



## Cooperative Research & Development Agreements (CRADA)

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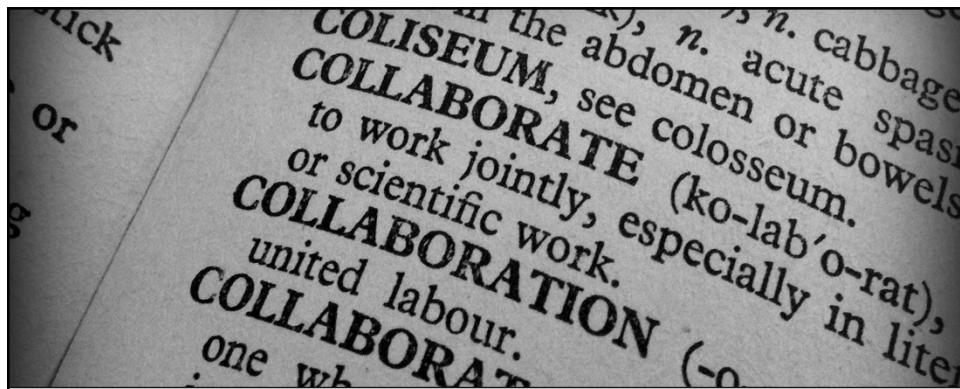
## Disclaimer

The opinions expressed by Mr. Charles during this presentation 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

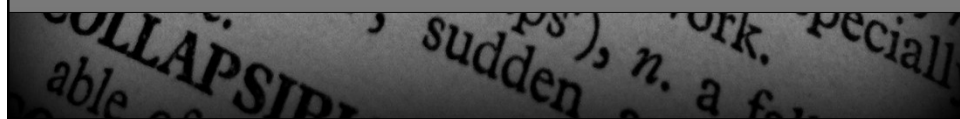


# Federal Technology Transfer

[www.youtube.com/watch?v=Krhpl0-auw&feature=youtube](http://www.youtube.com/watch?v=Krhpl0-auw&feature=youtube)



## What is a CRADA?



## CRADA SUCCESS STORY

### WaterStep

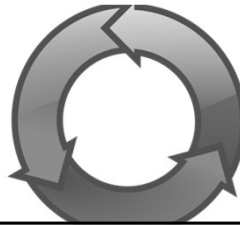
<https://www.youtube.com/watch?v=Db9M1Si0Jkk>

## The Big Picture – a CRADA is:

- A kind of **government contract** allowing **R&D collaborations** between federal labs & nonfederal parties



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;”

—15 USC §3710a(d)(1)



**“...the  
Government,  
through its  
laboratories,  
provides  
personnel...”**

Example:  
The federal lab sends 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.



***“...the  
Government,  
through its  
laboratories,  
provides...  
services...”***

Example:  
The federal lab uses 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



***“...the  
Government,  
through its  
laboratories,  
provides...  
facilities...”***

Example:  
The 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.



***“...the Government, through its laboratories, provides ... equipment...”***

**Example:**

The federal lab loans a specialized microscope to the partner’s for 6 months to carry out part of the effort under the CRADA.



***“...the Government, through its laboratories, provides... intellectual property...”***

**Example:**

The federal lab grants the partner a nonexclusive license to use a lab’s patented invention for three years to carry out CRADA research and to develop other specified commercial technology. The CRADA partner pays the lab \$10,000 for the license.



“...*the Government*, through its laboratories, **provides** (these 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



“...*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.

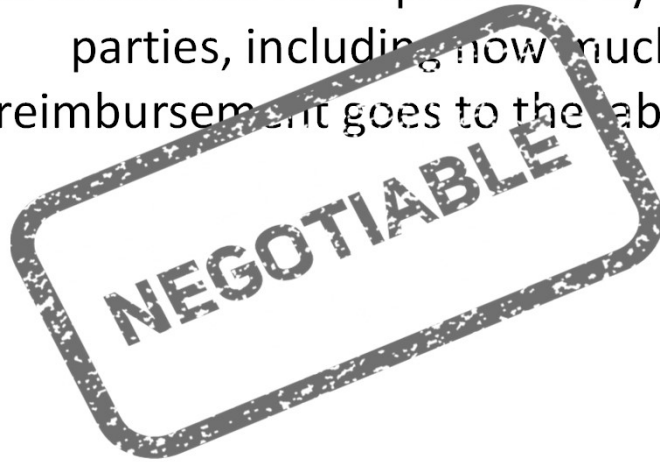
**(but not funds to the non-Federal parties)...”**

- “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  
*(e.g., FR/Vol. 70, No. 241, Friday, Dec. 16, 2005/Notices, page 74937, paragraph 9(c)(2)(i)-(iii); Assistance/Procurement Advisory Notice 15-01, U.S. Army Medical Research Acquisition Activity)*

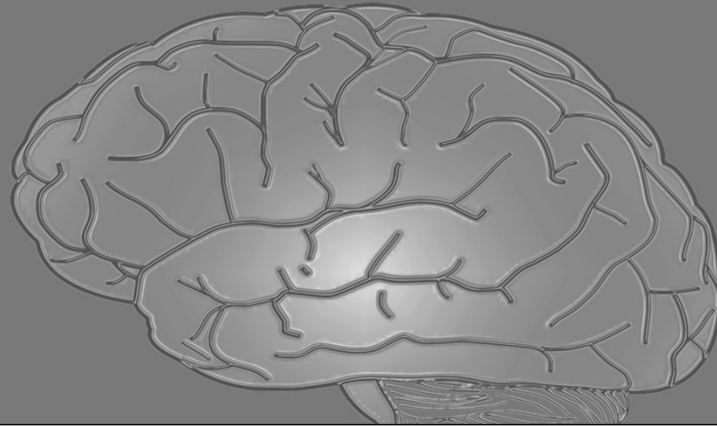
“...any agreement between one or more Federal laboratories and one or more non-Federal parties under which... **the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources...**”



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



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



## CRADA Authority & Intellectual Property



### 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)



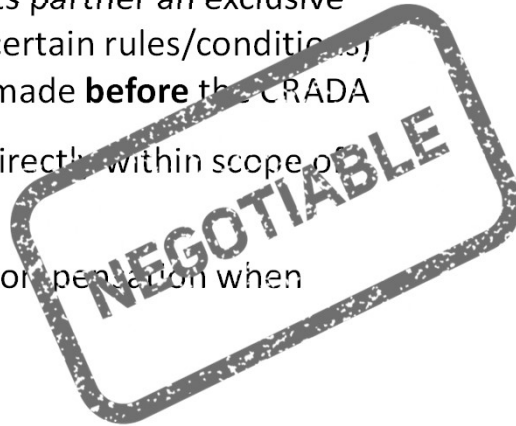
## CRADA Authority (15 USC 3710a(b))

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



## 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



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)





<https://www.youtube.com/watch?v=BYO6e9UH-6Q>



## 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)



## Miscellaneous Issues



**No Competition  
Required!**

[www.federallabs.org](http://www.federallabs.org)

*Advancing Federal Research and Technology*

## 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
- Gov Use License mandatory for Collaborator's Invention
- Allow a collaborator to just provide funds
- Are MTAs and NDAs CRADAs?
- Are "master" agreements allowed?
- Can CRADA signature authority be delegated?
- Must CRADA opportunities be competed?
- Allow CRADAs with foreign government entities?
- Is the agency head provided a 30-day review period?
- Pre-negotiated field-of-use licenses required

