

December 26, 2007

**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 (“grants”), such as those typically originating from nonprofit organizations and other Federal agencies, are not subject to this Directive.*

2. BACKGROUND: The Federal Technology Transfer Act of 1986, Public Law (Pub. L.) 99-502 created CRADAs to serve as a flexible form of agreement between Federal and non-Federal organizations for establishing the terms of collaborative research efforts. CRADAs were specifically designed to respect both government and non-governmental organizations’ rights to intellectual property in order to foster translation of research results into commercial products. CRADAs, which are legally binding on all parties, allow the Department of Veterans Affairs (VA) to establish ownership and licensing rights to inventions in advance.

3. POLICY: It is VHA policy that a CRADA must be used to establish the terms of new research collaborations involving use of resources provided by VA (including VA personnel whether salaried or serving under a without compensation (WOC) appointment) and by non-VA organizations when the non-VA partner desires commitment of ownership and licensing rights in advance of an invention being made. *NOTE: All existing executed Clinical Research Agreements will be grandfathered.*

4. ACTION

a. **Facility Director.** The facility Director, or designee, is responsible for ensuring that:

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

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

(b) Annually conducts quality assurance of compliance in accordance with VHA Handbook 1200.1, Research and Development Committee Handbook.

(2) When the principal investigator (PI) or co-PI is a dually-appointed VA and university personnel (DAP), specifications regarding intellectual property ownership and licensing in each CRADA are consistent with the applicable Cooperative Technology Administration Agreement (CTAA) or are subject to a locally negotiated agreement with the VA medical center’s academic affiliate.

THIS VHA DIRECTIVE EXPIRES ON DECEMBER 31, 2012

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b. **Director, Technology Transfer Program.** The Director, Technology Transfer Program, or designee, is responsible for:

(1) Developing and disseminating models to be used. **NOTE:** *Model agreements are available at http://vaww.research.va.gov/programs/tech_transfer/model_agreements/default.cfm*

(2) Developing and disseminating procedures to be followed.

(3) Providing guidance and responding to questions regarding use of CRADAs.

5. REFERENCES: Federal Technology Transfer Act of 1986, Pub. L. 99-502.

6. FOLLOW-UP RESPONSIBILITY: The Technology Transfer Program office is responsible for the content of this Directive. Questions may be directed to (202) 254-0224.

7. RESCISSION: None. This VHA Directive expires December 31, 2012.

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