

The Wonderful World of Cooperative Research and Development Agreements (CRADAs)

Jeff Moore, Ph.D.
Executive Director

Cleveland VA Medical Research and Education Foundation

CRADAs

What is a Cooperative Research and Development Agreement (CRADA)?

- 15 USC § 3710a - A legal agreement between a federal agency and one or more non-federal parties.
- Purpose is to foster federal/private collaborations to bring new technology to the marketplace.
- Government may provide personnel, services, facilities, equipment, intellectual property, and other resources, but not appropriated funds.

CRADA is NOT:

- A Procurement Contract under the Federal Acquisition Regulations (FAR)
- A Cooperative Agreement (31 U.S.C. 6305)
- A Grant (31 U.S.C. 6304)

CRADA Allows VA to:

- Accept funds from third parties
- Let a collaborator access VA personnel, service and property
- Enter into collaborative R&D with other entities
- Pre-commit intellectual property (IP) in advance of invention:
 - Assignment of rights; or
 - Exclusive patent licenses; or
 - Non-exclusive patent licenses; or
 - Options to CRADA Subject Inventions

-ALL while protecting human subjects and VA data

Using CRADAs:

- Government may provide
 - Personnel
 - Services
 - Facilities
 - Equipment
 - Intellectual Property
 - Other resources
- Government may not provide **ANY** funds

Industry partner may provide

- Funds
- Personnel
- Services
- Facilities
- Equipment
- Intellectual Property
- Other Resources

Parties to CRADA

- VA
- Industry Sponsor (“Collaborator”)
- NPC
- (Others?)

Benefits of Using a CRADA

- Protect Collaborator's background rights
(e.g. test article, patents)
- Delineate IP ownership and licensing options in CRADA before inventions are created
 - Option for exclusive patent licenses
 - Option for non-exclusive patent licenses
 - Assignments
- Collaborator may utilize VA expertise for research and development of products with commercialization potential

VA CRADA Models

- Clinical Trial (CT)
- Investigational Device CRADA
- Principal Investigator (PI) Initiated Clinical Study CRADA
- Material Transfer (MT) CRADA
- Basic Research
- ***Other***

When to use CT CRADA

When the collaborator:

1. Owns the investigational new drug (IND);
2. Designs the protocol; and
3. Funds the project

When to use the Device CRADA?

1. When the research is a collaborative research, development, engineering, testing or evaluation study involving devices.

2. May be PI initiated or not

PI Initiated CRADA

1. When a VAMC participates in a study of an FDA approved drug or device already on the market
2. When VA investigator designs the protocol and holds any investigational new drug (IND) application.
3. Commercial company may provide funds, materials and/or equipment.
4. The study may involve human subjects or materials derived from humans.

When to use Basic Research CRADA

1. Only for collaborative research, development, engineering, testing or evaluation studies
2. VA investigator designs or contributes substantively to the design of the statement of work
3. Study does not involve human subjects*

Material Transfer Agreements (MTAs)

- Reviewed locally (STAR review possibly)
 - signed by ACOS
- When to use which agreement:
 - Basic MTA (most simple)
 - No IP, No exchange of data
 - MT CRADA
 - IP, No exchange of data
 - Basic CRADA
 - IP, exchange of data

Who is involved in negotiating CRADAs?

- Legal Contractual
 - NPC (lead)
 - STAR Attorney
- Technical/Scientific
 - Principal Investigator (PI)
- Budget
 - NPC/PI/Study Coordinator

VA CRADA Options

Single-study CRADA

- Negotiated for a single study at a single VAMC site

Multi-site CRADAs

- Negotiated by one NPC/STAR (lead)
- Used at other NPC/VAs for same protocol

Master template CRADA

- Agreed upon at central office
- Used locally without review of the CRADA body
- Greatly expedites CRADA process
- Only variables are the Statement of Work (may be the protocol) and budget

The NPC Role in CRADAs

- NPC coordinates VA approvals (STAR attorney review, R&D Committee, IRB, MCD, etc.)
- NPC administers the study and funds
- NPC manages receipts and expenditures

Questions???

Contact Information

Cleveland VA Medical Research and
Education Foundation

Jeffrey.Moore5@va.gov 216-791-2300 x45304