



---

# Naval-Industry R&D Partnership Conference 2003

**Doing Business with the Navy “101”**

**CRADAs**



---

# Cooperative Research and Development Agreements CRADAS

**4 August 2003**

**Edward C. Linsenmeyer  
Coastal Systems Station, Panama City, FL**



# WHAT IS A CRADA?

---

- A unique mechanism to enable federal laboratories to engage in collaborative R&D with:
  - Industry
  - Academia
  - State and local governments
  - Other federal agencies
- CRADA must be:
  - Cooperative
  - Research
  - In laboratory's research mission
  - Win-win



# What is the authority?

---

- Federal Technology Transfer Act of 1986 (PL 97-219)
- **USC Title 15 Commerce and Trade**  
**Chapter 63 Technology Innovation, Section 3710a**  
**CRADAs**
- DoD Directive Number 5535.3 (May 21, 1999)  
DoD Domestic Technology Transfer (T2) Program
- DoD Instruction Number 5535.8 (May 14, 1999)  
DoD Technology Transfer Program
- SECNAVINST 5700.16A ONR 362 (7 March 2000)  
Domestic Technology Transfer (T2)



# What are the benefits to the Non-Navy party?

---

- Uniform CRADA throughout the Navy – we all use the same Agreement
- Access to federal expertise and facilities
- Opportunity to obtain rights to federally funded technology
  - The laboratory may grant (in advance) a patent license to any laboratory invention made under the Agreement
  - Government is permitted to grant licenses to federally owned inventions for which a patent license was filed before the signing of a CRADA
- Leveraging of resources through team efforts



# What are the benefits to the Navy?

---

- Easy process for forming the Agreement
- Enhanced funding for laboratory R & D
- Leverage resources not available
- Commercialization of laboratory intellectual property
- Recognition and Royalty Income



# Who may partner?

---

From the general authority of 3710a:

- **Other Federal agencies**
- **Units of State or local governments**
- **Industrial organizations**
- **Public and private foundations**
- **Nonprofit organizations including universities**

From the Technology Transfer Act of 2000 (PL 106-404)

- **Permits contract with partnership intermediaries**



# What type of work can be done?

---

Through the use of a Cooperative Research and Development Agreement (CRADA) the Federal Government through its laboratories may provide:

- Personnel
- Services
- Facilities
- Equipment
- Intellectual property
- Or other resources

with or without reimbursement for research and development efforts consistent with the laboratory mission



# CRADA Characteristics

---

- Collaborative effort between federal laboratory and partner
- Government may provide:
  - Federal personnel
  - Services
  - Facilities
  - Equipment
  - Intellectual property
  - No federal funds to the partner
- Nonfederal partner may provide:
  - Personnel
  - Services
  - Facilities
  - Equipment
  - Intellectual property
  - Funds



# CRADA Characteristics (2)

---

- Special consideration given to small businesses
- Legal agreement
- Not a procurement or grant
- Not subject to terms for procurement contracts
- Government retains license to inventions created under the CRADA
- CRADA must protect commercially valuable information



# Are commercial interests protected?

---

YES

From the statute 15 USC 3710a (c) (7) (A):

“No trade secrets or commercial or financial information that is privileged or confidential, under the meaning of 552(b)(4) of Title 5, which is obtained in the conduct of research or as a result of activities under this chapter from a non-Federal party participating in a cooperative research and development agreement shall be disclosed.”



# Who owns the data?

---

- Each collaborator shall have title to all Data generated by that Collaborator.
- The Collaborators shall have Unlimited Rights in all Subject Data that are not Proprietary Information or Restricted Access Information.
- The Collaborators shall have Unlimited Rights in any Non-Subject Data delivered under the CRADA that are not Proprietary Information.



# How is data protected?

---

## Standard clauses in CRADA

- Data shall be protected in accordance with the proper markings of its owner as provided by 15 USC 3710a.
- Restricted Access Information shall be protected from public dissemination for up to five years (by mutual agreement) from date of creation.



# Are there different CRADA types?

---

- STANDARD AND NON-STANDARD
  - Criteria Defined by ONR
- CLINICAL TRIALS CRADA
- PARTNERSHIP INTERMEDIARY AGREEMENT
- EQUIPMENT/MATERIAL TRANSFER AGREEMENT
- SBIR CRADA (requires SBA and agency approval)
- TECHNICAL ASSISTANCE CRADA
- CRADA for an INDIVIDUAL



# Standard CRADA

---

- The CRADA template is used WITHOUT MODIFICATION
- The CRADA is with only one Non-Navy Collaborator
- The Non-Navy Collaborator is:
  - a **U.S. entity**;
  - *not* a consortium;
  - *not* a venture capitalist;
  - *not* a partnership intermediary or “broker” for technology transfer
  - *not* directly or indirectly controlled by a foreign company or government
- The Non-Navy Collaborator does not provide more than \$1,000,000 to the Navy Collaborator over the life of the CRADA.
- The original CRADA duration is three years or less.



# QUESTIONS?

---



# CRADAS

---

SUPPLEMENTAL



# NAVY STANDARD CRADA - OUTLINE

---

- PREAMBLE
- DEFINITIONS
- OBJECTIVES
- RESPONSIBILITIES
- REPRESENTATIONS and WARRANTIES
- FUNDING
- REPORTS and PUBLICATIONS
- INTELLECTUAL PROPERTY
- TANGIBLE PROPERTY
- LIABILITY
- GENERAL PROVISIONS
- MODIFICATIONS and NOTICES
- SURVIVING PROVISIONS
- DURATION
- SIGNATURES
- Appendix A:  
STATEMENT OF WORK
- Appendix B  
CONFIRMATORY LICENSE AGREEMENT



# RESTRICTED ACCESS INFORMATION

---

“Restricted Access Information” means Subject Data generated by Navy that would be Proprietary Information if the Information had been obtained from a non-Federal Collaborator participating in a CRADA (15 USC 3710a). Under 15 USC 3710a(c)(7)(B), the Collaborators may mutually agree to provide appropriate protection to Subject Data generated by Navy (Restricted Access Information) against public dissemination or release under the Freedom of Information Act (FOIA) Subject Data for a period.



# CONTROLLED UNCLASSIFIED INFORMATION

---

“Controlled Unclassified Information (CUI)” means Government Data, Information, or materials provided to or resulting from this Agreement that may be export controlled, sensitive, for official use only, or otherwise protected by law, executive order, or regulation.



# PROPRIETARY INFORMATION

---

“Proprietary Information” means information that embodies trade secrets developed at private expense or business, commercial, or financial information that is privileged or confidential provided that such information:

is not known or available from other sources without obligations concerning confidentiality;

has not been made available by the owners to others without obligation concerning its confidentiality;

is not already available to the Government without obligation concerning its confidentiality; and

has not been developed independently by persons who have had no access to the information.



# CLINICAL TRIALS CRADA

---

- **CRADA covers pharmaceutical products**
  - **Additional definitions**
  - **Records, Audits, and Public Health Information**
  - **Additional Appendices including Clinical Trials Protocol**



# PARTNERSHIP INTERMEDIARY AGREEMENT

- Authorized under Title 15 U.S.C., Section 3715 and DoD Instruction 5535.8
  
- DoN defines a PIA as a *contract or memorandum of understanding between a Federal laboratory and a partnership intermediary*
  
- A Partnership Intermediary 's (PI) function must be to assist, counsel, advise, evaluate, or otherwise cooperate with small business firms or educational institutions
  
- The PIA model agreement is written in an abbreviated CRADA format
  - A DoN laboratory may not receive funds under a PIA.
  - The model agreement provided by ONR is not a contract to a PI
  - The laboratory CO must request signature authority from ONR
    - Must include laboratory legal review
    - Copy of the ONR PIA



# EQUIPMENT/MATERIAL TRANSFER AGREEMENT

---

- LIMITED PURPOSE CRADA
  - Non-Navy Provider to Navy Recipient
  - Navy Provider to Non-Navy Recipient
- Abbreviated CRADA structure
- Not a collaborative effort in the usual sense
- Allowed funding is restricted
- Duration is generally short term



# SBIR CRADA

---

- **NON-STANDARD CRADA**
  - Uses NCRADA 5<sup>th</sup> Edition (Revision 1) format
- **Special Provisions**
  - Added definitions: “SBIR Contract Data” and “SBIR Contractor”
  - Additional statement regarding SBIR funding
  - Special marking for Data that are SBIR Contract Data
  - Additional provisions on Subject Data originating under an SBIR contract
  - Include Signed Waiver as an Appendix



# SBIRs and CRADA

---

- **Small Business Innovation Research Program Policy Directive (RIN: 3245-AE72)**
- **No federal laboratory may receive SBIR awards funds to assist the award winner .....**
  - **Waiver process is now clearly acknowledged**
  - **Will be rarely used**
  - **Request for waiver must be submitted to SBA via Agency SBIR Program Manager prior to contract award**