ICO. The Policy Guide states that OT staff must also establish periodic reviews, at least once per fiscal year, of OT internal controls.

Measuring the Benefits of OTs

OPERA encourages, but does not require, OT staff to evaluate and measure the effectiveness and efficiency of their OTs. It suggests that ICOs establish and track any metrics of the benefits directly attributed to the use of OT authority.

NIH has used various metrics of success for other research initiatives. For example, the Science and Technology for America's Reinvestment: Measuring the Effect of Research on Innovation, Competitiveness and Science, or STAR METRICS, was a multi-agency

venture led, in part, by NIH that measured the impact of science investment in several key areas:

- Economic growth: measured by patents and business start-ups
- Workforce outcomes: measured by student mobility into the workforce and employment markers
- Scientific knowledge: measured by citations and publications.[12]

Methodology

We reviewed data for NIH OTs awarded in FY 2022 and 2023. We pulled the entire population of NIH OTs awarded during this period and used these data to conduct descriptive analyses (e.g., funding, types of research, types of recipients) for these OTs. See the Detailed Methodology for more information on our data collection and analysis for this review.

For our file review, we selected a purposive sample of 15 out of 107 OTs that began during our review period. In selecting our sample, we considered funding amount; awarding institute and center; type of project; and type of recipient. We reviewed all documentation associated with these 15 OTs.

The selected 15 OTs represented 14 percent of newly awarded OTs in 2022-2023 and 54 percent of the nearly $440 million in total funding for newly awarded OTs in 2022-2023. Our sample of 15 OTs contained 30 awards, ranging from one to four awards per OT. Awards are unique disbursements of money with a unique project number. There were often multiple awards made to the same OT, which has the same study title, primary investigator, and serial number.

Limitations

Our file review findings are not generalizable and apply only to our sample of 15 OTs. Additionally, our analysis for the file review is based on the documentation we received. We requested all files associated with the OTs in our sample from NIH and subsequently requested documentation that was missing in our best effort to ensure that our review covered all OT documentation for our sample.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued in 2020 by the Council of the Inspectors General on Integrity and Efficiency.

LANDSCAPE

Exhibit 1: Overview of NIH OTs awarded in 2022-2023

$2.4 Billion **206 OTs** **403 Awards** **142 Institutions**

Note: OTs represented 3.4% of NIH's total funding for research grants; research and development contracts; and OTs for FY 2022-2023.

OT - A funding mechanism other than grants, contracts, or cooperative agreements. An OT has a single study title, investigator(s), and serial number.

Award - Unique disbursement of money with a unique project number. Many OTs in our review were composed of multiple awards.

Exhibit 2: Most OT awards in 2022-2023 went to existing, rather than new, OTs

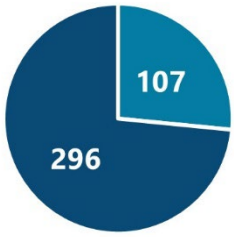


Exhibit 3: The funding per OT ranged from

$94.1K - $613.9M

Source: OIG analysis of 206 NIH OTs awarded in 2022-2023. See Appendix A for more information on NIH OT funding.

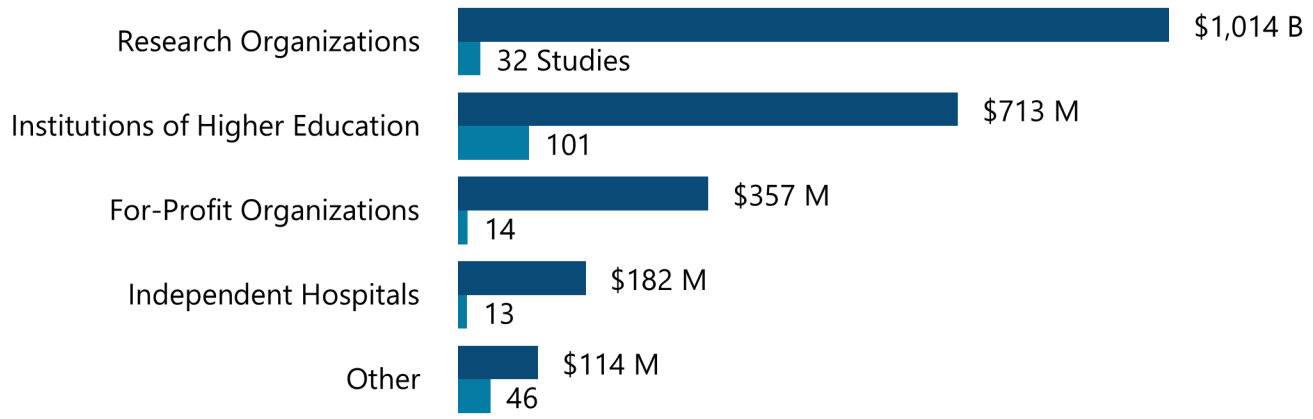
What kinds of recipients are receiving NIH OTs?

NIH awarded most OTs to domestic recipients and those with a history of traditional funding. Research organizations and institutions of higher education were the primary recipient types for NIH OTs.

Eighty-one percent of OT recipients (115/142) received traditional HHS funding at least once in the 10 years prior to our review. During this time, these OT recipients received a median total of $546 million in traditional HHS funding (Range: $200,000 - $7.1 billion).

Eighty-nine percent of OT recipients (126/142) were domestic. See Appendix B for more information on the 11 percent of recipients that were foreign.

Exhibit 4: NIH awarded $1 billion in OTs to research organizations, but institutions of higher education received the most OTs

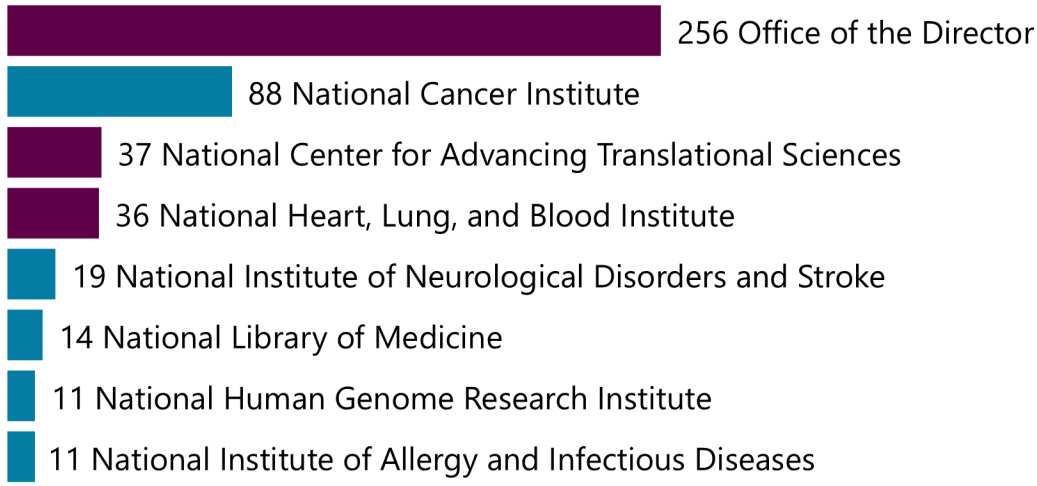


Source: OIG analysis of 206 NIH OTs awarded in 2022-2023. Note: The recipient type code is selected by the applicant organization according to its function, mission, or service. We truncated the "Other" category from its full title "Other Health, Human Resources, Environment/Community Service Organization."

Which ICOs are funding OTs at NIH?

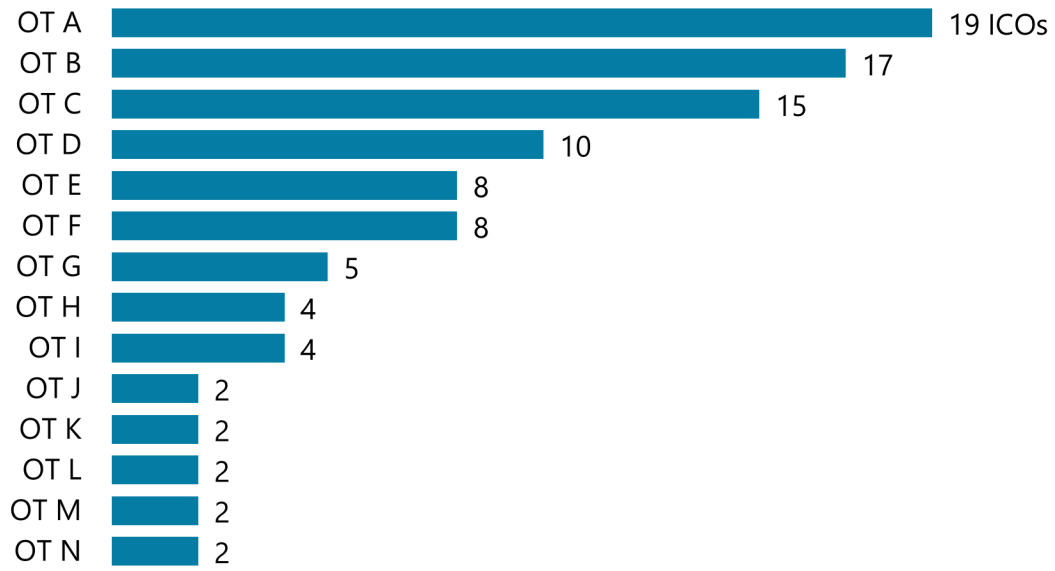
The Office of the Director; the National Center for Advancing Translational Sciences; and the National Heart, Lung, and Blood Institute have **direct statutory authority to fund OTs**. The NIH Director, under the Public Health Service Act, may also approve OT requests by other ICOs that carry out specific research. In 2022-2023, NIH approved 223 OT awards from 20 ICOs that **did not have direct statutory authority**.

Exhibit 5: The Office of the Director and the National Cancer Institute funded most of the OT awards in 2022-2023



Source: OIG analysis of 206 NIH OTs awarded in 2022-2023. Note: This graph only captures ICOs funding 10 or more OTs in our review. See Appendix C for more information on all ICOs' use of OTs in our review period.

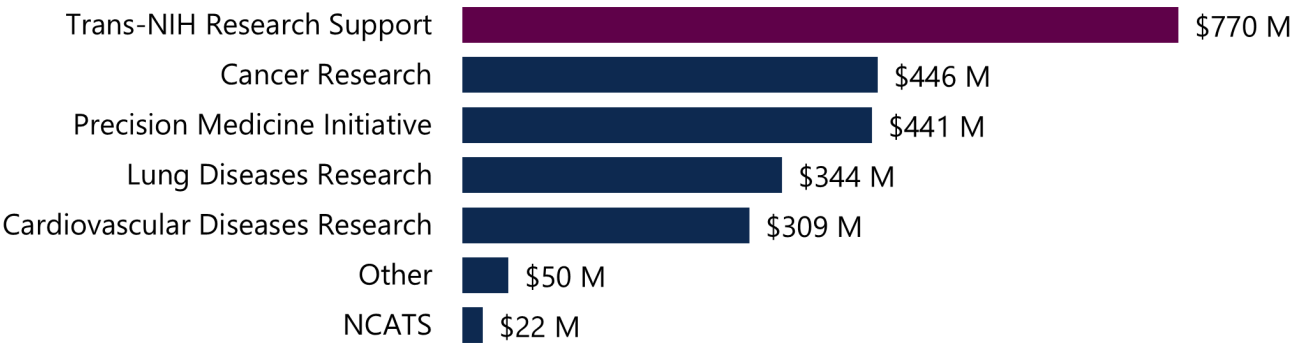
Exhibit 6: Multiple ICOs* contributed funding to the same OT for 14 of the 206 OTs in our population



Source: OIG analysis of 206 NIH OTs awarded in 2022-2023. Note: A few ICOs oversee their own OTs, but most do not have the capacity to administer their own OTs. In those cases, an ICO with the capacity and resources administers OTs for those ICOs.
*NIH RePORTER reports awarding Institute and Center, but not Office.[13] As such, this graphic contains data for OTs in our population by Institute or Center, not Institute, Center, or Office. As a result, the number of ICOs contributing funding to OTs may be underestimated.

What types of research are NIH OTs funding?

Exhibit 7: Nearly one-third of OT funding in 2022-2023 was for Trans-NIH Research Support, which funds projects in biomedical research that a single ICO cannot address



Source: OIG analysis of 206 NIH OTs awarded in 2022-2023. Note: Funding is rounded to the nearest million. See Appendix A-4 for the actual funding amount and non-aggregate categories.[14]

FINDINGS

ICOs' justifications for OTs in our sample were often missing, incomplete, or inconsistent with funding decisions

ICOs have fallen short in justifying their use of OTs. Justifications ensure that NIH is using OTs in accordance with statute; support NIH's use of the higher-risk OT award over more traditional, lower-risk funding mechanisms; and are required by the Policy Guide and, in some cases, Federal regulation. Of the three types of required justifications (i.e., statutory and scientific justification; bona fide need; and why a traditional funding mechanism cannot meet the purpose of the initiative), OT staff most often did not justify bona fide need nor justify why a traditional funding mechanism would not meet the purpose of the initiative.

The justifications that did exist were sometimes inconsistent with the OTs that were subsequently awarded. Several justifications stated the need to partner with non-traditional recipients as the primary reason for using an OT. However, in some of these cases, ICOs awarded OTs to recipients with histories of receiving traditional funding from HHS.

Twelve of the 15 OTs in our sample were not fully justified

Twelve OTs had minimal to no justification for at least one of the three required types of justifications, and 6 of the 12 had minimal to no justification for 2 types.

More than half of awards had no bona fide need justification. Nine OTs in our sample did not have any bona fide need justification, as required by Federal regulation and the Policy Guide.

Bona fide need justifications are required at the award level (each time money is disbursed) rather than at the OT level, so hereinafter we describe our analysis at the award level. Of the 30 awards in our review, 18 did not have bona fide need justifications. That is, OT staff did not justify any determination that the funds were being used to meet an agency need and that the funds met the purpose of their appropriation.

Four additional OT awards had minimal justification of bona fide need. Minimal bona fide need justifications only contained a check or statement that the bona fide need was met and did not explain how or have supporting evidence.

The remaining eight OT awards had stronger justifications for bona fide need. Stronger bona fide need justifications had a statement or check that the justification had been met and explained how or included supporting evidence. Exhibit 8 provides examples of minimal and stronger bona fide need justifications for awards in our sample.

Exhibit 8: Examples of bona fide need justifications in our sample

Minimal Justification

[Risk Checklist Question: Has the bona fide need been met for the funding allocated for this fiscal year?]

- "need established"
- "yes"

Stronger Justification

- "As Program Officer for the [X] OT…, I have provided this program summary for the [X] OT Year 1, Segment 2 funding requests and reviewed the associated milestones, objectives, tasks, requirements documentation, and budget proposals. I recommend approval for the total cost requested…"
- "The signed funding memo, confirmed that there are current year (FY23) funds committed for this project and that there is a bona fide need to utilize FY23 funds for the purpose of funding this clinical coordinating center."
- Stated that the bona fide need had been met and pointed to additional documentation in the pay plan justification.

Source: OIG analysis of a sample of 30 NIH OT awards (representing a total of 15 OTs) funded in 2022-2023.

Seven of 15 OTs had minimal justification for why a traditional funding mechanism could not meet the initiative's purpose. While the statutory definition for the use of an OT is broad, the Policy Guide requires ICOs to explicitly describe why a traditional funding mechanism cannot accomplish the purpose of the initiative. While no OTs in our sample were missing justifications for why a traditional funding mechanism could not meet the initiative's purpose, seven OTs had only minimal justifications. These justifications explained why an OT was needed, but they did not explicitly state why traditional mechanisms could not meet the initiative's purpose. As such, NIH used OTs when a traditional funding mechanism may have met the purpose of the initiative with lower risk to Federal funding.

The remaining eight OTs had stronger justifications that explicitly described why a traditional funding mechanism would not meet the initiative's purpose. See Exhibit 9 for examples.

Exhibit 9: Examples of justifications for why a traditional funding mechanism would not meet the initiative's purpose in our sample

Minimal Justification (states need for OT, but does not explicitly address why traditional funding mechanisms would not meet the initiative's purpose)

- "As detailed above, the funding collaboration… will rely on four features that are in conflict with standard NIH practices, but would be allowed by OT authority. These are: full and equal [non-NIH entity] participation in review and funding recommendations, establishing IP rights for successful applications, two stage applications, and dual roles for the expert panel."

Stronger Justification (detailed, specific, and explicit explanation of why traditional funding mechanisms would not meet the initiative's purpose)

- "**Grants and cooperative agreements** are governed by Federal Grant and Cooperative Agreements Acts, and **contracts** are subject to the Federal Acquisition Regulation, which would limit NIH's ability to negotiate terms and conditions that are most advantageous to both the community organizations and NIH in conducting the research initiative." [emphasis added]
- "**Contracts are insufficiently flexible** on the timescale needed to adapt to the changing data science environment. Alternatively, **grants don't have sufficient mechanisms** to enforce course corrections driven by Institute priorities once funding has been released." [emphasis added]

Source: OIG analysis of a sample of 15 NIH OTs awarded in 2022-2023

None of the 15 OTs were missing statutory or scientific justifications. OT staff justified both the statutory and scientific need, as required by Federal regulations and the Policy Guide, for every OT in our sample.[15] Justifying the scientific and statutory need of the proposed OT ensures that NIH is awarding OTs according to its statutory authority and ensuring that the OT is supporting high-impact, cutting-edge research.

Justifications for some OTs were inconsistent with funding decisions

OT staff justified the use of several OTs because they needed or wanted to partner with non-traditional recipients. However, some of these OTs were subsequently awarded to recipients that had received millions of dollars in traditional funding from HHS in the 10 years prior to our review. This rendered the original justification for the OT no longer applicable. This indicates that NIH may be using OTs when a traditional funding mechanism could have been more appropriate. Exhibit 10 provides further details for two OTs that ultimately went to recipients with extensive HHS traditional funding histories, despite the justification outlining the need for non-traditional recipients.

Eighty-one percent (115) of OT recipients in our population, and 73 percent of OT recipients in our sample (12), received an HHS grant or contract in the 10 years prior to our review.

Exhibit 10:Example of an OT justification that was inconsistent with later funding decisions

Justification "The OT award instrument was chosen primarily due to the need to partner with ***commercial entities who are nontraditional recipients of NIH funding*** **and** who have 'near-to-ready' made platform technologies…" [emphasis added]

Funded Two OTs were funded using this justification. **Recipient A** had received more than $4 billion and **Recipient B** had received more than $1 billion in HHS (primarily NIH) traditional funding in the 10 years prior to our review period.

Source: OIG analysis of a sample of NIH OTs awarded in 2022-2023.

In one case, OT staff updated the justification after making a funding decision that was inconsistent with the justification. The OT initially had a justification about needing non-traditional partners. NIH then awarded the OT to a traditional recipient. This recipient had received more than $2 billion in HHS traditional funding in the 10 years prior to our review period. OT staff updated this justification after awarding the OT, and the new justification for this OT did not mention the need for a non-traditional recipient. Instead, it focused on the need for a high degree of collaboration and flexible funding. The updated justification did not address why a traditional funding mechanism would not meet the initiative's purpose, which is one of the required OT justifications. Updating the initial justification to fit the chosen, traditional recipient raises concerns about whether NIH's approval of the OT funding mechanism for this award is still warranted or whether a traditional, lower-risk award mechanism may have met the initiative's purpose.

ICOs did not effectively manage the unique risks for 12 of 15 OTs in our sample

NIH put Federal dollars at greater risk of fraud, waste, and abuse by not effectively managing risks. Effective risk management involves two integral components: thorough analysis to identify risks and tailored efforts to mitigate those risks.

Of the 15 OTs we reviewed, 12 fell short in one or both components of risk management, and 3 were stronger in both. See Exhibit 11 for a breakdown of the 15 OTs in our sample.

Exhibit 11: Seven OTs in our sample had minimal risk analysis and no risk mitigation

	Risk Analysis	Risk Mitigation
OT 1	Minimal	None
OT 2	Minimal	None
OT 3	Minimal	None
OT 4	Minimal	None
OT 5	Minimal	None
OT 6	Minimal	None
OT 7	Minimal	None
OT 8	Stronger	None
OT 9	Minimal	Minimal
OT 10	Stronger	Minimal
OT 11	Stronger	Minimal
OT 12	Stronger	Minimal
OT 13	Stronger	Stronger
OT 14	Stronger	Stronger
OT 15	Stronger	Stronger

Source: OIG analysis of a sample of 15 NIH OTs awarded in 2022-2023.

Risk Analysis. OT staff conducted some type of risk analysis for all 15 OTs in our sample. However, they conducted only minimal risk analysis for eight of the 15 OTs in our sample, representing $136 million of the total $237 million in new OT funding in our sample. For these eight OTs, OT staff included only one component from the list of possible, but not exhaustive, risk analysis components provided in the Policy Guide. For six of those OTs, OT staff checked only a combination of Federal databases.

A stronger risk analysis involved conducting two or more components of risk analysis listed in the Policy Guide. Although these risks analyses were stronger, they most often only included a check of Federal databases and one other component of risk analysis outlined in the Policy Guide, such as a review of financial information. That is, OT staff did not consider many of the components in the Policy Guide for each OT.

Risk Mitigation. ICOs can mitigate risks using a risk management plan or OT terms and conditions. Eight OTs in our sample had no risk mitigation, representing nearly $181 million of the $237 million in new OT funding in our sample.

Minimal risk mitigation included strategies that were vague and not specific to the risk analysis. Four OTs in our sample had minimal risk mitigation. In contrast, three OTs in our sample had stronger risk mitigation. Stronger risk mitigation had more specific strategies to mitigate risks identified in the risk analysis. Exhibit 12 shows examples of stronger risk analysis and risk mitigation.

Exhibit 12: Stronger risk analysis and risk mitigation examples from our sample

Risk Analysis	Risk Mitigation
OT staff completed a detailed table that identified the risk as low, medium, or high across 16 categories and checked Federal databases OT staff checked Federal databases and reviewed financial information and determined that the prospective recipient was financially stable and had sufficient resources to complete the research.	"The risks will be minimized through assessment of progress via regular weekly, bi-weekly, monthly and quarterly meetings and reports (ad hoc emails, teleconferences). The risks will also be managed in terms of funding the awards on a quarterly basis."

Source: OIG analysis of a sample of 15 NIH OTs awarded in 2022-2023.

Risk mitigation is linked to risk analysis, as mitigation should address the risks identified in the analysis. If OT staff do not conduct robust or effective risk analysis, they may not identify risks that need to be addressed. In fact, seven of the eight OTs with only a minimal risk analysis had no risk mitigation (see Exhibit 11). Minimal risk analyses most often included only checking Federal databases.

Finally, even if a risk analysis does not identify heightened risks for a specific OT award, no award is risk-free, and some level of risk mitigation may still be advisable. For example, OT staff for one OT in our sample determined the recipient to be low risk (after conducting a stronger risk analysis) but still developed a risk

mitigation plan. The plan involved regular progress assessments and only funding the recipient on a quarterly basis.

NIH has opportunities to improve its guidance on risk management for OTs in ways that relate to the shortcomings we identified

While the Policy Guide includes guidance on identifying, assessing, and mitigating risks, we identified opportunities to make the guidance more effective in supporting the execution of good risk management in areas where many OTs in our review fell short.

Unclear expectations for risk analysis. The Policy Guide includes a list of possible risk analysis components and describes steps that risk analysis may include. However, other than requiring that OT staff conduct one, there are no requirements or clear expectations for what a risk analysis must include. Setting expectations for how robust risk analyses should be, while maintaining some flexibility to tailor a risk analysis to a specific OT and recipient, could lead to more meaningful risk analyses that better protect Federal dollars. In our sample, most ICOs included very few risk analysis components.

Additionally, the Policy Guide does not clearly direct OT staff to check the System for Award Management, despite Federal regulation requiring it, and OT staff for two OTs in our sample did not document checking the System for Award Management, totaling more than $19 million in funding in our review period.[16] This system indicates whether potential recipients are excluded from receiving Federal funding; not checking the system could result in NIH doing business with ineligible recipients.

Little and confusing guidance on risk mitigation. The Policy Guide offers less guidance on risk mitigation than it does on risk analysis. It states that that "any risks identified must be addressed prior to issuing an award," but also states that a risk management plan is only recommended, not required. NIH reported that ICOs can additionally use the terms and conditions of the OT award to mitigate risks, but this approach is not explicitly stated in the Policy Guide. As noted above, eight of 15 OTs did not have any risk mitigation, and seven of these OTs also had minimal risk analysis, most of which was simply checking Federal databases.

Dispersed and not readily identifiable guidance. In our review of the Policy Guide, we found that information and guidance on risk analysis and risk mitigation were located in multiple places within the guide that were not always cross-referenced well or readily identifiable. In addition to one paragraph in the main text, the Policy Guide contains two appendices with more information on risk analysis and risk mitigation. One appendix contains many considerations for risk analysis but does not specify how the considerations inform a recipient's risk level. The other appendix contains some information about risk analysis and risk mitigation that is not readily identified in the context of the whole appendix, which contained frequently asked

questions about OT agreements. Consolidating, linking, or cross-referencing the existing information could be useful for OT staff.

Three of seven ICOs in our sample had no internal controls to protect OTs from mismanagement and fraud

Internal controls are intended to prevent mismanagement and fraud by both NIH and recipients. Three of seven ICOs in our sample had no internal controls in their SOPs, despite their being required by the Policy Guide.[17] This means that all OTs funded by these ICOs, including those not in our sample, had no internal control policies documented to prevent mismanagement and fraud of Federal dollars. Further, two of these three ICOs administer and oversee other ICOs' OTs that do not have the capacity or resources to manage them. According to NIH, a few ICOs oversee their own OTs, but most do not have the capacity to administer their own OTs. In those cases, an ICO with the capacity and resources administers OTs for those ICOs. As such, these ICOs were responsible for overseeing OTs awarded by other ICOs, further exacerbating the potential negative effects of any mismanagement or fraud due to lack of internal controls.

Four ICOs had internal controls for either OT staff or OT recipients, but not both.

Of the remaining four ICOs in our sample, two established internal controls for only OT staff, and two established internal controls for only their OT recipients. The Policy Guide does not clarify whether NIH's OT internal controls are intended for OT staff, recipients, or both. See Exhibit 13 for examples. None of these four ICOs had guidance on establishing periodic reviews of their internal controls, as required by the Policy Guide.

Exhibit 13: Examples of internal controls established by ICOs in our sample

For OT Staff Only

- Separated duties to prevent real or perceived conflicts of interest.

For Recipients Only

- Required supporting documentation for accounting and separation of responsibility.
- Delineated roles and responsibilities; required written procedures; training; and performance assessments.

Source: OIG analysis of sampled ICO SOPs.

Few ICOs in our sample reported measuring the benefit of OTs, as encouraged, and NIH has not centrally tracked these metrics

The Policy Guide encourages, but does not require, OT staff to track metrics that measure the benefit of OTs. Measuring the benefits of OTs could give NIH insights in weighing the risks of OTs against the expected benefits when setting OT policy and deciding whether and when to use OTs versus other funding mechanisms. However, only three ICOs in our sample reported that they track or have tracked metrics that measure the benefit of OTs.[18] See Exhibit 14 for a description of the metrics ICOs reported using. Some ICOs noted that it was difficult to establish a standard set of comparable metrics that measure the value of each unique OT initiative.[19]

Despite the existence of some ICO-level metrics, OPERA has not centrally tracked metrics that measure the benefits of OT authority. OPERA's annual report to the Office of the Director, which details the use of OT authority across NIH each fiscal year, did not contain any metrics from ICOs that measured the benefit of OTs. It did include money spent on OTs. Without the aggregate collection of these metrics, NIH may not be able to make informed decisions about future OT use and policy.

Exhibit 14: ICO metrics for measuring the benefit of OTs

- One ICO reported tracking paradigm-shifting advances and discoveries; research tools and community resources; and translational outcomes generated by its OTs. Recipients reported these metrics to the ICO in annual reports.
- Another ICO referenced a 2020 evaluation that noted several recipients received NIH funding for the first time through its OTs, and that these recipients were critical to the success of the program.
- A third ICO reported a variety of metrics that were unique to its OT initiatives. These metrics included data stored in the cloud; computational analysis hours in the cloud; programs onboarded; cost avoidance and government savings; number of authorized user data requests; completeness of metadata; number of new researchers supported in relevant fields; publications; and presentations.

Source: OIG analysis of ICO written responses to OIG questions on metrics.

CONCLUSION AND RECOMMENDATIONS

In 2024, NIH awarded over $1.9 billion through its OT authority. This amount represents an increase from just under $900 million in 2020. Although OTs fund high-impact, cutting-edge research, it is essential that NIH oversee OTs and ensure that ICOs are meeting the requirements to protect Federal funding and accomplishing these intended research goals.

Our review raises concerns about NIH's ability to oversee OTs and mitigate the inherent and unique risks of these awards. Given that every OT in our sample had issues in at least one area of our review, representing $237 million in new OTs during a 2-year period, it is essential that NIH improve its oversight of this important yet high-risk funding mechanism.

Further, at the time of our review, NIH had not centrally tracked or reported metrics to measure the benefits of OTs despite its increased use of them in recent years. Without such metrics, NIH cannot measure the extent to which this high-risk funding mechanism is advancing science and health to help inform its decisions about OT policy and future use.

We recommend that NIH:

Assess the benefits of OTs to inform future OT policies and use

Given the magnitude of its financial and programmatic investment in OTs annually, NIH should evaluate the outcomes and lessons learned from using OTs to inform future use. This would enable NIH to make data-driven decisions to maximize the benefits of OTs relative to their risks. NIH leadership could use the metrics ICOs are already capturing on the benefits of OTs to inform future policies and decisions about OT use. Doing so would help ensure that NIH is only using OTs when the benefits outweigh the risks.

As a part of this, OPERA should centrally collect metrics from ICOs that already have them. OPERA could include these metrics in its annual report to the Office of the Director, as that report already includes general descriptions and the costs of ICOs' OTs.

Additionally, OPERA should further aid ICOs in measuring the benefits of OTs, by leveraging the experience of ICOs that are already tracking metrics, as well as other Federal research metric initiatives, such as STAR METRICS, to develop and disseminate possible metrics. OPERA's list could include metrics such as the number of publications; presentations; citations; patents; cost avoidance and government savings; commercialization; job creation associated with an OT; and the number of non-traditional recipients. Each ICO could then use this list to determine which metrics best measure the impact of its unique OT initiatives and propose new metrics

as needed. OT staff could collect data to measure some of these metrics from NIH RePORTER and use recipient reports to gather data on others.

Over time, NIH could assess the benefits of using OTs relative to more traditional funding mechanisms when justifying and approving the use of OTs.

Strengthen justifications for using OTs

OPERA should better ensure that all ICOs clearly justify their use of OTs and that those justifications are applicable to the OTs awarded under them. These justifications should include all parts required by statute, regulation, and/or NIH policy, such as bona fide need; why a traditional funding mechanism cannot meet the initiative's purpose; and statutory and scientific justifications. Additionally, OT staff should ensure that funding decisions are consistent with these justifications.

More effectively manage the unique risks of all OTs

Effective risk management is essential to reduce the unique risks each OT poses to Federal funding. Risk management must be two-fold: risk analysis and mitigation. Thorough risk analysis ensures that NIH has identified the unique risks associated with each OT. To better ensure that OT staff are effectively conducting risk analysis, OPERA should update its guidance for risk analysis to set clearer expectations for how thorough a risk analysis should be. To preserve flexibility and meet the unique needs of each OT, OPERA could retain deference to the ICOs on which risk analysis components to conduct. For example, OPERA could provide a risk matrix for ICOs to use that evaluates the level of risk for the nature of the program or project; the type of entity; the past performance of or experience with the recipient; and other factors. NIH should also update its Policy Guide to clearly state that ICOs must check the System for Award Management prior to awarding an OT, as required by Federal regulation.

To further protect Federal funds, OPERA should provide more guidance for risk mitigation in the Policy Guide to help ICOs develop strong risk mitigation strategies specific to the risks identified in the risk analysis. As a part of this, ICOs should be required to either develop a risk management plan or clearly mitigate specific risks in the terms and conditions of the OT agreement. Risk analysis alone does not protect Federal dollars once an ICO awards an OT; it can only help inform the awarding ICO as to what the risks may be. Risk mitigation is a crucial tool for OT staff to further protect Federal dollars from the unique risks posed by the OTs. OPERA may consider providing examples of risk management plans and terms and conditions for different risk levels and types of risks in the Policy Guide.

Further, because no OT is risk-free, the Policy Guide should include best practices for mitigating risks throughout the life of the OT, particularly when OT staff do not identify any unique risks during the risk analysis.

Establish internal controls to protect OTs from mismanagement and fraud by both OT staff and recipients

Internal controls help protect against fraud, waste, and abuse given the inherent risk of the OT award mechanism. OPERA should clearly state that ICOs must establish OT internal controls for OT staff and recipients. Additionally, OPERA should set expectations for what internal controls should include. For example, OPERA could provide examples in the Policy Guide to illustrate acceptable internal controls. Additionally, OPERA should take steps to ensure that ICOs are establishing internal controls and using and conducting periodic reviews of them. OPERA may consider prioritizing its focus on ICOs that administer OTs for other ICOs in addition to their own.

AGENCY COMMENTS AND OIG RESPONSE

NIH concurred with all four of our recommendations and described the actions it plans to take to implement them. OIG supports NIH's planned actions and believes these efforts will address the gaps identified in this report. Below is a summary of NIH's response to each recommendation.

NIH concurred with our recommendation to assess the benefits of OTs to inform future OT policies and use. NIH stated that it will require all ICOs to conduct an annual evaluation to measure the benefits observed or obtained from using an OT over a traditional award mechanism. Additionally, OPERA will update the Policy Guide to include metrics that ICOs can use. OPERA will also work to identify resources to develop an OT Dashboard on NIH RePORTER to populate the metrics from the annual reports and make them publicly available.

NIH concurred with our recommendation to strengthen justifications for using OTs. NIH noted that it has policies and an approval process that require ICOs to justify their use of OTs consistent with NIH's OT authority. To further strengthen this process, OPERA will implement a compliance review to verify that the OT is administered according to the approved justification and there is still a need to use an OT. OPERA will ensure that its internal SOPs are updated to implement these compliance reviews across OT programs and incorporate these updates into its existing staff trainings.

NIH concurred with our recommendation to more effectively manage the unique risks of all OTs. NIH stated that it will (1) consider ways to expand the existing risk checklist; (2) update the OT Policy Guide to further clarify and reinforce the mandatory use of the System for Extramural Award Risks module and appropriate risk mitigation procedures; and (3) enhance its training plan to highlight resources available to ICO staff to ensure consistent implementation of risk management practices across all OTs.

NIH concurred with our recommendation to establish internal controls to protect OTs from mismanagement and fraud by both OT staff and recipients. NIH noted that OPERA oversees the Management Controls and Compliance Model (MCCM) to assess and monitor internal compliance for NIH grants and cooperative agreements and it plans to extend these internal controls to OTs.

For the full text of NIH's comments, see Appendix D.

DETAILED METHODOLOGY

Population Analysis

We reviewed data for NIH OTs awarded in FY 2022 and 2023. We pulled data from NIH's eRA (Electronic Records Administration) databases on April 23, 2024, to get entire population of NIH OTs (403 awards, 206 OTs) awarded during this period and used this data to conduct the descriptive analysis. We determined the types of recipients NIH funded (e.g., for-profit, domestic, international), the amounts funded via OTs, and the types of projects for which NIH used OTs.

Sample Selection

We selected a purposive sample of 15 OTs from OTs newly awarded in FY 2022-2023. We selected our sample from OTs that NIH first funded after it updated its OT Policy Guide in 2021, as the changes were substantial, and we needed to review OTs that NIH held to the new requirements in the Policy Guide. There were no new OTs awarded between the start of our review period (October 2021) and the final version of NIH's OT Policy in November 2021.

We considered the following factors in selecting our sample:

Funding amount. We categorized funding as high (greater than $5 million), medium ($1-5 million), and low (less than $1 million). We prioritized selecting OTs in the higher funding category as they represented a higher risk to NIH funding, but we still selected awards from each of the three funding categories. Our sample of 15 OTs represented 14 percent of the population of newly awarded OTs in FY 2022-2023 and 54 percent of the total new award dollars during our review period.

Awarding Institute and Center (IC). There were six ICs that funded new awards in 2022-2023. We selected OTs from five of the six ICs. We did not end up selecting the one OT awarded by the sixth IC in our population in order to maintain as much variability as possible across the other categories for which we sampled. Additionally, NIH RePORTER reports awarding IC and not ICO. Therefore, while we sampled five of the six ICs in our sample, we did not have the population level data for how many offices funded OTs in our sample. Upon receiving the OT files for our sample, we learned we had seven ICOs in our sample.

Type of project. We used the NIH-assigned Catalog of Federal Domestic Assistance (CFDA) codes to identify the type of research (e.g., cancer, cardiovascular) for each OT. We included as many CFDA codes as possible in our sample (5 of 7) while also weighing their prevalence in the population, funding amounts, and variety among the other sample selection factors.

Type of recipient. We sampled OTs from every organization type in our sample (e.g., institution of higher education, research organization, for-profit).

Recipient location *(i.e., domestic, international)***.** We used the recipient country to determine which recipients were domestic and which were international. We included two international recipients, which matched the prevalence of international recipients in our subpopulation overall.

History of traditional funding. We also determined which recipients were traditional versus non-traditional (i.e., those that had received HHS funding in the in the form of a grant, contract, or cooperative agreement in the 10 years prior to our review period versus those that had not). We selected OTs for our sample to have a similar prevalence to the population overall (11:4 traditional to non-traditional) while maintaining diversity across other selection factors.

File Review

NIH maintains all records related to OTs within its Electronic Records Administration data system. For the 15 OTs in our sample, we requested all documentation associated with each OT. We analyzed the OT files by evaluating the extent to which and how OT staff documented the required justifications, risk management (which includes both risk analysis and risk mitigation), and internal controls. We conducted most of our file review at the OT level (15 OTs). However, for the bona fide need justification, we conducted our review at the award level (30 OT awards). We used this approach because the Policy Guide requires bona fide justification for the initial award and for every modification that adds money to an existing OT (additional awards).

To evaluate these OT files, we created and used the rubric below to categorize the NIH-required areas of our review into three categories (i.e., none, minimal, stronger).

We reviewed the documents associated with each OT to identify the required justifications and risk management (risk analysis and risk mitigation). After we identified all the elements in our review, we coded them according to the following definitions:

Categorical rating definitions for required OT documentation.

Rating	Statutory and Scientific Justification	Bona Fide Need Justification	Justification for Why Not Traditional Funding Mechanism	Risk Analysis	Risk Mitigation
No…	No documentation	No documentation	No documentation	No documentation	No documentation
Minimal…	Missing a justification (either statutory or scientific) or vague templated language that is not specific to the award	Just contained a check or statement that bona fide need was met without an explanation of how or supporting evidence	Explained why an OT is needed, but did not explicitly state why a traditional funding mechanism does not meet the initiative's purpose, or vague templated language that is not specific to the award	Checked only one component of risk analysis from the Policy Guide (e.g., checked Federal databases)	Vague, non-specific risk mitigation
Stronger* …	Complete with a detailed, specific, and relevant justification for both statutory and scientific justification	Statement or check that bona fide need had been met with supporting evidence	Complete with a detailed, specific, and explicit justification of why a traditional funding mechanism does not meet the initiative's purpose	Checked at least two components of risk analysis from the Policy Guide	Detailed risk mitigation specific to the OT and the risks identified in the risk analysis

Source: OIG analysis rubric. Note: * We labeled this category as "stronger" rather than "strong" because we often lacked criteria to determine if the documentation was sufficient to meet policy requirements or recommendations. We also often found limitations in even the most exhaustive documentation; thus, we were reluctant to label it as strong.

We performed additional qualitative analysis on select justifications that stated the need to work with non-traditional partners. For these justifications, we then checked to see whether the recipients had received traditional HHS funding in the 10 years prior to our review. Due to the burdensome nature of this analysis, we identified illustrative examples rather than quantifying the prevalence of this issue.

We requested policy documents and OT reports from NIH, including SOPs for each ICO represented in our sample, OPERA annual reports to the NIH Director, and the NIH OT Policy Guide. We also reviewed ICO SOPs for their internal controls; we used qualitative analysis to categorize the types of internal control approaches used and described those in the findings with examples. We counted only internal controls that the SOP explicitly identified as an internal control.

Additionally, we used the document reviews and interviews to determine the extent to which NIH and its ICOs established and tracked any metrics that measure the benefit of OTs. We interviewed NIH on various pieces of our analysis and followed up with written questions and additional document requests on multiple occasions.

APPENDICES

Appendix A: Detailed NIH OT Funding from 2022-2023

Exhibit A-1: NIH funded more OTs and spent more money on OTs in 2023 than 2022

	2022	2023	2022-2023
Funding Totals	$927,493,451	$1,453,507,495	$2,381,000,946
# OT Awards	195	208	403

Source: OIG analysis of 206 NIH OTs awarded in 2022-2023.

Exhibit A-2: The mean funding per award/OT was much higher than the median

	Award	OT
Funding Range	$500-$417,201,451	$94,138- $613,918,436
Mean Funding	$5,908,191	$11,558,257
Median Funding	$1,124,989	$1,495,763

Source: OIG analysis of 206 NIH OTs awarded in 2022-2023.

Exhibit A-3: Traditional recipients received the most OT funding and awards

	Traditional Recipients	Non-Traditional Recipients	All Recipients
Funding	$2,229,797,785	$151,203,161	$2,381,000,946
Mean Funding per OT	$12,526,954	$5,400,113	$11,558,257
Number of Recipients	115	27	142
OT Max to a Single Recipient	6	2	6

Source: OIG analysis of 206 NIH OTs awarded in 2022-2023.

Exhibit A-4: Most OT awards and funding were for Trans-NIH Research Support, which funds projects in biomedical research that a single ICO cannot address

Award CFDA Description	Funding	Awards
Trans-NIH Research Support	$769,700,932	322
Cancer Cause and Prevention Research	$27,660,585	69
Cardiovascular Diseases Research	$308,603,563	56
21st Century Cures Act-Precision Medicine Initiative	$440,519,752	41
National Center for Advancing Translational Sciences	$22,235,610	30
Child Health and Human Development Extramural Research	$2,294,528	9
Lung Diseases Research	$343,742,090	8
Cancer Biology Research	$1,505,379	7
Extramural Research Programs in the Neurosciences and Neurological Disorders	$45,110,686	6
Drug Abuse and Addiction Research Programs	$2,426,370	2
Cancer Research Manpower	$417,201,451	2

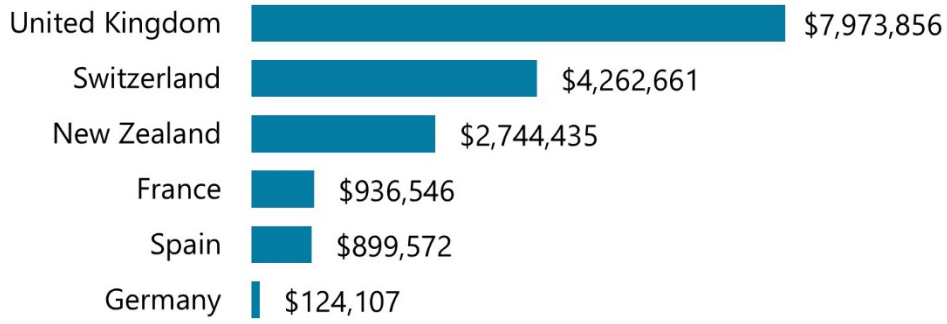
Source: OIG analysis of 206 NIH OTs awarded in 2022-2023.

Appendix B: Foreign Other Transactions

Exhibit B-1: NIH awarded OTs to foreign institutions in 2022-2023 totaling…

Source: OIG analysis of 19 NIH OTs awarded to foreign recipients in 2022-2023.

Exhibit B-2: The United Kingdom received 47% of the total foreign OT funding



Source: OIG analysis of 19 NIH OTs awarded to foreign recipients in 2022-2023.

Exhibit B-3: The United Kingdom received the most OTs and overall funding, but Switzerland and New Zealand received much more funding per OT

Country	OTs	Awards	Funding Amount	Mean Funding per OT
United Kingdom	13	24	$7,973,856	$613,373.54
Switzerland	1	2	$4,262,661	$4,262,661.00
New Zealand	1	3	$2,744,435	$2,744,435.00
France	2	4	$936,546	$468,273.00
Spain	1	2	$899,572	$899,572.00
Germany	1	2	$124,107	$124,107.00
All foreign OTs	19	37	$16,941,177	$891,640.89

Source: OIG analysis of 19 NIH OTs awarded to foreign recipients in 2022-2023.

Appendix C: ICO Breakouts

Exhibit C-1: ICO acronym key and number of awards by each ICO

ICO Acronym	ICO	Number of Awards
OD	Office of the Director	256
NCI	National Cancer Institute	88
NCATS	National Center for Advancing Translational Sciences	37
NHLBI	National Heart, Lung, and Blood Institute	36
NINDS	National Institute of Neurological Disorders and Stroke	19
NLM	National Library of Medicine	14
NIAID	National Institute of Allergy and Infectious Diseases	11
NHGRI	National Human Genome Research Institute	11
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases	9
NIDA	National Institute on Drug Abuse	9
NIEHS	National Institute of Environmental Health Sciences	8
NICHD	National Institute of Child Health and Human Development	7
NIMH	National Institute of Mental Health	7
NIA	National Institute on Aging	7
NEI	National Eye Institute	6
NIMHD	National Institute on Minority Health and Health Disparities	5
NIGMS	National Institute of General Medical Sciences	5
NIBIB	National Institute of Biomedical Imaging and Bioengineering	4
ARPA-H*	Advanced Research Projects Agency for Health	4
NIDCR	National Institute of Dental and Craniofacial Research	3
NINR	National Institute of Nursing Research	2
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases	2
NIDCD	National Institute on Deafness and Other Communication Disorders	1

Source: https://www.nih.gov/institutes-nih/list-institutes-centers and OIG analysis of NIH OTs awarded in 2022-2023.

*During our review period, the HHS Secretary established ARPA-H as an independent agency within NIH. In our population, we did not include OTs funded solely by ARPA-H. However, ARPA-H contributed funding to four OTs in our population. We included these OTs in our review as NIH ICOs also contributed funding to these OTs, and NIH ICOs administered them. See Exhibit 6 for more information on multiple ICOs contributing funding to a single OT.

Exhibit C-2: While 23 ICOs awarded OTs in 2022-2023, only seven administered those OTs; The Office of the Director administered 59% of OTs

ICO Abbreviation	ICO	Number of OT Awards Administered
OD	Office of the Director	328
NCI	National Cancer Institute	76
NHLBI	National Heart, Lung, and Blood Institute	66
NCATS	National Center for Advancing Translational Sciences	30
ODSS	Office of Data Science Strategy	25
NICHD	National Institute of Child Health and Human Development	22
NINDS	National Institute of Neurological Disorders and Stroke	5

Source: OIG analysis of NIH OTs awarded in 2022-2023. Note: NIH stated that some ICOs administer the OT awards for small ICOs without the capacity or resources to administer their own.

Appendix D: Agency Comments

Following this page are the official comments from NIH.

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

DATE: September 8, 2025

TO: Ann Maxwell
Deputy Inspector General for Evaluations and Inspections, HHS

FROM: Principal Deputy Director, National Institutes of Health

SUBJECT: NIH Comments on Draft Report: "*Gaps in NIH's Oversight Put Millions in Funding for Other Transactions at Greater Risk of Fraud, Waste, or Abuse"* (OEI-04-24-00140)

Attached are the National Institutes of Health's (NIH) comments on the Office of Inspector General's (OIG) draft report, "*Gaps in NIH's Oversight Put Millions in Funding for Other Transactions at Greater Risk of Fraud, Waste, or Abuse"* (OEI-04-24-00140).

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

Matthew J. Memoli, M.D., M.S.

Attachments

GENERAL COMMENTS FROM THE NATIONAL INSTITUTES OF HEALTH ON THE OFFICE OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL DRAFT REPORT ENTITLED – "GAPS IN NIH'S OVERSIGHT PUT MLLIONS IN FUNDING FOR OTHER TRANSACTIONS AT GREATER RISK OF FRAUD, WASTE, OR ABUSE" (OEI-04-24-00140)

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

NIH notes that although the OIG report title references fraud, waste, or abuse (FWA), the audit did not identify any instances of FWA related to funding of NIH's Other Transactions. This distinction is important to accurately reflect the scope and outcome of the audit.

OIG Recommendation 1:
We recommend that NIH assess the benefits of OTs to inform future OT policies and use.

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

NIH will require all Institutes, Centers, and OD Offices (ICOs) to conduct an annual evaluation that will measure the benefits that were observed/obtained from using an OT award instead of a grant, cooperative agreement, or contract. Annually, each December, the ICOs will submit the evaluation results to the Office of Extramural Research (OER)/ Office of Policy for Extramural Research Administration (OPERA).

OPERA will publish metrics in the Policy Guide to assist ICOs with providing detailed information, such as, but not limited to and depending upon the unique features of the OT, the following:

- number of citations,
- publications,
- job creations,
- number of non-traditional partnerships developed,
- number of times the program had to pivot in order to accelerate outcomes, and
- number of creative outcomes in the areas of prevention, diagnosis, and/or unique treatments.

OPERA will work to identify resources to develop an OT Dashboard to populate the metrics from the annual report and make them available in the publicly available system, RePORTER.

NIH will provide an update on our timeline for implementation in our Management Decision within 180 days following the issuance of the OIG's final report.

GENERAL COMMENTS FROM THE NATIONAL INSTITUTES OF HEALTH ON THE OFFICE OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL DRAFT REPORT ENTITLED – "GAPS IN NIH'S OVERSIGHT PUT MLLIONS IN FUNDING FOR OTHER TRANSACTIONS AT GREATER RISK OF FRAUD, WASTE, OR ABUSE" (OEI-04-24-00140)

OIG Recommendation 2:
We recommend that NIH strengthen justifications for using OTs.

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

NIH does have policies, along with an approval process, that requires the ICO to justify their use of an OT consistent with NIH's OT authority. OPERA reviews and requires revisions to these justifications to ensure they clearly demonstrate why traditional funding instruments, i.e., grants/cooperative agreements/contracts are inappropriate. OPERA will begin to implement a compliance review process that ensures the ICOs honored the justification provided to and approved by the NIH Director or delegee.

To further strengthen this process, NIH will begin to implement compliance reviews to verify that the ICO administered the OT in line with the approved justifications and to confirm that there is still a need to use OT as the award mechanism. Any deviations from the approved justification—such as the transition to traditional partners—will require additional review and approval to ensure consistency with NIH OT authority and policy, and OIG recommendations. OPERA will ensure that its internal Standard Operating Procedures are updated to implement compliance reviews across all OT programs, to ensure existing policy requirements are met. OPERA will incorporate these updates into its existing staff trainings.

NIH will provide an update on our timeline for implementation in our Management Decision within 180 days following the issuance of the OIG's final report.

OIG Recommendation 3:
We recommend that NIH more effectively manage the unique risks of all OTs.

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

NIH will continue to review its risk management practices and consider ways to expand our existing pre-award risk management tool (checklist). This risk assessment tool is designed to support all OTs and provides an area where ICOs can include additional OT project-specific questions that address unique risks for each OT.

NIH also requires ICOs to utilize the System for Extramural Award Risks (SEAR) module within eRA, which automatically checks for risks such as Sam.gov (suspension/debarment), the National External Audit Review (NEAR) list (Single Audit), and delinquent federal debts. When the SEAR module identifies potential concerns, OT staff are required to review and resolve these red flags prior to proceeding with the award. These requirements are outlined in the OPERA OT

Compliance Guidance. NIH will update the OT Policy Guide to further clarify and reinforce the mandatory use of the SEAR module and appropriate risk mitigation procedures.

Additionally, OPERA will enhance its training plan to highlight resources available to ICO staff to ensure consistent implementation of these risk management practices across all OTs.

NIH will provide an update on our timeline for implementation in our Management Decision within 180 days following the issuance of the OIG's final report.

OIG Recommendation 4:

We recommend that NIH establish internal controls to protect OTs from mismanagement and fraud by both OT staff and recipients.

NIH Response:

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

OPERA oversees the Management Controls and Compliance Model (MCCM), which is used to assess and monitor internal compliance for NIH grants and cooperative agreements.

NIH recognizes the importance of extending these internal controls to OT awards. OPERA has initiated efforts to adapt and apply the MCCM framework to OTs, including the development of tailored risk assessment, monitoring, and oversight procedures specific to the unique characteristics of OTs. Although implementation was delayed due to resource constraints, NIH is committed to resuming and prioritizing this effort.

As part of this initiative, NIH will:

- Finalize and implement OT-specific internal control procedures, including regular monitoring and audits of OT activities;
- Provide training to OT staff and recipients on fraud prevention and detection;
- Establish clear reporting mechanisms for suspected mismanagement or fraud;
- Periodically review and update internal controls to address emerging risks.

NIH will provide an update on our timeline for implementation in our Management Decision within 180 days following the issuance of the OIG's final report.

ABOUT THE OFFICE OF INSPECTOR GENERAL

Office of Inspector General
https://oig.hhs.gov

The mission of the Office of Inspector General (OIG) is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of the people they serve. Established by Public Law No. 95-452, as amended, OIG carries out its mission through audits, investigations, and evaluations conducted by the following operating components:

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The Office of Evaluation and Inspections. OEI's national evaluations provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. To promote impact, OEI reports also provide practical recommendations for improving program operations.

The Office of Investigations. OI's criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs and operations often lead to criminal convictions, administrative sanctions, and civil monetary penalties. OI's nationwide network of investigators collaborates with the Department of Justice and other Federal, State, and local law enforcement authorities. OI works with public health entities to minimize adverse patient impacts following enforcement operations. OI also provides security and protection for the Secretary and other senior HHS officials.

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ENDNOTES

[1] NIH, Other Transactions, October 1, 2024. Accessed at https://grants.nih.gov/funding/other-transactions.htm on June 6, 2025.

[2] The Public Health Service Act sec. 402(n), 42 U.S.C. sec. 282(n).

[3] NIH, eRA Other Transactions, July 21, 2022. Accessed at https://www.era.nih.gov/about-era/more-than-just-grants/other-transactions, on October 19, 2023.

[4] HHS is one of few Federal agencies with OT authority. Within HHS, only NIH; the Biomedical Advanced Research and Development Authority within the Administration for Strategic Preparedness and Response (ASPR); the Centers for Disease Control and Prevention; and the Advanced Research Projects Agency for Health (ARPA-H) are allowed to fund OTs. The FY 2026 President's Budget reflects the planned reorganization of ASPR and ARPA-H into the newly formed Assistant Secretary for a Healthy Future. Accessed at https://www.hhs.gov/sites/default/files/fy-2026-budget-in-brief.pdf on September 24, 2025. When referring to ASPR and ARPA-H's organization and authority, we are referring to them prior to this reorganization.

[5] The Office of the Director has OT authority according to Public Health Service Act sec. 402(n), 42 U.S.C. sec. 282(n). The National Heart, Lung, and Blood Institute has OT Authority according to the Public Health Service Act sec. 421(b)(3), 42 U.S.C. sec. 285b–3(b)(3). The National Center for Advancing Translational Sciences has OT authority specifically for the Cures Acceleration Flexible Research Awards according to Public Health Service Act sec. 480(e)(3)(C), 42 U.S.C. sec. 287a(e)(3)(C).

[6] The Public Health Service Act sec. 402(n), 42 U.S.C. sec. 282(n).

[7] The Precision Medicine Initiative is intended to be an innovative approach to medical treatments that takes into account individual differences in people's genes, environments, and lifestyles. Accessed at https://obamawhitehouse.archives.gov/node/333101 on June 11, 2025. The All of Us Research Program is the cohort program for the 21st Century Cures Act-Precision Medicine Initiative.

[8] "The NIH Common Fund is a funding entity within the NIH that supports bold scientific programs that catalyze discovery across all biomedical and behavioral research. These programs create a space where investigators and multiple NIH Institutes, Centers, and Offices collaborate on innovative research expected to address high priority challenges for the NIH as a whole and make a broader impact in the scientific community." Accessed at https://commonfund.nih.gov/about on June 11, 2025.

[9] There is a fourth justification required in the Policy Guide that was outside the scope of our review. The Policy Guide requires ICOs to justify the continued use of the OT agreement over the course of the life of the award dependent on any major pivots or considerations after the initial awarded period of performance. Given our 2-year review period of newly awarded OTs, the initial period of review had not been completed for our OTs and thus we did not include this criterion in this evaluation.

[10] The Bona Fide Need Rule states that "[t]he 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." 31 U.S.C. sec. 1502.

[11] Public Health Service Act sec. 402(n), 42 U.S.C. sec. 282(n).

[12] The National Science Foundation and the White House Office of Science and Technology Policy co-led this initiative with NIH. Accessed at STAR METRICS: New Way to Measure the Impact of Federally Funded Research | National Institutes of Health (NIH) on December 13, 2024. The NIH page is no longer available and can be accessed at an archived site. Accessed at https://web.archive.org/web/20250221181442/https:/www.nih.gov/news-events/news-releases/star-metrics-new-way-measure-impact-federally-funded-research on July 7, 2025.

[13] NIH RePORTER is an electronic tool that allows users to search a repository of NIH-funded research projects. Accessed at https://report.nih.gov/faqs on May 15, 2025.

[14] The Federal Assistance Listing Number (formerly the Catalog of Federal Domestic Assistance (CFDA) Number) is a five-digit number assigned to all Federal awards that indicates the awarding agency and the Federal program that is funding the award. We used the CFDA Number to determine the types of research that NIH funded through OTs at the population level of our analysis. UCSF Controller's Office, Understanding the Assistance Listing Number. Accessed at https://controller.ucsf.edu/news/202108/contracts-grants-accounting/understanding-assistance-listing-number on February 20, 2025.

[15] While bona fide need justifications are also statutorily required, NIH uses the term "statutory justification" to ensure that OTs are for high-impact cutting-edge research according to the Public Health Service Act sec. 402(n), 42 U.S.C. sec. 282(n).

[16] 45 CFR 75.205 requires Federal agencies to check the System for Award Management prior to making an award.

[17] One of the three ICOs' SOP referenced the requirements from the Policy Guide but did not establish any of its own internal controls.

[18] Of the seven ICOs in our sample, only five responded to our question about metrics.

[19] Three ICOs stated this, two did not report tracking metrics, and the remaining ICO had unique metrics for each of its OT programs.

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