Department of Veterans Affairs **VHA DIRECTIVE 1206**
Veterans Health Administration **Transmittal Sheet**
Washington, DC 20420 **June 19, 2018**

USE OF A COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA)

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive outlines the use of Cooperative Research and Development Agreements (CRADAs) in VHA research.

2. SUMMARY OF MAJOR CHANGES: The directive incorporates the requirements of VA Memo, Cooperative Research and Development Agreement (CRADA), dated January 19, 2017, to include the requirement that VHA's Office of Research and Development (ORD) be responsible for reviewing all Department of Veterans Affairs Central Office (VACO)-sponsored CRADAs. The major change is to require that the medical facility Director 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, Research and Development Program, dated May 13, 2016, and VHA Directive 1200.18, Determination of Rights for Inventions and Discoveries, dated January 11, 2017.

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. RESCISSIONS: VHA Directive 1206, Use of a Cooperative Research and Development Agreement (CRADA), dated May 13, 2015, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of June 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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Executive in Charge

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter*.

DISTRIBUTION: Emailed to the VHA Publications Distribution List on June 26, 2018.

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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 not covered by a CRADA, directly paid from Federal agencies to VA's Nonprofit Corporations (NPCs) are not subject to this directive*. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b); 15 U.S.C. 3710a.

2. BACKGROUND

a. A CRADA is an agreement established pursuant to 15 U.S.C. 3710a between Department of Veterans Affairs (VA) and one or more non-Federal and/or Federal parties under which VA may accept, retain and use funds, personnel, services, facilities, intellectual property, equipment or other resources from the other partner. 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 partner 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, subject to 38 CFR 1.650 et seq. CRADA model agreements can be found at: https://www.research.va.gov/programs/tech_transfer/model_agreements/default.cfm.

c. 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. For information about NPC procedures, see VHA Handbook 1200.17, VA Nonprofit Research and Education Corporations Authorized by Title 38 U.S.C. Sections 7361 Through 7366, dated April 27, 2016.

3. POLICY

It is VHA policy that a CRADA must be used to establish the terms of new research collaborations with a non-Federal or Federal partner in which VA provides the non-Federal partner with any of the following: personnel (VA employees as defined under VHA Directive 1200, Research and Development Program, dated May 13, 2016); services, facilities, equipment, intellectual property, or other resources, excluding funds. It is VHA policy that non-Federal parties may provide VA with personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement from VA.

4. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).

(2) Ensuring that each VISN Director has the sufficient resources to fulfill the terms of this directive in all of the VA medical facilities within that VISN.

c. **Chief Research and Development Officer, Office of Research and Development.** The Chief Research and Development Officer (CRADO), Office of Research and Development (ORD) is responsible for:

(1) Reviewing VA Central Office (VACO)-sponsored CRADAs to determine whether the activity is research. CRADO oversight is not required for field-based CRADAs and activity that is not research.

(2) Reviewing the CRADA, if the activity is determined by the CRADO to be a research activity, to evaluate whether the agreement complies with applicable research regulations and policies that protect human subjects, data, and intellectual property.

(3) Concurring on the CRADA language, if the activity is determined by the CRADO to be a research activity and in compliance with applicable research regulations and policies. If the agreement does not comply, the CRADO will return the CRADA to the program office.

d. **Director, Technology Transfer Program, Office of Research and Development.** The Director, Technology Transfer Program, ORD is responsible for overall management of VA's Technology Transfer Program, to include:

(1) Developing an annual report listing all active CRADAs from VA medical facility Directors by December 1.

(2) Submitting the annual summary report of all active CRADAs to the National Institute of Standards and Technology, for the Federal Laboratory Technology Transfer Summary Report to the President and the Congress.

e. **VACO Program Office Directors.** The Director of the VACO program office proposing the CRADA agreement is responsible for ensuring that the CRADA is submitted to the CRADO for review as mandated by this directive, prior to submitting the CRADA to VA Office of General Counsel (OGC) for final OGC approval.

f. **Veterans Integrated Service Network Director**. The VISN Director is responsible for ensuring that VA research programs at facilities within the VISN comply with current VA policies and guidelines related to CRADAs.

g. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Maintaining 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*).

(2) Ensuring a record of each executed CRADA is loaded in the electronic CRADA registry. (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*).

(3) Providing the Director, Technology Transfer Program, ORD, with an annual report listing all active CRADAs. Active CRADAs include CRADAs executed by the VA facility during the fiscal year as well as all CRADAs still active from previous fiscal years. Additionally, the report must include a list of any CRADAs terminated or completed during the fiscal year. This report is due by December 1 of each calendar year.

h. **Associate Chief of Staff for Research, VA Medical Facility Research Office.** The Associate Chief of Staff for Research at the VA medical facility research office is responsible for loading a complete record of each executed CRADA in the electronic CRADA registry not later than 30 days after the CRADA execution date. A complete record includes each field within the CRADA registry as well as a copy of the executed CRADA document. (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*).

5. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. If you have any questions regarding any aspect of records management you should contact your facility Records Manager or your Records Liaison.

6. REFERENCES

a. 15 U.S.C. 3710a, Cooperative Research and Development Agreements.

b. VHA Directive 1200, Research and Development Program, dated May 13, 2016.

c. VHA Directive 1200.18, Determination of Rights for Inventions and Discoveries, dated January 11, 2017.

d. VHA Directive 1400, Office of Academic Affiliations, dated September 14, 2009.

e. VHA Handbook 1200.01, Research and Development (R&D) Committee, dated June 16, 2009.

f. VHA Handbook 1200.17, Department of Veterans Affairs Nonprofit Research and Education Corporations Authorized by Title 38 Untied States Code (U.S.C.) Sections 7361 through 7366, dated April 27, 2016.