Comprehensive Other Transaction (OT) Training

Other Transaction Community (OTC)

Advanced Research Projects Agency for Health (ARPA-H)

November 19-20, 2024

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Purpose and Expectations

Purpose:
- Provide Other Transaction (OT) training
- Share information and identify resources to assist with real-word application

Expectations:
- Gain awareness of ARPA-H's OT Community (OTC) and its purpose/mission
- Understand OT authorities (OTs), agreements, terms, stakeholders, responsibilities, and processes
- Enhance OT knowledge and use (tied to planning, execution, and administration)

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Course Admin/Logistics Items

- Attendees can receive 12 hours of training credit from attending the entire course
  - Send requests for training certificates to OTCommunity@arpa-h.gov **after** completion
- Presentation materials will be shared
- Open environment → avoid discussing sensitive or confidential topics
- Participation is encouraged (ask questions during the event)
- Mute microphones during course (unless you intend to speak)
- 10-to-15-minute breaks throughout
- 1 hour lunch break
- Provide ARPA-H feedback on course/sessions to enhance future offerings

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Course Roadmap

Key Topics	Notional Time (ET)

Day 1 Intro / OT Community Update
Federal Contracting & Acquisition Review
OT Overview
  - Terms / Definitions / Stakeholders
  - What Applies / What Does Not Apply
  - Review of OT Authorities
Lunch
Business Strategy & Approaches
Value Analysis
Payable Milestones
Resource Sharing
	0800 – 0820
	0820 – 0915
	
	0930 – 1130
	(w/ break)
	
	1130 – 1230
	1230 – 1330
	1340 – 1420
	1435 – 1530
	1530 – 1600

Day 2 Teaming Intellectual Property (IP) Property (Government Furnished Property) OT Resources Sample Agreement	0800 – 0850 0900 – 1000 1000 – 1015 1030 – 1045 1045 – 1200

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OT Community Update

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Why is an OTC Needed?

- Broadly speaking, OT authority is misunderstood (not embraced) across the Federal Gov't and not utilized to the greatest extent

- ARPA-H personnel have diverse OT and professional training experience and are willing to assist others

- OT training and outreach opportunities are not widely available across the Federal Gov't

- Not all Federal Gov't agencies have OT authority, but some have obtained the authority in recent years and some without authority are seeking it

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Benefits of the OTC

- Assist entities appropriately and effectively use OTs relative to authorities

- Create and maintain a network of OT experts across the Federal Gov't

- Share OT information/resources (i.e., samples, templates, guides, FAQs, lessons learned, best practices) and promote valuable collaborations between gov't entities and industry

- Participate in OT policy and guidance development or changes at the Federal/Department/Agency level

- Enable personnel to receive professional development (training) and career broadening opportunities

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How to Connect?

- Website: https://arpa-h.gov/engage-and-transition/other-transaction-community

- Email: OTCommunity@arpa-h.gov (for OT questions, request assistance, suggestions to enhance OTC website, etc.)

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Federal Contracting & Acquisition Review

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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 General Services Administration issues civilian procurement regulation

1972 OTA granted to the National Institutes of Health (NIH)

1974 Procurement regulations total about 3,000 pages

1977 ASPR becomes the Defense Acquisition Regulation (DAR)

1978 Federal Grant and Cooperative Agreement Act

1984 The Federal Acquisition Regulation (FAR) codified in Title 48 Code of Federal Regulations

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Federal Contracting History and Events (cont.)

1989   OTA granted to the Defense Advanced Research Projects Agency (DARPA)…later 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 Biomedical Advanced Research and Development Authority (BARDA) –- within ASPR (Health and Human Services)

2011   OTA granted to the Advanced Research Projects Agency for Energy

2022   Creation of ARPA-H (with OTA granted)

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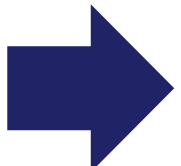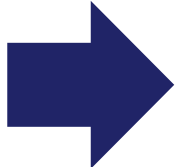
Ratio of U.S. R&D to GDP

Science & Technology (S&T) Community

PAST

Innovation fueled by the Gov't

Commercial sector wanted to work with the Gov't

The Gov't was the primary driver of technology innovation by making substantial research and development (R&D) investments

PRESENT

Innovation fueled by the commercial sector

Cutting edge commercial firms with large R&D investments are reluctant to work with the Gov't

Focus and pace of S&T innovation in leading technology areas have shifted from Gov't to the commercial sector (industry spends nearly 10 times more on R&D than the Gov't)

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Impediments to Commercial Sector 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 <u>cumbersome</u>

  - Specialized accounting and audit systems
  - Actual and perceived oversight excesses

- Small businesses and start-ups may be able to secure funding much more quickly and more easily from venture capitalists

- Government's approach to intellectual property (IP) and technical data rights can be <u>overreaching</u>

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Tool Box (ARPA-H Example)

Acquisition		Non-Acquisition		
Procurement Contracts	**Non-FAR Contracts**	**Grants**	**Cooperative Agreements**	**OTs**
31 U.S.C. § 6303	Non-Appropriated funds (NAF) contracts	31 U.S.C. § 6304	31 U.S.C. § 6305	ARPA-H OT authority
↓	NASA Space Act	2 CFR Part 200	2 CFR Part 200	Single/Multi-Party
Federal Acquisition Regulation (FAR)	Unique authority at 9 civilian agencies	Bayh-Dole Act	HHS/NIH policies	New/Unique Arrangements
	ARPA-H OT authority		Bayh-Dole Act	Bailments Lease Arrangements
PART 15 Contracting by Negotiation / PART 12 Commercial Items	HHS Policies			Loan-to-Own
Cost/ Price Based / Price Based	Exceptions to Bayh-Dole Act			Exception to Bayh-Dole

Cooperative Research & Development Agreement (CRADA) — A legal agreement between a federal laboratory and industry used for the transfer of commercially useful technologies from federal laboratories to the private sector and to make accessible unique technical capabilities and facilities

Partnership Intermediary Agreement (PIA) — A contract, agreement, or memorandum of understanding with a nonprofit partnership intermediary to bring together academia and industry on behalf of the Gov't to speed up tech transfer and licensing

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Acquisition vs. Non-Acquisition

- **Acquisition Instruments**

  - Procurement contracts or OTs
  - Used to acquire goods and services for the Gov't's direct benefit
  - Procurement contracts are traditionally subject to the acquisition statutes and the FAR and supplements (i.e. HHSAR, DFARS, NASA FAR Supplement)

- **Non-Acquisition Instruments***

  - Grants, cooperative agreements, and OTs
  - Used to support and stimulate an activity for the general public good
  - Traditionally subject to the assistance statutes and regulations in 2 CFR Part 200

* Grants and cooperative agreements are federal financial assistance instruments

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Instrument Definitions

- **OT**
  - A legally binding agreement (other than a procurement contract, grant, or cooperative agreement) with industry for the Gov't to conduct research and development efforts and promote innovation to achieve its goals

- **Procurement contract**
  - A legally binding instrument which shall be used only when the principal purpose is the acquisition of supplies or services for the direct benefit or use of the Federal Gov't

- **Grant**
  - A legally binding instrument used to transfer a thing of value to the Gov't or other recipient to carry out a public purpose of support of stimulation instead of acquiring property or services for the direct benefit or use of the Gov't
  - <u>Substantial involvement</u> is not expected between the Gov't and the recipient when carrying out activity contemplated

- **Cooperative agreement**
  - A legally binding instrument used to enter into the same kind of relationship as a grant except <u>substantial involvement</u> between the Gov't and recipient is expected when carrying out the activity contemplated

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OT Overview

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

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# OTs – Purposes and Potential Benefits

- Provide the flexibility to adopt and incorporate business practices similar to those within commercial industry

- Provide the Gov't 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 Gov't

- Broaden the Public Health Industrial Base (PHIB), Defense Industrial Base (DIB), or other

- 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

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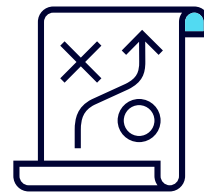
OTs – Potential Performers

- **The Gov't can enter into OTs with various types of entities and organizations*:**
  - Large business, including traditional government performers
  - Small businesses, including those participating in Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) programs
  - Nonprofit research institutions
  - Academic institutions, including Minority Serving Institutions (i.e., Historically Black Colleges and Universities, Hispanic Serving Institutions, and Native American-Serving Non-Tribal Institutions)
  - Other: Foreign entities, Consortium Management Firms (CMFs), etc.

* Use competitive procedures to the maximum extent practicable

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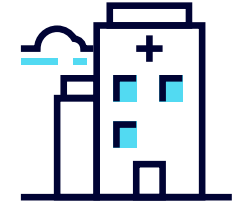
OTs – Risks and Challenges*

- Nontraditional 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 performer base
- Inadequate means to measure/manage performance
- Inconsistent processes/practices and lack of transparency with consortia use

* Sources: Various GAO and Office of Inspector General reports

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Key Elements to Effective OT Use

- Top level (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 (PMs), and OT Agreements Officers (AOs) 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/DFARS/etc. and inhibiting the flexibility provided by the OTA
- Choosing OTs as the appropriate award vehicle after fully determining program or project goals and objectives

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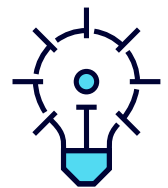
Common OT Terms and Definitions

- **Other Transaction (OT) Authority**
  - The authority allowing Gov't entities to enter into OTs
- **Agreement File**
  - A collection of important files to maintain key supporting documents related to each OT (similar to contract file)
- **Articles**
  - Terms and conditions for OT agreements (similar to clauses for procurement clauses)
- **Industrial Base (Ecosystem)**
  - A network of people, organizations, facilities, and resources that provides the Federal Gov't with materials, products, and services (e.g., Public Health, Defense, Transportation)
- **Resource Sharing**
  - A portion of the total project costs paid by sources other than the Federal Gov't

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Common OT Terms and Definitions (cont.)

- **Advance Payment**
  - A form of payment made by the Gov't to the Performer in advance of its normal schedule

- **Consortium**
  - A collection of business entities (such as nonprofits, academic institutions, or contractors) and individuals focusing on a specialize technology area working together to achieve a common goal and solve a defined challenge

- **Key Supporting Documents (KSDs)**
  - Necessary documents, physical or electronic, that support each OT and the associated business or acquisition activities throughout the project life-cycle (typically maintained within OT agreement files) → examples include written determinations for approval authority, business strategy documentation, and correspondence with potential Performers

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OTs – "The Project Team"

- **Each OT project will differ in size, scope, and duration (not a one-size-fits-all)**
- **The PM or Team Lead should consider involvement from various offices/divisions (ARPA-H example below):**
  - Director's Office
  - Mission Office → PMs
  - Business Innovation Division (BID) → AOs
  - Comptroller Office
  - Division of Communications
  - Division of Legislative Government Affairs
  - Project Accelerator Transition Innovation Office → Commercialization/Tech Transfer
  - Division of General Counsel

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Ideal AO Characteristics*

- Business acumen

- General understanding of traditional gov't contracting and commercial best practices

- Innovative / creative

- Collaborative

- Calculated risk-taking (thriving in "the gray" area)

- Understanding of respective industrial base(s)

- Experience with negotiations (terms & conditions)

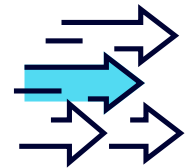*** Also applicable to Agreements Officer's Representatives and other involved team members**

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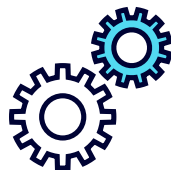
OTs – What Laws and Regulations Apply?

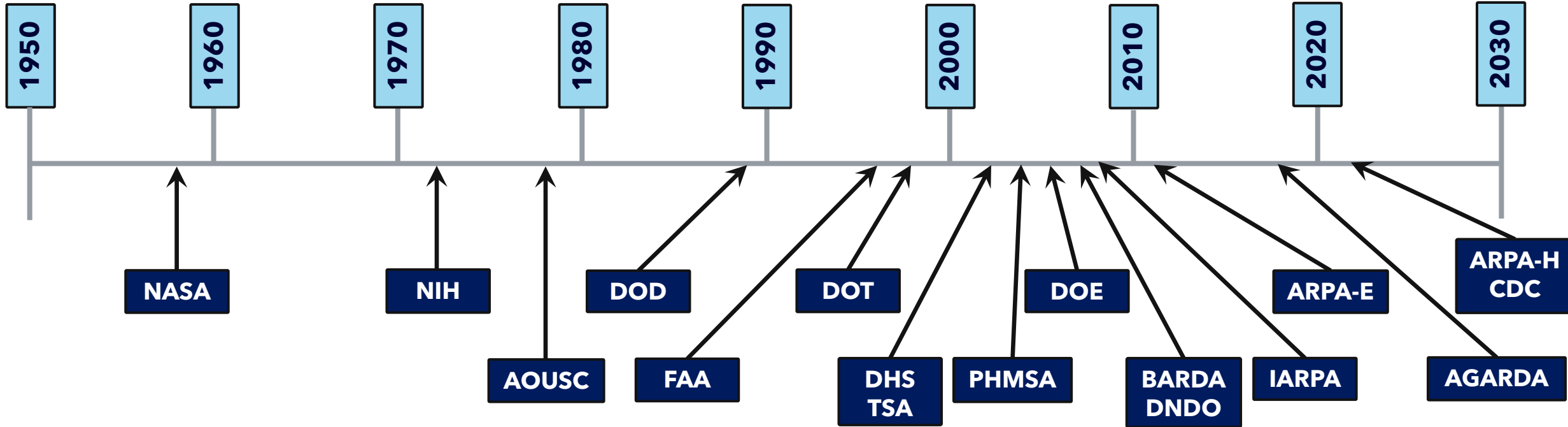| Laws & Regulations that Apply to OTs	
False Claims Act – 31 U.S.C. § 3729	Antideficiency Act (ADA) – 31 U.S.C. § 1341/1342/1517
False Statements – 18 U.S.C. § 1001	Restrictions on Obtaining and Disclosing Certain Information (formerly Procurement Integrity Act) – 41 U.S.C. § 2101, et seq.
Civil Rights 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

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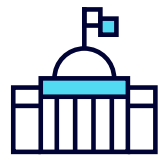
OTs – What Laws and Regulations Do Not Apply?

Laws & Regulations that Do Not Apply to OTs	
Competition in Contracting Act (CICA) – 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)

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Gov't Entities with OT Authority

Review of OT Authorities (1 of 6)

U.S.C. Reference	Organization	Authority Details / Highlights
6 U.S.C. § 391(a)* * Pilot program (authority available until 9/30/2024)	Department of Homeland Security (DHS)	- Permits OTs for basic, applied, and advanced R&D projects or prototype projects exercising the same authority with respect to projects the DoD may exercise (reference 10 U.S.C. § 4021 and 10 U.S.C. § 4022) - Requires a determination that a contract, grant, or cooperative agreement is not feasible or appropriate - Requires annual report to Congress on authority use
7 U.S.C. § 3319k** ** Pilot program (authority terminated on 12/21/2023)	Agriculture Advanced Research and Development Authority (AGARDA) – within Department of Agriculture	- Permits OTs for advanced R&D of agricultural technology, qualified products and projects, and research tools - Prioritizes projects: 1) that address critical R&D needs for technology for specialty crops or 2) prevent, protect, and prepare against intentional and unintentional threats to agriculture and food - OT authority shall be used in the same manner and subject to the same terms and conditions as DoD OTs under 10 U.S.C. § 4021 - May negotiate terms for technology transfer in the same manner as a Federal laboratory - OT use requires Performers to make all data relating to or resulting from the activities available on an ongoing basis - May use milestone-based awards and payments and terminate a project for not meeting technical milestones

Review of OT Authorities (2 of 6)

U.S.C. Reference	Organization	Authority Details / Highlights
10 U.S.C. § 4021	Department of Defense (DoD)	- Permits OTs for basic, advanced, or applied research - 50/50 resource sharing to maximum extent practicable (default position) - Research conducted should not duplicate research done by other DoD programs
10 U.S.C. § 4022	Department of Defense (DoD)	- Permits OTs for prototype projects and follow-on production efforts - Requires competition to the maximum extent practicable - Four possible conditions for use (at least one nontraditional defense contractor (NDC), all significant participants are small businesses or NDCs, 1/3 resource sharing, or exceptional circumstances as determined by SPE) - Written determinations required for OTs > $100M - "Successful completion" a prerequisite for follow-on production efforts - Competition may not be required for follow-on production efforts
28 U.S.C. § 604	Administrative Office of the United States Courts (AOUSC)	- Enter into and perform OTs as the Director may deem appropriate as may be necessary to the conduct of the work of the judicial branch of Gov't

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Review of OT Authorities (3 of 6)

U.S.C. Reference	Organization	Authority Details / Highlights
42 U.S.C. § 284(n)	National Institutes of Health (NIH)	- Permits OTs for projects that carry out the Precision Medicine Initiative - Cannot use > 50% of annual appropriations available through the Common Fund (funding for bold scientific programs) - Intended for high-impact 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 - Requires approval by NIH Director for each use of authority - Requires annual reporting to NIH Director for each project
42 U.S.C. § 285b-3(b)(3)	National Heart, Lung, and Blood Institute (NHLBI) – an NIH institute	- Specific OT authority for National Heart, Blood Vessel, Lung, And Blood Diseases and Blood Resources Program - Permits OTs necessary in the conduct of the NHLBI Director's functions
42 U.S.C. § 287a(e)(3)(C)	National Center for Advancing Translational Sciences (NCATS) – an NIH center	- Permits OTs for research projects in support of the Cures Acceleration Network Program - An option if goals and objectives cannot be adequately carried out by contract, grant, or cooperative agreement - Cannot use > 20% of annual appropriations available for funds specifically designated to the program

Review of OT Authorities (4 of 6)

U.S.C. Reference	Organization	Authority Details / Highlights
42 U.S.C. § 242c(e)(1)	Centers for Disease Control and Prevention (CDC) – an HHS operating division	- Permits OTs for the purposes of infectious disease research, biosurveillance, infectious disease modeling, and public health preparedness and response - Written determination required for any OTs expected to cost > $40M - Requires establishment of guidelines and auditing requirements regarding OT use
42 U.S.C. § 247d-7e	Biomedical Advanced Research and Development Authority (BARDA) – part of ASPR (an HHS operating division)	- Can be used for projects supporting BARDA's mission/goals and to respond to public health emergencies - Intended to promote: 1) innovation in technologies that's may assist with countermeasure and advanced R&D; 2) research on and development of research tools/devices/technologies, and; 3) research to promote strategic initiatives - Requires competition to the maximum extent practicable - Written determination required for any OTs expected to cost > $100M

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Review of OT Authorities (5 of 6)

U.S.C. Reference	Organization	Authority Details / Highlights
42 U.S.C. § 290c	Advanced Research Projects Agency for Health (ARPA-H) – part of HHS	- Requires competition to the maximum extent practicable - Requires an approved written determination for each use of the authority - Requires annual reporting to ARPA-H Director for each project - Prioritize awards to entities that will conduct work in the US
42 U.S.C. § 7256	Department of Energy	- Permits OTs for research, development, and demonstration projects exercising the same authority with respect to projects the DoD may exercise (reference 10 U.S.C. § 4021 and 10 U.S.C. § 4022) - Requires competitive, merit-based selection procedures - Requires written determination that the use of a standard contract, grant, or cooperative agreement is not feasible or appropriate - Requires annual report to Congress on OT use
49 U.S.C. § 106(l)(6)	Federal Aviation Administration (FAA)	- Permits OTs to carry out the functions of the Administrator or Administration
49 U.S.C. § 114(m)	Transportation Safety Administration (TSA)	- Permits OTs for the same purposes as provided to the FAA

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Review of OT Authorities (6 of 6)

U.S.C. Reference	Organization	Authority Details / Highlights
49 U.S.C. § 5312(b)	Department of Transportation (DOT)	- Permits OTs for projects and activities to advance innovative public transportation R&D - Requires an annual report of project activities to be made available on DOT's public website - Gov't share of costs may not exceed 80% (exceptions apply)
49 U.S.C. § 601	Pipeline and Hazardous Materials Safety Administration (PHMSA)	- Permits OTs for the development, improvement, and promotion of one-call damage prevention programs, research, risk assessment, and mapping
50 U.S.C. § 3024(n)	Director of National Intelligence (DNI)	- Permits OTs for basic, applied, and advanced R&D projects or prototype projects exercising the same authority with respect to projects the DoD may exercise (reference 10 U.S.C. § 4021 and 10 U.S.C. § 4022) - OTs cannot exceed $75M - Requires annual reporting to Congress on use of the authority
51 U.S.C. § 20113(e)	National Aeronautics and Space Administration (NASA)	- Permits OTs for the conduct of the Administration's work

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Business Strategy & Approaches

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Disclaimer

We provide general information and details for some elements of the OT process; however, please adhere to local Agency-level policies and guidance, when required, on certain topics:

- Approaches

- Payment structures

- Resource sharing

- Intellectual property (IP)

- Property

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OT Process (General)*

1 Identify Need or Problem → **2** Form Project Team and Draft Business Strategy → **3** Conduct Market Intelligence

6 Evaluate and Select Performer(s) ← **5** Solicit Opportunity ← **4** Finalize Business Strategy

7 Award OT(s) and Report Award Data → **8** Manage Performance (modify OT(s) as needed) → **9** Close-Out OT(s)

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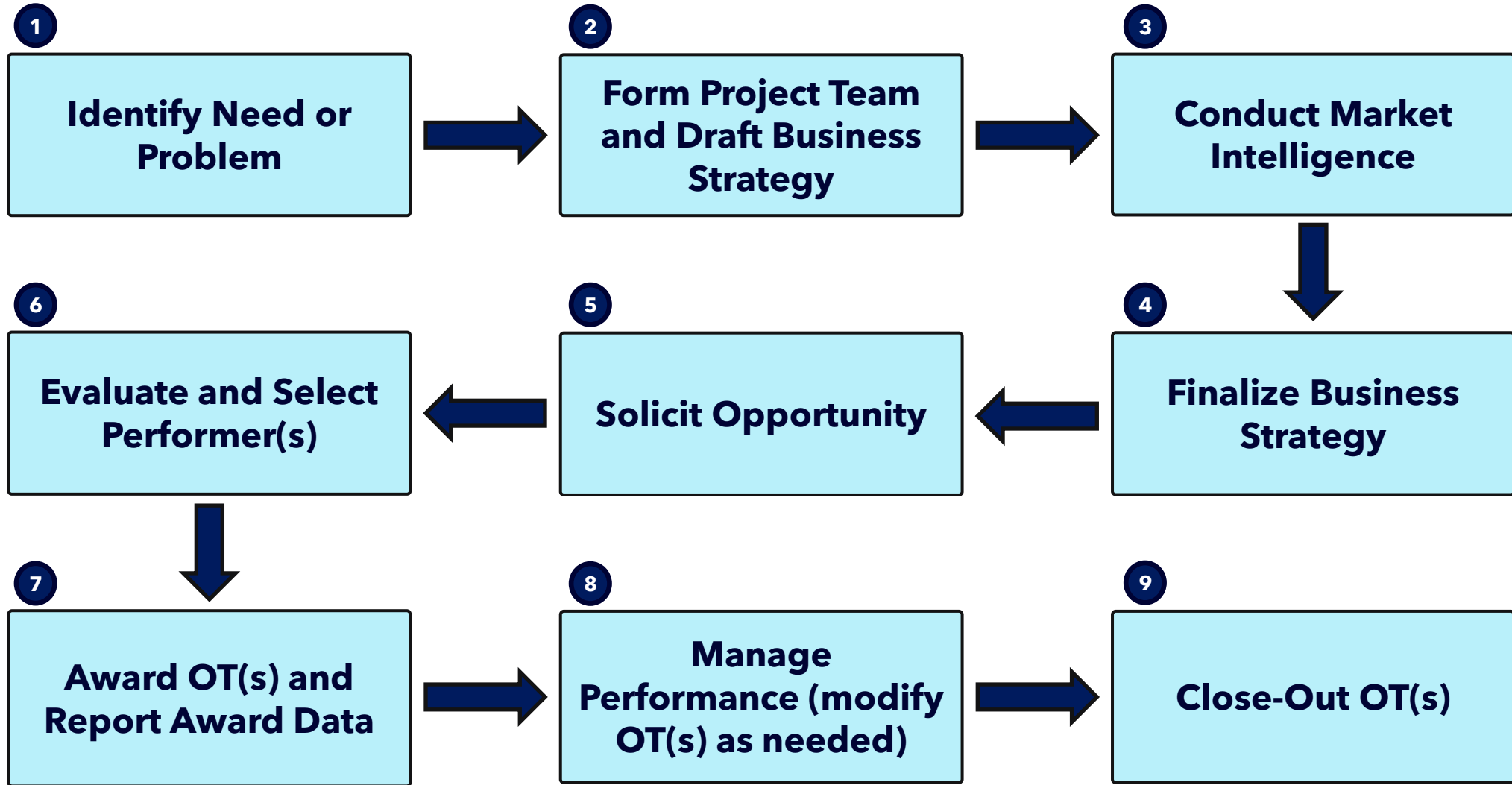
* Each OT will possess unique characteristics

Business Strategy

- The culture of requirements generation is part of the Federal Gov't affordability problem

- The key to using the Tool Box is understanding what impediments exist and what tool will best address the current situation
  - Analyze the pros, cons, and risks of potential approaches
  - Verify that preferred approach is compliant with applicable statutes and OTA

- Gov't teams must involve all relevant personnel from various disciplines as early in the planning stages as possible
  - Contracts, Technical, Legal, Finance, industry, etc.

- Market research per FAR Part 10 does not apply, so creatively leverage outreach activities based on the need and technology area

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Business Strategy (cont.)

- **Industry has an important role to plan and can provide valuable information and insight to the Gov't team**
  - Early involvement can help determine program/project direction
  - Identify requirements barriers
    - What the Gov't needs
    - How the Gov't inspects
    - What the Gov't desires as a deliverable
  - Identify teaming barriers
  - Overcoming preconceived notions of Gov't requirements
  - Demonstrate business norms in the technology sector

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OT Approaches – Potential Pathways*

1. Open Announcement → award(s) via a Broad Agency Announcement (BAA) or other merit-based solicitation (usually covering a wide array of scientific or technology areas)

2. Direct → award(s) via a specific scientific or technology area

3. Consortium → award(s) via existing or new consortium management firm

4. "Stacking" Authorities → award(s) in conjunction with another authority (i.e., Prize Challenges via 15 U.S.C. § 3719)

5. Cosponsoring projects → award(s) by or in conjunction with another gov't entity (common goals/interests)

* The above are not intended to be limiting...be creative in your approach

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Soliciting Opportunities

- **Plainly word program/project solicitations**
  - Include a detailed discussion of the entire program/project plan, including all phases and follow-on potential, schedule, budget, management processes, and risks
  - Consider issuing a draft solicitation for industry to review and provide comments
    - Include any true requirements
    - May include notional Task Description Document (TDD) or Statement of Work (SOW), payable milestone, deliverables
    - Include a draft agreement with the Gov't preferred terms and conditions
  - Remind potential Proposers that everything (except for any true requirements) is negotiable
    - Emphasize that the notional TDD, milestones, and agreement terms are offered to give them somewhere to begin
    - Industry is expected to design and propose their solution to the problem
- **Consider holding an Industry Day event (aka Proposers Day), especially if the Gov't or the potential Performers are new to OTs**
  - Publish the draft solicitation and FAQs prior to event
  - Allow the questions and even private (one-on-one) breakout sessions
  - Think of ways to facilitate attendee networking for teaming purposes

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Soliciting Opportunities (cont.)

- **Remain fair and transparent throughout process**
- **Creatively announce/market/post opportunities:**
  - SAM.gov
  - Gov't website
  - Proposers' day events / Reverse industry day events
  - Industry resources:
    - Conferences / conventions / seminars / trade shows
    - Trade publications (magazines, blogs posts, internet articles)
    - Technology demonstrations
  - Social media (commensurate with Gov't policies):
    - LinkedIn
    - X (Twitter)
    - YouTube
    - Facebook

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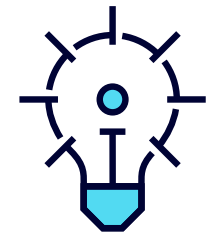
Soliciting Opportunities (cont.)

- **Creatively announce/market/post opportunities (cont.):**
  - Technology Scouting events
  - Standards committee (e.g., FDA)
  - Communities of interest events
  - Crowdsourcing events / surveys
  - Academic institutions (outreach and research departments)
  - APEX Accelerators (formerly Procurement Technical Assistance Centers)
  - Industry associations

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Selection Process

- **Come up with any process that works well for you organization and results in the receipt of quality proposals**
  - Not required to use the processes in the FAR (Parts 13, 15, or 35), but can incorporate useful aspects
  - Keep the process streamlined and simple (put yourself in the potential Performer's position)
  - Key aspects to include in any selection process:
    - Give the Offerors detailed notice in the solicitation
      - Clearly describe the selection process to the Offerors
      - Clearly describe what is expected from the Offerors
      - Include evaluation factors and stick with them
    - One big difference is the level of documentation
      - Evaluator consensus report to the Selection Authority may be the sole documentation describing the detailed technical, cost, and management evaluation and deliberations
      - Selection Authority's ultimate decision will be documented in a separate memo

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Selection Process (cont.)

- **Consider the following options (where appropriate) to engage industry and maximize interest:**
  - Panel pitches / oral presentations
  - Rolling down-selections
  - Video proposals
  - "Shark Tank"-like presentations
  - Technology demonstrations
  - Hackathons
  - Innovation workshops

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Rolling Down-Selections

No issue of scope or competition issues as the program/project continues since OTs are not subject to CICA

Programs/projects can be structured into phases <u>without</u> having to pre-negotiate options at the time of award – additional phases will be negotiated and included in the agreement at the end of the prior phase

Advantages

- Allows the negotiation process to move more quickly
  - In earlier phase, the terms and conditions are simpler or some can be deferred
  - Cost/price is generally lower and easier to estimate
- Allows the Gov't to watch and learn during each phase before soliciting for the next phase
- Maintains the Gov't competitive leverage until later in program/project
  - Low dollar value initial phases allows for award to multiple competitors
  - Puts off the decision of "the winner" until later in the program
- Allows for discrete programmatic decision points

Disadvantages

- Can be time-consuming to track multiple teams, issue multiple solicitations, and/or renegotiate at various decision points
- Too much work for small programs/projects

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Sample Structure of a Rolling Down-Select

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Phase I

- **Scope** = Design concepts and/or trade studies

- **Duration** = Generally shorter duration (i.e. less than 12 months)

- **Payment terms** = Often payable milestones with fixed Gov't obligation

- **Terms and Conditions** = Usually simple and flexible/little need to address difficult negotiation issues yet like IP rights as long as competition is maintained

- **Awards** = Multiple

Phase II

- **Scope** = Detailed design

- **Duration** = Generally longer duration (often12 months or more)

- **Payment terms** = Milestone payments are often the most reasonable/specific approach should consider program, cost and technical risks

- **Terms and conditions** = If there's still on-going competition, terms will be more detailed but many difficult negotiation issues (i.e. IP) may not be addressed/finalized

- **Awards** = Multiple

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Phase III

- **Scope** = Prototype build

- **Duration** = Will depend on the complexity and number of prototypes (often 12 months or more)

- **Payment terms** = Milestone payments often still most reasonable/specific approach should consider program, cost and technical risks

- **Terms and Conditions** = Terms and conditions must be fully negotiated before competition leverage is lost

- **Awards** = One

Phase IV

- **Scope** = Test and Evaluation

- **Duration** = Usually based on negotiated test plan

- **Payment terms** = Fixed price with incentives or reasonable approach to address risk

- **Terms and Conditions** = No additional terms generally needed

- **Awards** = One

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Phase V

- **Scope** = Fabrication of additional prototypes or production quantities

- **Duration** = Dependent on complexity and quantity

- **Payment terms** = Firm fixed price, payable milestones

- **Terms and Conditions** = If any, additional terms might be necessary relating to production

- **Awards** = One

Phase VI

- **Scope** = Life-cycle operations and support

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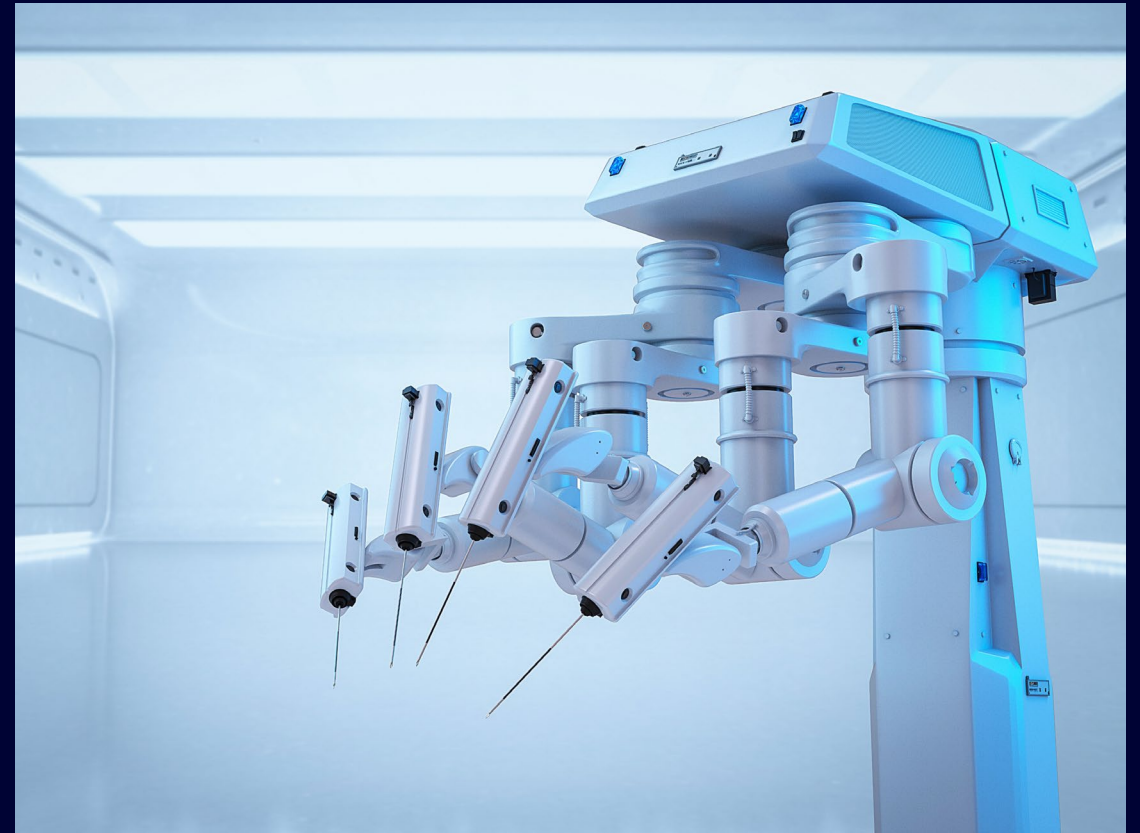
Value Analysis

Why is Analysis Important?

- **The Gov't must be responsible stewards of taxpayer dollars, even with OTs**
- **In general, there are no required analyses techniques for OTs**
- **Analysis is required for any type of award where funding is involved**
- **AOs are responsible for evaluating the proposed price/costs to ensure the final price/costs are reasonable**
- **The Gov't negotiation position may be formed by technical analysis performed by the Program Manager and analysis of value/costs/price by the AO**
- **Various analyses types:**
  - Value analysis
  - Cost/price analysis
  - Technical analysis
- **Solicitations should reflect planned analysis as much as possible**

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Cost Analysis and Cost Realism

- Cost analysis → the evaluation of separate cost elements and profit or fee in a proposal to determine a fair and reasonable price or to determine cost realism, and the application of judgment to determine how well the proposed costs represent the proposed scope of work

- Cost analysis is performed on cost elements such as:

Direct Labor Cost	Subcontractors	Travel
Materials	Profit/Fee	

- Contracting personnel seek advice technical experts (PMs and AORs) by the way of technical/analysis and completed for all instrument types (new awards, effort changes, and cost growths)

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Technical Analysis

- **Should be performed by personnel with expertise in engineering, science, or management**

- **Should examine proposed elements that require technical expertise to determine whether costs are reasonable**

- **Potential elements or components:**
  - Direct labor
  - Material, equipment, and other direct costs
  - Subcontracts
  - Travel
  - Profit or fee
  - Non-cost elements

- **Should note any technical issues that will be need to be resolved during negotiations**

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Price Analysis

- **Price analysis → the process of examining and evaluating a proposed price without evaluating its separate cost elements and proposed profit**

- **Preferred methods**
  - **Competitive pricing**
  - **Historical pricing**

- **Alternative methods (independent government estimate, parametric method, price lists, etc.)**

- **Value analysis**

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Value Analysis: What is it?

Method to determine the Gov't receives <u>at least</u> $1 in value for every $1 of taxpayer money spent (i.e., a reasonable price) without considering the make-up of each $1 or using other price analysis techniques (e.g., competitive pricing)

Way to formalize analysis contracting professionals perform (consciously and subconsciously) when they spend their own money
- If I decide to go out for dinner, how do I decide which restaurant?
- Afterwards, what makes me feel like it was a good choice, like I received a good value?

Well-suited for OTs

Strongest in conjunction with other analysis techniques
- Price or cost analysis of specific elements of total price (e.g., labor rates proposed with market sources)
- For FAR procurements, it <u>must</u> be used in conjunction with other price analysis techniques
- For OTs, there are no requirements to use other techniques

While subjective in nature, look for ways to quantify objectively, and above all else; be able to tell the story of why what you have identified results in value to the Gov't

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Possible Value Analysis Approaches

When strategizing for each project/program and the associated technical requirements (e.g., technical area metrics), consider the following:

Intellectual property

Impact on the organization/mission

Milestones/schedule to develop the solution

Innovation and scientific merit of solution/science

Resource share (inherent value because we don't pay the full $1)

Anticipated life cycle costs of the solution

Commercial efficiencies

The above is not all encompassing; and whatever is chosen is ideally quantitative as well as qualitative (e.g., calculating ROI rather than simply speculating about qualitative benefits).

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Implementing Possible Approaches

- **Which areas of value do you intend to target?**

- **What information do you <u>need</u> from proposers to perform this analysis?**

- **What areas might you evaluate outside of your value analysis? (e.g., cost element analysis)**

- **Plan to structure your solicitation accordingly, recognizing the Gov't must follow whatever approach is articulated in the solicitation.**

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Technical Analysis for OTs

- Value analysis is best accomplished with help and information from technical experts

- Often, market intelligence and understanding of the value of Government funding for a particular effort or program has already been accomplished

- Technical experts may be able to provide information on:
    - Why a proposed effort (specific solution) merits funding
    - Why the overall program (big picture) was deemed worthy of Government funding
    - Current state vs. potential savings or improvements
    - The impact and how is this beneficial for the American people

- Work with program/technical experts early and throughout the acquisition process

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Payable Milestones

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Payment Structures

- **Two <u>broad</u> OT types:**

  - Fixed price → Payments <u>not</u> based upon amounts generated from the Performer's financial / cost records

  - Cost-based → Payments based upon amounts generated from the Performer's financial / cost records

- **OT types and payment structures are negotiable (not a one-size-fits-all)**

  - Apply good business sense

  - Document OT type and payment structure within agreement file

  - Identify the basis and procedures for payment within OT articles

  - Schedule, delivery, performance incentives are allowable

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Payment Structures

Considerations when setting up a payment structure...

Nature of the agreement
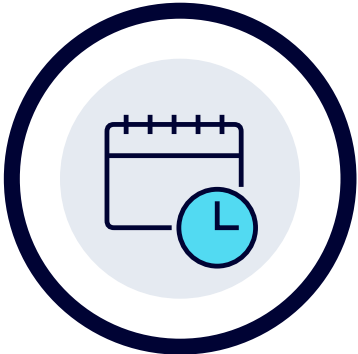
State or phase of the project/program

Risk or complexity involved

Established milestones

Performer's accounting system
- Consider the Performer's current accounting system capabilities
- Avoid imposing system requirement that cause the Performer to revise and/or add system(s)

- Performer registration generally required in existing Gov't procure-to-pay applications for payment processing (i.e., PMS, PIEE, etc.)

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Payment Structures – Payable Milestones

- **Why create a different payment methodology for OTs?**
    - There is a concern in the private sector over the way the Gov't pays
        - Firm Fixed Price
        - Cost Reimbursement

- **The Gov't needed to foster a new relationship with industry that included getting them paid more quickly and using their own internal systems/processes**

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Milestone Payments

- **Methods to finance the Gov't's share of agreement expenditures**
  - Similar to progress payments
  - May help the Performer with cash flow needs
  - Management tool to verify observable achievements on the critical path to ensure OT success
  - Reduce administration burden
  - May be non-consecutive, conditional, contingency-based, incrementally funded, or designed in any other manner or combination of manners
  - May include priced options

- **Teams shall clearly document the milestones in the agreement**

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Milestone Payments (cont.)

- **Milestones should typically reflect observable technical events or other key actions**
  - Generally quarterly events (i.e., kick-off, management reviews, technical reports, final report)
  - Some activity significant to the progress of the project/program
- **Each milestone has a value that is negotiated at the time of award**
  - Value typically based on a good faith estimate to reach the milestone
  - Milestones may have to be prospectively adjusted as project progresses
- **Payment is dependent on achieving the associated milestone**
  - Achievement of milestones does not necessarily mean the technology or event was successful
  - Establish exit criteria for each milestone
  - Focus on the necessary effort to reach the milestone and perform the event
  - Even if the event or technology is a failure, the Performer should still be paid if they put in the necessary effort to be fully prepared

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Milestone Payments (cont.)

Fixed Milestones

- Each milestone amount is fixed at time of award
- If the Performer achieves the milestone, it is paid the milestone amount (regardless of actual cost)

Expenditure-based Milestones

- Milestones have an estimated amount, but payment may be based on actual costs
- If the Performer achieves the milestone, it is paid based on actual costs (actual payments may or may not match the milestone award amounts)
- Milestone award amounts may not match actual expenditures at the time payment is made

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Advance Payments

- OTs allow for advance payments (unless statutory language specifically prohibits use)

- Scenarios where advance payments may be appropriate:

Large, up-front expenditures required	Long-lead items involved	Aggressive project/program schedule and associated milestones	Performers (typically small companies) without sufficient/ regular cash flow

- Exercise sound business judgement before allowing advance payments

- Document if advance payments are used (within agreement file and agreement articles)

- If advance payments are used, address interest earned and the need to establish an interest-bearing account

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Milestone Payment Example

Milestone	Task(s)	Due Date (**Months after award**)	Milestone Definition	ARPA-H Payment
1	10	1	**Kickoff and Program Management** *Exit Criteria:* • Attend kick off meeting • Complete hiring of all required personnel; subcontract negotiations underway *Deliverables:* • Kickoff slides/materials • Project Plan for all tasks deliverables across milestones. • Report on progress of subcontract awards **(DATA RIGHTS)**	$50K
Appropriation Data/Funding amount:				
2	4	3	**Commercialization Plan** *Exit Criteria:* • Meeting with Government Team to develop commercialization strategy • Up to date on technical status reporting requirements *Deliverables:* • Report detailing initial commercialization & marketing plan **(DATA RIGHTS)**	$100K
Appropriation Data/Funding amount:				

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Milestone Payment Example – Advance Payment

Milestone	Task(s)	Due Date (**Months after award**)	Milestone Definition	ARPA-H Payment
1	10	1	**Kickoff and Program Management** *Exit Criteria:* • Attend kick off meeting • Complete hiring of all required personnel; subcontract negotiations underway *Deliverables:* • Kickoff slides/materials • Project Plan for all tasks deliverables across milestones. • Report on progress of subcontract awards **(DATA RIGHTS)**	$300K
Appropriation Data/Funding amount: $300K				

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Milestone Payment Example – Incentive Payment

Milestone	Task(s)	Due Date (**Months after award**)	Milestone Definition	ARPA-H Payment
3a	1, 2, 3	4	**Initial Design of "X" technology** *Exit Criteria:* • Completed design, validation, and optimization of "X" technology • Up to date on technical status reporting requirements *Deliverables:* • Report detailing the validated technology • Phase 1 Final Report **(DATA RIGHTS)**	$245K
Appropriation Data/Funding amount:				
3b	1, 2, 3	6	**Initial Design of "X" technology** *Exit Criteria:* • Completed design, validation, and optimization of "X" technology • Up to date on technical status reporting requirements *Deliverables:* • Report detailing the validated technology • Phase 1 Final Report **(DATA RIGHTS)**	$215K
Appropriation Data/Funding amount:				

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Resource Sharing

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Resource Sharing

- May be required as a condition for OT use:
  - DoD research OT has a default 50/50 going-in position but that can be adjusted based on the circumstances
  - DoD prototype OT requires 1/3 of project costs to be paid by parties other than the Gov't if other statutory conditions not met
  - DoT only allows Gov't to cover 80% of project costs (exceptions apply)
- Could be leveraged depending on the Performer's commitment to pursue the technology into commercialization
- Resource sharing requirements should differ based on unique project characteristics and Performer circumstances
- Should make good business sense
- Can be easier with fixed amount agreements
- Offeror/Performer does not get profit/fee when there's resource sharing

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Resource Sharing (cont.)

- **Should be evidence in Offeror's proposal of its commitment to and self-interest in project success**
  - May reduce the need of level of Gov't oversight
  - Reflected in resource share proposals

- **Instances when resource sharing may <u>not</u> be appropriate:**
  - To attract participants, particularly small businesses or innovative entities
  - Unusual technical or business risks expected with project
  - Performer has limited investment or involvement with prior projects related to focus area
  - The Gov't has inadequate budgets for planned efforts and is relying on industry to provide funding
  - Uncertainty with regards to technology's dual-use

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Resource Sharing (cont.)

- **If resource sharing is used:**
  - The Offering Team must meet the requirement as a whole (does not need to be uniformly imposed on all Offeror team members)
  - The Gov't's primary goal should be resource sharing (not resource matching)
  - Involve assets that will be used in the project performance (not just items with inherent value)
  - Expectations should be as straightforward and clear as possible to all parties (clearly defined within articles and other agreement documents as needed)
  - Offerors do not get profit/fee
- **Two components of resource sharing:**
  - Cash: funds/outlays to support the project
  - In-Kind: reasonable value or equipment, materials, or other property used in the performance of the work to be done under the OT

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Resource Sharing (Cash)

- **Components**
  - Direct labor
    - Benefits
    - Direct overhead
  - Materials expense

- **Sources:**
  - Profit or fee from another Gov't contract
  - Overhead or capital equipment expense pool

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Resource Sharing (Quality of Sources)

Quality Rating	Resource Sharing Sources
High	- Cash - Other liquid assets
Moderate	- In-kind commitments of resources - Fair market value of facilities and equipment dedicated to project
Low	- Non-dedicated personnel - Non-dedicated in-kind
Poor	- Cash which availability is not clearly or convincingly demonstrated - In-kind which availability is not clearly or convincingly demonstrated

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Teaming

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Teaming

- **In complex acquisitions or programs/projects, it is rare that a single Performer can accomplish all tasks**

- **Performers come together to accomplish a project for a variety of reasons**

  - Most common reason is to make money

  - Goal may also be to create strategic alliances (short-term or long-term) in both Gov't and commercial sectors

- **Commercial companies often work together in structures based on two different sets of market forces**

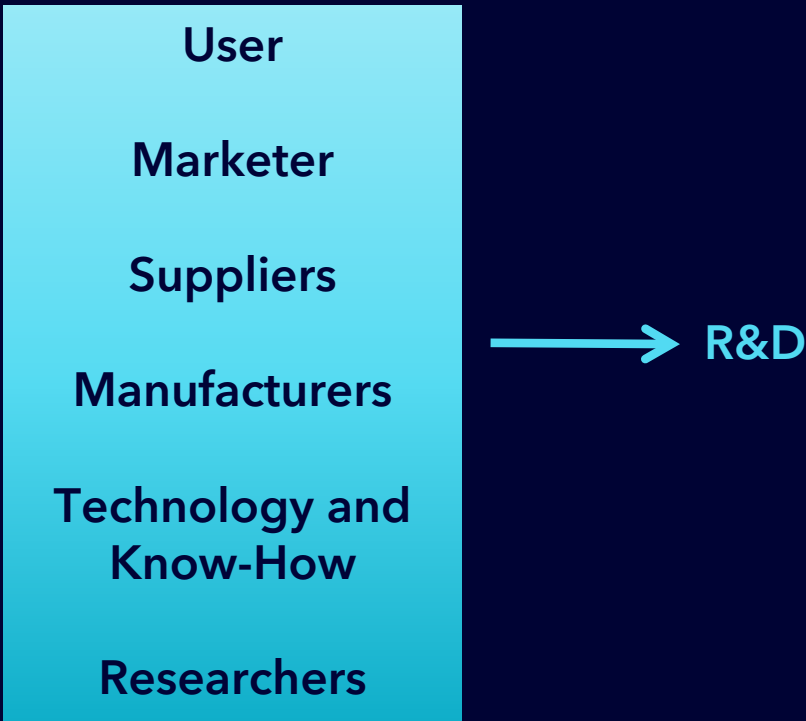ARPA**H**

Teaming Structures

Horizontal

- Multiple competitors who come together to accomplish a common goal or solve a common problem
- Resources plentiful, but trust may be an issue

| T1 | T2 | T3 | T4 | T5 |

R&D

Vertical

- Multiple performers who each play a role at a different stage of a product's life-cycle
- Symbiotic relationships, but time may be an issue

User

Marketer

Suppliers

Manufacturers

Technology and Know-How

Researchers

→ **R&D**

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Teaming Structures (cont.)

There is a variety of team structures that might evolve but they tend to fall under three basic groupings

Prime/sub relationship

Partnership

Multi-party relationship

Each has its advantages and disadvantages

Some entities are more familiar to the Gov't

Some work better in certain types of arrangements

Some are easier to manage (either by the team itself or the Gov't)

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Teaming (Privity of Contract)

- Regardless of structure, before entering into an agreement, the Gov't needs to understand the legal relationship it will have with the Performer team

- A contract law doctrine that prevents any person from seeking the enforcement of a contract or suing on its terms, unless they are a party to the contract

- Privity of contract = the signatories to the contract are the parties and only they will be bound to the contract terms

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Privity of Contract in Prime/Sub Relationship

Gov't enters into a contract under federal law with prime contractor (single signatory)

Prime enters into commercial contracts under applicable state law with subs

As the only other party to the contract, prime is the only one responsible to the Gov't for performance

Gov't has no contractual relationship with the subs

Gov't contracts with the Prime

Prime contracts with the Subcontractor

No privity of contract between the Gov't and the Subcontractor

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Prime/Sub Relationships

Advantages

- The most familiar arrangement for most people
- There is one person that is clearly responsible to the Gov't
- There is only one person with whom to negotiate
- The prime is responsible for managing the subs and addressing any issues
- Only the prime can file suit with the Gov't

Disadvantages

- Creates an artificial separation between the Gov't and sub-tier participants
- If the prime does not perform, the whole thing falls apart
- If the prime does not manage the team well, it can either fall apart of the Gov't finds itself in the middle
- You cannot change leadership mid-program
- There is a cost to having a prime (pass-through fee)

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Privity of Contract with a Partnership

- Performer A and Performer B enter into a partnership relationship governed under state law
- Partnership becomes a separate legal entity and is treated like a separate person
- Both partners share jointly in the responsibilities and rewards of the partnership
- Gov't enters into a federal contract with the partnership
- Partnership enters into commercial contracts with the subs
- Gov't has privity of contract with the partnership – and by extension each partner
- Gov't has no privity of contract with the subs


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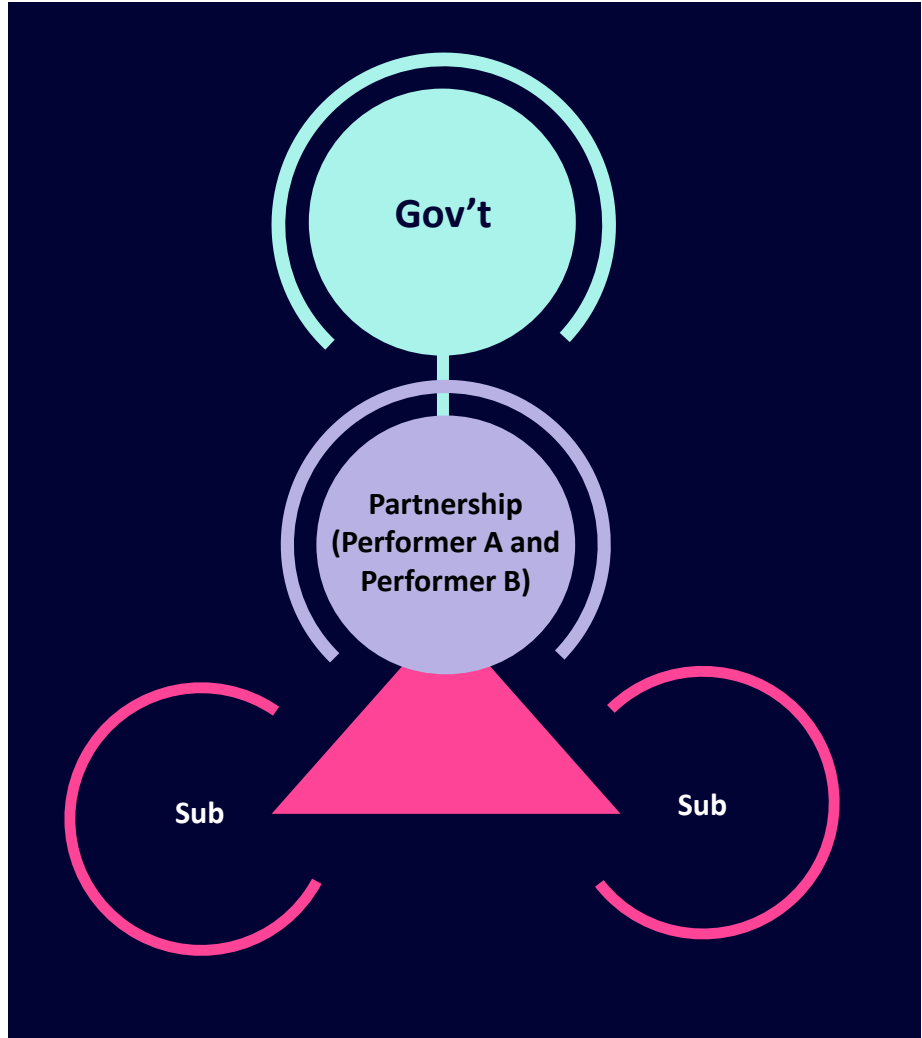
Partnership Relationships

Advantages

- The partnership is a legal entity so, in many ways, it's like dealing with a prime
- The partnership can leverage the resources and talents of all the partners
- The partnership determines how it will internally manage and present a united front to the Gov't
  - The terms of the partnership may allow new members to be added or some to leave the partnership
  - Leadership of the partnership can adjust and evolve with program progression
- The partners are generally jointly and severally liable for the partnership performance

Disadvantages

- The relationship of the partners can cause internal conflict(s)
  - If the partners are usually competitors, they may not easily share info or work between them
  - If the partners don't have an equal relationship – either in voting on partnership decisions or in benefits received – it can make for a difficult relationship
- The partnership needs to be established and formalized before negotiating with the Gov't (which can add time to the process)

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Privity of Contract with a Multi-Party Team

- Team membership and dynamics defined by a contract signed by all members (i.e., Article of Collaboration)
- Team elects one member to act as their agent with the Gov't or hires an administrative coordinator
- Gov't signs agreement with the team as a whole (the team agent actually signs the agreement)
- Gov't has direct privity with all team members
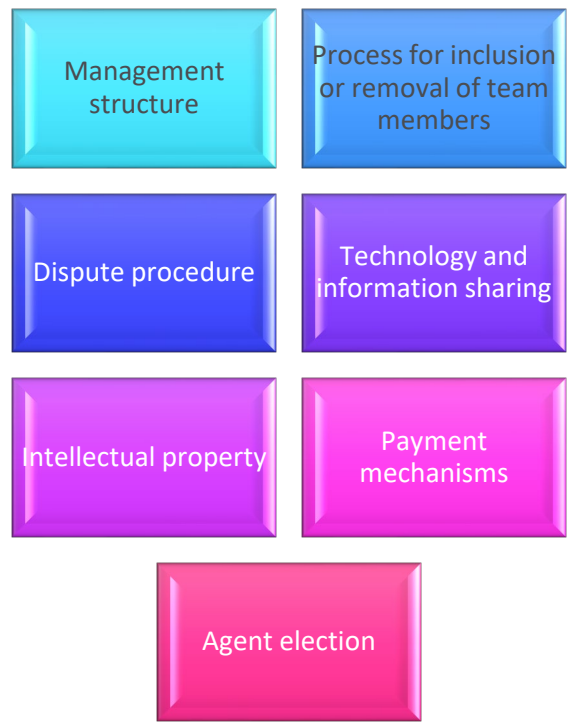

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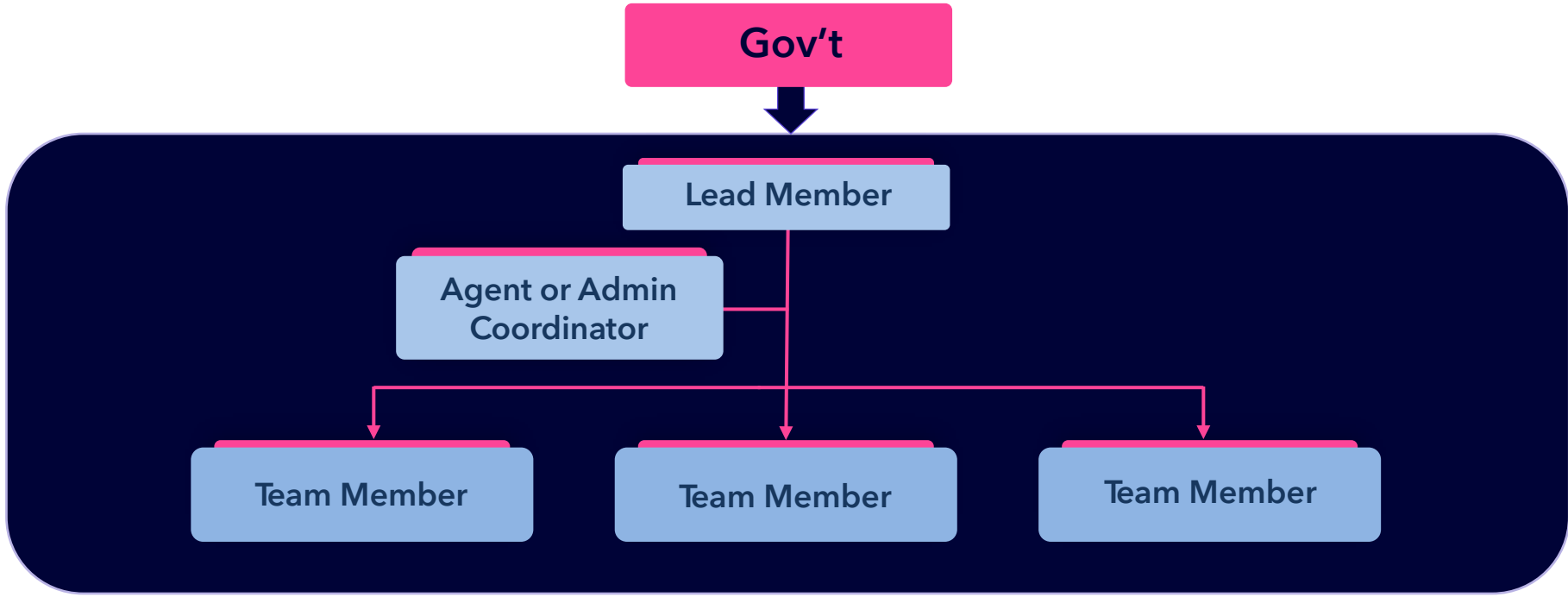
Multi-Party Relationship

Advantages

- Because the team has chosen to work together in a collaborative way, the hope is that the alliance will be advantageous to all members and continue past this agreement
- Since the Gov't has signed the agreement with the entire team, it can have technical insight and visibility into all levels of technical and management actions
- If any resource sharing is required or leveraged, it will come from the team as a whole (how they choose to allocate the resource sharing is up to them)
- Since the team is bound to the Gov't and responsible for performance, the responsibility is on the team to self-police the effort and quickly respond to issues
- Leadership of the effort can change as the effort evolves

Disadvantages

- While the teams as a whole is the party to the agreement and the Gov't has privity with all the members, it is still important that membership select a strong leader to maintain the vision and effort direction
  - Loose confederations and management by committee does not really work well
  - The larger the team membership, the more important strong leadership and management is
- This type of relationship is relatively unfamiliar to the Gov't and may cause some cultural problems

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Multi-Party Relationships – Key Attributes for Success

- The team/consortium does not have to be a legal entity (i.e., partnership, JV), but must be bound together legally before signing the OT with Gov't

  - This binding document will be some type of teaming agreement or Article of Collaboration (includes a set of terms/procedures which will govern the activities and relationships of the participants in the team and how they will interact as a group with Gov't under the agreement)

  - The Gov't is <u>not</u> a party to the document and should <u>not</u> dictate its terms

    - It's a commercial arrangement

    - At most, we want to know it's been signed and that the Gov't does not have any responsibilities under it

- The binding document needs to be in place and executed by the members before the agreement with the Gov't can be signed

    - Ideally it should be in place prior to negotiations with the Gov't

    - The team needs to address how risks, rewards, and responsibilities will be handled internally before they can effectively negotiate terms with the Gov't

Management structure	Process for inclusion or removal of team members
Dispute procedure	Technology and information sharing
Intellectual property	Payment mechanisms
Agent election	

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Multi-Party Relationships – Consortia or Team

Multiple performers form one consortium usually to focus on a singular goal, different performers may focus on different aspects of performance

Participating teams agree on (and sign) articles of collaboration or teaming arrangement (forming the consortium)

Consortium usually appoints a lead member (may be primary point of contact for administration, performance, payments, etc.,)

Why might this teaming structure be beneficial?

Programs may have different aspects (phases/stages/complexity), requiring different types of performers to work together

Consortium may be fluid – membership can change, lead member can change

Consortia will generally self-police performance

Contract administration is streamlined

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Teaming Examples*

- Gov't IDIQ Consortia
  - Gov't Sponsor, Consortium Manager, and Consortium Members
- Gov't non-IDIQ Consortia
  - Gov't Sponsor and Consortium Members (represented by a lead member)
- Airbus Industrie GIE
  - Comprised of four companies
- Hulu
  - Comprised of four companies

* Not all are organized under the "IDIQ" consortium model

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Teaming Best Practices

Generally, teaming works best if it's organic

Teams should generally "live" and flourish past Gov't funding and involvement

There may be reasons for the Gov't to dictate a particular structure, but teams tend to work together better if the decision is left to them

Gov't should not be "matchmaking" or "marriage brokering"

Gov't can encourage teaming via solicitations, Proposers' Days

Consider flexible teaming arrangements that may address different goals in different phases (as priorities shift during stages in a program or effort, consortia lead members may rotate in and out)

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Intellectual Property (IP)

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Intellectual Property (IP)

- An intangible creation of the human mind, usually expressed or translated into a tangible form, that is assigned certain rights of property

- Why is it important?
    - Protection of IP is one of the few specific topics mentioned in the US Constitution (Article I, Section 8, Clause 8) grants Congress the right to create the patent and copyright system
    - The Patent and Trademark Office and the Copyright Office in the Library of Congress are two of the oldest civilian agencies in the Federal Gov't
    - The Founding Fathers wanted authors and inventors to share their creative works with society at-large with the understanding that their rights in those works would be protected for a limited period of time

- What protects it?
    - A myriad of federal and state laws
    - As to traditional regulatory guidance, the FAR provides the main coverage of patentable inventions for all agencies

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Basic Protection Methods

Over the years, four basic IP protection methods have been created

Patent	Copyright	Trademark	Trade Secret
• Protects new, unobvious, and useful inventions • Can include utility, design, and plant/animal patents	• Protects original works of authorship embodies in a tangible medium of expression	• Establishes exclusive rights to use marks that distinguish one's goods and services from another	• Protects secret business information from unauthorized use or disclosure

In exchange for making IP public, authors and inventors are granted a limited monopoly to use their IP and prevent others from doing so within their permission

Once the limited monopoly expires, however, the IP becomes available to society for any one to use within restriction

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Patents

- To qualify for a patent, an invention must:
  - Be within the statutory subject matter
  - Be useful and novel
  - Not be obvious from the prior art to a skilled person
- Types of patents
  - Utility – covers processes, machines, and manufacturing methods
  - Design – covers visual ornamental characteristics of an item
  - Plant and Animal – covers asexually reproduced plants and animals
- What can't be patented?
  - Laws of nature or scientific principles (i.e., biology, chemistry, physics, math)

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Patent	Duration
Utility and Plant/Animal	20 years from application filing date (before 6/8/1995 → 17 years from issue date or 20 years from filing date)
Design	15 years from issuance (before 5/13/2015 → 14 years)

The Bayh-Dole Act

- Major statutory framework governing ownership and use of patentable inventions in Gov't contracts

- Passed in 1980 and codified at 35 U.S.C. § 202-204

- The original statutory language applies to nonprofits, including universities and small businesses

- In 1983, by executive order, the President extended coverage to large businesses

- Applicable to procurement contracts, grants, and cooperative agreements (not OTs)

- General policy of the Act

  - Promotion of commercialization and public availability of inventions created under Gov't contracts

  - Assurance that the Gov't would receive sufficient rights in the inventions for its use

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The Bayh-Dole Act (cont.)

- What rights does the Gov't get in the invention?
  - A license that is Federal Government-wide and:

Non-exclusive	Nontransferable	Irrevocable	Paid up
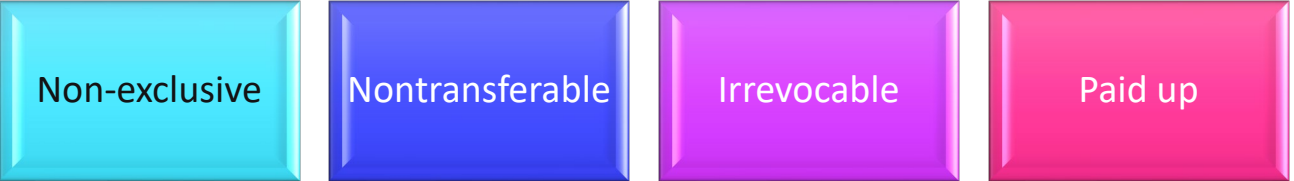
- What does the license allow the Gov't to do?
  - Practice the invention itself
  - Have it practiced for or on behalf of the Gov't throughout the world

- This type of license is commonly referred to as a "Government Purpose Right" (GPR)

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Copyrights

- What is covered under copyrights?
  - Original works of authorship embodied in a tangible medium of expression
  - Confers a bundle of rights

Reproduce the work	Make derivative works of the work	Distribute copies of the work	Publicly perform the work	Publicly display the work

  - The owner can give away one right in the bundle, any combination of rights, or the whole bundle

- Unique aspects of copyright
  - You can only copyright your expression of the idea (not the idea itself)
  - You cannot prevent someone else from independently creating and disseminating the work
  - Your work must be embodied in a tangible medium to be protected
  - To be protected it must be original
  - It can include published or unpublished works that are marked or unmarked
  - U.S. Gov't employees can never get a copyright for works created during their official duties

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Copyrights (cont.)

- Copyright is also unique in that the law allows for infringement in certain situations called fair use. Factors to consider if a use is "fair":

  - The purpose and character of the use (commercial vs. nonprofit vs. educational)

  - The nature of the work (factual vs creative/ published vs unpublished)

  - The amount and substantiality of the portion used in relation to the whole

  - The effect on the potential market for the work

Copyright	Duration
Works created after 7/1/1987	- Life of the author plus 70 years - For joint works, the 70-year period begins with whoever dies last
Works for hire (anonymous and pseudonymous)	- 95 years from first publication or 120 years from creation (whichever is shorter)

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License Rights Levels (FAR 27.4 and 52.227-14)

Type	Definition
Unlimited	Right to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permits others to do so.
Limited	Right of the Gov't in limited rights data as set forth in a Limited Rights Notice.
Restricted	Right of the Gov't in restricted computer software as set forth in a Restricted Rights Notice.

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What Rights Do You Get? (FAR 27.4 and 52.227-14)

Type	Description
Unlimited	- Data first produced in data first produced in the performance of the contract - Form, fit, and function data delivered under the contract - Data delivered under this contract (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under the contract - All other data delivered under the contract unless provided otherwise for limited rights data or restricted computer software
Limited	- Data (other than computer software) that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.
Restricted	- Computer software developed at private expense and that is a trade secret, is commercial or financial and confidential or privileged, or is copyrighted computer software, including minor modifications of the computer software.

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Regulatory License Rights Types – DoD Example

Type	Definition
Unlimited	Right to modify, reproduce, perform, release or disclose technical data in whole or in part, in any matter, and for any purpose whatsoever, and have or authorize others to do so.
Government Purpose (GPR)	Right to use, modify, reproduce, release or disclose the technical data or computer software within the Gov't without restriction and outside of the Gov't for a Gov't purpose.
Limited*	Right to use, modify, reproduce, release, perform, display, or disclose technical data, in whole or in part, within the Gov't.
Restricted**	Basically a shrink-wrap license. Right to: use a computer program with one computer at one time; transfer a computer program to another Gov't agency without permission of the Contractor if the transferor destroys all copies of the program and related computer documentation; make the minimum number of copies of computer software required for safekeeping (archive); backup or modification purposes; modify computer software; and permits contractors or subcontractors performing services in support of a contract to use computer software for correcting deficiencies.

* Applies only to technical data
** Applies only to noncommercial computer software

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What Rights Do You Get? – DoD Example

Type	Definition
Unlimited	- Data or software developed exclusively with Gov't funds - Software documentation required to be delivered under the contract - Studies, analyses, test data, and similar data produced by the contract - Form, fit, and function data (describing overall physical, functional, and performance characteristics of an item)
Government Purchase (GPR)	- Software, items, components, or processes developed with mixed funding - The Gov't gets GPR for five years or other negotiated period, after which the right converts to unlimited
Limited*	- Items, components, and processes developed exclusive at private expense - This category foes allow for release of Gov't support contractors and gives the owner the right to ask for NDAs executed directly with the support contractors
Restricted**	- Noncommercial computer software developed exclusively at private expense - This category does allow for release to Gov't support contractors and gives the owner the right to ask for NDA's executed directly with the support contractors

* Applies only to technical data
** Applies only to noncommercial computer software

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IP Coverage by Contracting Vehicle

Vehicle	FAR / HHSAR / Other	Bayh-Dole	2 CFR 200	Negotiable?
Procurement Contract	YES	YES	NO	Somewhat
Grant	NO	YES	YES	Somewhat
Cooperative Agreement	NO	YES	YES	Somewhat
OT	NO	NO	NO	YES

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Questions for Negotiations

- Who owns the invention?

- Does the performer or U.S. Gov't have the right to use the invention?

- If the U.S. Gov't has rights, what can they disclose?

- What does the U.S. Gov't intend to use the rights to do?

- What are the Offeror's commercialization plans/goals?

- What does the PM consider negotiable based on project/program objectives?

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Lessons Learned and Suggestions

- OTs allow for <u>complete flexibility and freedom</u> in negotiating rights
  - No statutory or regulatory requirements or restrictions
  - FAR/HHSAR/other regulations and statutes are not applicable, but may be leveraged

- Develop and document an IP strategy at project initiation
  - Capture IP rights in initial project phase(s) and consider long-term IP needs (commercialization)
  - Update IP rights as project progresses (as appropriate)

- Model OT IP Article for Patents and Data Rights
  - All aspects of the article are negotiable upon consideration of the project and Offeror's rationale
  - Typical "going-in" position:

| Notification of invention and patent election (for patents) | Definition of "data" (for data rights) | Definition of (negotiated) rights (for data rights) | March-in rights |

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Lessons Learned and Suggestions (cont.)

- Negotiation factors:
  - Allocation of rights may depend on the technology or pre-existing commercial rights or license
  - Become familiar with standard rights in the industry
  - Consider Offeror's investment through previous investments and resource sharing
  - Recall the goals of the Performer and Gov't as identified in an agreement vision statement and commercialization plan
  - Remember there are no standard approaches or required positions
  - Use a team approach (PM needs to identify what is key for project/program success and what is negotiable)

- Some items to consider:
  - Dealing with the Freedom of Information Act (FOIA)
  - Gov't support contractors

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Lessons Learned and Suggestions (cont.)

- During negotiations, the Gov't should consider leveraging IP rights for cost savings

- The level of IP rights offered by the Offeror can be considered in the evaluation of the overall business deal

- Remember that generally IP rights given to the Gov't live on forever (long after the OT agreement is over):

  - Consider the life-cycle of the technology, not the OT period of performance

  - Negotiate as complete an IP package when possible while the Gov't still has competitive leverage

- If the Gov't is flexible with regards to IP (or cannot be), be upfront and clear with industry and clearly articulate the Gov't's position in the solicitation

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Property (Government Furnished Property)

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Property

- **The term "property" means any tangible personal property other than property actually consumed during the execution of work under an OT**
  - Does not include IP
- **Background statutes and decision:**
  - Federal Property and Administrative Services Act (FPASA) of 1949 (P.L. 81-152), Title II
    - Disposal provisions apply
  - Federal Grant and Cooperative Agreement Act of 1977 (P.L. 95-224, as amended)
    - Applies to extramural activities
  - Comptroller General Decision (51 Comp. Gen, 162, 165 (1971))
    - Officers of the Gov't have no authority to give away money or property of the US
    - Per the FPASA, through the disposal process, property may be donated to state and local government, universities, and nonprofit entities
- **Title to Property – The Gov't is not required to, and generally should not, take title to physical property acquired or produced by a private party signatory to an OT, except property the agreement identifies as a deliverable (if any)**

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Property (General Considerations)

- **<u>Do not</u> take title to property under OT unless specifically necessary**
  - The Gov't is <u>not required</u> to take title to the property acquired or produced by the Performer
  - Focus on the OT deliverables
  - If possible, acquire property outside of the OT agreement
- **The majority of the OT funding should be used for labor related to the scientific/technical efforts**
- **Consider (whether known or expected in the future) if efforts will be fostered by the Gov't owning the property**
- **For OTs involving property, the Performer:**
  - Retains title and responsibility until delivery
  - Retains responsibility for day-to-day maintenance (assumes risk of loss) of the property until the delivery or agreement ends
  - May use commercial best practices to maintain the property
- **When funding an effort when property is acquired, the Gov't should delay taking title until the end of the agreement**

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Property (General Considerations)(cont.)

- **If the Gov't takes title to, or if the Gov't furnishes property (GFP) to the Performer, the OT agreement documents and terms should identify the following:**
  - List of property to be furnished for the performance of the OT
  - Entity responsible for maintenance, repair, or replacement of property
  - Entity liable for loss, theft, destruction of, or damage to property
  - Entity liable for loss or damage resulting from property use
  - Procedures for accounting for, controlling, and disposing of property*
  - Guarantees (if any) regarding the property's suitability for intended use

- **If the Performer provides physical property as in-kind for resource sharing purposes, the property will become a program asset, will need to be valued, and dispositioned upon agreement completion**

* Commercial property management systems can be used

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OT Resources

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Key OT Stakeholders and Responsibilities

- **Agreements Officer (AO)**
  - The warranted individual with authority to award, administer, modify, and terminate OTs (responsibilities are similar to those of a warranted Procuring Contracting Officer for procurement contracts)
- **Agreements Officer's Representative (AOR)**
  - The individual that assists the AO in the development and management of OTs and helps ensure performers meet the commitments of their OTs (responsibilities are similar to those of a Contracting Officer's Representative for procurement contracts)
- **Approval Authority**
  - The official with authority to approve the use of OTs
- **Performer**
  - The entity(ies) that is/are the signatory authority to an OT agreement and responsible for project performance
- **Sub-Performer**
  - An entity, other than the Performer, performing effort under an agreement via an arrangement with the Performer

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Key OT Stakeholders and Responsibilities (cont.)

- **Senior Procurement Executive (SPE)**
  - The official responsible for the procurement system and providing procurement authority (usually involves managing OT-related processes)
- **Program Manager (or Project Manager) (PM)**
  - The individual assigned to manage the OT (cost, schedule, and technical progress)
- **Project Team**
  - A team comprised of personnel from various functional areas with the shared objective to execute an OT project and achieve the project goals
- **Consortium Manager (or CMF)**
  - The entity that manages a consortium and serves as the primary interface between the Gov't and consortium members for an OT project (if applicable)

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OT Resources

- **ARPA-H's OT Community**
  - **https://arpa-h.gov/engage-and-transition/other-transaction-community**
- **National Contract Management Association (NCMA) Agile/Innovative Contracting Community of Practice (must be active NCMA member to join)**
- **DoD OT Guides (DoD-focused):**
  - **OTs Guide (2023)**
  - **Guide to Research OTs (2023)**
- **Defense Acquisition University's OT Community of Practice and Counsel Corner sites (DoD-focused)**
  - **https://www.dau.edu/cop/ot**
  - **https://www.dau.edu/events/ot-counsel-corner**
- **DARPA Acquisition Innovation site (DoD-focused)**
  - **https://acquisitioninnovation.darpa.mil**

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OT Resources

- **BARDA's OT Agreements site (BARDA-focused)**
  - **https://aspr.hhs.gov/AboutASPR/ProgramOffices/BARDA/Pages/Other-Transaction-Agreements.aspx**
- **NIH's OTs Guide – May 2017 (NIH-focused)**
- **NIH's OT Authority Training (Participant Guide) – Jan 2018 (NIH-focused)**
- **Department of Energy (DoE) OT Guide – Aug 2023 (DoE-focused)**
- **DoE OT site (DoE-focused)**
  - **https://www.energy.gov/management/other-transaction-authority**
- **MITRE's Current OT Consortia site:**
  - **https://aida.mitre.org/ota/existing-ota-consortia**

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Sample Agreement

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Conclusion

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Conclusion

- OTs are not a new contracting instrument, but opportunities for innovation remain

- Awarding more quickly may be a side effect of using OTs, but it is not the main reason to use the authority

- Organizations may not make OT awards faster (initially) than traditional procurement contracts

  - The organization must fully embrace the inherent flexibility provided by the authority and streamline award processes

  - It may take some time for the Gov't team to get used to the new paradigm and learn how to negotiate terms and conditions

  - There is a learning curve with OTs

- To be truly efficient, the Gov't participants must work from the start of every program/project as a team, including program, contracting, legal, financial and other personnel

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Conclusion (cont.)

- Marketing your solicitation may be the hardest part
  - Publishing on SAM.gov is not enough for maximum interest from industry
  - It is important to get the solicitation/opportunity to the nontraditional performers
  - The program office will be an important resource
- OTs are not appropriate for all acquisitions – at its heart, its an R&D tool
- Fairness and transparency are paramount to OT success
- Although there is little policy/guidance (purposely), OT practice is ever evolving
- Use good business judgment, there are no templates or checklists
- With the renewed popularity of OTs, expect some oversight (both internal and external)

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Conclusion (cont.)

- Apply sound recordkeeping and documentation for agreement files
- OTs have inherent flexibility but will only benefit if people using them are willing to embrace the flexibility
  - Senior leadership buy-in
  - Coordinated team
  - Resistance to replicate FR-like actions
- Educating industry is also valuable
  - Traditional contractors may be resistant
  - Nontraditional contractors may not believe the Gov't is willing to behave differently
- Utilizing discretion and good business sense can be a difficult cultural change
- The Gov't <u>must</u> change or the Gov't will continue to miss out on important opportunities

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