COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

CRADA
GUIDELINES

INTRODUCTION

The FTTA (Federal Technology Transfer Act) of 1986, Public Law 99-502, codified at 15 U.S.C. 3710 et seq., and further amended on March 7, 1996, by Pub. L. No. 104-113, authorized the CRADA (Cooperative Research and Development Agreement) as a new mechanism to encourage the transfer of the results of Federal research and development to the private sector. The following information will:

- Define the CRADA;
- Provide a model CRADA and an accompanying model license agreement;
- Describe the legal authorization for CRADAs;
- Describe the governmental purposes to be achieved by these agreements and the possible benefits to Federal scientists,
- Present criteria for the selection of non-Federal collaborators in CRADAs;
- Summarize policies and procedures for negotiating and entering into CRADAs, special considerations where investigators have either a dual appointment (DAP) or an appointment with an affiliated university and for handling funds associated with CRADAs; and
- Provide guidance for dealing with potential problems of conflict of interest and fair access.

DEFINITION OF A CRADA

A CRADA is an agreement between VA (Department of Veterans Affairs) 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, <u>but not funds</u> 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.

A MODEL CRADA

a. The proposed CRADA is intended as a model. However, justification must be provided for any significant change from that model CRADA to expedite the review process in the OGC (Office of General Counsel). Changes or additions should be indicated by underlining, and deletions should be marked through for easy identification.

b. Specific information and that contained in the brackets in the model agreement is intended as an example; it should be changed to reflect specific information pertaining to each CRADA.
c. Paragraphs 6.2 through 6.5 of the model CRADA concern the disposition of patent rights to inventions. The VA Medical Center (VAMC) Director, on behalf of the government must always retain a nonexclusive, irrevocable, paid up license to subject inventions that are assigned to private entities under those provisions. The amount of royalties to be retained under paragraph 6.7 on subject inventions assigned to private entities is discretionary.
d. Attached to the model CRADA is Appendix A, Statement of Work. Statement of Work should contain a detailed explanation of the research work to be performed under the agreement, and the time estimates for completion of the overall research project and the various identifiable phases leading to the completion of the research project.
e. The license agreement, Appendix B of the Model CRADA, is to be used for any inventions for which VA has ownership rights when a collaborating party is interested in further developing such an invention through a CRADA. The license agreement may also be used to license inventions of other parties when a collaborating party under CRADA has assigned to VA the rights to a subject invention and VA has determined to file for patent protection and is seeking to market the subject invention (see Article. 6.5 of the Model CRADA).
f. Resolution of any disputes under the CRADA, as specified in paragraph 11.2 of the model CRADA, shall be referred to arbitration in accordance with the arbitration Rules of the American Arbitration Association then in effect, if the parties are unable to resolve the dispute.

LEGAL AUTHORITY FOR CRADAs

a. Statutory Authority. The statutory basis for Federal agencies entering into CRADAs is provided by FTTA and Executive Order 12591 (April 10, 1987) entitled, Facilitating Access to Science and Technology.
b. Regulatory Authority. Under 38 CFR (Code of Federal Regulations) 1.653 authority has been delegated to the VAMC Directors, as "laboratory directors" under FTTA, within existing resources, to enter into CRADAs or license agreements as described by Section 2 of FTTA (15 U.S.C. 3710a (a)(1) and (2)) between the laboratory and the private sector. Although VAMC Directors have authority to enter into CRADAS, they shall obtain prior approval for these agreements from OGC (024). An unsigned copy should be sent initially to the Research and Development Office (RDO), Director, Technology Transfer Program (TTP / 122). Once the Director, TTP has reviewed the draft, the VAMC Director will be notified of any necessary changes. A final agreement should then be forwarded to Director, TTP (122) for review and OGC approval. The OGC has 30 days from the receipt of the final agreement to modify or reject it (see Article 9.1.3 of model CRADA); however, such modification or rejection will be accompanied by a written explanation. (Submittal of a draft agreement will expedite the final review process and will largely diminish the need to modify or reject final agreements).
c. VA Policy. VA fully supports the goal of the FTTA and Executive Order 12591 and specifically encourages the development of cooperative research and development agreements.

ADVANTAGES OF CRADAs

a. General. 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, foundation (profit and nonprofit) and industry, thereby facilitating the transfer of federal technology from federal laboratories to the private sector for further development and commercialization. This interaction is to be stimulated by the sharing of resources and of rewards resulting from the creation of intellectual property among the participating organizations and their employees.

b. Advantages for VA Investigators. CRADAs can provide three major benefits for VA investigators:
    1. Their research can be supported completely or partially by resources provided by the non-federal collaborator.
    2. Reference VA Royalty Distribution Policy
    3. VA employees or former employees may be permitted to participate in the commercialization of inventions they make or made while VA employees.

c. Advantages for VA Research Program (local and national):
    1. VA has the advantage of free use of the invention for all time, and/or VA has the advantage of royalty income.
    2. Royalty income is disbursed in accordance with the VA Royalty Distribution Policy.
    3. 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)).
    4. Royalty income would be available for obligation by VA HQ and the recipient laboratories during the fiscal year in which they are received or during the succeeding fiscal year for the following purposes:
        (a) to reward scientific, engineering, and technical employees of the laboratory;
        (b) to further scientific exchange among the laboratories of the Department;
        (c) for education and training of employees consistent with the research and development missions and objectives of VA, and for other activities that increase the potential for transfer of the technology of VA laboratories;
        (d) for payment of expenses incidental to the administration and licensing of intellectual property by VA or a VA laboratory with respect to inventions made at that laboratory, including the fees or other costs for the services of other agencies, persons, or organizations for intellectual property management and licensing services; or
        (e) for scientific research and development consistent with the research and development missions and objectives of the laboratory.

d. Advantages for Non-Federal Collaborators. The primary incentive for the non-federal collaborator to enter into CRADAs is the access to federally developed know-how and technology, with the potential for profit making that such access brings.

CRITERIA FOR SELECTING NON-FEDERAL COLLABORATORS

In negotiating CRADAs, laboratory directors shall give preference to:

a. 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
b. 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 an Inter-Institutional Agreement (IIA) for technology management exists and one of the investigators is either a DAP or university employee.

PROCEDURES FOR NEGOTIATING AND ENTERING INTO A CRADA

a. Investigator(s) informs ACOS (Associate Chief of Staff)/Research & Development (R&D) or Coordinator/R&D of an intent to develop a CRADA.

b. Investigator(s) identifies potential collaborator(s). Where an IIA exists, investigators are required to coordinate with the affiliated university.

c. 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.

d. Investigator(s) completes a Conflict of Interest survey.

e. Investigator(s) completes a Fair Access survey.

f. ACOS/R&D or Coordinator/R&D informs the Medical Center Director, that a CRADA is to be developed.

g. Investigator(s) and collaborator(s) draft a CRADA, with assistance of Regional Counsel and/or ACOS/R&D or Coordinator/R&D, using the model CRADA as a guide. The VA RDO, TTP (122) is available for assistance during the development of the CRADA.

h. If applicable, the investigator(s) and the collaborator(s) draft a license agreement following the model license agreement.

i. ACOS/R&D or Coordinator/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, i.e. a merit review proposal.

j. ACOS/R&D or Coordinator/R&D requests VAMC Director to submit the CRADA and license agreement, if appropriate, to the RDO, Director, TTP (122), 810 Vermont Avenue NW, Washington DC 20420 for review and approval.

k. RDO submits CRADA (and associated license agreement) with recommendations to the OGC (024) for legal review and response.

l. OGC responds to the VAMC Director, within 30 days, indicating either approval of CRADA or recommending changes.

m. VAMC Director distributes the executed CRADA and copies thereof as follows:
    1. One original to VAMC Director's office;
    2. One original to each collaborator(s) named in CRADA;
    3. One reproduced copy to the RDO, Director TTP (122), VA HQ; and
    4. Reproduced copies to the principal investigator and other VA employees performing research under the CRADA.

n. RDO, TTP (122) maintains a central file of CRADAs and license agreements.

o. ACOS/R&D or Coordinator/R&D shall submit to the RDO, Director, TTP (122), VA HQ, copies of all required reports specified in the CRADA

PROCEDURES FOR HANDLING FUNDS ASSOCIATED WITH CRADAs

a. Two classes of funds are associated with CRADAs:
    1. Funds contributed by the non-Federal party in support of the CRADA; and
    2. Funds received from marketing and licensing intellectual property resulting from the collaborative research.
b. Funds contributed by the non-Federal party will 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 HQ of reimbursement earned and transfer appropriate amount of funds from the suspense account to the research appropriation as a reimbursement. VA HQ will increase research obligation authority by the amount of reimbursement collected.
c. VA HQ, TTP (reference VA Royalty Distribution Policy) will distribute funds received from marketing and licensing intellectual property. All payments to VA required under this CRADA shall be in U.S. Dollars and shall be by check or bank draft drawn on United States banks and shall be payable, as appropriate, to "Department of Veterans Affairs (royalty)." All such payments shall be sent to the following address: Department of Veterans Affairs, Technology Transfer Financial Management Office (12TT), 810 Vermont Avenue, N.W., Washington, D.C.20420. Each check must be accompanied by the first page of this CRADA. For multiple inventions, an itemized list must accompany the check clearly delineating the royalty amount designated for each individual invention.
d. Any royalty income or other income generated from a CRADA, which is not used or obligated at the end of the fiscal year following the fiscal year in which it was received, shall be paid to the U.S. Treasury.
e. VAMC Directors may transfer funds received under a CRADA for the conduct of its research to a nonprofit research corporation for administration.

f. Royalties and other income from licensing or assignment of inventions are not received for the conduct of VA research and may not be transferred to and administered by a nonprofit research corporation.

INVENTION MANAGEMENT SERVICES

Royalty income may be used for the payment of expenses incidental to the administration and licensing of inventions, e.g., by contracting for the services of a private sector firm.

a. However, any agreement intended to cover services of other agencies, persons, or organizations for invention, management and licensing services as permitted by 15 U.S.C. 3710c(a)(1)(B)(iv) and (a)(4) shall be sent to the OGC for review and approval prior to their execution and implementation.
b. However, as intended by 15 U.S.C. 3710(a)(1)(B), invention identification and evaluation and the filing of patent applications on those inventions retained are the responsibility of the VAMC Directors or other persons designated by the VAMC Directors without further review or approval. An option available to the VAMC Director is to reassign or seek guidance from the RDO, TTP (122) on these matters.
c. Such invention identification and evaluation and the filing of patent applications may be undertaken through the use of distributed royalties or other income, as part of a cooperative or license agreement or from other available resources.

CONFLICT OF INTEREST CONSIDERATIONS

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.

FAIR ACCESS CONSIDERATIONS

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. VA shall ensure that outside organizations have fair access to collaborative opportunities, licensing of federal technologies, and scientific expertise, giving special consideration to small business and preference to those that are located in the US and agree to manufacture in the US products developed under the agreement. 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 Commerce Business Daily; presentations at professional meetings and publications. The Fair Access Survey must be completed and accompany the CRADA submission and be maintained in the CRADA file.

NONPROCUREMENT 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 nonprocurement debarment and suspension regulations promulgated at Part 44 of title 38 CFR. VA policy is to **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

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