

INTELLECTUAL PROPERTY

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Handbook provides revised guidance and instruction regarding intellectual property (inventions) and the transfer of new scientific discoveries to benefit the public good (technology transfer).

2. SUMMARY OF MAJOR CHANGES: Corrects title of the agreement from Inter-institutional Agreement (IIA) to Cooperative Technology Administration Agreement (CTAA).

a. **Paragraph 2:** Describes dual appointment personnel, joint ownership, and Department of Veterans Affairs (VA) Without Compensation (WOC) Appointee Intellectual Program Agreement.

b. **Paragraph 4:** Adds additional definitions.

c. **Paragraph 6:** Corrects title from IIA to Cooperative Technology Administration Agreement (CTAA).

d. **Paragraph 12:** Notes requirements for State Department approval of foreign Cooperative Research and Development Agreement (CRADA)'s and that no inconsistencies exist between CTAA's and CRADA's.

3. RELATED DIRECTIVE: VHA Directive 1200.

4. RESPONSIBLE OFFICE: The Office of Research and Development (12) is responsible for the contents of this VHA Handbook.

5. RESCISSION: This VHA Handbook rescinds VHA Handbook 1200.18, dated May 17, 2001.

6. RECERTIFICATION: This document is scheduled for recertification on or before the last working date of November 2007.

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INTELLECTUAL PROPERTY

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides guidance and instruction regarding intellectual property (inventions) and the transfer of new scientific discoveries to benefit the public good (technology transfer). **NOTE:** *The provisions of this Handbook apply to all research services within the Office of Research and Development (ORD) i.e., Medical Research Service (MRS), Rehabilitation Research and Development (RR&D), Health Services Research and Development Services (HSR&D), and the Cooperative Studies Program (CSP).*

2. BACKGROUND

a. Under Executive Order 10096, and Department of Commerce implementing regulations, Title 37 Code of Federal Regulations (CFR) Part 501, the Department of Veterans Affairs (VA) has the right to assert a right, title, and interest in and to all inventions made by any VA salaried employee under certain circumstances. Employees must have a duty to perform research for VA, which could consist of being assigned research duties and/or receiving any VA research intra-mural funding award. Executive Order 10096 also requires that the invention be made during working hours; with a contribution by VA of facilities, equipment, materials, funds, or information, or of time or services of other VA employees on official duty; or which bear a direct relation to, or are made in consequence of, the official duties of the inventor. In the case of a determination under 37 CFR 501, VA must promptly provide the employee with a signed and dated statement of its determination, a Determination of Rights Letter, and the reasons therefor, and a copy of 37 CFR Part 501. **Authority:** *37 CFR §501.7.*

b. VA recognizes that not all inventors may be full-time employees. Some may be part-time VA employees and part-time employees of another organization such as a university affiliate. Inventors may also be full-time employees of another organization granted access to VA resources (space, supplies, equipment, patients, etc.) after executing a VA-Without Compensation (WOC) Appointee Intellectual Property Agreement [see http://vaww.research.va.gov/programs/tech_transfer/policies/ for specific instructions and form]. **NOTE:** *This is an internal VA Web site that is not available to the public.* As a result of this unique relationship, an invention can be made while the inventor is acting as an employee of one or both organizations. It is important to realize that VA determines ownership rights only to the extent the invention was made in connection with the inventor's VA employment or with a substantial VA contribution. The Determination of Rights letter does not address any ownership rights another organization may have through the inventor. If another organization has a joint ownership interest, VA must contact and work with the joint owner to expedite the development of the invention. VA will also substantially share with the inventor and the facility any ensuing royalties.

3. SCOPE

a. The mission of the VA Technology Transfer Program (TTP) is to serve the American public by translating the results of worthy discoveries made by employees of VA into practice. This requires a program that educates inventors concerning their rights and obligations, rigorously evaluates all inventions, obtains patents, and assists in the commercialization of new

products. It also requires consistent policies that govern the necessary relationships between investigator (i.e., inventor), academic partners, local VA medical centers, industry, and the Department of Commerce. It requires close collaboration between ORD and the VA Office of General Counsel (OGC).

b. The TTP public mission requires aggressive dissemination of educational information to investigators and of products to the market. It is also necessary that VA assert an ownership interest whenever appropriate, so that discovery can be built upon. This ensures access to technologies by veterans.

NOTE: TTP is committed to supporting the highest quality intramural research program. This means not only moving discovery from the laboratory to clinical practice in a timely manner, but also ensuring that inventors and their host VA medical centers receive optimal advice and support so that they may realize equitable compensation and recognition.

4. DEFINITIONS

a. **Intellectual Property (Invention).** Intellectual property is any art, machine, manufacture, design, or composition of matter, or any variety of plant, which is or may be patentable under the patent laws of the United States (U.S.). **Authority:** 38 CFR 1.651.

b. **Inventor.** The inventor is the individual responsible for the conception or reduction to practice of a device or process.

c. **Employee.** The term employee or Government employee means any officer or employee, civilian or military, of VA. For purposes of asserting VA ownership under Executive Order 10096, employee means an individual receiving salary from VA. **Authority:** 38 CFR 1.651.

d. **Dual Appointment Personnel (DAP).** This term means a person who has an appointment, either salaried or without compensation with both VA and a university affiliate or other nonprofit organization.

e. **WOC Appointment.** This term refers to a situation where an individual has an appointment with VA, but is receiving no salary from VA, and whose invention cannot be claimed by VA under Executive Order 10096. **NOTE:** *This individual may be an employee of a university affiliate or other nonprofit organization.*

f. **VA-WOC Appointee Intellectual Property Agreement.** This term means a document signed by an individual who has a WOC appointment and is performing research within VA.

g. **Disclosure.** Disclosure is the formal written process of documenting all aspects relating to the development of potential intellectual property for the purpose of determining and assigning ownership.

h. **Re-disclosure.** Re-disclosure is the formal written process of documenting all aspects relating to any improvement of a previously disclosed invention for the purpose of issuing a new determination on the improved invention.

i. **Premature Disclosure.** Premature disclosure is the presentation of too much data related to unpatented intellectual property in a public forum, e.g., scientific meeting, etc.

NOTE: Premature disclosure may result in the loss of patent filing rights.

j. **Patent.** A patent is an official written document securing to an inventor for a term of years the exclusive right to make, use, or sell an invention.

k. **License.** A license is a written authority granted by the owner of a patent to another person, empowering the latter to make or use the patented article for a limited period or in a limited territory.

l. **Royalty.** A royalty is compensation for an invention.

m. **Copyright.** A copyright is a form of protection provided by Title 17 United States Code (U.S.C.) to the authors of "original works of authorship" including literary, dramatic, musical, artistic, and other intellectual works, for a limited period of time. A copyright protects the form of expression, rather than ideas or the subject matter of the work. The copyright owner controls a number of exclusive divisible rights, the most fundamental one being the right to reproduce the work in copies.

5. INVENTION DISCLOSURE

a. In the case of an invention (to include improvement of an invention) or believed invention, the inventor must complete a VA certification page and prepare a statement for submission to the inventor's supervisor. These documents are available at the TTP website http://vaww.research.va.gov/programs/tech_transfer/policies/. *NOTE: This is an internal VA Web site that is not available to the public.* This statement consists of a:

(1) Narrative, detailed description providing sufficient information and detail for VA to ascertain ownership rights and to file the appropriate legal documentation required to protect the invention.

(2) A statement setting forth the circumstances attending the making of the invention. The statement must include:

(a) The full name and address of the inventor.

(b) The grade and title of the inventor's position.

(c) The inventor's employment status (full-time or part-time).

(d) The inventor's duties at the time the invention was made.

(e) The facts pertinent to a determination whether the invention bore a direct relation to, or was made in consequence of, such official duties.

(f) Whether there was, and if so the terms of, any special agreement or understanding with respect to the use or manufacture of the invention.

(g) The date of the invention, when and where it was conceived, constructed, and tested.

(h) Whether it was made entirely during working hours.

(i) Whether, and to what extent, there was a contribution by the Government of any of the following:

1. Facilities,
2. Equipment,
3. Materials or supplies,
4. Funds,
5. Information,
6. Time, or
7. Services of other Government employees on duty. **Authority:** *38 CFR §1.656.*

b. **Review and Submission.** The inventor's supervisor must review the employee inventor's statement. The file is then submitted via the local Research and Development (R&D) Office for review and approval and sent via courier to the Program Manager, R&D Technology Transfer Section (122TT) using the address listed under Contact Information. Once processed, TTP submits the disclosure to OGC. **Authority:** *38 CFR §1.656.*

c. **Potential Outcomes.** There are three possible outcomes to an invention disclosure. They are that the Government:

- (1) Maintains right, title, and interest in, and to, any invention of a Government employee;
- (2) Is entitled to a royalty free license with ownership remaining with the inventor; or
- (3) Claims no interest or license; i.e., all rights remain with inventor.

d. **Appeals.** Any Government employee who is aggrieved by an agency determination may obtain a review of the determination by filing (within 30 days after receiving notice of such determination) two copies of an appeal with the Under Secretary of Commerce for Technology, c/o The Office of Federal Technology, Room 4837, U.S. Department of Commerce, Washington, DC 20230. On receipt of a copy of an appeal, the agency must furnish both the Under Secretary of Commerce for Technology and the inventor with a copy of a report containing the following information about the invention involved in the appeal:

- (1) A copy of the agency's statement. **Authority:** *37 CFR §501.7.*
- (2) A description of the invention in sufficient detail to identify the invention and show its relationship to the employee's duties and work assignments.
- (3) The name of the employee and employment status, including a statement of official duties and responsibilities at the time the invention was made.

(4) A detailed statement of the points of dispute or controversy, to include copies of any statements or written arguments filed with the agency, and of any other relevant evidence that the agency considered in making its determination. **Authority:** 37 CFR. §501.8.

6. COOPERATIVE TECHNOLOGY ADMINISTRATION AGREEMENTS (CTAA)

a. Retention of ownership and protection of intellectual property developed by VA investigators are key issues of importance. It is also important to acknowledge cases where co-ownership issues exist with VA academic affiliates. To address this issue, a model CTAA was developed in collaboration with the Office of General Counsel (OGC). This legal agreement outlines relevant definitions, terms, and conditions for handling intellectual property between both organizations.

b. Using the CTAA allows VA a co-ownership interest while providing the academic affiliate unimpeded access and authority to patent and market the intellectual property in question. This makes the invention attractive to manufacturers ensuring that if they develop the product for the marketplace, they will have exclusive rights to produce and market the invention. The overall benefit to the Government and the taxpayers is that an invention resulting from Federally-funded research will be protected by a patent.

c. Successful patents licensed to manufacturers provide a royalty stream. As a result, VA inventors benefit from royalties for their personal use, as well as a return of royalties to their research laboratories and facility. The American taxpayer gains by the return of funds to the laboratories to further medical research. Using CTAA's provides a win-win situation for VA and academic affiliates, while maintaining, strengthening, and/or expanding existing partnerships to the mutual benefit of both organizations. **NOTE:** *CTAAs are used with academic affiliates whenever possible.*

d. CTAAs are developed by the TTP staff, OGC, and the academic affiliate. For additional information, sample CTAAs are available at the TTP internet web site under the Technology Transfer link (see App. A for web site address).

7. PATENTS

a. Once intellectual property has been disclosed and reviewed by OGC and a determination has been made to retain ownership of an invention, the VA patent process begins. Under 35 U.S.C. §207, VA is authorized to apply for, obtain and maintain patents or other forms of protection in the U.S. and in foreign countries on inventions in which VA owns a right, title or interest.

NOTE: *Any invention owned by the Government under the criteria set forth in 37 CFR §501.6 needs to be protected by an application for a domestic patent and other necessary documents executed by the employee inventor prepared by or through the General Counsel, Deputy General Counsel, or the Assistant General Counsel for Professional Staff Group IV.*

Authority: 38 CFR §1.654.

b. VA may elect to use outside counsel (or other means to be identified), if it is determined appropriate. All VA-owned inventions not covered by CTAAs must receive centralized patenting support arranged and coordinated through the TTP. This support includes handling

patent applications, provisional patents, patent filings, follow-up requests for information concerning pending patent applications, international filings where applicable, and other necessary actions. *NOTE: These services are provided at no cost to the facility or investigator.*

c. If it is determined that the employee inventor is entitled to full ownership under 37 CFR §501.6, subject to a non-exclusive, irrevocable, royalty-free license in the Government, it is the duty of the employee inventor to notify OGC of the status of the patent application, including the patent application number so that VA may protect interests reserved to the Government.

Authority: 38 CFR §1.655.

8. COPYRIGHT

a. Title 17 U.S.C. Section 105, the U.S. Copyright Act, provides that copyright protection is not available for any "work of the United States Government" defined under the Copyright Act as a work prepared by an U.S. Government employee as part of that person's official duties (17 U.S.C. § 101). Consequently, works such as instructional materials prepared exclusively by VA employees as part of their official duties are not copyrightable, but are placed into the public domain. Section 105, however, permits the U.S. Government to receive and hold copyrights transferred to it by assignment, bequest, or otherwise.

b. Works prepared for the U.S. Government under a U.S. Government contract or grant may be copyrighted by the contractor or grantee unless the U.S. Government provides in the contract or grant that copyright is prohibited or, in a written instrument signed by the parties, that the U.S. Government owns all of the rights comprised in the copyright. It is U.S. Government policy to:

(1) Recognize that the owner of a copyright has a legally enforceable property right in the copyrighted work, and

(2) Obtain or procure a proper license or permission to use copyrighted works.

9. MARKETING

a. A critical component of any successful intellectual property program involves marketing new inventions or technologies to ensure timely production and introduction into the marketplace. All VA-owned inventions not covered by CTAAAs receive centralized marketing support arranged and coordinated through VHA Central Office. *NOTE: Currently, contractor expertise is available in the areas of initial technology screening and comprehensive technology assessment.*

b. The comprehensive technology assessment provides:

(1) Industry feedback,

(2) Identification of potential licensees,

(3) Comparison of competing technologies,

- (4) Evaluation of trends and market size, and
- (5) Identification of alternative applications.

c. In-house or contractor service is provided to identify market potential and compatible industry partners interested in commercialization of new products.

NOTE: A Technology Transfer Advisory Group consisting of experts familiar with, and experienced in, the field of intellectual property and commercialization of new products assists in guidance, oversight, and monitoring of VA technology transfer operations.

10. LICENSE

a. All VA owned inventions not covered by CTAA's receive centralized support arranged and coordinated through VHA Central Office in negotiating licenses with commercial entities for intellectual property owned by VA. These efforts ensure that industry partners identified through marketing efforts receive a license to manufacture and sell the intellectual property in question. These services must be provided at no cost to the facility or investigator.

b. Under 35 U.S.C. §207, VA is authorized to grant non-exclusive, exclusive, or partially exclusive licenses under federally owned inventions. Prior to granting a license application, VA must ensure that the criteria in 35 U.S.C. §209 have been satisfied.

c. License applications received from interested parties requesting the use of intellectual property owned by VA are reviewed to determine if specific legal requirements are met. The license application must satisfy the requirements and criteria set forth in 37 CFR Part 404.

11. ROYALTIES

a. Royalty income to VA is accepted, monitored, and distributed by the TTP. Centralized handling of royalty income allows compilation of data for evaluating and reporting on the program's effectiveness, and ensures compliance with applicable laws; e.g., the current Federal royalty income cap of \$150,000 per year per employee. *NOTE: Royalties paid to employees from non-Federal sources such as universities are not subject to this ceiling.*

b. Royalty payments must be made in U.S. dollars only by check or bank draft drawn on a U.S. bank payable to Department of Veterans Affairs (royalty) and sent to: Department of Veterans Affairs, Technology Transfer Program (122TT), 810 Vermont Avenue, NW, Washington, DC 20420. Under this policy, 85 percent of royalty funds received is returned to the local facility to support ongoing research activities. *NOTE: The most recent royalty policy is available at the TTP internet web site under the Technology Transfer link.*

12. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA)

A CRADA is an agreement between VA and one or more non-Federal parties under which VA "laboratory directors" (defined herein as medical center Directors) may accept, retain, and use funds, personnel, services, facilities, equipment, or other resources from collaborating parties in order to conduct R&D in a particular project. This may include the further

development of a VA-owned invention and may be entered into in cooperation with a license agreement. **NOTE:** *Proposed CRADA's can not be inconsistent with CTAA terms.*

a. 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 R&D efforts consistent with VA's mission. The CRADA may provide for potential licenses or, in exceptional circumstances, assignments, or options, for reasonable compensation (when appropriate) to collaborating parties for any inventions made by a Federal employee under such agreements. However, a non-exclusive, non-transferable, irrevocable, paid-up license to practice, or have practiced, the invention throughout the world, by or on behalf of the Government, must be retained. In such cases where it is determined to grant any of the rights in advance, those rights must be granted directly to the collaborating party.

b. CRADAs are negotiated by the VA medical center and regional counsel attorneys. Following review and approval by OGC, they are returned to the medical center for execution. CRADAs dealing with foreign countries require advance State Department approval prior to execution. This could add considerable time to the overall approval process. The most recent information regarding CRADAs, including sample agreements, is available at the TTP internet web site under the Technology Transfer link.

13. INQUIRIES

Information regarding points of contact for issues related to intellectual property is contained in Appendix A.

CONTACT INFORMATION

1. Inquiries regarding intellectual property need to be directed to:

- a. Program Manager
Technology Transfer Program
Department of Veterans Affairs (122TT)
810 Vermont Avenue, NW
Washington, DC 20420
(410) 962-1800 x267

or

- b. Director (or Deputy Director)
Technology Transfer Program
Department of Veterans Affairs (122TT)
810 Vermont Avenue, NW
Washington, DC 20420
(202) 408-3670

2. Additional information can be obtained at <http://www.vard.org> by clicking Department of Veterans Affairs Technology Transfer Program link.