

Other Transactions (OTs)

Overview

Business Innovative Division (BID)

August 2024



ARPA 

Federal Contracting History and Events

- 1948** Armed Services Procurement Act/Armed Services Procurement Regulation (ASPR)
- 1958** Grants Act & National Aeronautics and Space Administration (NASA) Space Act signed (created NASA & "Space Act Agreements")
- 1959** GSA issues civilian procurement regulation
- 1972** OT Authority (OTA) granted to the National Institutes of Health (NIH)
- 1974** Procurement regulations total about 3,000 pages
- 1977** ASPR becomes Defense Acquisition Regulation (DAR)
- 1978** Federal Grant and Cooperative Agreement Act

Federal Contracting History and Events (cont.)

- 1984** The Federal Acquisition Regulation (FAR) codified in Title 48 Code of Federal Regulations (CFR)
- 1989** OTA granted to the Defense Advanced Research Projects Agency (DARPA)...later to the broader Department of Defense (DoD)
- 1993** Era of "procurement reform" - Federal Acquisition Streamlining Act
- 1994** DARPA's OTA expanded to include prototype projects...later to the broader DoD
- 2001** OTA for follow-on production introduced to the DoD
- 2006** OTA granted to the Department of Health and Human Services (HHS)
- 2011** OTA granted to the Advanced Research Projects Agency for Energy
- 2022** Creation of ARPA-H (with OTA granted)



Science & Technology (S&T) Community

PAST

Innovation fueled by the Government

Private sector wanted to work with the Government

The Government was the primary driver of technology innovation by making substantial R&D investments

PRESENT

Innovation fueled by the private sector

Cutting edge commercial firms with large Research and Development (R&D) investments are reluctant to work with the Government

Focus and pace of S&T innovation in leading technology areas have shifted from Government to the private sector (industry spends nearly 10 times more on R&D than the Government)

Impediments to Commercial Firm Participation

- Traditional procurement process is too slow, bureaucratic, and doesn't effectively incorporate commercial best practices
- Traditional procurement contracts (FAR-based contracts) are based on "regulation" rather than negotiation
- Government's cost-based pricing system is cumbersome
 - Specialized accounting and audit systems
 - Actual and perceived oversight excesses
- Small businesses and start-ups may be able to secure funding more quickly and more easily from venture capitalists
- Government's approach to intellectual property (IP) and technical data rights can be overreaching



OTs - What They are and What They Are Not

- **What They Are:**

- Flexible/innovative/streamlined contract vehicles with characteristics similar to those within the commercial industry
- Require personnel with business acumen and negotiation skills (and OT training or experience)
- Require performance measurement and management (cost, schedule, and technical progress)
- Vehicles by which the Government Accountability Office (GAO) has limited jurisdiction to review decisions and protests

- **What They Are Not:**

- Appropriate for all ARPA-H offices/divisions
- Procurement contracts (FAR-based), grants, or cooperative agreements
- Subject to all acquisition laws and regulations
- New vehicles available to the Government (including HHS and NIH)
- One-size-fits-all vehicles with standard checklists
- Vehicles used strictly to avoid following the FAR
- Guarantee ARPA-H teams to complete awards faster than traditional contracts

OTs - Purposes and Potential Benefits

- Provide ARPA-H the flexibility to adopt and incorporate business practices similar to those within commercial industry
- Provide the Government access to state-of-the-art technology solutions
- Foster new relationships and practices with solutions providers, especially those that may not be interested in entering into FAR-based contracts with the Government
- Broaden the health ecosystem or Public Health Industrial Base (PHIB)
- Encourage flexible, quicker, and cost-effective projects design and execution when compared to other vehicles
- Leverage commercial industry investments in science/technology and research/development
- Collaborate in innovative and flexible arrangements



OT Advantages / Disadvantages



Advantages

- The most flexible authority when compared to contracts, cooperative agreements, and grants
- Instrument characteristics are similar to contracts within the commercial sector
- Processes based on negotiations rather than regulations/policies
- Bayh-Dole Act (Intellectual Property) does not apply → more flexibility
- Does not require excessive oversight or specialized accounting/audit requirements and systems



Disadvantages

- Some industry partners, primarily academic institutions, may not have experience with OTs
- Does not guarantee ARPA-H teams to complete awards faster than CAs or procurement contracts
- For now, requires pre-award approval by HHS leadership for awards with estimated amounts above \$4.5M → may impact award schedule

OTs - Potential ARPA-H Awardees

- **ARPA-H can enter into OTs various types of entities and organizations*:**
 - Large business, including traditional government performers
 - Small businesses, including those participating in Small Business Innovation Research or Small Business Technology Transfer programs
 - Nonprofit research institutions
 - Academic institutions, including Historically Black Colleges and Universities
 - Minority Serving Institutions, including Hispanic Serving Institutions and Native American-Serving Non-Tribal Institutions
 - Consortium Management Firms

*** Focus is on using competition to the maximum extent practicable)**



OTs - Risks and Challenges*

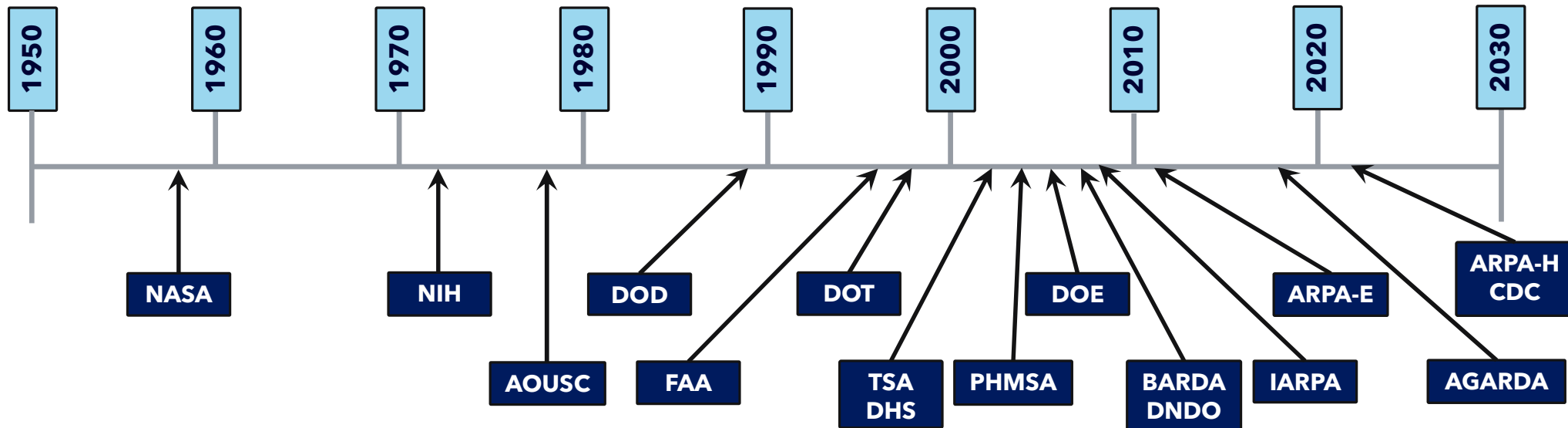
- Non-traditional form of Federal Government doing business
- OT usage not meeting Congress' intent
 - Insufficient transparency, reporting, and controls
- Not obtaining or maintaining adequately trained personnel with appropriate skills sets
- Limited training available on subject matter
- Lack of structured procedures or "guardrails"
- Avoiding sufficient competition
- Not maintaining or expanding the health ecosystem or PHIB
- Inadequate means to measure/manage performance
- Inconsistent processes/practices and lack of transparency with consortia use

Key Elements to Effective OT Use

- Top level (ARPA-H leadership) interest and support
- Cohesive team from project initiation (e.g., PM, Acquisition, Legal, Comptroller)
 - Buy-in from entire team and key stakeholders is crucial
 - Culture: collaboration, communication, inclusion, mutual trust, empowerment, and measured risk
- Program Management, Project Managers, and OT Agreements Officers who understand the OTA and identify opportunities to use OTs
- Participation by and cooperations among various functional areas (“right people on the bus”)
- Not following/mimicking the FAR/HHSAR and inhibiting the flexibility provided by the OTA
- Choosing OTs as the appropriate award vehicle after fully determining program or project goals and objectives



Gov't Entities with OT Authority



AGARDA	Agriculture Advanced Research and Development Authority	DOE	Dept of Energy
AOUSC	Administrative Office of the US Courts	DOT	Dept of Transportation
ARPA-E	Advanced Research Projects Agency for Energy	FAA	Federal Aviation Administration
ARPA-H	Advanced Research Projects Agency for Health	IARPA	Intelligence Advanced Research Projects Activity
BARDA	Biomedical Advanced Research and Development Authority	NASA	National Aeronautics and Space Administration
CDC	Centers for Disease Control and Prevention	NIH	National Institutes of Health
DHS	Dept of Homeland Security	PHMSA	Pipeline and Hazardous Materials Safety Administration
DNDO	Domestic Nuclear Detection Office	TSA	Transportation Security Administration
DOD	Dept of Defense		



OTs - What Laws and Regulations Apply?

Laws & Regulations that Apply to OTs	
False Claims Act - 31 U.S.C. § 3729	Antideficiency Act (ADA) - 31 U.S.C. § 1341/1342/1517
False Statements - 18 U.S.C. § 1001	Procurement Integrity Act - 41 U.S.C. § 2101, et seq.
Civil Rights Act - 42 U.S.C. § 1981	Federal Property and Administrative Services Act - 40 U.S.C. Subtitle I
Clean Air Act - 42 U.S.C. § 7401	Debarment and Suspension - 2 CFR 376
Clean Water Act - 33 U.S.C. § 1251	Research Misconduct - 42 CFR 93
Endangered Species Act - 16 U.S.C. § 1531	Human Subjects Protections - 45 CFR 46
National Environmental Policy Act - 42 U.S.C. § 4321, et seq.	Humane Care and Use of Laboratory Animals - Public Health Service Policy



OTs - What Laws and Regulations Do Not Apply?

Laws & Regulations that Do Not Apply to OTs	
Competition in Contracting Act - 41 U.S.C. § 3301	Buy American Act (in part) - 41 U.S.C. § 83
Truthful Cost and Pricing Data Act (formerly "Truth in Negotiations Act") - 41 U.S.C. § 3501, et seq.	Antikickback Act of 1986 - 41 U.S.C. § 51-58
Cost Accounting Standards - 41 U.S.C. § 1502	Service Contract Act - 41 U.S.C. § 351 et seq.
Contract Disputes Act - 41 U.S.C. § 7102	Procurement Protest Process - 48 CFR 33.1
Procurement Protest System - 31 U.S.C. § 3551, et seq.	Federal Acquisition Regulation (FAR)
Bayh-Dole Act - 35 U.S.C. § 202-204	HHS Acquisition Regulation (HHSAR)



Financial Assistance* vs Acquisition

Assistance	Acquisition
Support or stimulation	Acquire/Buy
Public purpose	Goods/services for the direct benefit of the Government
Level of support	Price
Partnership/collaboration	Buyer/seller
Profit /fee unallowable	Profit/fee allowable
Unilateral right to terminate by recipient	Unilateral right to terminate by Government

*** Cooperative agreements and grants (OTs are not financial assistance instruments)**

OTs - Intellectual Property (IP)

- IP rights will likely be the most complicated part of negotiations and take the most time
- Commercial companies are very protective of their IP rights and are very good at negotiating rights
- Educating the Government team on IP options and determining the Government's long-term needs/desires will help the team reach a reasonable position for negotiations
- Factors to consider in planning for negotiations:
 - There are no standard approaches or required positions (complete flexibility and freedom in negotiating rights)
 - Appropriate allocation of rights will depend on the technology and where it is in development
 - Standard rights in the particular industry
 - Take into account performer investment(s) through both resource sharing and previous investments
 - Always keep in mind the goal of both the proposing team and the Government set out in the agreement vision statement and their commercialization plan

OT Community (OTC)

Objective: provide a one-stop-shop to assist individuals and organizations with OT planning, execution, and administration

Resources: training, on-the-job support, policies/guidance, reports, publications, and more

Location: ARPA-H's public website → <https://arpa-h.gov/engage-and-transition/other-transaction-community>

Cost: Free

How to Connect?

Email OTCommunity@arpa-h.gov

