



# Cooperative Research and Development Agreements (CRADAs)

Office of Legal and Technology Services  
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*Facilitating Research for Our War Fighters.*



# INTRODUCTION

- What is a CRADA
- When to Use a CRADA
- Types of CRADAs
- Funding Agreements & CRADAS
- CRADA Initiation Process
- Success Story





# What is a CRADA?



A CRADA is a written agreement to facilitate research collaboration between federal laboratories and non-federal partners on a project.

Stevensen Wydler Technology Innovation Act of 1980  
Federal Technology Transfer Act of 1986  
P.L. 99.502



# COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA) TEMPLATE DECISION MODEL

## INFORMATION INPUTS

## TEMPLATE OUTPUTS

### 1. PARTNERS

- a. Federal Entities Only
- b. At least one private Entity

- 1.a. Memorandum of Agreement
- 1. b. CRADA

### 2. RESEARCH

- a. One -way Transfer of Materials
- b. Preclinical or clinical research, collaborate on publication

- 2. a. Limited Purpose CRADA
- 2. b. Standard Clinical or Observational CRADA

### 3. FUNDING

- Industry Collaborator to Transfer Funds**
- a. Federal Funding Source
  - a. Non-Federal Funding

- 3. a. Federal Inter-fund Transfer (MIPR) + No Cost CRADA
- 3. b. Funded CRADA with up front milestone payments



# Agreement Scenarios



## **MATERIAL TRANSFERS** *(At Least one Non-Federal Entity)*

One way transfer of samples or data for research use - Limited Purpose CRADA (See Outgoing and Incoming templates on the web).

One way transfer of clinical Samples for research use - Clinical Limited Purpose CRADA (Template attached. To be added to web).

## **COLLABORATIONS** *(At Least one Non-Federal Entity)*

Collaborative Research (pre-clinical) - Standard CRADA

Collaborative Research involving human data, samples - Observational Clinical CRADA

Collaborative Research involving tests of drugs, vaccines or devices for FDA approval -

Clinical Trial CRADA

## **FEDERAL ENTITIES ONLY**

Material Transfers or collaborations among Federal entities - Memorandum of understanding or other support agreement.



# NAVY CRADA TEMPLATES

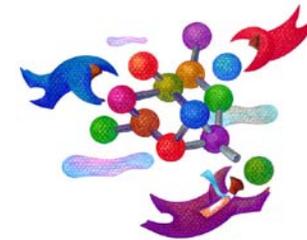
## Limited Purpose CRADA

Material or Equipment  
Transfer for research  
purposes



## Standard/Non Standard CRADAs

Full Collaboration with  
Statement of Work





# New CRADA Template: Observational Clinical CRADA

Work involves humans or human samples, but no drug, vaccine or device will be tested for FDA approval.





# When do I need a non-disclosure agreement (NDA)?

- Under an NDA, parties can restrict disclosure of sensitive information to 3<sup>rd</sup> parties.
- We recommend NDAs for detailed sharing of proprietary or restricted knowledge, or information between one or more parties in preparation for use under a Limited Purpose CRADA, full CRADA or contract.



# CRADA KEY POINTS

## A CRADA IS:

- A contractual agreement for research and Development.
- A collaborative effort with a non-federal party.
- A mechanism that may provide funds to support and enhance a government laboratory's ability to perform its mission

## A CRADA IS NOT:

- An acquisition tool or procurement agreement.
- A grant
- A fund generator for private industry.

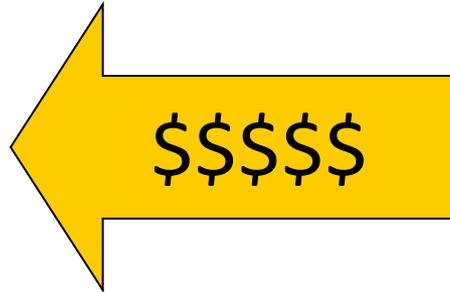


# CRADA Funding

## How does a CRADA differ from a Contract?

GOVT SHARES  
FACILITIES, EQUIPMENT  
OR PERSONNEL  
EXPERTISE

CRADA



COLLABORATOR  
PROVIDES FUNDS,  
SHARES FACILITIES  
EQUIPMENT OR  
PERSONNEL  
EXPERTISE

GOVT NEEDS SERVICE  
OR PRODUCT

CONTRACT

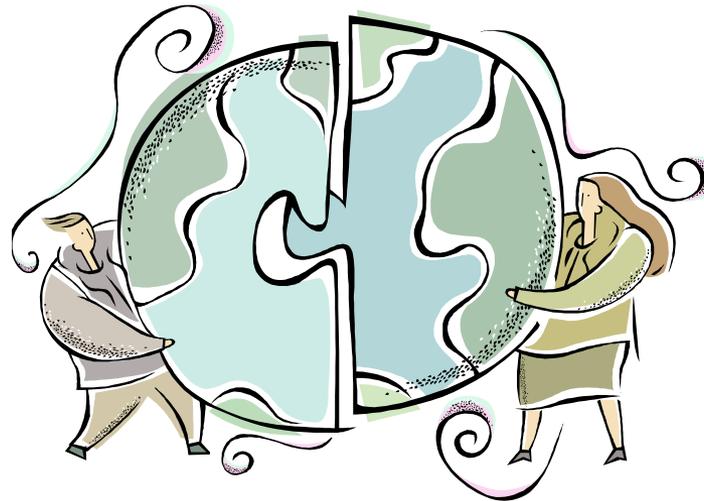


CONTRACT SERVICE OR  
PRODUCT



# How do I collaborate when I have a contract with the CRADA Partner?

Statements of work must be distinct!





# Can we accept CRADA \$\$ from SBIR awardees?

**Yes.** The Small Business Innovation Research (SBIR) awardee must request a waiver from Small Business Administration (SBA). The SBA grants waivers to CRADA collaborators on a case-by-case basis.

(2002 SBIR Policy Directive)

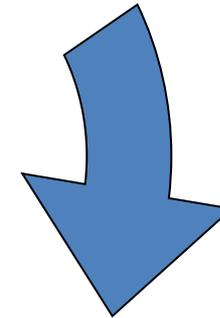
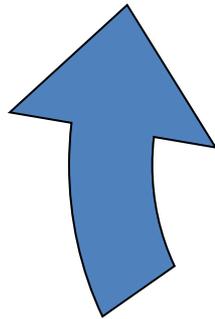


# PROCESS

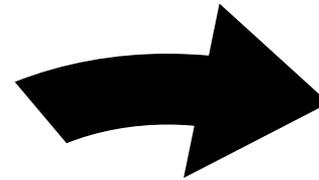
## CRADA Initiation in a Nutshell

**3. Legal Approvals & Execution**

**1. Division Approval**

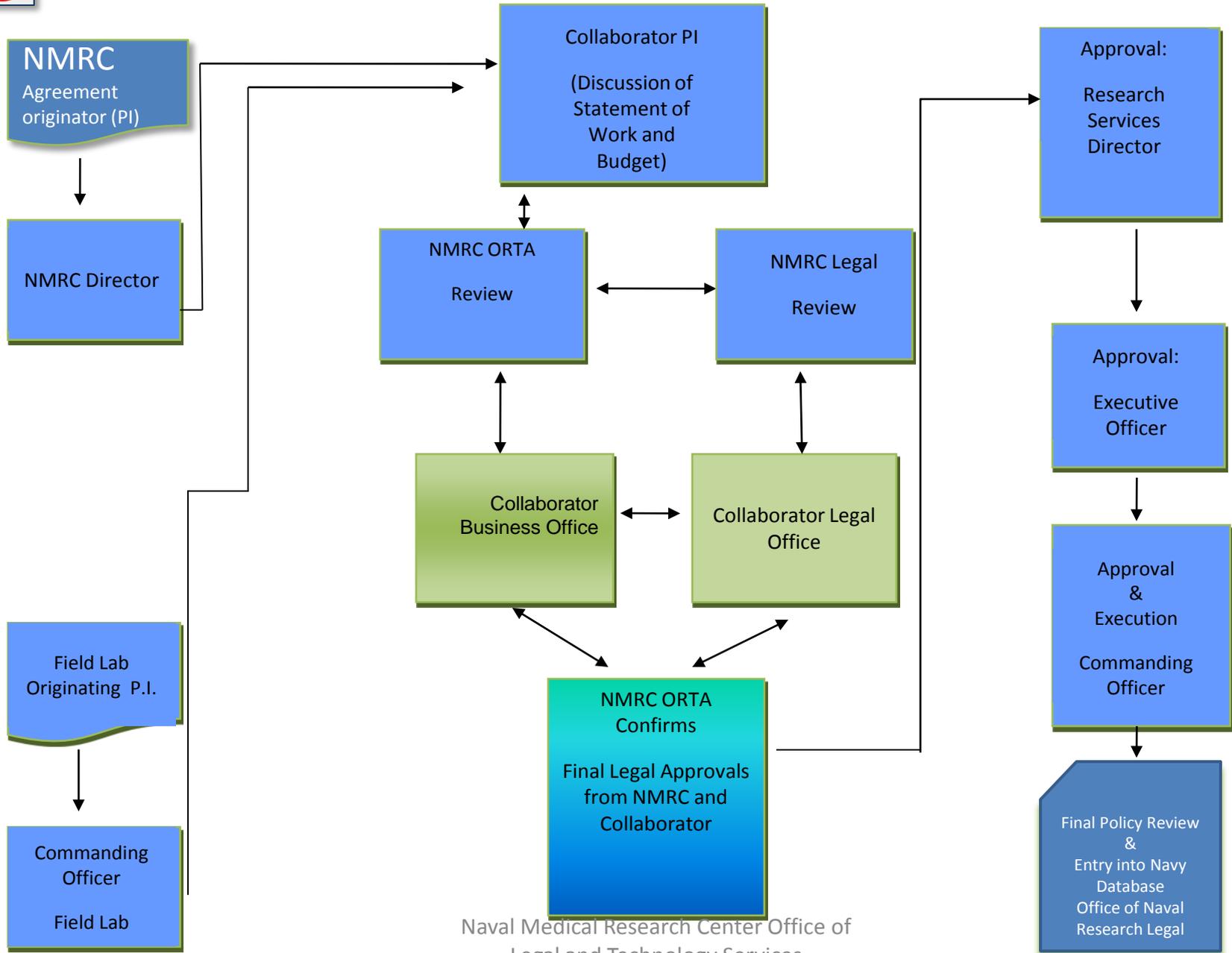


**2. Technology Transfer Review  
& Negotiation**





# DETAILED PROCESS





# Phase 1 - Initiation

## Department/Division Checklist

- Supporting grant, collaborator SBIR award funding or 3<sup>rd</sup> party contract information.
- Protocol Titles and Numbers.
- Negotiated Budget including milestones as necessary.
- Non-subject inventions of the NMRC.
- Complete Statement of Work including (*Who, What, Where, When*) description of tasks for all collaborators.
- If multiple parties are involved, ensure that contact information and SOWs are included for all parties.





# Phase 2 - Negotiation



- Once the information in your application or template is complete, the ORTA will assign an NMR # to your agreement. This initiates the negotiation process.
- Technology Transfer office will take outstanding legal issues to weekly legal review meetings for Legal and - if necessary – RSD and IRB approval.
- Upon agreement on the document terms by both federal and non-federal negotiators, the document will be immediately forwarded through the approval chain for signature.



# Phase 3 - Execution



- The Navy CO is the last signatory to execute the document,
- Signed copies of the CRADA will be distributed to the collaborators
- Forwarded to the Office of Naval Research for Navy-wide policy review & docketing.



# Working with your ORTA

## Questions

- ▶ The company review takes too long so their PI will sign off on the agreement to get the deal going. Should I share this with the ORTA?
- ▶ Should I edit the CRADA to include terms I think may be favorable to the collaborator?
- ▶ Should I give a realistic timeline for starting the project when I submit the template?

## Answers

- ▶ **Yes.** The Head of the company may be different from the technical point of contact. The ORTA will ensure that the signatory has the authority to bind the collaborator.
- ▶ **No.** Contact your ORTA legal office before making changes to the 'legalese' in your CRADA.
- ▶ **Yes.** The ORTA is your advocate. Sharing as much information about your project timeline up front will allow the ORTA to prioritize the agreement appropriately.



# CRADA Success Story

United States government contributed research and clinical trial support.

American BioHealth Group invested funds, time, marketing and business expertise





**Now the real work of advancing  
research and development begins . . .**

