2024 SRAI SO/NE
SECTION MEETING
HILTON HEAD, SC
MAY 7 - 10

All About Other Transactions Authority at NIH

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LEARNING OBJECTIVES

Research Administration Professionals will be able to:

- Define Other Transactions Authority (OTA)
- Define Other Transactions (OT)
- Learn the history of OTA
- Learn what OT initiatives are utilized by NIH
- Why OT instead of other awarding instruments
- OT submission process
- Learn about the staff managing an OT award

Other Transactions Authority

Knowledge Pre-Check #1

What is Other Transactions Authority?

a. Other Transactions Authority allows recipients to receive awards.

b. Other Transactions Authority allows Federal Government agencies to enter into Other Transactions.

c. Other Transactions Authority is subject to the FAR.

What is Other Transactions Authority?

Other Transactions Authority (OTA) allows Federal Government agencies to enter into Other Transactions (OT).

What are Other Transactions?

Special type of legal instruments other than contracts, grants or cooperative agreements

Not subject to regulations that apply specifically to Federal Acquisition Regulations (FAR) or to Uniform Guidance

Subject to the OTA that governs an initiative and applicable mandates

Knowledge Pre-Check #2

In what year was the first Other Transactions Authority granted to NIH?

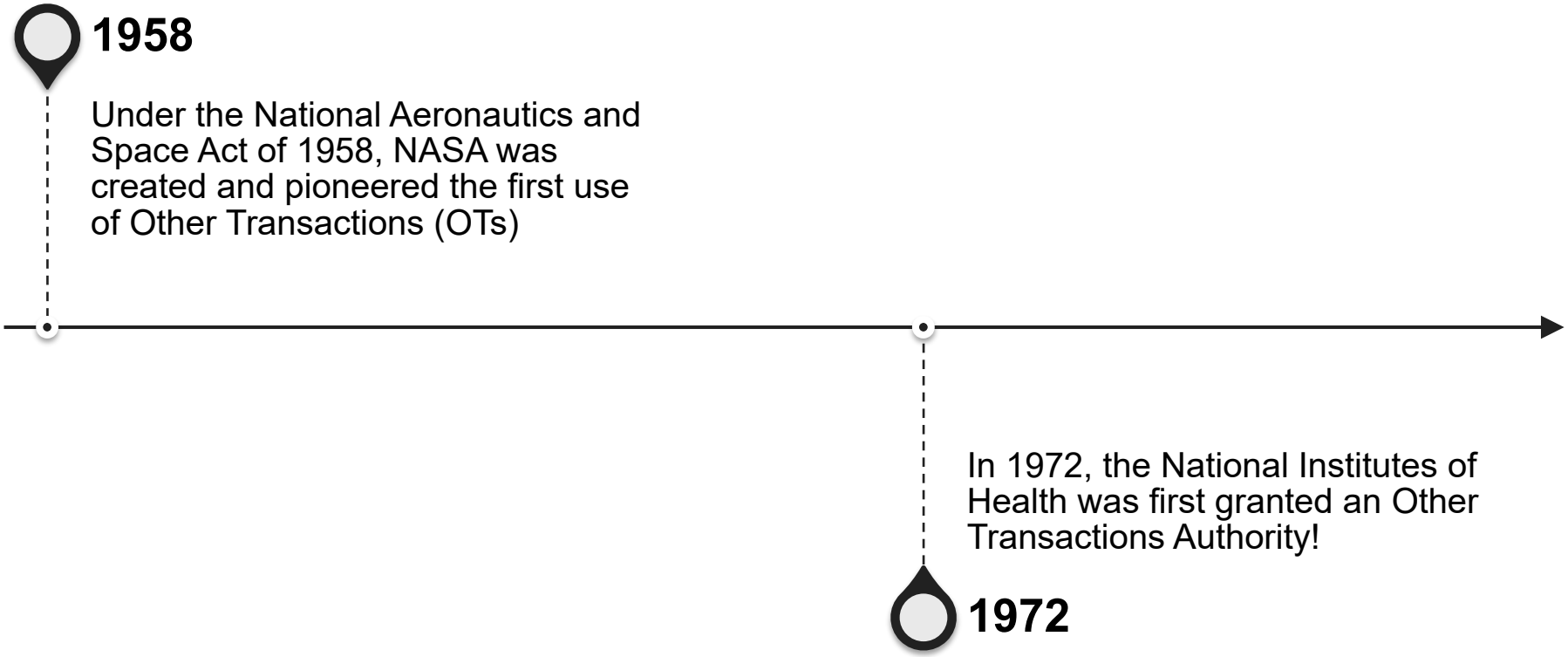
a. 1958

b. 1971

c. 1972

History of Other Transactions Authority

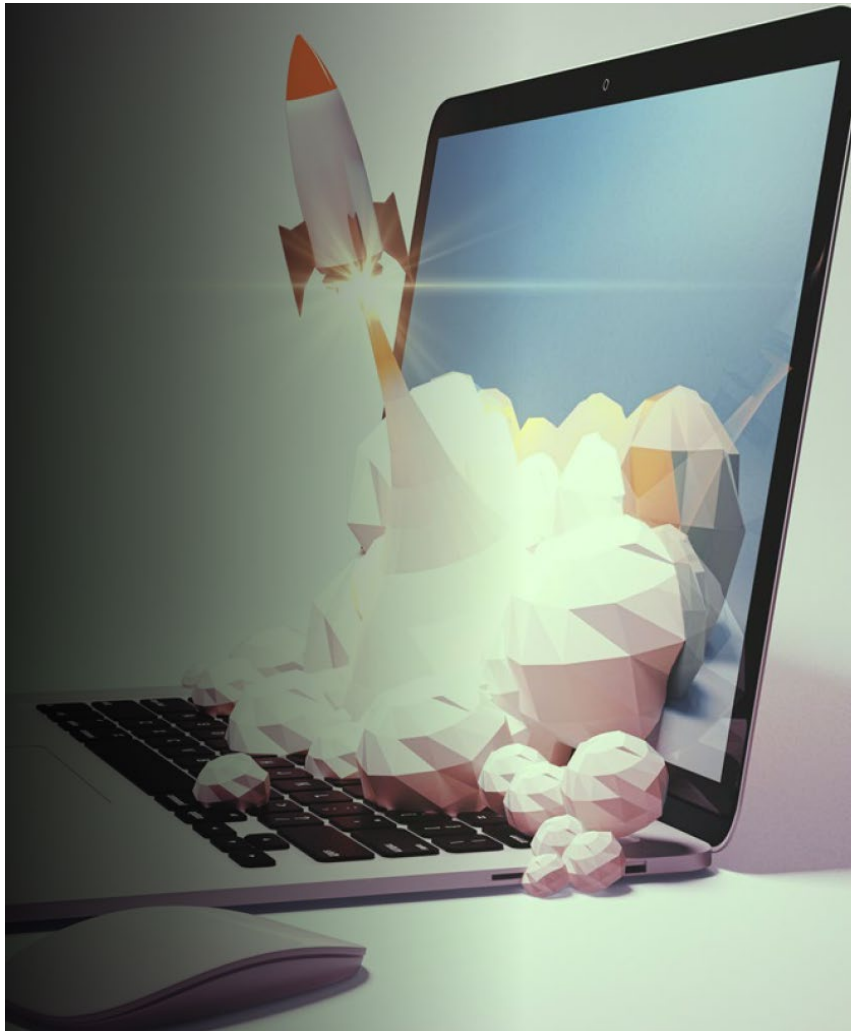
Origination of Other Transactions Authority



Federal Departments and Agencies with OTA

Congress has authorized many Federal Departments & Agencies to use Other Transactions Authorities, including:

- 1958 – NASA (National Aeronautics and Space Administration)
- 1972 – NIH (National Institutes of Health)
- 1989 – DOD (Department of Defense)
- 1996 – FAA (Federal Aviation Administration)
- 1998 – DOT (Department of Transportation)
- 2002 – TSA (Transportation Security Administration)
- 2002 – DHS (Department of Homeland Security)
- 2005 – DOE (Department of Energy)
- 2006 – HHS (Department of Health and Human Services)
- 2011 – ARPA-E (Advanced Research Projects Agency – Energy)



Other Transactions at NIH

Knowledge Pre-Check #3

Which of the following is the "Broad Authority" allowing NIH to enter in Other Transactions?

a. PHSA sec. 421(b)(3) 42 U.S.C. sec. 285b–3(b)(3)

b. PHSA sec. 480(e)(3)(C), 42 U.S.C. sec. 287a(e)(3)(C)

c. 42 U.S.C. sec. 284n(b)(1)

Other Transactions Authority at NIH

PHSA sec. 402(n), 42 U.S.C. sec. 282(n)(1)

42 U.S.C. sec.284n(b)(1)

PHSA sec. 421(b)(3) 42 U.S.C. sec. 285b–3(b)(3)

PHSA sec. 480(e)(3)(C), 42 U.S.C. sec. 287a(e)(3)(C)

**OTAs are subject to change and to the availability of funds*

PHSA sec. 402(n), 42 U.S.C. sec. 282(n) – Unique Research Initiatives

The Director of NIH may approve requests by national research institutes and centers, or program officers within the Office of the Director to engage in transactions other than a contract, grant or cooperative agreement.

42 U.S.C. sec.284n(b)(1) – NIH's "Broad Authority"

Our NIH Director made the decision to offer interested extramural ICO's the opportunity to request the use of an OTA 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.

Initiatives under NIH's "broad authority"

- *All of Us* Research Program
- AIM-AHEAD Consortium
- Biomedical Data Translator Program
- Bridge to Artificial Intelligence (Bridge2AI)
- Cancer Grand Challenges
- Common Fund Data Ecosystem
- Designing a Public-Private Partnership to Support Pediatric Medical Device Development and Commercialization
- Early Phase Pain Investigation Clinical Network (EPPIC-Net)
- Helping to End Addiction Long-Term(HEAL) Initiative

Initiatives under NIH's "broad authority"

- Human BioMolecular Atlas Program (HuBMAP)
- NIH Generalist Repository Ecosystem Initiative (GREI)
- Public-Private Partnership (PPP) for COVID-19 Biomedical R&D Acceleration
- Rapid Acceleration of Diagnostics Underserved Populations Initiative(RADx-UP)
- RADx-UP: Return to School Diagnostic Testing Approaches
- Ultra-rare Gene-based Therapy (URGenT) Network
- Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability Initiative(STRIDES)
- Stimulating Peripheral Activity to Relieve Conditions (SPARC) Program

Why Other Transactions?

Reasons to use Other Transactions

- Other Transactions Authority
- Need for flexibility to negotiate terms and conditions appropriate for the specific program requiring fluid implementation
- Science expected to be highly evolving, with requirements for additional aims or expertise added to, or removed from, the project throughout the term of execution
- Intellectual property rights
- Nontraditional research recipients

Advantages to Using OT

Pooling government R&D with industry's resources to facilitate development, thereby devoting more effort to the actual product and obtain the latest state-of-the-art technologies

Attracting nontraditional entities with promising technological capabilities to work with agencies

Achieving better use of industry resources through innovative business agreements and project designs

Lowering costs and risks by eliminating requirements associated with the Federal Acquisition Regulations (i.e. costs associated with required reporting and administrative activities)

Advantages to Using OT

Speeding up the acquisition process

Increasing technical insight with visibility at all levels

Removing oversight requirements and encouraging more self-policing/autonomy

Improving management of risks and uncertainties through freedom to modify the programs as it evolves

Disadvantages to using OT

Requires more negotiation and due diligence

Not always faster than traditional contracting

No standard FAR clauses and procedures. With these removed, uncertainty may fill the void

Other legal implications

Disadvantages to using OT, continued

Special reporting about the benefits of using OTs expected and achieved. This kind of information is desired by higher HQ and Congress

Probability of external reviews from GAO and IG

NIH Awarding Instruments

Grants	Cooperative Agreements	FAR-based Contracts	Other Transactions Agreement
Financial assistance mechanism to support research for the public good	Financial assistance mechanism to support research for the public good	Legally binding instrument to acquire goods or services for the direct use or benefit of the Government	*Legally binding instrument that may be used or a broad range of research and activities based on an OT activity*
Peer review of broad criteria	Peer review of broad criteria	Award based on stated evaluation factors	*Scientific Evaluation or Objective Review*
Limited Government oversight and control	Substantial Federal Staff Involvement	More Government oversight and control	*Negotiated*
Reports	Reports	Deliverables	*Negotiated*
OMB Uniform Guidance & NIH Grants Policy Statement	OMB Uniform Guidance & NIH Grants Policy Statement	Federal Acquisition Regulation (FAR)	*Federal laws and NIH policy applicable to all awarding instruments & authorizing language*

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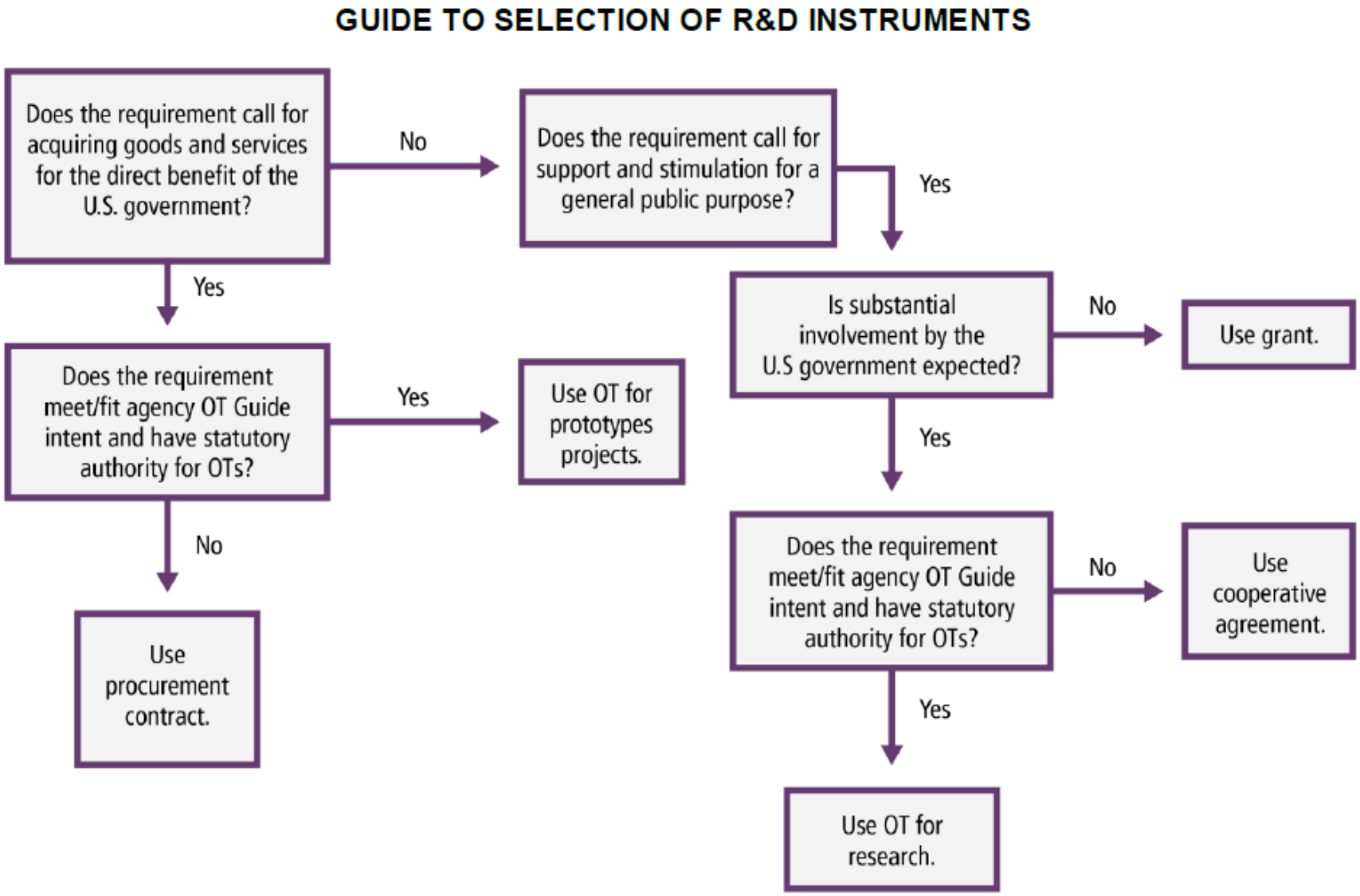
Decision Tree for NIH Awarding Instruments



OT Submission Process

Other Transactions Mechanism - OT2

These are funding instruments which do not incorporate the standard terms and conditions of the OMB Circulars, NIH Grants Policy Statement, and FAR based Contract requirements but rather, all terms and conditions are negotiated between the federal sponsor (NIH) on a case-by-case basis with the Awardee.

- Substantial and active NIH program negotiation and management, before, during and at the end of the project
- Milestone-driven projects with contingency plans
- Special award terms
- Flexibility to alter the course of the project (e.g., expanded, modified, discontinued) and to design unique collaborations with other partners and between awardees

Research Opportunity Announcements (ROAs)

ROAs may be located on NIH institutes, centers, or initiatives' websites; NIH Guide for Grants and Contracts; sam.gov; and other locations known to industry for specific research initiatives

NIH may reach potential applicants via other means, including but not limited to oral presentations, panel pitches, and targeted solicitations

Research Opportunity Announcement (ROA): OTA-23-011 Designing a Public-Private Partnership to Support Pediatric Medical Device Development and Commercialization

Participating Organization (s)	National Institutes of Health
Components of Participating Organizations	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) National Institute of Biomedical Imaging and Bioengineering (NIBIB)
ROA Title	Designing a Public-Private Partnership to Support Pediatric Medical Device Development and Commercialization
Activity Code	OT2: Application for an Other Transaction Agreement
Research Opportunity Number	OTA-23-011
Related Notices	NOT-HD-23-018 NOT-EB-22-008
Application Due Date	June 30, 2023
Earliest Start Date	August 1, 2023
Funding Instrument	Other Transaction: An assistance mechanism that is not a grant, contract, or cooperative agreement. Other Transactions awards are subject to the requirements of the NIH Other Transactions Policy Guide
Funds Available and Anticipated Number of Awards	NICHD and NIBIB intend to fund 1 sole source award for approximately $750,000 in FY2023.
Award Budget and Project Period	18 months

ROA Components

https://www.nichd.nih.gov/sites/default/files/inline-files/PMD_OTA-23-011.pdf

- Purpose
- Background and Overview
- Statutory Justification for use of the Other Transaction Authority
- Program Components
- Proposal Format and Requirements
- Award Project Duration
- Data Sharing Requirements
- How to Submit the Application
- Objective Review Process
- Reviewer Selection
- Conflicts of Interests
- Review Criteria
- Agency Contacts

Knowledge Pre-check #4

Other Transactions must be reviewed at Council just like grants.

a. True

b. False

Submission of the OT applications

- Specific instructions found ROAs
- Apply through eRA ASSIST (Application Submission System & Interface for Submission Tracking)

*Specific Guide for OTA Applications:
https://era.nih.gov/help-tutorials/assist/era-training-assist.htm

Tasks for FNIH beyond the performance period for this PPP may include coordination, management of research contracts that support the goals of the partnership, or other tasks. These will be negotiated with FNIH as planning for the partnership nears completion. Funding to FNIH for these subsequent tasks will be entirely contingent upon completion of milestones and receipt of appropriations for the government portion of the partnership, recruitment of funds from private partners, and agreements to be arranged with partner organizations.

Award Project Duration:

The period of performance anticipated for this OT award will be an 18-month base period.

Data Sharing Requirements

No data sharing requirement applies to this ROA. It is not expected that this project will gather or develop data.

How to submit the application

NIH uses the eRA Commons system to administer OT awards. If you are selected to participate you may need to submit additional information in eRA ASSIST, you will need to be registered in eRA Commons. Applications must be submitted through NIH's ASSIST site by **5:00 p.m. local time on July 17, 2023** at https://public.era.nih.gov/assist/public/login.era. Paper applications will not be accepted. Applications from institutions must be submitted by an authorized organizational representative. Please, see eRA Training ASSIST for additional guidance about Resource only for Other Transaction Authority (OTA) Users of ASSIST.

Objective review process

Submissions will undergo an objective review process. An OT award will be made if the recipient can sufficiently demonstrate the organization's ability to build and manage a complex, multi-entity public-private partnership that seeks to consolidate a national ecosystem that optimizes the translation of technological advancements into medical devices designed, evaluated, and approved for pediatric populations. An award will be made pending review of plans to deliver a PPP in a timely manner and pending review of the budget.

OT Applications Reviewed/Evaluated

- Scientific evaluation or Objective review
- Contents outlined in ROA
- Performed by persons expert in field of endeavor for support requested
- Financial capability review, risk analysis and budget analysis

Review Criteria:

Reviewers will weigh in on the qualifications and prior track record of the sole source with similar tasks, qualifications of the Team, likelihood of accomplishing the proposed work in the allotted time, appropriateness of the budget requested. Specific binary questions (Yes/No) are as follows:

1. Does the Applicant have proven track record of performing similar tasks/projects?
2. Are the qualifications of the Team appropriate to support the proposed work?
3. Are the proposed deliverables and milestones adequate to support the proposed work?
4. Is the indicated timeline appropriate for the proposed Scope of Work?
5. Is the requested budget breakdown appropriate for the proposed Scope of Work?
6. Is third-party subcontract work justified?
7. Overall Assessment: __Recommend __Do Not Recommend

Additionally, reviewers will be asked to provide comments and a brief summary supporting their recommendations.

OT Agreements Development

Negotiations

Process that involve discussing and reaching agreement on the terms and conditions for an Other Transaction or OT modification between NIH and applicant/recipient prior to the issuance of the award

OT Agreements Terms & Conditions

1. OT Identification Number
2. Parties
3. Other Transactions Authority
4. Description
5. Term of Execution
6. Termination
7. Modification
8. Accounting and Management
9. Funding

OT Agreements Terms & Conditions, cont.

10. Obligation and Payment
11. Cost Sharing
12. Audits
13. Disputes
14. Statutes and Regulations
15. Flow Down
16. Reporting
17. Restrictions
18. Closeout

OTHER TRANSACTIONS AGREEMENT

BETWEEN

UNIVERSITY OF WRIGHT
1234 NIH Place Avenue
Kensington, WA 98195-9472

AND

NATIONAL INSTITUTES OF HEALTH (NIH)
Office of the Director (OD)
***Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)**
9000 Rockville Pike
Bethesda, MD 20892

CONCERNING

RADx-UP RETURN TO SCHOOL DIAGNOSTIC TESTING APPROACHES

Agreement No.: 1OT2HD101234-01
Authority: 42 U.S.C. 282(n)

This Agreement is entered into between the National Institutes of Health, an agency of the United States Government, and University of Wright pursuant to and under United States Federal law.

For University of Wright:	For OD/National Institutes of Health:
_____	_____
Artisha Wright Date	Artisha Wright Date
Authorized Organization Representative	Other Transactions Agreements Officer

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ARTICLE I. SCOPE OF THE AGREEMENT

A. Background

SARS-CoV-2 is a novel coronavirus, which is the causative agent of COVID-19, a respiratory disease that exhibits a wide range of clinical outcomes: from asymptomatic and mild disease to severe manifestations. The impact of the COVID-19 pandemic on children, adolescents, and their families is broad, but returning children to in-person instruction in schools poses a particular challenge. Lack of in-person school opportunities is widening the achievement gap that affects children who are racial and ethnic minorities or socioeconomically disadvantaged and will exacerbate disparities that existed prior to the pandemic. Policymakers, public health officials, and educators require scientific evidence to develop policies and procedures to safely return children to in-person schooling. NIH is committed to creative approaches to address the challenge of safe return to in-person schooling with an emphasis on testing in combination with other strategies especially in underserved and vulnerable populations.

The purpose of this Agreement is to establish the Rapid Acceleration of Diagnostics for Underserved Populations (RADx^{SM}-UP) Return to School Diagnostic Testing Approaches Program, hereafter referred to as "RADx^{SM}-UP Return to School". This will consist of a consortium of organizations that will collaborate with the National Institutes of Health (NIH), and each other, to understand and address COVID-19 diagnostic testing access and effectiveness to enable the safe return-to-school for students (preferably age 16 and younger), teachers, and supporting staff, particularly in schools serving underserved populations across the United States. This effort is part of Phase II of the RADx^{SM}-UP initiative, a consortium of community-engaged research projects to understand factors that have led to the disproportionate burden of the pandemic on underserved and/or vulnerable populations so that interventions can be implemented to reduce these disparities.

B. Authorization

1. This Agreement is made under the Other Transactions Authority as authorized by section 402(n) of the Public Health Service Act (PHSA), 42 U.S.C sec. 282(n). It is not intended to be, nor shall it be construed as a partnership (in the strict legal sense), corporation, or other business organization. This Agreement is not governed by the Federal Acquisition Regulation, 2 CFR 200 or the NIH Grants Policy Statement.

2. Research and Development (R&D)

   Other Transactions awards issued by the NIH are deemed to meet the definition of "Research and Development" at 45 CFR Part 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for

F. Data Sharing Policy

Sharing research data supports the NIH mission and facilitates the translation of research results into knowledge, products, and procedures that improve human health. The NIH endorses the sharing of final research data to serve these and other important scientific goals and expects and supports the timely release and sharing of final research data from the NIH- supported studies for use by other researchers. The Recipient therefore agrees to comply with the NIH Data Sharing Policy and Implementation Guidance (https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm). "Timely release and sharing" is defined as no later than the acceptance for publication of the main findings from the final data set. In addition, genomic data must be shared in accordance with the NIH Genomic Data Sharing Policy (https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/).

G. Data Sharing Requirements

This Agreement is part of the RADx℠-UP Initiative, which is managed by the RADx℠-UP CDCC. The Recipient is required to share data through the RADx℠-UP CDCC funded through RFA-OD-20-013. De-identified data will be deposited in the RADx℠-UP CDCC and archived in NIH RADx℠ Data Hub. This will enable properly authorized community members, health researchers, and the Federal government to understand the impact of the COVID-19 pandemic on well-being, risk, resilience, and disparities in vulnerable communities across the United States and the US Territories. Projects will share study instruments and other research products through the CDCC with other RADx℠-UP funded projects.

NIH requires data sharing for all COVID-19 projects, except where prohibited (by Tribal data sovereignty). The NIH requires sharing of interim and final research data from NIH-supported studies for use by other researchers to expedite the translation of research results into knowledge, products, and procedures to improve human health and to address disparities in the current and future pandemics.

Organizations that believe they will be unable to meet these data sharing expectations at any time following execution of this Agreement should promptly contact the OTAO to discuss the circumstances, obtain information that might enable them to share data, and reach an understanding in advance of the award.

H. Human Subjects Data Sharing

The NIH recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, and local, state and federal laws and regulations, including the HIPAA Privacy Rule (https://www.hhs.gov/hipaa/for-professionals/privacy/index.html). The rights and privacy of individuals who participate in the NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. Recipients must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers such as codes linked to the donors or subjects. Also important is compliance with human subjects requirements that apply to the use and sharing of human data (e.g., 45

ATTACHMENT 1: STATEMENT OF BUDGETARY PROJECTIONS

STATEMENT OF BUDGETARY PROJECTIONS					
The Recipient is authorized to expend funds up to the amounts reflected in the "Funds Authorized" section. It is the responsibility of the Recipient to manage within this level of obligated resources consistent with the Statement of Milestones and Objectives (SOM).					
Funding Action/Modification	**Date**	**Federal Funds Authorized**	**Funds Restricted**	**Period of Performance**	**Authorization Description**
Initial Award	[06/XX/2021]	$X,XXX,XXX	$ X,XXX,XXX	06/XX/2021 – 06/XX/2022*	**See note immediately below.**
Bilateral Agreement. Recipient is authorized to expend funds in accordance with SOM with additional funds.					

*NOTE: Pre-award costs in the amount of $XXX,XXX are authorized, effective from the period of June X, 2021 through the date funding was obligated. *(If Applicable)*

ATTACHMENT 2: STATEMENT OF MILESTONES

I. BACKGROUND

The purpose of this Agreement is to establish the RADx^{SM}-UP Safe Return to School Program as a consortium of organizations that will collaborate with each other and with the National Institutes of Health (NIH) to develop scientific evidence that enables the safe return-to-school for students, teachers, and supporting staff, with an emphasis on schools serving underserved and/or vulnerable populations across the United States. This effort is part of Phase II of the Rapid Acceleration of Diagnostics for Underserved Populations (RADx^{SM}-UP) initiative (a consortium of community-engaged research projects) to understand factors resulting in the disproportionate burden of the pandemic on underserved and/or vulnerable populations so that interventions can be implemented that reduce these disparities.

The OT award mechanism allows significant ongoing involvement from NIH Program and Project Managers and provides the NIH the flexibility to alter the course of the project in real-time to meet the overarching goals. This may mean an awarded activity could be expanded, modified, partnered, not supported, or discontinued based on program needs, emerging methods or approaches, performance, or availability of funds. Performance during the award period will be reviewed on an ongoing basis and course corrections will be made as necessary. As a result, the NIH reserves the right to:

- Fund projects in increments and/or with options for continued work at the end of one or more phases;
- Fund projects of two or more entities (potentially across different applications) as part of a reorganized collaboration, teaming arrangement, or other means acceptable to the government;
- Request additional documentation (certifications, etc.); and
- Remove participants from award consideration should the parties fail to reach a finalized, fully executed agreement prior to a date determined by the NIH, or the proposer fails to provide requested additional information in a timely manner.

II. MILESTONES

1. By May 1, 2021:
    a. Execute study framework
    b. Submit to NIH Human Subjects and Clinical Trials information, if applicable
    c. Attain IRB approval
    d. Demonstrate finalization of data collection system
    e. Implement data coordination, collaboration, communication pathway with RADx-UP CDCC
    f. Document and validate distribution of testing supplies
    g. Complete at least 1 weekly rounds of COVID-19 surveillance testing of students and staff in at least 3 Charter Schools in Durham, NC – (at least 100 participants/week and continue weekly data collection
2. By June 1, 2021:

ATTACHMENT 3: FINANCIAL STATUS REPORTS

SAMPLE FINANCIAL STATUS REPORT

National Institutes of Health FINANCIAL STATUS REPORT - OTHER TRANSACTIONS AGREEMENT	Other transactions No.:	Reporting Period:	Date Report Completed:
Recipient Name and Address:	**Principal Investigator Name:**	**Project Title:**	

Reporting Category		Cumulative
Federal Funds Authorized:		
Funds Restricted :		
Federal Expenditures (Total) (sum of lines a - k):		
Federal Expenditures by Budget Category:		
a.	Personnel (Salary + Fringe)	
b.	Equipment	
c.	Travel	
d.	Materials and Supplies	
e.	Publication Costs	
f.	Consultants	
g.	ADP/Computer Services	
h.	Subawards	
i.	Equipment or Facility Rental/User Fees	
j.	Other Expenses	
k.	Indirect costs	
Federal Unobligated Balance (federal funds authorized minus funds restricted minus federal expenditures) :		
Recipient Share (Cost Share, *if applicable*)		
Report Completed By:		
Comments:		

ATTACHMENT 4: DEFINITIONS

In this Agreement, the following definitions apply:

Term	Definition
Agreement	This Agreement and any Attachments or other documents that are expressly incorporated in and made a part of the Agreement, including but not limited to Attachments 1, 2, 3 and 4.
Authorized Organization Representative (AOR)	Individual responsible for the legal commitment by the Awardee and for the administrative and financial reporting compliance with terms and conditions of this Agreement. All official correspondence must be submitted by the AOR.
Data	Recorded information, regardless of form or method of recording, which includes but is not limited to, technical data, software, mask works and trade secrets. The term does not include financial, administrative, cost, pricing or management information and does not include subject inventions.
Foreign Firm or Institution	A firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions. The term includes, for purposes of this Agreement, any agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.
Government	The United States of America, as represented by the National Institutes of Health (NIH).
Invention	Any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.
Know-How	All information including, but not limited to discoveries, formulas, materials, inventions, processes, ideas, approaches, concepts, techniques, methods, software, programs, documentation, procedures, firmware, hardware, technical data, specifications, devices, apparatus and machines.
Lower Tier Agreement	A written agreement between the recipient and a subrecipient.

Made	Relates to any invention and means the conception or first actual reduction to practice of such invention.
Matching or Cost Sharing	The portion of project costs not paid by Federal funds (unless otherwise authorized by Federal statute). This may include the value of allowable third-party in-kind contributions, as well as expenditures by the recipient. These costs are only required when identified in specific FOAs.
Non-Federal entity	A state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization that carries out an award as a recipient or sub-recipient.
Notice of Award (NoA)	The legal document electronically signed by an OTAO that includes the Federal funding limits and obligations. The NOA provides the documentary basis for recording the obligation of Federal funds in the NIH accounting system. It may also contain or reference the Other Transactions Agreement.
Other Transactions Agreements Officer (OTAO)	The OTAO is an NIH federal employee who is certified and responsible for legally committing funds on behalf of the Federal government to Other Transactions (OT). The OTAO is the only federal employee who has signatory authority for Other Transactions. The OTAO is the focal point for receiving and acting on requests for NIH prior approval and is the only NIH official authorized to change the funding, duration, or other terms and conditions of award. All government officials involved in the administrative and financial aspects of the project are referred as **OT Agreements staff**.
Other Transactions Agreements Specialist (OTAS)	The OTAS is an NIH federal employee with delegated responsibility by the OTAO to perform administrative and financial aspects of the award. The OTAS is generally the first line of official OT correspondence with an applicant and/or recipient. The OTAS is assigned responsibility for the day-to-day review and management of applications, Other Transactions/modifications official correspondence. All government officials involved in the administrative and financial aspects of the project are referred as **OT Agreements staff.**
Party	Includes the Government/NIH/OD, or the Recipient, or both.
Pass-through entity	A non- Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program.
Payment Management System	The HHS centralized payment system operated by the Payment Management Service, Program Support Center. Most HHS (and some other Federal government agencies') recipients receive payments through this system.
Practical Application	To manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the

Staff on an OT Award

Many staff from all parties may work on OT and at minimum contain:

- Recipient Business Official and Principal Investigator/Co-Principal Investigator(s)
- NIH OT Agreements Officer, Agreements Specialist and Program Official

NIH Staff managing an OT Award

Other Transactions Agreements Officer (OTAO)

Other Transactions Agreements Specialist (OTAS)

Other Transactions Program Official (OTPO)

Other Transactions Agreements Officer (OTAO)

Federal employee who is certified and responsible for legally committing funds to Other Transaction awards on behalf of the Federal Government. Responsibilities include but are not limited to:

Ensuring that business decisions are made on an informed basis, in good faith, and in honest belief that actions are taken in the best interests of NIH.

Administrating, managing, and closing out OTs.

Negotiating OT financial and administrative requirements, as well as terms and conditions that appropriately reflect risk(s) to be undertaken by all parties.

Obligating NIH to expenditure of federal funds.

Changing funding, duration or other terms and conditions on OTs.

Approving actions related to award and administration of OT agreements.

Ensuring that all required documentation is included in the official record.

Tracking each recipient's use of OT funds, as well as reviewing any requested invoices, vouchers, or other documentation for allowability of costs.

Obtaining and retaining NIH Other Transactions Certification of OT Agreement Officers.

Other Transactions Agreements Specialist (OTAS)

Federal employee assigned responsibility for the day-to-day review and management of applications Other Transactions/modifications, and official correspondence. Responsibilities include but are not limited to:

Completion of OTAS checklist and management of an official record for each OT in eRA.

Documenting in each OT official record rationale or using an Other Transaction as awarding instrument.

Documenting in each OT official record final determinations that costs, terms, and conditions for each OT agreement for fair and reasonable.

Documenting in each OT official record bona fide need.

Evaluating submitted documentation for administrative content and compliance with applicable statutes, regulations and guidelines.

Obtaining and retaining NIH OT certification for OT Agreement Specialists.

Other Transactions Program Official (OTPO)

Federal employee responsible for programmatic, technical and/or scientific management aspects of an Other Transaction.

Responsibilities include but are not limited to:

Providing Federal voice of scientific and technical expertise to recipients.

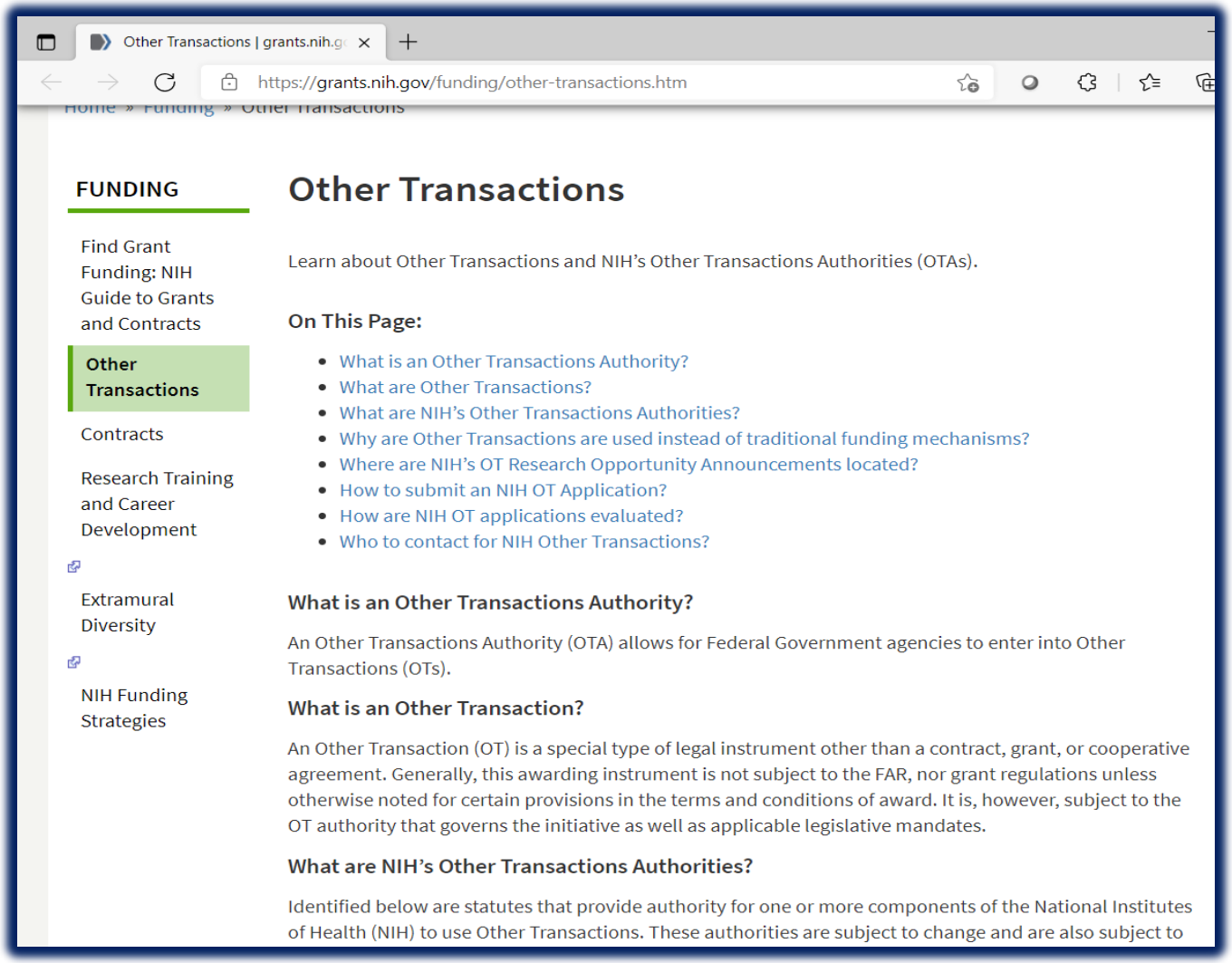
Conducting timely pre-, post-, and closeout award administration, including review of reports/deliverables, participation in site visits, monitoring performance, and conducting other activities complementary to those of OTAO and providing a copy of reviews/reports to OTAS to upload into official record.

Upholding government regulations on appropriate use of federal funds.

Completing OTPO checklist in eRA prior to award.

Maintaining a level of responsibility, formal training, and judgement to best serve as a program official on NIH Other Transactions.

NIH OT Informational Webpage



https://grants.nih.gov/funding/other-transactions.htm

Questions