

Department of Health and Human Services
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September 2026 | OAS-25-04-137

NIH Awarded Other Transaction Agreements for the Autism Data Science Initiative in Accordance With Federal Requirements

REPORT HIGHLIGHTS



September 2026 | OAS-25-04-137

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Why OIG Did This Audit

- [NIH](#) launched the Autism Data Science Initiative (ADSI) to explore contributors to the causes and rising prevalence of autism.
- The agency awarded \$51 million through 13 other transaction (OT) agreements to fund the initiative. Because OTs are subject to fewer requirements than contracts, grants, or cooperative agreements, they inherently carry greater risk.
- This audit examined whether NIH awarded ADSI OT agreements in accordance with Federal requirements, including internal policies and procedures.

What OIG Found

NIH followed applicable Federal requirements when awarding ADSI OT agreements. Specifically:

- NIH reviewed 248 applications for ADSI awards and used subject-matter experts and an executive committee to prioritize and select a balanced portfolio of high-quality proposals across four priority areas: (1) prevalence, (2) etiology and causation, (3) clinical treatments and services, and (4) replication and validation.
- NIH negotiated budgets, personnel, indirect cost rates, and special award terms with each awardee.

What OIG Recommends

This report does not contain recommendations.

TABLE OF CONTENTS

INTRODUCTION	1
Why We Did This Audit	1
Objective	1
Background	1
National Institutes of Health	1
Autism Data Science Initiative	2
How We Conducted This Audit	2
RESULTS OF AUDIT	2
NIH Awarded Other Transaction Agreements in Accordance With Federal Requirements	3
Application Review and Selection	3
Finalization of Other Transaction Agreements	4
CONCLUSION	4
APPENDICES	
A: Audit Scope and Methodology	6
B: Related Office of Inspector General Reports	7

INTRODUCTION

WHY WE DID THIS AUDIT

In 2025, the National Institutes of Health (NIH) launched the Autism Data Science Initiative (ADSI) to use large-scale data resources to explore contributors to the causes and rising prevalence of autism spectrum disorder (autism). In fiscal year 2025, NIH awarded 13 other transaction (OT) agreements totaling approximately \$51 million to support the initiative. NIH uses OT agreements to provide considerable flexibility in meeting government objectives. However, because OT agreements are subject to fewer requirements than contracts, grants, or cooperative agreements, they inherently carry greater risk.¹ Prior Office of Inspector General (OIG) reports identified risks associated with NIH's use of OT award authority.² The short application timeframe for ADSI funding, combined with the generally higher-risk nature of OT agreements, increased the potential risk to the integrity of NIH's award process for this initiative.

OBJECTIVE

Our objective was to determine whether NIH awarded ADSI OT agreements in accordance with applicable Federal requirements.

BACKGROUND

National Institutes of Health

NIH is the largest public funder of biomedical research in the world and invests in medical research seeking to enhance life and reduce illness and disability. NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

¹ NIH's OT authority is governed by 42 USC § 282(n). NIH is one of four components within the Department of Health and Human Services with the authority to fund programs through OTs, which generally are not subject to the Uniform Guidance for grants or the Federal Acquisition Regulation for contracts.

² See Appendix B for related OIG reports.

Autism Data Science Initiative

The goals of the ADSI are to identify new contributors and to characterize the collective contributions of numerous factors to the causation of autism and their potential role in increasing the prevalence of autism. The ADSI also seeks to identify how existing treatments/interventions are used and better understand their outcomes to inform the design of future clinical studies. It also supports independent research teams in replicating analyses funded through the initiative. Beginning in September 2025, NIH awarded 13 OT agreements totaling approximately \$51 million to support the ADSI. Award recipients received up to \$5 million per 24- to 36-month project period.³

ADSI Awards Statistics During Our Audit Period

248 Applications received	13 Awards issued
Approx. \$51M Funded	Up to \$5M Per project

HOW WE CONDUCTED THIS AUDIT

We reviewed NIH's process for awarding the 13 ADSI OT agreements, totaling \$50,759,945, from May 27, 2025, through September 19, 2025 (audit period) for compliance with Federal requirements. Specifically, we developed a checklist to determine whether NIH followed requirements detailed in (1) the ADSI research opportunity announcement (ROA), (2) NIH's *OT Policy Guide* (NIH's OT Policy), and (3) NIH's Division of Other Transactions Management's *Standard Operating Procedure* (the SOP); and reviewed NIH's official records for compliance with items on our checklist.

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

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

RESULTS OF AUDIT

NIH awarded all 13 ADSI OT agreements in accordance with applicable Federal requirements. Specifically, NIH followed its policies and procedures for reviewing applications for ADSI funds and selecting OT recipients for funding based on the requirements in the ROA.

³ An OT is a unique type of legal instrument defined by what it is not, a contract, grant, or cooperative agreement.

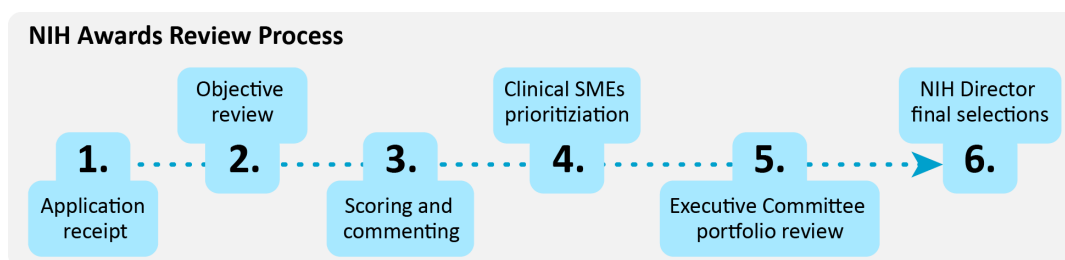
NIH AWARDED OTHER TRANSACTION AGREEMENTS IN ACCORDANCE WITH FEDERAL REQUIREMENTS

NIH solicited, ranked, and selected applications for ADSI awards in accordance with requirements found in the ADSI ROA, NIH's OT Policy, and the SOP. For example, NIH:

- Conducted a risk analysis for each OT agreement prior to awarding ADSI funds
- Analyzed proposed budgets for allowable, allocable, and reasonable costs
- Confirmed that each application included a Community Engagement Plan identifying partners (autistic individuals, families, clinicians, advocacy organizations) and describing collaborative engagement and feasibility
- Verified that each applicant had properly registered in the U.S. Government's System for Award Management and NIH's grants management system
- Ensured that applicants were eligible, U.S.-based organizations
- Recruited scientists who met conflicts of interest requirements from the autism research community to review and rate applications

Application Review and Selection

NIH published the ADSI ROA on May 27, 2025. By the close of the June 27, 2025, application window, NIH received 248 applications. Figure 1 outlines NIH's process for reviewing the ADSI OT award applications.



NIH conducted “objective reviews” of the ADSI OT award applications.⁴ Specifically, these reviewers rated applications using a five-point scale to reflect their qualitative assessments,

⁴ Per NIH's OT Policy, an “objective review” is a process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the application. The review is performed by persons expert in the field of endeavor for which support is requested and is intended to provide advice to the individuals responsible for making award decisions. Individuals who serve on an objective review may be internal or external experts.

documented their rankings, and included written comments for every application and task they assessed.

After completing the objective reviews, NIH convened a team of clinical subject matter experts (SMEs) to further evaluate the applications.⁵ The clinical SMEs analyzed the assessments of the initial reviewers and ranked applications based on each of the ADSI ROA's four priority areas: (1) prevalence, (2) etiology and causation, (3) clinical treatments and services, and (4) replication and validation.

To prioritize highly rated applications that would achieve the ADSI's goals and develop a balanced portfolio across the four priority areas, the clinical SMEs organized applications into groups corresponding to each priority area. Within each group, the clinical SMEs identified primary and secondary candidates that they believed would produce the highest quality science and meet the ADSI's goals.

The clinical SMEs presented their list of recommended applicants to the ADSI Executive Committee—NIH executives with oversight of autism-related work. The committee reviewed the list and made recommendations of a proposed portfolio of ADSI applicants that, according to NIH officials, sought to balance the portfolio of awards across the initiative's four priority areas.

The Executive Committee submitted its list of recommendations to the NIH Director, who made the final selection of the 13 awardees.

Finalization of Other Transaction Agreements

After the NIH Director made the final selections, the OT Agreements Officer and Program Officer for the ADSI reviewed, negotiated, and finalized each OT agreement. Collectively, their review included evaluating proposed budgets and budget justifications, assessing cost reasonableness, confirming indirect cost rates and salary caps, and verifying the personnel assigned to work on each project. In addition, they ensured that each OT agreement satisfied applicable special award requirements (e.g., restrictions on the use of animal research and human embryonic stem cells). The officials also discussed project execution plans with applicants to ensure that the proposed research could be completed within expected timeframes. They were also responsible for ensuring all necessary documents were finalized and uploaded to NIH's records system.

CONCLUSION

NIH used a multi-phase process during the ADSI OT award application review, selection, and finalization of the ADSI OT agreements. Specifically, in less than 4 months, NIH solicited

⁵ The team consisted of eight program officers representing the five NIH institutes that manage the majority of autism-related research.

prospective awardees, reviewed applications, and executed the 13 ADSI OT agreements in accordance with applicable Federal requirements.⁶

Based on our audit results, this report contains no recommendations.

⁶ NIH officials stated that, given the breadth and volume of high-quality science across all applications, the size and complexity of the ADSI, and the limited time available for review, they had to prioritize applications and make difficult funding decisions with limited funds. As a result, NIH officials stated that some strong applications could not be funded.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit period covered May 27, 2025, through September 19, 2025 (i.e., the ADSI application submission and selection window). We reviewed NIH's process for awarding the 13 ADSI OT agreements, totaling \$50,759,945, for compliance with Federal requirements.

We did not assess NIH's overall internal control structure. Rather, we limited our review to internal controls directly related to our audit objective, including NIH's policies, procedures, and practices for reviewing ADSI applications and awarding ADSI funds.

We conducted our audit from January through July 2026.

METHODOLOGY

We took the following steps to accomplish our objective:

- Met with NIH officials to gain an understanding of NIH's process and procedures for awarding OT agreements
- Created a checklist of 82 applicable requirements from the ADSI ROA, NIH's *OT Policy Guide*, and the NIH Division of Other Transactions Management's SOP
- Obtained from NIH award files, governance documents, and other relevant documentation for all 13 recipients of ADSI OT agreements
- Reviewed award files for compliance with items on our checklist
- Discussed the results of our audit with NIH officials

We provided NIH with a draft report on July 24, 2026, for review. NIH elected not to provide formal comments; however, it provided technical comments, which we addressed as appropriate.

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

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Vibrent Health Claimed Unallowable Costs Under a National Institutes of Health Other Transaction Award</i>	A-04-24-02049	4/2/2026
<i>Gaps in NIH's Oversight Put Millions in Funding for Other Transactions at Greater Risk of Fraud, Waste, or Abuse</i>	OEI-04-24-00140	11/20/2025
<i>The National Heart, Lung, and Blood Institute Did Not Fully Comply With Federal Requirements for Other Transactions</i>	A-04-20-04078	4/23/2021

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