



*United States Department of*

**Health & Human Services**

**Office of the Assistant Secretary for Preparedness and Response**



# **Use of Other Transactions at ASPR**

**Presented By:**

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**BARDA/ AMCG**



# Agenda



- OT Overview
- Benefits of OT
- Award of first OT by ASPR
- Solicitation Procedures
- Cost Share Discussion
- Consortiums
- Federal Laws and Regulations
- Questions?



# Other Transaction Authority



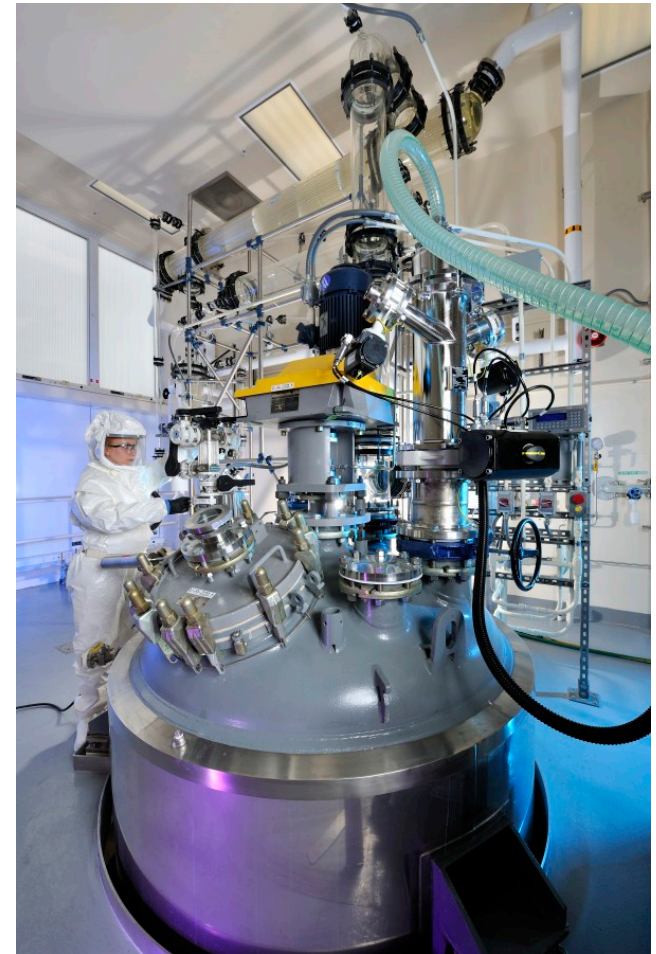
- The Pandemic and All Hazards Preparedness Act (PAHPA) granted to the Secretary of HHS additional authority called Other Transactions. This authority was delegated to the ASPR and subsequently to AMCG on a per agreement basis.
- There are two types of OTs used within the government
  - Other Transactions for Research, which is the authority granted in PAHPA
  - Other Transactions for Prototypes.
- The term OT comes from the definition in the statute:
  - “Transactions other than procurement contracts, grants and cooperative agreements”



# Why OT's Are Valuable to BARDA



- Another tool available for promoting MCM Product Advanced Research & Development and Technology Innovation.
- Provide a unique opportunity to engage with new and/or non-traditional government contractors.
- Results in broadening the industrial base.
- Increases potential for commercial investments in critical Bio-medical countermeasures.



# Benefits of OT's

The process is viewed as a win-win negotiation because OTs for Research:

- Allow for Generally Approved Accounting Procedures rather than Government cost accounting standards



- Allow cost and pricing data and certifications to be negotiable rather than mandatory
- Allow for commercially friendly intellectual property provisions
  - Handling of patents
  - Handling of technical data

# Benefits of OT's

- Allow partnering between AMCG and “teams” of entities generally called consortium
- Allow for flexibility in management of agreements
  - Innovative business arrangements
  - Open lines of communications among “team”
  - Industry’s internal management
- Allow for supply chain relationships
  - Long-term strategic relationships with key suppliers





# BARDA's Use of OT's

- The first award of an OT was May 2013.
- It is an innovative arrangement of a drug development portfolio for Broad Spectrum Antibiotics.
- The terms included substantive cost sharing.
- The portfolio will allow for BSAs to enter into the agreement at different stages of development.
- The agreement would not be possible using traditional means such as the contract or grant mechanism.







# Use of Other Transaction Authority



- HHS's authority points back to DoD's statute 10 USC 2371.
- Key elements of the HHS OT authority are as follows:
  - Must use competitive procedures to the maximum extent practicable.
    - AMCG will use Broad Agency Announcement (BAA)
  - Does not require 50/50 cost sharing, as practicable.
  - Must be used for Research.
    - These terms are not defined in 10 USC 2371
    - PAHPA does give guidance



- In order to award an Other Transaction, there has to be at least one non-traditional government contractor participating to a significant extent.



- Or the Senior Procurement Executive for the agency determines in writing that exceptional circumstances justify the use of an OT because a conventional arrangement would not be feasible.



# Solicitation Procedures



- **Broad Agency Announcements (BAAs)**
- If an OT is not the correct mechanism, the BAA process has the flexibility to award a FAR based contract.
- Recommended Steps
  - Tech Watch
  - White Paper Submission
  - Full Proposals
  - During this process, please use your POC in the solicitation, the COs and the Technical Points of Contact!



# Cost Sharing



- Cost sharing demonstrates a commitment by the recipient of the OT. That is valuable in the evaluation of instrument type within ASPR.
- As stated previously, cost-sharing is not legislatively required.
- Traditionally, *two* type of cost share are identified
  - **Cash** (labor costs, material costs or overhead expenses) the preferred type of cost share
  - **In Kind** (the value of materials, equipment or other items supporting the effort).



# Consortiums

- An opportunity for more than one entity to propose together.
- The group of entities participate as partners.
- Consortium members can be large or small businesses, universities, non-profits and commercial firms.
- Each member may participate in
  - Performing the technical effort
  - Interfacing with the entire OT team reviewing technical progress
  - Overseeing business matters
- A teaming agreement or consortium agreement is negotiated between the parties.



# Exempt from Laws & Regulations



- Generally not subject to federal procurement and assistance laws and regulations governing procurement contracts, grants and cooperative agreements.
  - OTs are not subject to Bayh-Dole Act, which allows for the flexibility in negotiation of Intellectual Property and Data Rights, however Limited-Rights Data clause (FAR 52.227-14, Alternate II) may be included during negotiations.
- Other federal laws applicable:
  - Fiscal laws
  - Laws of general applicability, e.g., Civil Rights Act and Clean Air and Water.



# Co-Author Recognition



Glynis Fisher, Associate Director,  
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# Questions?



**"Your proposal is innovative. Unfortunately, we won't be able to use it because we've never tried something like this before."**