

# CRADA Workshop

Robert L. Charles, J.D., LL.M., M.P.H.

Jason Martinez, J.D., M.B.A.

# Agenda

Topic	Time
Introduction	8:30-8:45
Background	8:45-9:30
What Is a CRADA?	9:30-12:00
<b>Break</b>	<b>10:30-10:45</b>
<b>Lunch</b>	<b>Noon-1:00</b>
CRADA Authority and Intellectual Property	1:00-2:00
CRADA Responsibilities	2:00-3:00
<b>Break</b>	<b>3:00-3:15</b>
Miscellaneous Issues	3:15-4:15
Q&A	4:15-5:00
<b>Adjourn</b>	<b>5:00</b>

# Course Materials

- Your materials include:
  - Course book and handouts
  - “The Green Book”
- Don’t have materials? Check in at registration to pick them up

# Sign-in Procedures

- Sign in this morning and afternoon to verify that you completed the course
- We will pass around the sign-in sheet

# Add/Drop

- Not the course for you? You can add/drop till 9:45 am
- Trade in your books at the registration desk
- Sign in to your new course

# Evaluate the Course

- Your feedback is our most useful tool!
- Evaluation form in your books
- Hand it in at registration

# Credit

- You can still register for continuing education credit at [eu.montana.edu/flc](https://eu.montana.edu/flc)
- You'll receive “credit” for completing this course in the form of an online badge you can share with your social networks. Look for an email from Credly for your badge

# Robert L. Charles, Esq.

- Chief, Medical Research Law, Army Medical Research and Materiel Command
- Former Chair, FLC Legal Issues Committee (2002-2011)
- Former Editor and contributor: FLC “Green Book” and T2 Handbook

Army Medical Research and Materiel Command  
Fort Detrick, Maryland  
(301) 619-7663

[robert.l.charles4.civ@mail.mil](mailto:robert.l.charles4.civ@mail.mil)

# Disclaimer

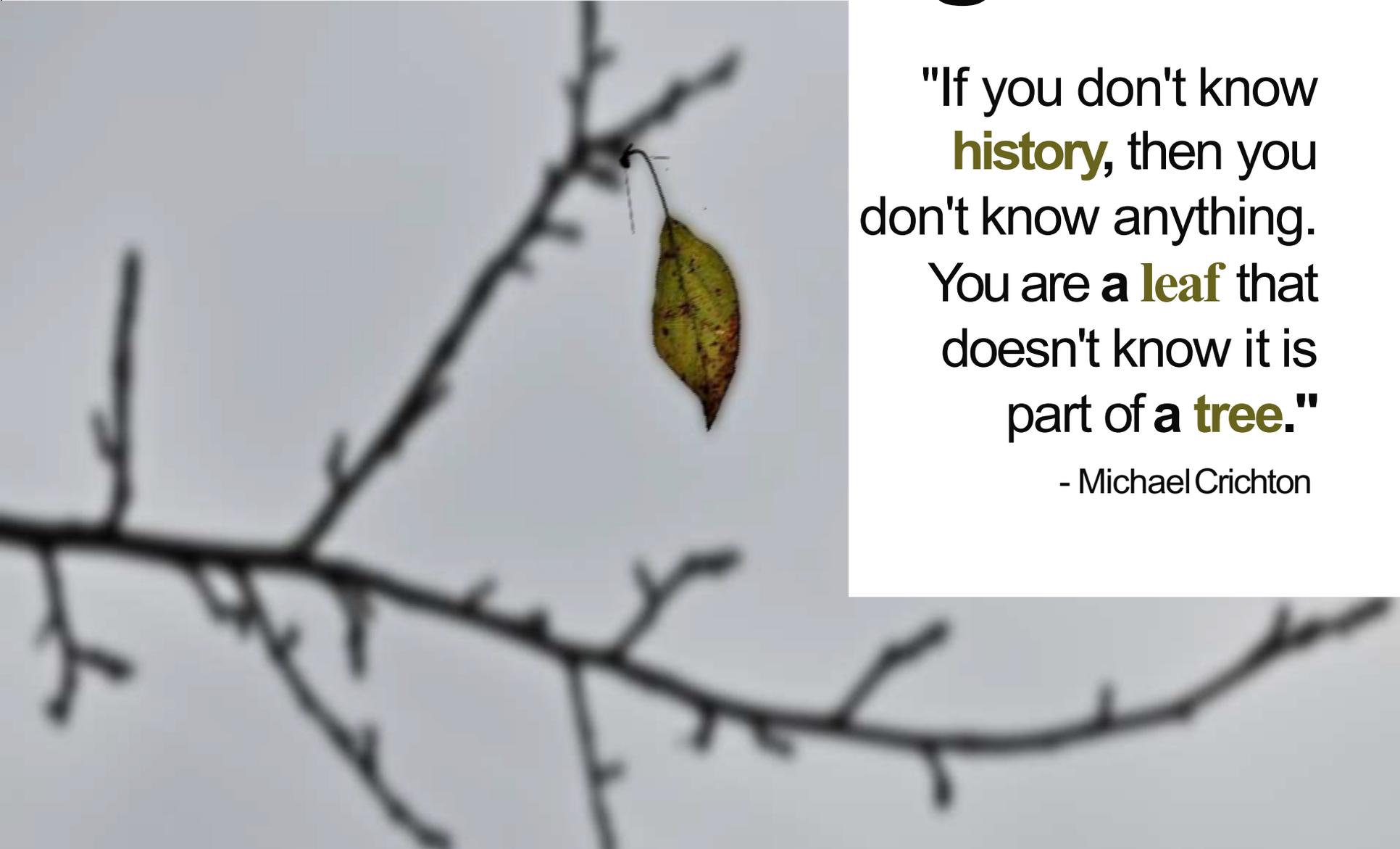
The opinions expressed by Mr. Charles during this workshop are his own and do not represent the position of the U.S. Government, the U.S. Department of Defense, the U.S. Army, Mrs. Charles, the Charles children, or grandchildren

# Jason Martinez

- Lead Portfolio Development CRADA Specialist, Sandia National Labs
- In 5 years, executed 150+ CRADAs with a contract value of \$150+ million
- M.B.A. and J.D., University of New Mexico

Sandia National Laboratories  
Albuquerque, N.M.  
(505) 284-4392  
[jdmarti@sandia.gov](mailto:jdmarti@sandia.gov)

# Part 1 - Background

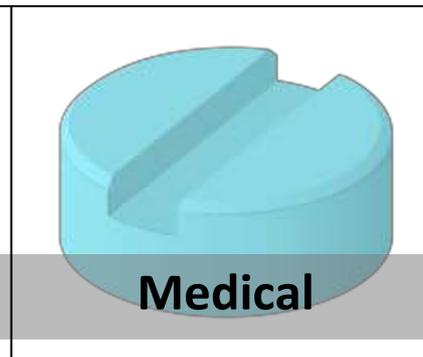
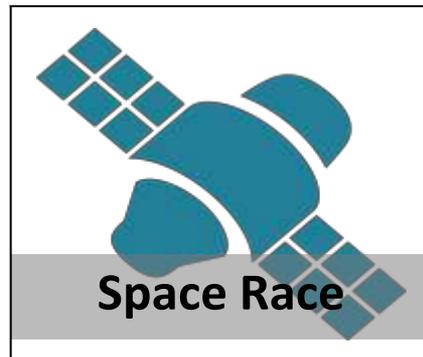
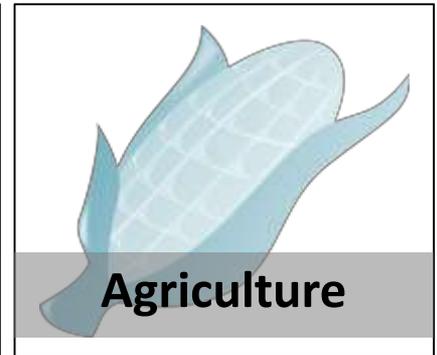
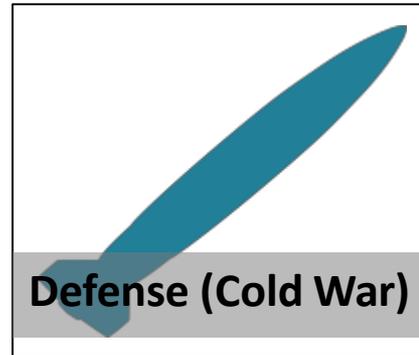
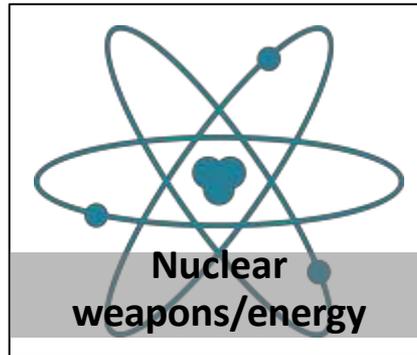


"If you don't know **history**, then you don't know anything. You are a **leaf** that doesn't know it is part of a **tree**."

- Michael Crichton

# Post-WWII: Federally Funded R&D Booms

Federal government was providing **70% of the R&D funding** in the U.S.



# Policy Changes to Protect Govt. Investment

## Pre-1950

Federal **employees owned** their government-funded inventions

*(U.S. v. Dubilier Condenser Corp., 289 U.S. 178 (1933))*

## Post-1950

Federal **government owned** both:

- Its employees' inventions  
*(Executive Order 10096)*
- The inventions arising from its R&D funding agreements  
(procurement **contracts and grants**)



# Mid-1970s: Losing Ground

- U.S. economy starts to tank
- Japan and Germany remain vibrant
- **Congress looks for reasons and solutions**

# Significant Problem

**Very little transfer** of commercially viable technology invented with tax dollars

Existing laws left **no policies, means, or mechanisms** to pump the federal R&D investment into the U.S. economy to create new products and jobs



# 1980: Radical Solution – Part I

- **Stevenson-Wydler Act**
- **Bayh-Dole Act**



# Results

T2 is  
prioritized

Transfer of technologies invented in federal laboratories to state and local governments and the private sector becomes a **mission** of the federal government

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ORTA is born

**Offices of Research and Technology Applications** are mandated and funded from laboratory budgets

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Federal  
ownership is  
loosened

Small businesses, universities, and not-for-profits may **keep title** to their inventions made with federal funds

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# 1980-1986: Labs Need New Tools to Meet Their Mandate

Federal labs lacked **legal authorities and mechanisms** for the types of technology collaborations and exchanges Congress envisioned



## 1986: Radical Solution – Part 2

Federal Technology  
Transfer Act gives labs:

- **A**uthorities
- **I**ncentives (royalties)
- **M**echanisms  
(CRADAs and PLAs)

to enter T2  
collaborations,  
patent licenses



COLISEUM, abdomen or bowels  
COLLABORATE, see colosseum.  
to work jointly, especially in liter  
or scientific work.  
COLLABORATION (-o-ra'shun)  
united labour.  
COLLABORATOR (-lo-  
one who assists  
in literary or

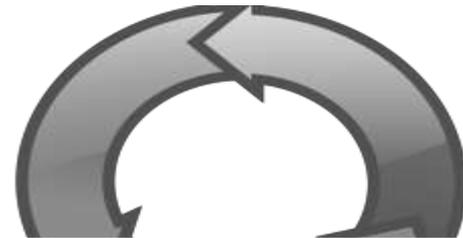
## Part 2 – What Is a CRADA?

# The Big Picture

- The **means and mechanism** given to federal agencies and labs to **implement** the Stevenson-Wydler Act T2 mandate
- A new kind of **government contract** allowing **R&D collaborations** between federal labs & nonfederal parties
- [www.youtube.com/watch?v=KrhplT0-auw&feature=youtu.be](http://www.youtube.com/watch?v=KrhplT0-auw&feature=youtu.be)



Allows labs great  
flexibility/discretion



Enables transfer of resources to  
and from federal govt

# Legal Definition

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, intellectual property, or other resources, with or without reimbursement (but not funds to the non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources toward the conduct of specified research and development efforts which are consistent with the missions of the laboratory; except that such term does not include a procurement contract or cooperative agreement as those terms are used in sections 6303, 6304, and 6305 of title 31;”

—15 USC §3710a(d)(1)

“...any  
agreement  
between one or  
more *Federal  
laboratories*...”

“A facility or group of facilities owned, leased, or otherwise used by a Federal Agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government.”

—15 USC 3710a(d)(2)(A)



# Yellowstone National Park is a federal laboratory

*Edmonds Institute, et al. v. Bruce Babbitt, et al., 93 F. Supp 63 (USDC DC, April 12, 2000)*

“...any agreement between one or more Federal laboratories and one or more *non-Federal parties*...”

“units of State or local government; industrial organizations (including corporations, partnerships, and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons (including licensees of inventions owned by the Federal agency).”  
—15 USC § 3710a(a)(1)

# Acceptable Nonfederal CRADA Parties



British government-owned lab?



German government-owned university?



World Health Organization?



Industrial development org.  
founded under the UN?

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which **the Government**, through its laboratories, **provides personnel...**”

— See 15 CFR Part 17

**Example:**

CRADA Statement of Work (SOW) that provides for the federal lab to send an engineer and a technician to the CRADA partner's facility for two weeks to carry out tests and evaluation of the partner's technology using both parties' unique testing equipment

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which *the Government*, through its laboratories, *provides...*

*services...*”

**Example:**

CRADA SOW that provides for the federal lab to use its proprietary assay technology to test CRADA partner's drug for new use, with the lab providing the partner a report and the partner paying for the lab's costs

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which *the Government*, through its laboratories, *provides... facilities...*”

**Example:**

Nonfederal party is allowed to use an otherwise empty facility on a federal installation near the laboratory for one year to carry out CRADA activities and facilitate collaboration with laboratory scientists

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which *the Government*, through its laboratories, *provides ... equipment...*”

**Example:**

CRADA SOW that provides for the federal lab to buy a microscope and send it to the CRADA partner's overseas lab for the partner's contracted technician to read slides, and the parties agree that the microscope becomes the property of the partner at the end of the agreement

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which **the Government**, through its laboratories, **provides... intellectual property...**”

**Example:**

CRADA SOW provides for the federal lab to grant to the nonfederal CRADA partner a nonexclusive license to use a lab's patented invention for five years to carry out CRADA research and to develop other specified commercial technology. The CRADA partner pays the lab \$10,000 for the license

*\*(We will discuss CRADA IP issues in more detail later!)*

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which *the Government*, through its laboratories, *provides* (these and other resources) *with or without reimbursement...*”

This is stand-alone, discretionary to the lab, statutory authority to negotiate and receive reimbursement from \$0.00 up to fair market value for whatever the lab will provide or has provided

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which *the Government*, through its laboratories, *provides* personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement (*but not funds to the non-Federal parties*)...”

The lab cannot provide funds, but it can direct the partner to other potential funding sources, such as grants, SBIR, state economic development funds, etc.

## **(but not funds to the non-Federal parties)...”**

- “Relationship to other laws - Nothing in this section is intended to limit or diminish existing authorities of any agency.”

*15 USC 3710a(f)*

- “Nevertheless, this section is not intended to prohibit Federal financial contributions as might be authorized and appropriated by other acts of Congress.”

*Senate Report 99-293, April 21, 1986*

- Agencies can award contract, grant, cooperative agreement, or STTR funding to a CRADA collaborator, which can then, in turn, provide those funds to a federal lab under a CRADA

*15 C.F.R. Section 17.3*

*(but not funds to the non-Federal parties)...”*

What else is still allowable?

- One federal lab can provide funds **to another federal lab** under a CRADA (or other authority)
- A federal lab can **contract with a third party** to carry out some part of its CRADA R&D (but maybe it would be easier/better for the non-federal party to do it)

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which... *the non-Federal parties provide funds...*”

- No **augmentation of appropriations** problem
- No **miscellaneous receipts** problem
- Can use funds to **hire personnel** to carry out the agreement who will not be subject to the full-time-equivalent restrictions of the agency

*(see 15 USC 3710a(b)(3)(B))*

“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which... *the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources...*”

Provides authority for the lab to accept, retain, and use funds, personnel, services, and property from a collaborating party

*(see 15 USC 3710a(b)(3)(A))*

All resources to be provided by the parties, including how much reimbursement goes to the lab, are



## GOCO Note



DOE requires **advanced payment**, minimum 60 day reserve plus first 30 days of work, prior to work commencing. FAC



Many DOE CRADA partners prefer a payment plan



100% funds-in CRADA partners ***must also demonstrate in-kind***; otherwise, it is a Strategic Partnership Project

# DOE Specific Note on Funding

- Funds-in
- LDRD
- OFA
- DOE (either through FOA or work authorization)
- Must always have in-kind

## Q: How does this statute define R&D?

“...any agreement between one or more Federal laboratories and one or more non-Federal parties... toward the conduct of *specified research and development efforts*...”

**A: It doesn't.**

## What Is R&D?

SBIR statute (15 USC 638(e)(5)) indicates that R&D means:  
“any activity which is

- (A) a **systematic, intensive study** directed toward **greater knowledge or understanding** of the subject studied;
- (B) a systematic study directed specifically toward **applying new knowledge** to meet a recognized need; or
- (C) a systematic **application of knowledge toward the production** of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.”

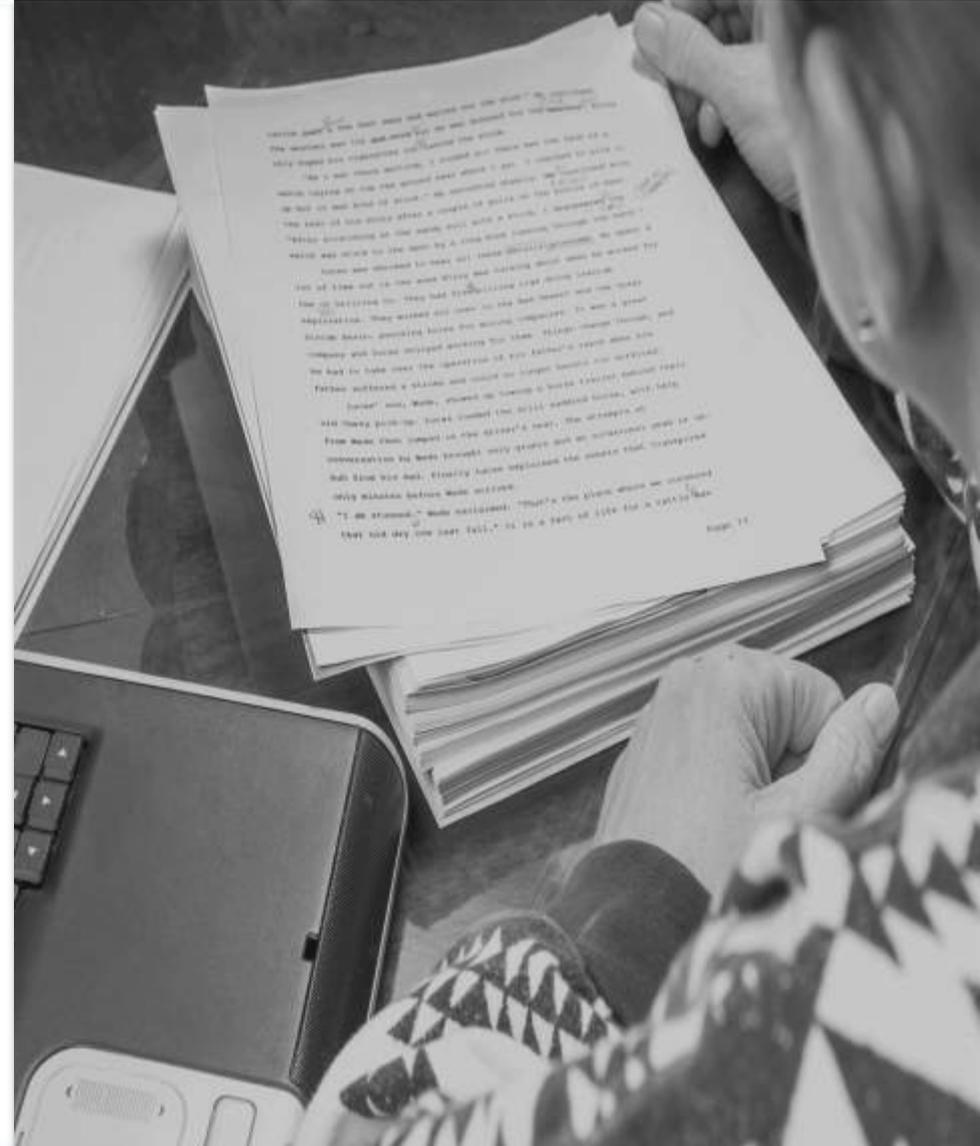


## Would This Be Considered R&D?

A **collaboration of prostate cancer funding organizations** (federal and nonfederal) (each party to give \$ and their data) to **create a publicly accessible database** of their current areas of funded research that will give prostate cancer researchers, doctors, and patients information on the state of funded research

# Would This Be Considered R&D?

A federal lab scientist **edits a book** comprised of numerous articles by other experts in his/her field for a collaborator/publisher



# What Can Be Done Under a CRADA?

A **co-sponsored conference, seminar, or similar event** with a scientific, technical, educational, or professional organization (nonfederal collaborator) when the subject matter is **scientific, technical, or professional** issues that are **relevant to the mission** of the federal laboratory

*Joint Ethics Regulation, DoD 5500.07-R, paragraph 3-206*



“...any agreement between one or more federal laboratories and one or more non-Federal parties... toward the conduct of specified research and development efforts *which are consistent with the missions of the laboratory...*”

The **agency** determines the mission or missions of each of its laboratories

*(see 15 USC 3710a(e))*

<https://www.youtube.com/watch?v=Db9M1Si0Jkk>

*“...except that such term does not include a procurement contract or cooperative agreement as those terms are used in sections 6303, 6304, and 6305 of title 31...”*

- Procurement Contracts (31 USC 6303) are regulated by the Federal Acquisition Regulations (FAR) and agency supplements
- (Grants and) Cooperative Agreements (31 USC 6304 & 6305) are regulated by “old” OMB Circulars (now 2 CFR Part 200) and agency supplements
- These do not apply to CRADAs – no flowdowns!
- **No government-wide regulations exist for CRADAs**

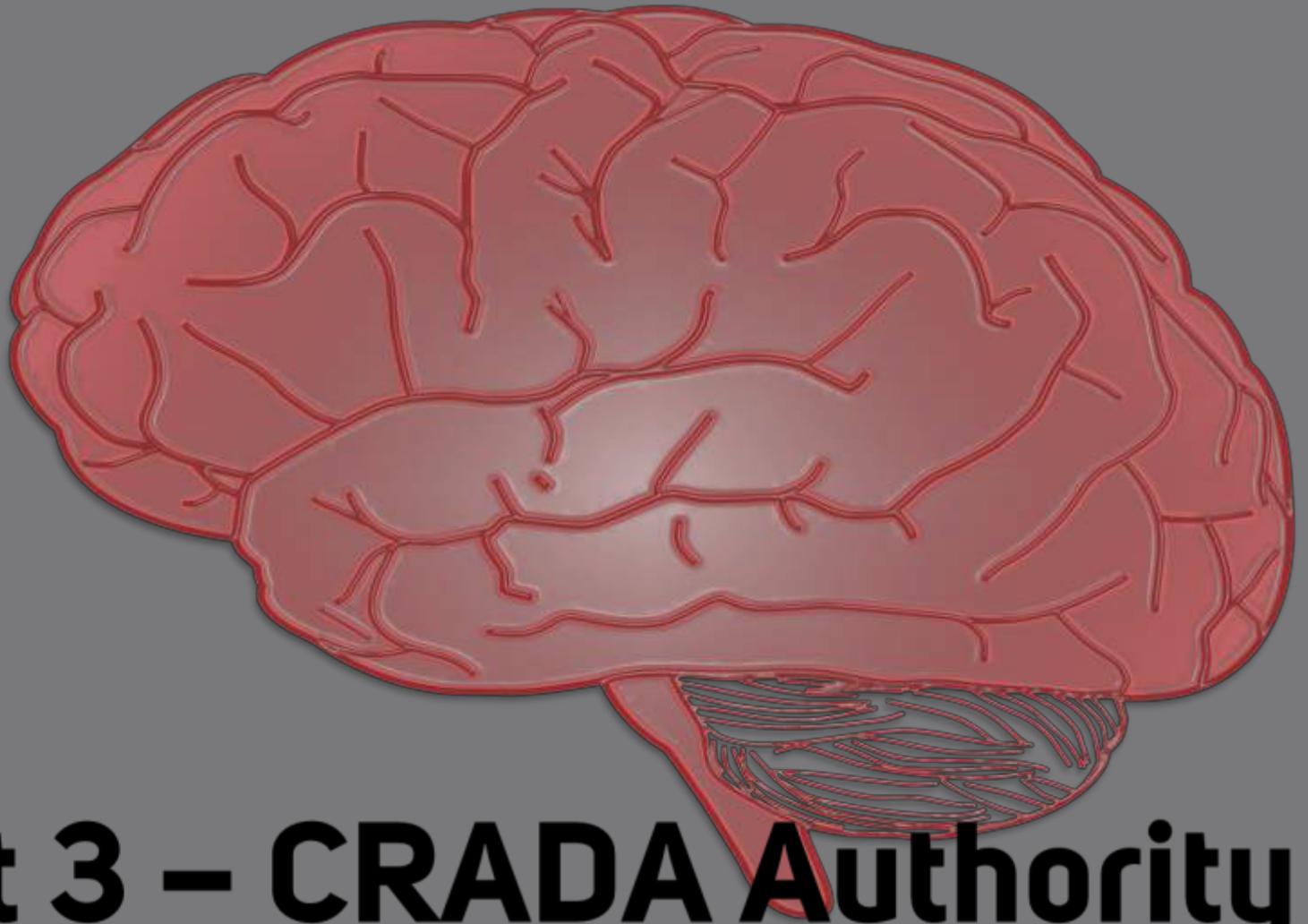
# Department of Energy Regulations

- DOE Order 483.1B (under revision)
- DOE Order 485.1 (foreign approvals)
- GOCO: know your prime contract requirements



CRADAs **may not** be used by an agency to **circumvent** the statutory and regulatory requirements of federal **procurement laws**

(See Chem Services, Inc., v. US EPA, 12 F.3d 1256 (USCA 3<sup>rd</sup> Cir., 1993))



# **Part 3 – CRADA Authority & Intellectual Property**

# CRADA Authority – Who Can Do What?

“Each Federal agency *may* permit the *director* of any of its Government-operated Federal laboratories...”

“(1) to enter into cooperative research and development agreements on behalf of such agency . . .”

—15 USC 3710a(a)(1)

- Delegation of Authority - Look to your Agency regulations

# CRADA Authority

“Each Federal agency *may* permit the *director* of any of its Government-operated Federal laboratories...

“(2) to *negotiate licensing agreements* under section 207 of title 35 . . . *for inventions made or other intellectual property developed at the laboratory* and other inventions or other property that may be voluntarily assigned to the Government.”

—15 USC 3710a(a)(2)

- Covers inventions made **under CRADAs or otherwise**

# Back to CRADA Authority (15 USC 3710a(b))

Laboratory may **grant or agree to grant** in advance to CRADA partner:

- Patent licenses
- Assignments, or
- Options to either

in a lab employee's **CRADA Subject Invention** (either sole or joint invention)



# CRADA Authority (15 USC 3710a(b))

Lab shall ensure that  
CRADA partner(s)  
has an option to  
choose an exclusive  
license **for a pre-  
negotiated field of  
use**

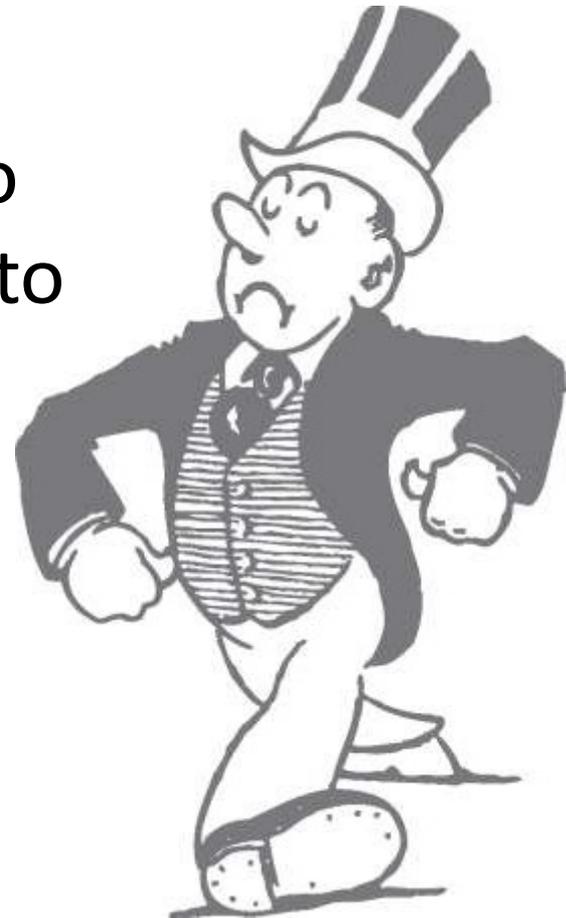


# Pre-negotiated Field of Use - **Reality** **Check**

- Counter to nature of scientific endeavor
- Opposed by many potential collaborators
- Field of use can be negotiated as part of the licensing process **after** the invention is made
  - **NOTE: DOE rarely sees the above; most CRADA partners negotiate the field of use prior to signing CRADA**
- Agencies/labs handle this differently

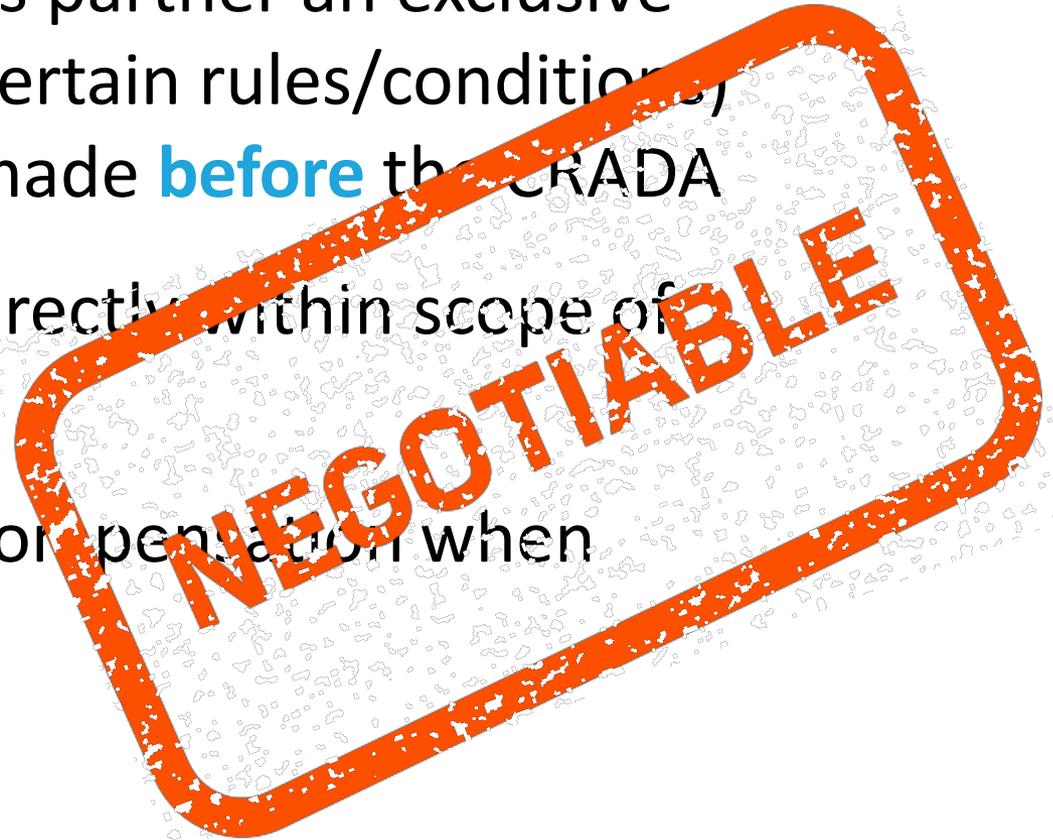
# Partner's Exclusivity Option

- Very important **incentive** to induce a potential partner to agree to enter a CRADA
- Partner's chance at a **monopoly against its competition**

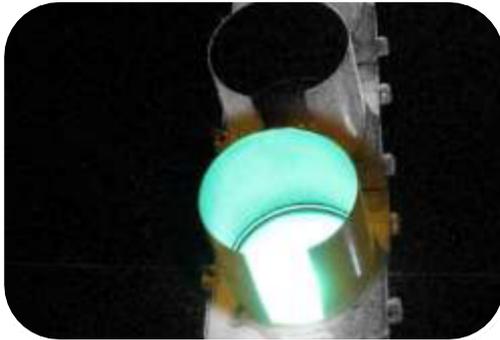


# Granting Exclusivity

- The lab may grant its partner an exclusive license (subject to certain rules/conditions) for a lab invention made **before** the CRADA
  - If the patent is directly within scope of the CRADA
  - For reasonable compensation when appropriate
- Why do this?



In consideration for the government's contribution under the CRADA, the license grants from the lab are subject to two "explicit (i.e., non-negotiable) conditions"



Government  
Use License

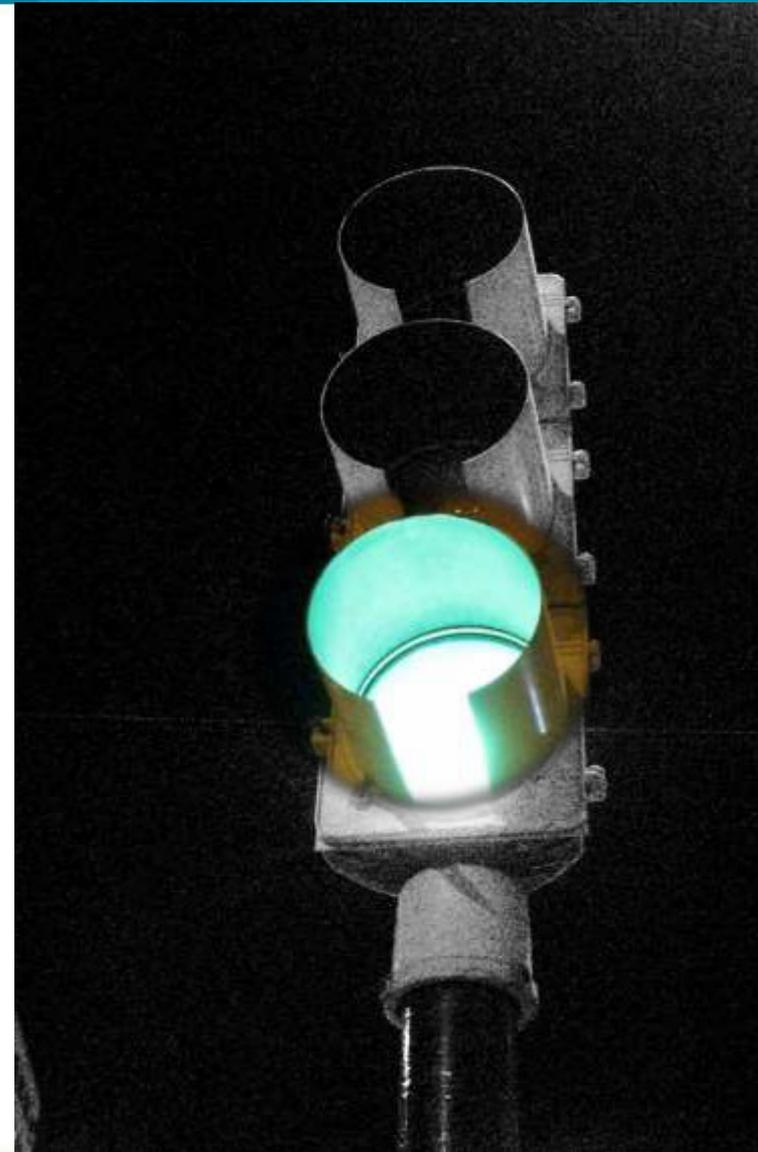


March-in Rights

# Condition #1: Government-Use License

Government maintains a nonexclusive, nontransferable, irrevocable **paid-up license** to:

- **Practice** the invention
- Have it practiced throughout the world **by or on behalf of** the government



# Condition #1: Government-Use License – Reality Check

Some potential collaborators are **concerned** that the federal government will use this license to **compete against them** in a procurement action

## Condition #2: “March-in Rights”

Government maintains for  
“exceptional circumstances”

- Public **health or safety emergency**
- **Public use** requirement
- Partner not substantially **manufacturing in U.S.** or is **controlled by a rogue country**



## Condition #2: “March-in Rights”

Government can:

- **Require the partner** to license to someone else, or
- **Grant someone else** a license



# Condition #2: “March-in Rights” – Reality Check

- While occasionally partners express concern about the prospect of the government activating “march-in” rights, **it has never, ever happened**
- Abbott’s Norvir anti-AIDS cocktail

The government should “normally” get the **same nonexclusive license** for any collaborator CRADA subject invention, but it is **not required**  
—15 USC 3710a(b)(2)

Negotiable

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Agencies vary in their practice

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Labs may **waive**, in advance, any government ownership rights to joint CRADA subject inventions subject to the reservation of a nonexclusive license

— 15 USC 3710a(b)(3)(D)



Lab may permit its **employee** or former employee/inventor to **help commercialize** the invention (subject to ethics rules)

—15 USC 3710a(b)(3)(C)



# Digression

- **Inventor involvement** is often key and essential to getting early **“angel” investors** willing to put up the big \$\$\$ necessary to prepare a product for commercialization
- The inventor is the **best “champion”** for the invention



Matthew Yohe. Licensed under Wikimedia Commons

# CRADA Implementation

A federal **agency** may issue **regulations**  
on procedures to implement 10 USC

3710a

—10 USC 3710a(c)

# CRADA Implementation

- The head of a federal agency may leave him/herself a **30-day window to review** and disapprove or modify a proposed CRADA
- A **written explanation** of a disapproval or modification is required

—15 USC 3710a(c)(5)

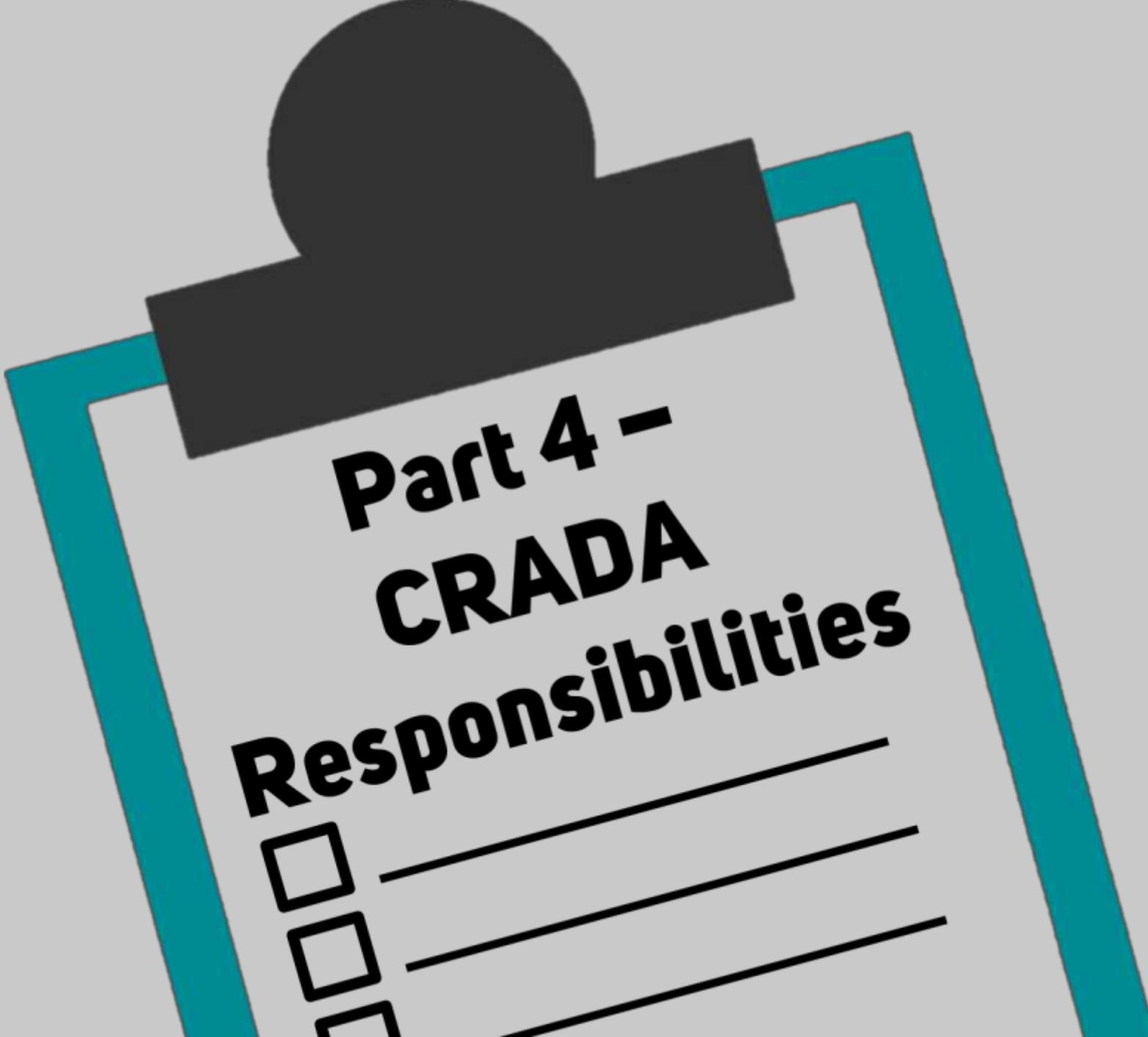
# CRADA Implementation

Agency Heads review for:

- Pros
- Cons
- Waivers

of the agreement

<https://www.youtube.com/watch?v=oFlsjK-R8hU>



**Part 4 -  
CRADA  
Responsibilities**

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# Conflicts of Interest

Agency shall:

- Review **standards of conduct** for resolving conflicts of interest
- Establish **guidelines**
- Propose **statutory changes** if necessary to resolve conflict-of-interest situations  
—15 USC 3710a(c)(3)



# Typical Conflict-of-Interest Issues

Government inventor:

- As **licensee**
- As **champion**
- As **stockholder**
- As **moonlighter** for developer or commercializer
- Builds potentially **competing** portfolio



# GOCOs

- Know your limitations with your M&O
- OCI review varies by site

# Lab Director Responsibilities

Must give:

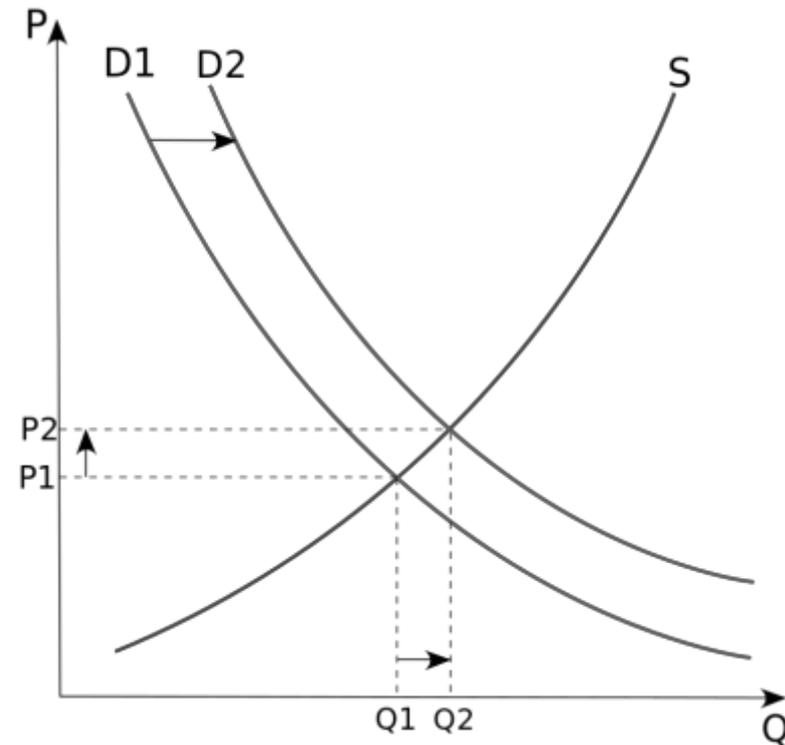
- “Special consideration” to **small businesses** and small business consortia
- “Preference” to **U.S. businesses** that agree to “manufacture substantially” in the U.S.



—15 USC 3710a(c)(4)

# Lab Directors - Reality Check

- Whoever **owns** the underlying technology and has the requisite **expertise and interest** determines partner options
- Manufacturer depends on **market forces**
- **No statutory requirement** to **compete** CRADAs



By Paweł Zdziarski (faxe), Astarot - Own work, CC BY-SA 3.0, <https://commons.wikimedia.org/w/index.php?curid=741993>

# For “Foreign CRADAs”

Lab Director shall:

- “Consult” with U.S. Trade Representative

- Executive Order 12591

- **DOE labs must adhere to 485.1; DOE sensitive country list**

Consider parity of treatment issues

- 15 USC 3710a(c)(4)(B)

# Foreign CRADAs - **Reality Check** for Lab Directors

- Whoever owns the underlying technology and has the requisite expertise and interest **determines partner options**
- Political **balance** vs. political suicide vs. importance of the R&D
- **Negotiate** out manufacturing site in CRADA as appropriate



# Agency Responsibilities

- Maintain a **record** of all CRADAs  
– 15 USC 3710a(c)(6)
- **Report T2 activities** to OMB/Congress  
– 15 USC 3710(f)
- Make **“separate determinations”** of the mission(s) of each of its labs  
– 15 USC 3710a(e)

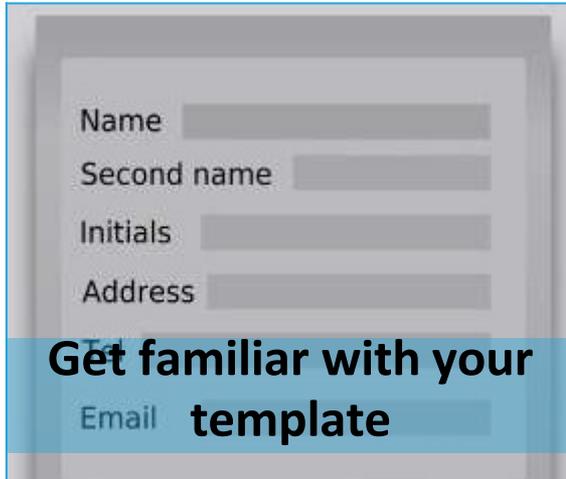
For DOE: ensure you have your Project Accomplishment Summary



# Part 5 – Miscellaneous Issues



# Getting Started



Name

Second name

Initials

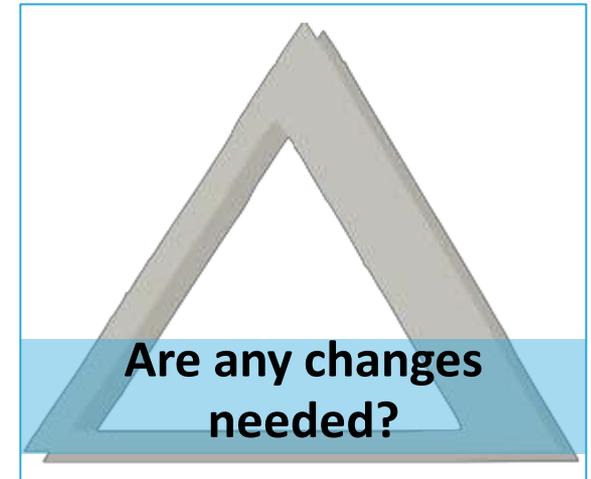
Address

Email

**Get familiar with your template**



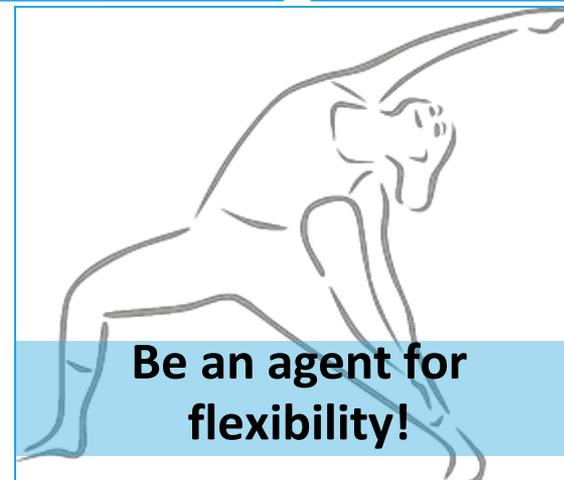
**Reach out to researchers**



**Are any changes needed?**

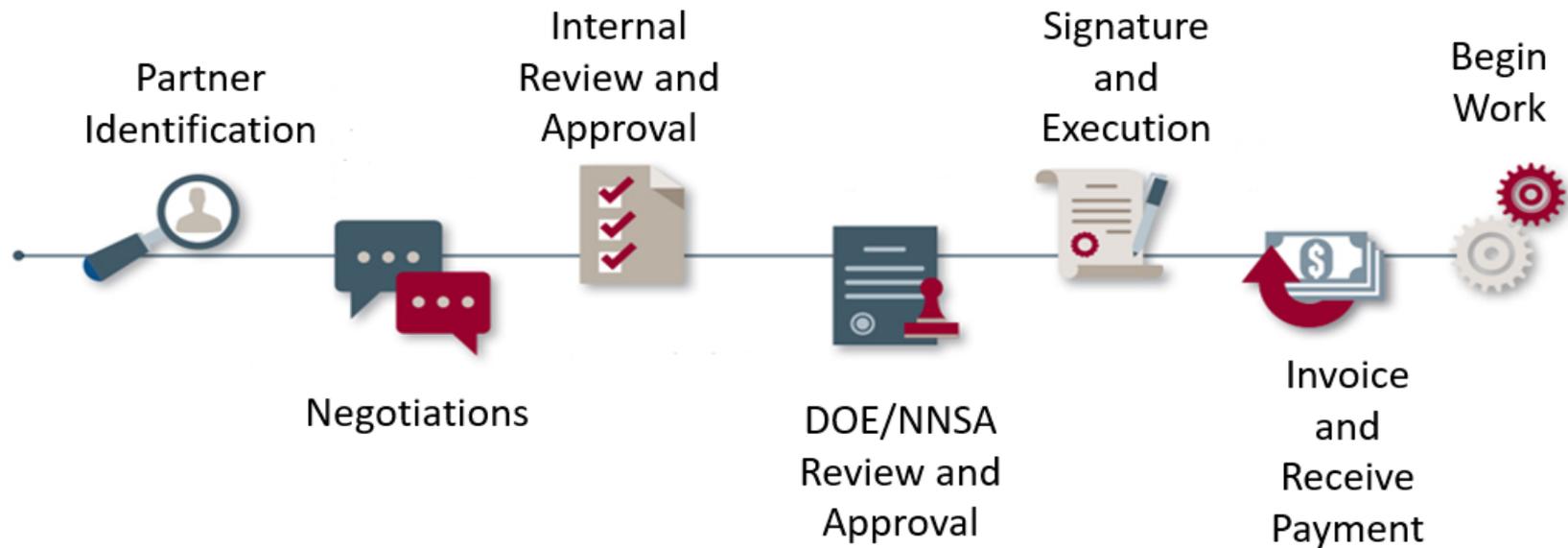


**Ask Legal what can and can't be changed**



**Be an agent for flexibility!**

# GOCO CRADA Facilitation



# DOE Labs Must Satisfy Fairness

- Stems from DOE Order
- Likely in your prime contract
- Differs by Lab
- Totality of the Circumstances

# DOE Labs: Decide if SPP or CRADA

- Different Orders/Different Mechanisms
- Preposition “with” or “for”
- Technical objectives should drive mechanism and not the other way around

# CRADA Negotiations

- T2 is a \_\_\_\_\_ sport. Do you enjoy \_\_\_\_\_?
- Don't assume you \_\_\_\_\_ your collaborator.
- YOU take the \_\_\_\_\_. YOU call back.
- T2 is \_\_\_\_\_ doing \_\_\_\_\_; think more like \_\_\_\_\_, less like \_\_\_\_\_.
- One \_\_\_\_\_ does not fit all.
- If it's really important, \_\_\_\_\_ ASAP.
- Most negotiations are \_\_\_\_\_; be prepared!

# Why Do Agencies' Practices Differ?

- **No government-wide regulations** exist
  - Each agency can issue its **own regulations** to implement the law
  - Lab Director maintains great **discretion** on whether to collaborate and terms
- Agencies' **R&D missions** differ greatly
  - Some focus on **spinning out** tech (e.g., USDA)
  - Others **spin in** technology or have higher **security** concerns (e.g., DOD or NSA)

# Why Do Agencies' Practices Differ?

- BIG factor: **personality** of agency legal staff
  - May be **risk-averse or conservative**
  - **Interpret** what the law requires/allows
- While the **law authorizes a broad range** of cooperative R&D arrangements, some agencies are **more concerned with uniformity**

# Examples of Different Agencies' Practices

- Mandatory use of agency's CRADA formats
- Mandatory grant of Government Use License of Collaborator's Sole CRADA Subject Invention under 15 USC 3710a(b)(2)
- May a collaborator just provide funds to the federal laboratory as its contribution under a CRADA?
- Are MTAs and NDAs CRADAs?
- Are "master" agreements allowed with collaborators?
- Can CRADA signature authority be delegated?
- Must CRADA opportunities with the federal lab be competed?
- Are CRADAs allowed with foreign government entities?
- Is the agency head provided a 30-day review period?
- Pre-negotiated field-of-use licenses



**Pitfall: “1) a hidden or unsuspected danger or difficulty;  
2) a covered pit for use as a trap.”** –Concise OED

- PI with a **personal financial agenda**
- CRADAs for technologies in **advanced** development
- CRADAs with **commercial competitors**
- Maintaining “**good faith**” collaboration
- Avoiding laboratory **schemes** to make **money**



# Data Rights

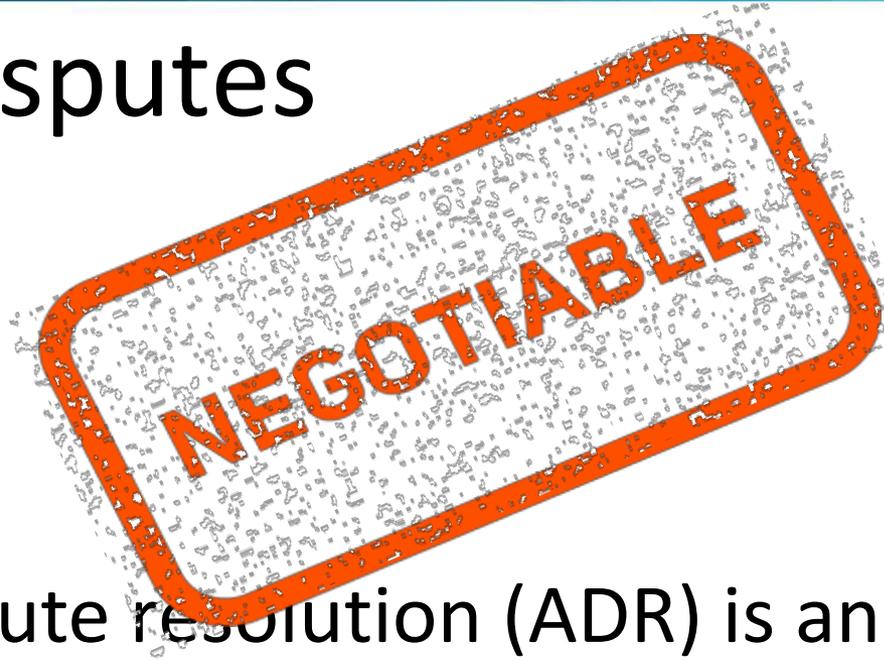


# CRADA Format



- Substance is much more important
- Not for DOE Labs (must model after 483.1B)

# Handling Disputes



- Alternate dispute resolution (ADR) is an option
- CRADAs are federal contracts (see Chem Services, 816 F. Supp 328), thus parties have access to U.S. Claims Court under Tucker Act (28 USC § 1491)

# Applicable Law

In the **U.S.**, **federal law**, as applied in a federal court of the United States

- **Location** of federal court in which to litigate is **negotiable**
- Outside U.S., **ask** your legal counsel
- Has there ever been any **litigation** between CRADA collaborators? **Yes!**

# Liability

- Agencies bound by the **Federal Tort Claims Act**
- **State entities** are bound by their **state laws**
- **Nothing has** to be in a CRADA; laws exist
- For clinical trials with private company, get copy of **insurance** and negotiate **indemnification** policy of U.S.

# Indemnification

- Labs are bound by **federal laws**
- State entities are bound by **state laws**
- **Nothing has** to be in a CRADA, but should **protect government** for clinical trials
- **Negotiate** with private parties

# Statement of Work (SOW)

- Can include
  - Milestones
  - Go/no-go decisions
- Payments before or after are OK; but remember, **partners do go bankrupt**
- Can be **renegotiated** as circumstances change

# GOCOs Must Have JWS

- Some labs see JWS and SOW as synonymous
- Probably cleaner if two different documents

# “Master” Agreements

- Used with **recurrent** CRADA collaborators
- Part I (the “Master”) contains legal terms and boilerplate
- Part II contains the particular/discrete SOW
- Each agreed-to SOW constitutes a separate CRADA

# Using **In-house** Contractors for CRADA Work

- Issue concerns Bayh-Dole rights
- See *Federal Register*: April 2, 2004 (Vol. 69, Number 64, pages 17299-17301)
- Seek to **get a waiver** from contractor before work starts
- Modify contract to **exchange contractor's IPR for royalties** under 15 USC 3710c

# Using **Outside** Contractors for CRADA Work

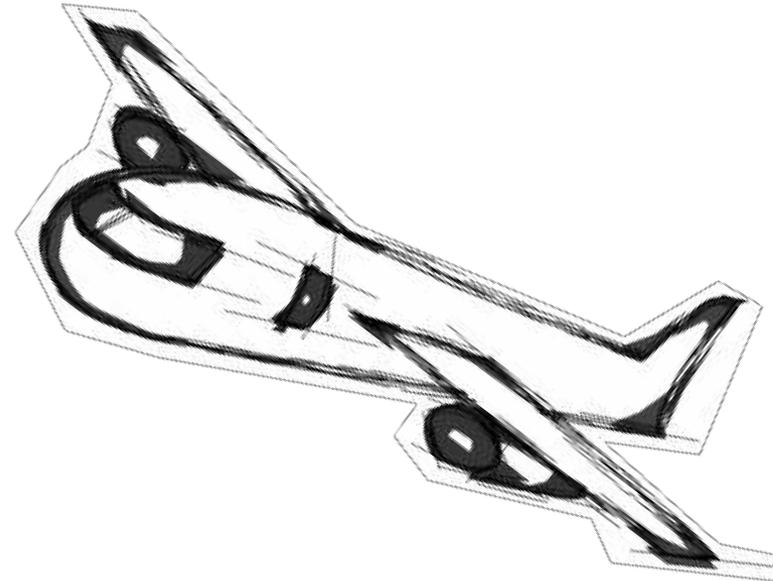
- Issue is Bayh-Dole rights
- Let the potential CRADA partner know
- Seek to **get a waiver** from contractor before work starts
- Have the CRADA **partner hire** the contractor

# Outside Contractors - **GOCOs**

- Issue is Bayh-Dole rights
- Let the potential CRADA partner know
- Notify staff: **no subcontract inventors**, no “212” inventors (35 USC §212)
- Seek to get a waiver from contractor before work starts – **but no coercion**
- Have the CRADA partner hire the contractor – *Caution:*
  - If the partner hires a **small business or nonprofit**, any resultant IP may be cross-obligated or resultant IP may be non-GOCO owned

# Travel Reimbursement

- **Agencies handle differently**  
depending on their application of 31 USC 1353 and 5 USC 4111
- Use existing ethics/conflict-of-interest review and procedures for gifts of travel from nonfederal sources
- **GOCOs: For contractor employees, CRADA partner bills time against CRADA funds**



# CRADAs w/Contractors/Grantees

Federal R&D contract, grant, or STTR money goes to a party intending to collaborate with a federal lab under a CRADA to do the R&D

- Allowable  
15 C.F.R. Section 17.3
- Granting activities have different rules on reimbursement for the federal lab “sub”  
(e.g., NIH grant policy does not allow reimbursement for federal labs’ indirect costs or federal employee time)

# Excluded Parties

- System for Award Management (“SAM”, formerly the Excluded Parties List System, 2 CFR Part 180)
- Government may exclude (**suspend or debar**) non-federal parties from federal “contracting” for reasons that indicate parties’ **lack of present responsibility**
  - Poor performance, integrity, financial capability
  - Violations of law or regulations

# Excluded Parties

- CRADAs are “covered transactions,” 2 CFR 180.200, 180.970
- Federal officials must check if the party excluded/disqualified, <https://www.sam.gov>
- Get certification, FAR 52.209-5



# Your Turn!

Are there any scenarios you've seen,  
heard about, or are just curious about?

Let's discuss!



**Questions?**

