

STANDARD OPERATING PROCEDURES FOR BASIC COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

Purpose:

This document establishes procedures for negotiating and executing Cooperative Research and Development Agreements (CRADAs) for basic research.

Scope:

The Basic CRADA model is to be used only for the purposes of collaborative research, development, engineering, testing and evaluation.

For all other CRADA models, to include Phase I, II, III, or IV Clinical Trials and the transfer of material only, please refer to our website:

http://www.research.va.gov/programs/tech_transfer/model_agreements/default.cfm

Responsibility: Technology Transfer Program (TTP) Staff

Information:

A CRADA is an agreement between Department of Veterans Affairs (VA) and one or more non-Federal parties under which VA "Laboratory Directors" (defined herein as VA Medical Center Directors) may accept, retain and use funds, personnel, services, facilities, equipment, or other resources from collaborating parties, and in exchange for what VA receives from a collaborating party, VA may provide personnel, services, facilities, equipment, or other resources, but not funds toward the conduct of specified research and development efforts which are consistent with VA's mission. (See 15 U.S.C. 3710a(d)(1)). The Laboratory Director may also, in advance, grant licenses or assignments, or options thereto, for reasonable compensation when appropriate, to collaborating parties for any inventions made by a Federal employee under such agreements; and also in advance, may waive Federal government ownership to any joint inventions made under such agreements. However, a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the invention throughout the world by or on behalf of the government must be retained. (See 15 U.S.C. 3710a(b) (1) (A) and (2).) In such cases where it is determined to grant any of the rights in advance, they shall be granted directly to the collaborating party.

The Model CRADA is available at the TTP website:

http://www.research.va.gov/programs/tech_transfer/model_agreements/crada-model.doc

I. Legal Authority for CRADAs

a. Statutory Authority. The Federal Technology Transfer Act (FTTA) of 1986, Public Law 99-502, codified at 15 U.S.C. §3710 et seq., and amended on March 7, 1996, by Pub. L. No. 104-113, authorized the CRADA as a new mechanism to encourage the transfer of the results of

Federal research and development to the private sector. Further, the statute provides the agency with an opportunity to disapprove or require modification of any such agreement. The agency is afforded a 30 day period within which such action must be taken beginning on the date the agreement is received from the Laboratory Director.

b. Regulatory Authority. Under 38 CFR §1.653 authority has been delegated to the VAMC Directors, as "Laboratory Directors" under the FTTA to enter into CRADAs consistent with 15 U.S.C. 3710a (a)(1) and (2).

c. VA Policy. VA fully supports the goal of the FTTA and Executive Order 12591 and specifically encourages the utilization of CRADAs. An unsigned copy of the proposed CRADA shall be forwarded by the Laboratory Director to the Director of TTP (12TT) for review and approval. TTP will coordinate the review and approval with the Office of General Counsel (023). A detailed response will be provided within 30 days of receipt of the proposed CRADA outlining approval, disapproval or required modifications prior to execution by the Laboratory Director.

II. Advantages of CRADAs

a. The ultimate objective of the provisions of the FTTA, including the authorization of CRADAs, is to improve the economic, environmental, and social well-being of the citizens of the United States by stimulating the utilization of federally funded research and development. This objective is to be accomplished by encouraging increased interactions between the federal government, universities, foundations (profit and nonprofit) and industry, thereby facilitating the transfer of federal technology from federal laboratories to the private sector for further development and commercialization and to utilize special federal resources to aid the development, transfer and commercialization of non-federal inventions.

b. CRADAs can provide three major benefits for VA investigators:

- Their research can be supported completely or partially by resources provided by the non-federal collaborator.
- VA employees or former employees may be permitted to participate in the commercialization of inventions they make or made while VA employees.
- If any royalties are received as a result of intellectual property made within the CRADA, the investigator would receive a portion consistent with VA's Royalty Distribution Policy.

c. Advantages for VA Research Program (local and national):

- VA has the advantage of free use of any subject inventions for research.

- VA may receive royalty income which would be distributed consistent with VA's Royalty Distribution policy.
- VA may use funds, received under a CRADA from a collaborating party, to hire personnel, who will not be subject to full-time equivalent restrictions of VA, to carry out the CRADA. (See 15 U.S.C. § 3710a(b)(3)(B)).

d. The advantage for the non-federal collaborator to enter into CRADAs is access to federally developed know-how and technology, VA investigators, VA patients and the potential for profit.

III. Procedures for negotiating and entering into a CRADA:

a. Non-federal collaborators:

- In negotiating CRADAs, Laboratory Directors shall give preference to:
 1. Business units located in the United States which agree that products embodying inventions made under CRADAs will be manufactured substantially in the United States, and
 2. Small businesses and consortia involving small business firms. Laboratory directors must follow the requirement of 15 U.S.C. §3710a(c)(4)(B) pertaining to the preference for business units located in the United States.
- Coordination with affiliated university is required if a Cooperative Technology Administration Agreement (CTAA) for technology management exists and one of the investigators is a dual appointment personnel (DAP) or is a university employee. Where no CTAA exists and an investigator involved in the CRADA has a university appointment, the university must be contacted with the details of the CRADA and VA employee must either receive a waiver from the university or the university agrees that VA has the exclusive right to protect and license any Subject invention.

b. Negotiating and entering into a CRADA:

1. Investigator(s) informs Associate Chief of Staff (ACOS) for Research or Coordinator for Research and Development (R&D) of intent to develop a CRADA. Where a DAP employee is involved, the investigator is required to coordinate with the university (see last par. in III.a above.)
2. Investigator(s) identifies potential collaborator(s)

3. Investigator(s) informs potential collaborator(s) of statutory requirements for CRADAs by presenting a copy of the model CRADA when discussion of collaborative agreement first begins.
4. Investigator(s) completes a Conflict of Interest survey. (See link below.)
5. Investigator(s) completes a Fair Access survey. (See link below.)
6. ACOS for Research or Coordinator for R&D informs the Medical Center Director, that a CRADA is to be developed.
7. Investigator(s) and collaborator(s) draft a CRADA, with assistance of Regional Counsel and/or ACOS for Research or Coordinator for R&D, using the model CRADA as a guide. TTP is available for assistance during the development of the CRADA.
8. Where VA has a protected background invention involved in the CRADA, and the collaborator desires a commercial license from VA, TTP will work with the investigator(s) and the collaborator(s) to draft a license agreement following VA's model license agreement available on the TTP website. (If there is a question as to whether a license agreement is needed, contact the TTP office as soon as possible.)
9. ACOS for Research or Coordinator for R&D assures that the research to be performed under the CRADA has been or will be approved by the R&D Committee and appropriate subcommittee. The source of any funds to be used for VA resources must be identified and any conditions noted.
10. ACOS for Research or Coordinator for R&D requests VAMC Director to submit the CRADA, to the Director, TTP (12TT), 810 Vermont Avenue NW, Washington DC 20420 for review and approval.
11. TTP will coordinate with OGC (023) for legal review and comments.
12. TTP responds to the VAMC Director, within 30 days of receipt of the agreement, indicating approval, disapproval, or recommended changes to the CRADA prior to execution.
13. The CRADA is executed. The VA Laboratory Directory is the last to sign the CRADA.

14. The VA Laboratory Director, or designee, distributes the executed CRADA and copies thereof as follows:
 - One original to each signatory of the CRADA;
 - Copies to Director TTP; ACOS for Research and principal investigator performing the research;
 - If funds are administered through a VA nonprofit corporation (NPC) then a copy should be provided to the NPC.
 15. TTP maintains a central file of CRADAs along with a CRADA registry.
 16. ACOS for Research or Coordinator for R&D shall submit to the Director, TTP copies of the final report as specified in the CRADA.
- c. Handling funds associated with CRADAs: Funds contributed by the non-Federal party in support of the CRADA can be distributed in one of two ways:
1. Funds contributed by the non-Federal party may be deposited to budget clearing account 36F3875. When the laboratory (VAMC) performs the work related to a CRADA, the laboratory director will establish receivable reimbursements, notify VA Central Office of reimbursement earned and transfer appropriate amount of funds from the suspense account to the research appropriation as a reimbursement. VA Central Office will increase research obligation authority by the amount of reimbursement collected.
 2. Funds may be deposited with and administered by the local NPC.

d. Conflict of Interest Considerations:

The Conflict of Interest (COI) Survey is available at the TTP website:
http://www.research.va.gov/programs/tech_transfer/model_agreements/conflict.doc

The basic VA requirements regarding employee conduct standards in general and the avoidance of conflict of interest in particular is contained in 38 CFR 0.735. In order to comply with the FTTA, any potential conflict identified in the conflict of interest survey or arising during the negotiation and conduct of a CRADA or in the commercialization of inventions resulting from a CRADA should be immediately discussed with the Regional Counsel.

A copy of the COI Survey must be provided with the CRADA submission. The original must be maintained in the CRADA file at the VA Medical Center.

e. Fair Access Considerations:

The Fair Access Survey is available at the TTP website:

http://www.research.va.gov/programs/tech_transfer/model_agreements/fair-access.doc

In compliance with the intent of the FTTA, it is required that laboratories widely disseminate information on opportunities to participate with the laboratory in technology transfer, including CRADAs. Fair access to CRADAs is not to be considered as synonymous with the term "open competition", as defined for contracts and small purchases. Evidence of fair access or discussion of unique resource requirements utilized in the selection of the commercial partner should be maintained as part of the official CRADA file. Examples include announcement in the Federal Register and/or; presentations at professional meetings and publications.

If a Collaborator initiates negotiations for a CRADA the agency would not be required to announce if any other companies are interested in the same or similar subject collaboration. However, should another company approach VA, TTP will entertain another CRADA on a similar collaboration consistent with Fair Access obligations.

A Fair Access Survey must be provided with the CRADA submission. The original must be maintained in the CRADA file at the VA Medical Center.

f. Non-procurement Debarment and Suspension:

Prospective participants (non-Federal) in CRADAs shall submit the certification required by 38 CFR 44.510 as a basis for VA's deciding that these participants should not be subject to VA's non-procurement debarment and suspension regulations promulgated at Part 44 of title 38 CFR.

It is VA policy not enter into a CRADA with a company who cannot certify that they are in good standing to do business with the federal government regarding debarment, suspension, proposed debarment or other matters rendering them ineligible.

REFERENCES

- VHA Handbook 1200.18
- a. 15 U.S.C. 3710
- b. 38 CFR 1.653
- c. Part 44 of Title 38 CFR

FOLLOW UP DATE

January 2009