

**USE OF A COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
(CRADA)**

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Directive provides policy for the use of Cooperative Research and Development Agreements (CRADAs) in VHA research.
- 2. SUMMARY OF MAJOR CHANGES:** The major change is to require that the medical facility Director, or designee, be responsible for ensuring that a record of all CRADAs executed by the facility is maintained by the medical facility and that the Director, Technology Transfer Program, is provided an annual report listing all CRADAs which were executed by the facility during the fiscal year.
- 3. RELATED ISSUES:** VHA Directive 1200 and VHA Handbook 1200.18.
- 4. RESPONSIBLE OFFICE:** The Office of Research and Development's Technology Transfer Program (10P9T) is responsible for the contents of this Directive. Questions may be addressed to 202-443-5600.
- 5. RESCISSION:** VHA Directive 2007-044, dated December 26, 2007, is rescinded.
- 6. RECERTIFICATION:** This VHA Directive is scheduled for recertification on or before the last working day of May 2020.

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USE OF A COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA)

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy on mandatory use of Cooperative Research and Development Agreements (CRADAs).

NOTE: *Research assistance awards such as grants and sub awards directly paid from Federal agencies to VHA's Nonprofit Corporations (NPCs) are not subject to this Directive.* **AUTHORITY:** 38 U.S.C. 7301(b).

2. BACKGROUND:

a. A CRADA is an agreement established pursuant to the Federal Technology Transfer Act of 1986, Public Law (Pub. L.) 99-502 between Department of Veterans Affairs (VA) and one or more non-Federal, and Federal parties under which VA may accept, retain and use funds, personnel, services, facilities, intellectual property, equipment or other resources from the other party. In exchange, VA may provide personnel, services, facilities, intellectual property, equipment, or other resources, excluding funds, for research and development efforts that are consistent with VA's mission. If VA funding is required, VA must go through the acquisition and procurement channels.

b. A CRADA defines the responsibilities and obligations of each party in conducting collaborative research and development, and provides the collaborating parties with certain rights to any patentable invention made by a Federal employee in the performance of the agreement.

3. POLICY:

a. It is VHA policy that a CRADA must be used to establish the terms of new research collaborations with a non-federal partner in which VA provides the non-federal party: personnel (VA employees as defined under VA Directive 1200), services, facilities, equipment, intellectual property, or other resources, excluding funds. Non-federal parties may provide VA: personnel, services, facilities, equipment, intellectual property or other resources with or without reimbursement to VA.

b. VA NPCs are highly encouraged to use the appropriate VA CRADA model for research assistance awards, including but not limited to grants and sub awards originating from nonprofit organizations, or when the nonprofit or for profit organizations are the prime awardee on a grant or sub award originating from a Federal source.

4. RESPONSIBILITIES OF THE MEDICAL FACILITY DIRECTOR: The medical facility Director, or designee, is responsible for ensuring that:

a. When reviewing proposed research projects, the facility Research and Development (R&D) Committee:

(1) Verifies use of the form of agreement (CRADA, grant, contract, or other) appropriate for the research being proposed; and

(2) Annually conducts quality assurance of compliance in accordance with VHA Handbook 1200.01, Research and Development (R&D) Committee.

b. When any personnel involved in performance under the CRADA are dually-appointed VA and university personnel (DAP), provisions regarding intellectual property ownership and licensing in each CRADA are consistent with the applicable Cooperative Technology Administration Agreement, Invention Management Agreement, equivalent agreement, or are subject to a locally negotiated agreement with the VA medical facility's academic affiliate.

c. The VA medical facility maintains a copy of all executed CRADAs in accordance with VHA Records Control Schedule 10-1 (see <http://www.va.gov/vhapublications/rcs10/rcs10-1.pdf>). **NOTE:** *This is an internal VA Web site that is not available to the public.*

d. A record of each executed CRADA is loaded in the electronic CRADA registry by the VA NPCs or other applicable personnel at the VA medical facility research office. (See <http://vaww.pubtracker.research.cfdi.webdev.va.gov/crada/>). **NOTE:** *This is an internal VA Web site that is not available to the public.*

e. The Director, Technology Transfer Program, is provided an annual report listing all CRADAs which were executed by the medical facility during the fiscal year. This report is due by December 1 of each calendar year.

5. REFERENCES:

a. Federal Technology Transfer Act of 1986, Pub. L. 99-502, codified at 15 U.S.C. 3710a et seq.

b. VHA Directive 1200, Veterans Health Administration Research and Development Program.

c. VHA Handbook 1200.01, Research and Development (R&D) Committee.

d. VHA Handbook 1200.17, Department of Veterans Affairs Nonprofit Research and Education Corporations Authorized by Title 38 United States Code (U.S.C.) Sections 7361 through 7366.

e. VHA Handbook 1200.18, Intellectual Property.

f. VHA Records Control Schedule 10-1.