Addendum to Presentation & Chat, November 3, 2021
Beyond Grants and Contracts: Other Transactions
NIH Virtual Seminar on Program Funding and Grants Administration
Office of Policy for Extramural Research Administration (OPERA)

PRESENTATION
Per participants request and interest, below is additional detail to the **presentation**, *Beyond Grants and Contracts: Other Transactions.*

Slide 4 - Other Transactions Authority (OTA)
- Other Transactions Authorities allow for Federal Government agencies to enter into Other Transactions (OTs). Other Transactions Authorities have been given to federal agencies by Congress to provide them with the flexibility necessary to adopt and incorporate business practices that reflect commercial industry standards and best practices into its award instruments.

Slide 5 - Other Transactions (OTs)
- An Other Transaction is a legal unique awarding instrument that is not a contract, grants nor cooperative agreement. These awarding instruments are not subject to the FAR, nor grant regulations unless otherwise noted for certain provisions in the terms and conditions of award. They are, however, subject to the OT authorities that govern the initiative and/or programs as well as applicable legislative mandates and are used to promote unique research initiatives and opportunities.

Slide 6 - OTA Origination
- 1958: National Aeronautics and Space Administration

Slide 7 - Federal Departments & Agencies with OTA
- Since 1958, Congress has authorized many Federal Departments & Agencies to use Other Transactions Authorities. These include, among others, the Department of Defense; the Department of Energy; the Department of Homeland Security; the Department of Transportation; the Federal Aviation Administration; the Department of Health and Human Services; and our National Institutes of Health. The first HHS/NIH Other Transactions Authority was extended in 1972 to the National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program. Since, the NIH has received additional Other Transactions Authorities.

Slide 8 - NIH Other Transactions Authorities
- NIH currently has three active OTAs:
    - NIH OTA for NIH Director's unique research initiatives
        - PHSA sec. 402(n), 42 U.S.C. sec. 282(n)
        - Allows all extramural ICOs the discretion of the ICO Director to use an OT awarding instrument to further promote the ICO and NIH's mission
        - Not every ICO opts to use these awarding instruments for varying reasons from a huge tap/lift on human resources, to hesitation with the lack of regs/guardrails
    - National Heart, Lung, and Blood Institute (NHLBI) OTA for NHLBI Director's functions
        - PHSA sec. 421(b)(3) 42 U.S.C. sec. 285b–3(b)(3)

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- National Center for Advancing Translational Sciences (NCATS) OTA for Cures Acceleration Flexible Research Awards
  - PHSA sec. 480(e)(3)(C), 42 U.S.C. sec. 287a(e)(3)(C)
  *PHSA = Public Health Service Act

Slide 9 - NIH OT Initiatives
- Currently, NIH has 25 Initiatives using Other Transactions
- NIH Initiatives under OTAs, include:
  1. AIM-AHEAD Consortium (OD)
  2. *All of Us* Research Program (OD)
  3. Biomedical Data Translator Program (NCATS)
  4. Bridge to Artificial Intelligence (Bridge2AI) (OD)
  5. Broadening the Benefit of AI/ML (OD)
  6. Central IRB (cIRB) (NHLBI)
  7. Common Fund Data Coordinating Centers (OD)
  8. Common Fund Data Ecosystem (OD)
  9. Cure Sickle Cell Initiative (CureSCi) (NHLBI)
  10. Early Phase Pain Investigation Clinical Network (EPPIC-Net) (NINDS)
  11. Grand Challenges Initiative (Cancer Grand Challenges) (NCI)
  12. Helping to End Addiction Long-Term (HEAL) Initiative (OD)
  13. Human BioMolecular Atlas Program (HuBMAP) (OD)
  14. NHLBI BioData Catalyst (NHLBI)
  15. NIH Community Engagement Alliance (CEAL) (NHLBI)
  16. NIH Generalist Repository Ecosystem Initiative (GREI) (OD)
  17. Platform technology provider for the NIH COVID-19 RADx Data Hub (OD)
  18. Post-Acute Sequelae in COVID19 (PASC) (NHLBI)
  19. Public-Private Partnership (PPP) for COVID-19 Biomedical R&D Acceleration (OD)
  20. Rapid Acceleration of Diagnostics Underserved Populations Initiative (RADx-UP) (OD)
  21. Regenerative Medicine Innovation Catalyst (RMIC) (NHLBI)
  22. Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability Initiative (STRIDES) (OD)
  23. Stimulating Peripheral Activity to Relieve Conditions (SPARC) Program (OD)
  24. StrokeNet Thrombectomy Endovascular Platform (STEP) (OD)
  25. Ultra-rare Gene-based Therapy (URGenT) Network (NINDS)

Slide 10 - NIH Awarding Instruments
- A grant is a financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH Institute or Center anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities. Grants Management staff and recipients follow OMB's Uniform Guidance & NIH's Grants Policy Statement.
- A cooperative agreement is like a grant but instead of limited oversight, it has substantial federal staff involvement.

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- A procurement <u>contract</u> is a legally binding instrument to acquire goods or services for the direct use or benefit of the Government. Contracting Officers and awardees follow the Federal Acquisition Regulations (FAR).
- <u>Other Transactions</u> (OTs) are not grants, cooperative agreements or contracts. An Other Transaction is a legally binding instrument that may be used for a broad range of research and activities. It is determined by the statute, as well as by the opportunity announcement. Applications for Other Transactions go through a scientific evaluation or objective review. Terms and conditions are subject to negotiation. The amount of involvement by federal staff will be negotiated and written into the terms of the agreement. The types and number of reports will be negotiated and written into the agreement. OTs must be awarded in a manner that ensures proper stewardship of Federal funds and comply with requirements applicable to all Federal funding, regardless of the funding mechanism.

Slide 11 - OTs Used in Research
- Reasons to use OTs may include a combination of the following, among others:
  - 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

Slide 12 - 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

Slide 13 - OT Applications
- Specific instructions in 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
  - These instructions are different than those for organizations applying for grants trough this system.
    - Should anyone have questions about their application, they can reach out to the contacts listed on the ROA or to the eRA service desk by submitting a web ticket or calling them at 866.504.9552.
    - Should anyone reach out to the service desk, indicate that you are requesting assistance for an Other Transitions application, so it is clear from the beginning of the request being made.

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Slide 14 - OT Applications Reviewed/Evaluated

- Scientific evaluation or Objective review
- Contents outlined in ROA
- Performed by persons expert in field of endeavor for support requested
- Ensure an application is meritorious
- Process involves the thorough and consistent examination of each application based on an unbiased evaluation of scientific or technical merit or other relevant aspects
- Individuals who serve on an OT objective review or scientific evaluation may be internal or external experts
- Each review or evaluation will have its criteria and composition to ensure integrity, fairness, and transparency
- Everyone involved must protect the confidentiality of comments from the objective reviews and scientific evaluations

Slide 15 - Staff on OT Award

- Many staff from all parties may work on an OT award, including but not limited to Compliance Team Leads, Initiative Leads, Program Analysts, Program Leads, Program Managers, Project Team Leaders, Project Managers, Scientific Program Director, Strategic Coordination Representatives, and Technical Officers among others deemed appropriate.
- At minimum, the OT award must include:
  - Recipient Business Official and Principal Investigator/Principal
    - Recipient Business Official (BO): The individual, named by the applicant, who is authorized to act for the organizations and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to Other Transactions. This individual may be equivalent to the Signing Official (SO) in eRA.
    - Recipient Program Director/Principal Investigator (PD/PI): The individual(s) designated by the applicant to have the appropriate level of authority and responsibility to direct the project or program to be supported by the Other Transaction. Applicants may designate multiple individuals as program directors/principal investigators (PD/PIs) who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PD/PIs are named, each is responsible and accountable to the applicant and collaborating organizations for the proper conduct of the project or program including the submission of all required reports. The presence of more than one PD/PI on an OT diminishes neither the responsibility nor the accountability of any individual PD/PI. Each PD/PI should be listed on an Other Transaction.
      - The BO and the PD/PI may be the same individual on an NIH OT.
  - NIH OT Agreements Officer, Agreements Specialist, and Program Official

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- Other Transactions Agreements Officer (OTAO): A certified federal employee authorized to execute Other Transactions on behalf of the government. An OTAO is responsible for legally committing the government to an Other Transaction and can enter into, administer, and terminate Other Transactions.
- Other Transactions Agreements Specialist (OTAS): A federal employee who serves as a delegate of the OTAO, assigned responsibility for the day-to-day administrative management of Other Transactions.
- Other Transactions Program Official (OTPO): A federal employee that is responsible for the programmatic, scientific, and/or technical aspects of an Other Transaction.
  - The OTAO, OTAS, and OTPO must be three different individuals on an NIH OT.

Slide 16 - OT Agreements Development
- Other Transactions are based off of an application, the review or evaluation, the needs of the NIH, and the negotiations between the NIH and the applicant.
- Unique to this awarding instrument, all terms and conditions can be negotiated for the award.
- Negotiations are a process that involve discussing and reaching agreement on the terms and conditions for an Other Transaction. Throughout the negotiation, the recipient business official and the NIH OT agreements officer to be present throughout each step of the negotiations for each potential award. Depending on where the project falls on the research spectrum, the ability to establish allowable cost, schedule, and performance requirements, will vary from best effort to clearly identifiable and enforceable requirements. The negotiated terms and conditions must be appropriate for each Other Transaction. In negotiating the terms and conditions for each OT, restrictions imposed by appropriations and policy requirements based on the type of activity and compliance obligations must be considered.

Slide 17 - OT Agreement Terms & Conditions
- The business official who signs the award should understand each term and condition on the award.
- Since OTs are not bound to the FAR or Uniform Guidance, the team who works on an OT should know what is written into the agreement and any modification thereafter.
- At minimum, OT sections include in no particular order:
  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

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

Slide 18 - Lessons Learned

- Agency
- Institute/Center/Office
    1. A purpose behind OTs is flexibility and adapting our process and agreement to fit the circumstances that we face at that moment.
    2. Time commitment by team members is needed as these awards are evolving and modifying.
    3. At the commencement of the pre-award cycle, set aside significant time to devote to pre-award meetings (internally and externally), and to negotiate the agreements.
    4. A negotiation team may be part of an institution's plan for the potential award/award.
    5. Business officials at organizations may need to be specifically designated for OTs because they are different than other awarding mechanisms.
    6. All parties' team members should understand the OT agreement and all succeeding modifications.
    7. Working on an OT may be out of a colleague's comfort zone since OTs may be completely different than any other award they've worked on before.
        o Teams need to allow time for training and collaboration.
        o Not everyone is well suited to the OT environment.
        o Some people can't let go of the FAR or Uniform Guidance.
        o Some people have a really good business sense and are well aware of federal regulation for all awarding mechanisms
    8. Because OTs are different and exempt from many of the traditional rules, they tend to invite interest and concern from auditors which lead to reviews.

Slide 19 - NIH OT Informational Webpage

- NIH has a public facing website that discusses many of the items we reviewed here, including:
    - What is an Other Transactions Authority?
    - What are Other Transactions?
    - What are NIH's Other Transactions Authorities?
    - Why are Other Transactions are used instead of traditional funding mechanisms?
    - Where are NIH's OT Research Opportunity Announcements located?
    - How to submit an NIH OT Application?
    - How are NIH OT applications evaluated?

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- Who to contact for NIH Other Transactions?

Slide 20 - NIH OT Contacts
- For general OT information, contact OER/OPERA Other Transactions Mailbox at NIHODOTA@nih.gov
- For specific initiative information, contact NIH staff listed on the OT initiative ROA(s) or OT initiative websites

Slide 22 – Recapitulation
- Other Transactions Authorities allow for Federal Government agencies to enter into Other Transactions (OTs). OTs are special type of legal instruments other than contracts, grants or cooperative agreements that generally are not subject to Federal laws and regulations that apply specifically to procurement contracts, grants, or cooperative agreements.
- Opportunities for Other Transactions may be published in a variety of ways, including on an NIH initiative's website or sam.gov or industry distribution lists or websites.
- For all awards, particularly for Other Transitions, it's important to be organized, collaborate, and communicate to ensure full understanding and partnership throughout the course of the award.

CHAT
Per participants request and interest, below are responses to the question in the **chat** from the presentation, *Beyond Grants and Contracts: Other Transactions* (November 3, 20210.

Chat Question/Comment
- *Are they still considered an "assistance" award?*
  - Each statute defines the Other Transactions Authority (OTA). The word assistance is not used in NIH's OTAs to define the Other Transactions.
  - Other Transactions are not defined as assistance programs like federal grants, loans, scholarship, counseling, and other assistance programs available to the American public.

- *Can other transaction authorities be "Gift Agreements"? More specifically, Gift Agreements to one federal agency, using funds from another federal agency?*
  - No. OTs are a separate authority and mechanism from gift agreements.

- *Hello, I work for a publicly traded company. Are we still able to seek funding or work with the NIH for collaborative medical research and human subject trials?*
  - A statute and/or a Research Opportunity Announcement may identify the type of recipient for an Other Transaction. If specific recipient types are not identified, any organization or individual may apply for an Other Transaction.

- *Outside of the lack of FARS clauses, what else makes an OTA more flexible and quicker to execute?*
  - An Other Transactions may be considered more flexible due to the Other Transactions

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Authority; the ability to negotiate terms and conditions appropriate for the specific program requiring fluid implementation; ability to negotiate intellectual property rights; nontraditional review and award management practices because the science is expected to be highly evolving, with requirements for additional aims or expertise added to, or removed from, the project throughout the term; collaborative involvement by the NIH in the technical direction and oversight of the research, which can be akin to partnering; and participation sought by nontraditional research recipients, such as: patient advocacy organizations, pharmaceutical companies, foreign entities, or other organizations that are typically not inclined to work with the Federal Government; consortia comprised of various entities that collaborate as peers with the NIH to manage the project and share its costs; nonprofit entities that have an interest in the goals of the program; and individuals. The pace of OT award development is tied to many factors, including but not limited to the review process; development of risk mitigation plans; negotiations; and individual terms and conditions for each agreement. Speed can be a side effect of an Other Transaction, but it is not the goal.

- *What type of mechanism(s) are used for NIBIB's RADx program and the competitions that they run?*
  - Information about NIBIB's specific RADs program can be located here: https://www.nibib.nih.gov/covid-19/radx-tech-program
  - Information about the RADx program can be located here: https://www.nih.gov/research-training/medical-research-initiatives/radx/radx-programs
  - A list of funded RADx projects (grants, cooperative agreements, and OTs) can be located here: https://www.nih.gov/research-training/medical-research-initiatives/radx/funding

- *What specific administrative burdens are associated with use of OTAs?*
  - Because OTs are new to many organizations, perceived burdens may include learning the nuances of the OT mechanism. Also, there may or may not be more reporting requirements in comparison to other awarding instruments.

- *It's been stated that if/when ARPA-H is approved, it may use OTs as an awarding mechanism. Will this mechanism help get around the requirement to allocate all funding by the end of a fiscal year?*
  - NIH does not know what flexibilities ARPA-H will provide.

- *What is meant by these are not subject to grant regulations? Are they subject to uniform guidance?*
  - An Other Transaction (OT) is a unique type of legal instrument other than a contract, grant, or cooperative agreement. This awarding instrument is not subject to the FAR, nor grant regulations (e.g., uniform administrative regulations), unless otherwise noted for certain provisions in the terms and conditions of award. It is, however, subject to the OT authority that governs the initiative as well as applicable legislative mandates.

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- *Will OTs be moving to the standard due dates or will they still be issued independently of the standard dates?*
  - Other Transactions are individually developed, and therefore will have due dates based on what is agreed to in the negotiation and written into the award.

- *How are OTAs announced or published? I don't believe they show up in NIH's Friday listserv, correct?*
  - NIH's Friday listserv issued by the NIH Guide is specific to grants and contracts. Research Opportunity Announcements (ROAs) for OTs may be found on NIH institutes, centers, or initiatives' websites; the NIH Guide for Grants and Contracts; sam.gov; and other locations known to industry for the specific research initiative. Additionally, NIH may reach potential applicants via other means, including but not limited to Requests for Proposals (RFPs), white papers, oral presentations, panel pitches, and targeted solicitations.

- *Will the turnaround times for the OTAs always be short?*
  - There is not a standard turnaround time for OTs.
  - Should you have interest in an opportunity, we recommend that you reach out to the contact on the Research Opportunity Announcement for a tentative expectation for their awards.

- *Do we need to use the NIH Salary Cap?*
  - Yes.
  - The NIH Salary Cap is a legislatively mandated provision limiting the direct salary for individuals working on NIH grants, cooperative agreement awards, and extramural research and development contracts and other transactions. Individuals whose salaries are paid with NIH award funds may not be paid at a rate more than the salary cap prescribed by federal law. An organization may pay an individual beyond the cap with non-Federal funds. For information on current and historical salary cap rates, refer to https://grants.nih.gov/grants/policy/salcap_summary.htm.

- *Are summary statements still provided in this review process?*
  - Summary statements are not required unless outlined in the opportunity announcement.

- *We were invited to serve as a sub on an OTA and have asked to see a copy of the terms that will flow down to us. So far, they refuse to share any part of the OTA. If we are to participate, must we rely on their accurate translation of the terms, or is there some requirement for limited, but direct information sharing with us? Does NIH post specific terms for given OTA-funded programs?*
  - A flow down is a provision that the NIH requires the recipient to incorporate into the specific terms of the OtherTransactions agreement between the recipient and a participant in a lower tier agreement. The OT will outline if there are any flow down requirements.

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- *Considering that OTAs can exist outside of Uniform Guidance regulations, what are the subrecipient monitoring requirements required of potential awardees and subawardees prior to flowing down federal OTA award funds?*
    - The written agreement between the recipient and subrecipient will outline the flow down requirements, monitoring and reporting.

- *What are the most commonly negotiated terms and conditions? For example, is indemnification often asked to be negotiated to mutual indemnification by the grantees?*
    - Most terms and conditions can be negotiated in an OT so this will vary.
    - Examples of terms negotiated include: Term of Execution; Termination; Modification; Intellectual Property; and Reporting.

- *Are there indirect cost limitations on an OT? For instance, if the prime is a company with a 10% indirect cost rate. can we still use our NICRA?*
    - Indirect costs may or may not be applicable to an OT and can be negotiated.
    - The Research Opportunity Announcement may inform a potential applicant of this requirement.

- *Just to clarify, if the financial spending terms changed that should be issued via a mod[ification] on the NoA [Notice of Award]? I have some costs that were decided to not incur IDCs mid-way into our first year. We have only received email communication directing this, not an official mod. Should I emphasize to my OT team that this should be incorporated into the NoA?*
    - If it is written into your OT that any change must be made in a modification, then yes. If there is a clause in the OT that reports that such changes can be made in an email or another form of official correspondence, then that would be okay. Definitely read/review your OT agreement and if needed, follow up with your team and your NIH OT Agreements Officer.

- *Since these are not paid on Uniform Guidance or FAR clauses, should lead applicant organizations ensure any subcontractors/sub awardees agree to these same T&Cs before the prime agreement is fully negotiated?*
    - Every organization may do business differently. That may be a good practice.

- *Will NIH's OTAs incorporate the requirements of EO 14042? I know that the FAR is not incorporated but was wondering if this was planned as a deviation.*
    - The NIH is waiting for HHS' General Law Division to provide us with the requirement. We will be updating our NIH OT Enterprise. Should there be a requirement, our NIH staff will inform recipients.

- *Is funding/budget for OT specifically and separately appropriated from another agency appropriation?*
    - NIH OTs are from NIH's appropriation.

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- *Can you point to any definitive guidance regarding whether OTs are subject to FFATA?*
  - At this time, Other Transactions are not included. Currently, FSRS.gov supports contracts and grants reporting. See https://www.fsrs.gov/ and https://www.fsrs.gov/#a-faqs for information and FAQs about FFATA.