

DETERMINATION OF RIGHTS FOR INVENTIONS AND DISCOVERIES

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive provides revised guidance and instruction regarding management of inventions and the transfer of new scientific discoveries to benefit Veterans' health care and the public good (technology transfer).
- 2. SUMMARY OF MAJOR CHANGES:** This VHA directive updates every section of the previous handbook to reflect current VHA procedures. Title has changed from Intellectual Property and the Technology Transfer Program.
- 3. RELATED ISSUE:** VHA Directive 1200.
- 4. RESPONSIBLE OFFICE:** The Office of Research and Development (10P9) is responsible for the content of this directive. Questions may be referred to 202-443-5600.
- 5. RESCISSION:** VHA Handbook 1200.18, dated November 1, 2002, is rescinded.
- 6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of January 2022. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

David J. Shulkin, M.D.
Under Secretary for Health

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DETERMINATION OF RIGHTS FOR INVENTIONS AND DISCOVERIES**1. PURPOSE**

This Veterans Health Administration (VHA) directive provides policy and guidance regarding invention disclosure and the management and commercialization of new scientific discoveries to benefit Veterans' health care and the public good (technology transfer). Any inventions made by Department of Veterans Affairs (VA) employees involved in VA research, including those with Without Compensation (WOC) or Intergovernmental Personnel Act (IPA) appointments, will be processed and managed in accordance with this directive. **AUTHORITY:** 15 U.S.C. 3710a, 35 U.S.C. 207-209, 38 U.S.C. 501, 7301(b); 37 CFR 404, 501; 38 CFR 1.650-1.663

2. BACKGROUND

a. Under Executive Order 10096, the Federal Technology Transfer Act of 1986 (Public Law 99-502), 15 U.S.C. Chapter 63, §§ 3701-3715, 37 CFR Parts 404 and 501, and 38 CFR §§ 1.650-1.663, VA has the authority to determine the respective rights of the Federal Government and of the employee-inventor in and to any inventions made by any VA employee. See 38 C.F.R. § 1.652. All VA employees, including full and part-time employees, WOC employees, and those working under an IPA agreement are required to disclose all inventions to VA as a condition of their VA employment or appointment. See 38 CFR §§ 1.651, 1.655, 1.656, and 1.662. **NOTE:** *Although most VA inventions are generated by the work of VA researchers, all employees whether or not hired to perform VA research must disclose any inventions to VA. All employees must disclose all inventions, including inventions made while off duty and without any contribution from VA.*

b. VA's decision to take title to an invention is based upon a review of the circumstances of the invention by the VHA Office of Research and Development (ORD) Technology Transfer Program (TTP). TTP's recommendation to the Office of General Counsel (OGC) and OGC's review are based on the applicable laws and regulations (37 CFR § 501.6).

c. The determination of any rights to reported inventions will be made by OGC by issuing a Determination of Rights (DOR) letter to the employee summarizing the facts considered in reaching the conclusion. See 37 CFR § 501.7 and 38 CFR § 1.657.

(1) Many VA employees, including Without Compensation (WOC) and IPA, may also be employees or appointees of an outside organization such as an academic affiliate. Inventions can be made during a period in which the employee is both employed by VA and another institution (Dual Appointment Personnel). VA's determination of ownership rights is only with respect to the employee's role at VA as described above (paragraph 2.b.).

(2) A DOR letter does not address any ownership rights another organization may have through the inventor. If another institution has a joint ownership interest in the invention, VA must contact and coordinate with the joint owner to expedite the

commercialization of the invention and coordinate the patent filing, prosecution, marketing, and licensing.

3. DEFINITIONS

The following definitions are applicable to this directive:

a. **Applicant.** An applicant is a party under whose name a patent application is filed in the United States or in a foreign jurisdiction. The applicant may be different from the inventor and the applicant (or co-applicant) should be the VA in cases where VA asserts ownership interest in a patent application.

b. **Disclosure.** A disclosure occurs when the invention is made public. This includes written or oral disclosures of any kind. Disclosure of an invention may, in some circumstances, prevent VA from obtaining patent coverage. **NOTE:** *Examples of disclosure include posting on Web sites, sharing manuscripts, presentations, and abstracts.*

c. **Dual Appointment Personnel.** Dual appointment personnel (DAP) are individuals who hold simultaneous appointments at both VA and an affiliated university or other affiliated institution, regardless of whether the appointments are full-time or part-time or are compensated or uncompensated.

d. **Employee or Government Employee.** “The term *employee* or *Government employee* means any officer or employee, civilian or military, of the Department of Veterans Affairs. Part-time, without compensation (WOC) employees and part-time consultants are included.” 38 CFR §1.651(b). Additionally, the term “employee” or “Government employee” includes any “special Government employee” as defined in 18 U.S.C. § 202; an individual working for VA pursuant to an IPA (5 U.S.C. §§ 3371-3375); a WOC (38 U.S.C. § 7405(a)(1)); or a consultant (5 U.S.C. § 3109).

e. **Intellectual Property.** Intellectual property (IP) refers to creations of the mind such as inventions, literary and artistic works, designs, symbols, names and images used in commerce. IP is protected as a property right under federal and state law, and includes primarily patents, trademarks, copyrights, and trade secrets.

f. **Invention.** The Stevenson-Wydler Technology Innovation Act of 1980, as amended, defines an invention as “any invention or discovery which is or may be patentable or otherwise protected by title 35 or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act.” See 15 U.S.C. § 3703(7). Section 101, Title 35 of the United States Code states “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” See 35 U.S.C. § 101.

g. **Invention Certification.** An Invention Certification is a formal statement by a VA inventor detailing VA involvement in the process leading to an Invention Disclosure. The Invention Certification should address each of the inquiries required at 37 CFR §

501.6, including whether VA funds, facilities, information or employee time was utilized in the research and whether the invention occurred as a result of the inventor's VA duties or bears a relation to the inventor's VA duties.

h. **Invention Disclosure.** An invention disclosure is a document that formally describes an invention and should contain (1) a detailed description of the invention, (2) a listing of possible inventors and their affiliations, (3) supporting data or documents and (4) any manuscript intended for publication which incorporates a description of the invention. An Invention Disclosure is not a Disclosure as defined under 4 (b). See http://vaww.research.va.gov/programs/tech_transfer/reporting.cfm for more details. **NOTE:** *This is an internal VA Web site that is not available to the public.*

i. **Inventor.** An inventor is an individual who makes an intellectual contribution to the creation of an invention, which is essential to the invention's novelty, utility, or non-obviousness. See 35 U.S.C. §§ 101-103. For an individual to be considered an inventor in a patent or patent application, the inventor must have contributed essentially to the novelty, utility, or non-obviousness of at least one claim in an issued or pending patent application. An inventor is presumed to have an ownership interest in a patent application unless the interest is extinguished (e.g., an assignment to his or her employer or through the VA Determination of Rights process). See 37. C.F.R. § 3.73(a); 37 CFR §§ 1.650-1.663.

j. **Patent.** A patent is a property right granted for a limited time by the U.S. Government to the patent owner to exclude others from making, using, offering for sale, or selling the subject matter claimed in the patent throughout the U.S. or importing the invention into the U.S. **NOTE:** *Patent protection is territorial. Foreign patent rights may be sought as provided for in each jurisdiction's local laws.*

k. **Patent License.** A patent license is, in effect, a contractual agreement that the patent owner will not sue the licensee for patent infringement if the licensee makes, uses, offers for sale, sells, or imports the claimed invention, as long as the licensee fulfills its obligations and operates within the bounds delineated by the license agreement. See Manual of Patent Examining Procedure Section 301; see also 35 U.S.C. § 261.

l. **Royalty.** A monetary consideration paid to the owner of IP subject to terms and conditions of a license.

m. **Without Compensation (WOC).** A WOC employee is an individual that has an official VA appointment, but does not receive any salary or benefits from VA. See 38 U.S.C. § 513; 38 U.S.C. § 7405(a)(1). This appointment may allow the individual to support VA's research program in various capacities including, but not limited to, investigator, research coordinator, and administrator while at VA for a defined period of time. WOC employees are subject to all laws and regulations pertaining to government personnel, including, but not limited to, Government ethics laws and Standards of Conduct and VHA Handbook 1100.19, Credentialing and Privileging.

n. **Without Compensation Employee Intellectual Property Agreement.**

(1) The VA Without Compensation Employee Intellectual Property (WOC IP) Agreement is a document that must be signed by an individual who has a VA WOC appointment and is performing VA research.

(2) WOC employees and their inventions are subject to the VA determination of rights process and the provisions of this directive. To ensure that this is clear, the WOC IP Agreement must be signed upon appointment. For those whose research or development duties are added or accrue later, a WOC IP Agreement must be signed upon initiation of those duties. Any individual who has not previously signed a WOC IP Agreement will be required to sign one after an invention has been disclosed to TTP. See Appointee Intellectual Property Agreement VA-WOC IP Information at the following link for instructions: http://vaww.research.va.gov/programs/tech_transfer/policies/default.cfm. **NOTE:** *This is an internal VA Web site that is not available to the public.*

4. POLICY

It is VHA policy that VA employees involved in VA research (including compensated, WOC, and IPA) disclose all inventions to VA, including inventions made while off duty or without any contribution of VA.

5. INVENTION DISCLOSURES BY VA EMPLOYEES

a. **Invention Disclosure.** Each VA employee who contributes to the conception of or reduction to practice of an invention must disclose the details of the invention to VA. The disclosure may be in the form specified by VA at http://vaww.research.va.gov/programs/tech_transfer/reporting.cfm or could be in a form used by the inventor's affiliated institution, provided the institution's form includes at least the information required in VA's disclosure form. **NOTE:** *This is an internal VA Web site that is not available to the public.*

b. **Invention Certification.** Each VA employee who contributed to the conception of or reduction to practice of an invention must complete the VA Invention Certification, and provide certain other facts and information to TTP. The certification form is found at http://vaww.research.va.gov/programs/tech_transfer/reporting.cfm. **NOTE:** *This is an internal VA Web site that is not available to the public.*

c. **Complete Invention Submission.** VA employees must submit to the Director of TTP both the Invention Disclosure information and Invention Certification for each Invention to which the employee has contributed, whether or not the employee believes a VA interest exists in the invention. See 38 CFR § 1.656. The Invention Disclosure and VA Invention Certification must be sent to the TTP Invention Disclosure mailbox at vattid@va.gov. It is the obligation of each VA employee to follow the Invention Submission Process to TTP even if the invention has already been reported to the employee's academic affiliate. The employee's supervisor or the Associate Chief of Staff for Research (ACOS/R) must review and sign each form.

d. **Invention Submission Process.** Only complete Invention Submissions will be acted on by TTP. Once a complete Invention Submission package has been received from a VA employee, TTP will review the information and draft a recommendation regarding VA's interest in the Invention. This recommendation will be forwarded to OGC for review and issuance of the final DOR letter.

e. **Potential Outcomes of an Invention Disclosure.** VA may:

(1) Obtain right, title, and interest in any invention of a VA employee;

(2) Leave title, right, and interest to the employee subject to the U.S. Government retaining a non-exclusive, irrevocable, royalty-free license for all governmental purposes; or

(3) Leave right, title, and interest to the employee. See 37 CFR § 501.6.

f. **Appeals.** Upon issuance of the DOR, an employee who disagrees with the outcome may obtain a review of the determination by filing, within 30 calendar days of receipt of the DOR, two copies of an appeal to the Secretary of the U.S. Department of Commerce at the address provided in the DOR letter. See 37 CFR § 501.8.

g. **Novelty-Destroying Public Disclosure.** Novelty-destroying public disclosure may occur when a description of an Invention is published, demonstrated, sold, offered for sale or disclosed orally or in writing to a third party prior to filing a patent application (***NOTE: A formal Invention Disclosure within VA is not a public disclosure.***) See 35 U.S.C. § 102(b). A public disclosure prior to patent filing could negatively affect VA's ability to obtain patent protection for an invention in the United States. Public disclosure prior to filing precludes filing for patent rights in most other countries. Examples of novelty-destroying public disclosures include oral or written presentations at scientific meetings or talks; a pre-conference posting of a poster, slide, or abstract; a statement made on a radio talk show or online medium, or a publication, whether online, in print, or other medium. ***NOTE: In order to adequately protect an invention, an inventor should contact TTP as far in advance of a disclosure as possible. TTP will work with inventors to develop an approach that will protect the rights of inventors and VA.***

6. INTELLECTUAL PROPERTY MANAGEMENT AGREEMENTS

VA's ownership and protection of intellectual property developed by VA employees is important. In some situations, VA and an academic affiliate may jointly own an invention. VA has executed Cooperative Technology Administration Agreements (CTAAs), Inter-Institutional Agreements (IIAs) or Invention Management Agreements (IMAs) with many of its academic affiliates. CTAAs, IIAs and IMAs are agreements that cover inventions jointly-owned with a particular institution and outline terms and conditions for cooperatively managing inventions including patent prosecution, marketing, licensing, Royalty distribution, and license compliance.

7. PATENTS

a. VA is authorized to apply for, obtain, and maintain patents or other forms of protection in the U.S. and in foreign countries to inventions in which VA has an ownership interest (35 U.S.C. § 207(a)(1)). Employees are required to cooperate with VA in the patent prosecution process, including signing an assignment document in favor of VA, as well as in any subsequent efforts to license patents or otherwise commercialize inventions. The CTAA, IIA, and IMA determine whether VA or its academic affiliates will take the lead in patenting, marketing, and licensing of jointly-owned inventions. If the affiliate does not take the lead in patenting or the invention is solely owned by VA, then TTP may patent, market, and license the technologies where appropriate. Documents for patent prosecution for any VA-owned invention shall be executed by the employee as necessary and processed by VA as appropriate. See 38 CFR § 1.654.

b. VA may elect to use outside patent counsel for patent filing and prosecution, and VA employees are required to cooperate with VA's patent counsel. If a VA academic affiliate is responsible for patent prosecution under an IMA, CTAA, or IIA, VA employees are required to cooperate with the academic affiliate's patent counsel. When VA is managing patent prosecution, TTP will directly arrange and coordinate patenting support. **NOTE:** *These services are provided at no cost to the VA facility or inventor.*

c. If it is determined that VA will leave the title to the invention with the employee subject to a government use license, the employee must comply with all requirements specified in the DOR letter. This includes identification of the government use license retained by VA in all patent applications filed. The employee is also required to notify TTP and OGC of any and all applications filed relating to the disclosed inventions, including the patent application number, so VA may protect those interests reserved to the government. See 38 CFR § 1.655 and 37 CFR § 501.6.

8. COMMERCIALIZING VA INVENTIONS

a. A critical component of any successful intellectual property management program is marketing new inventions or technologies to prospective industry partners for licensing and further development. This facilitates timely production and introduction of inventions or technologies into the marketplace for the benefit of Veterans and the public. All VA solely-owned inventions, and jointly-owned inventions for which VA has the lead in commercialization, receive centralized marketing, as appropriate, through TTP. **NOTE:** *TTP may use a contractor to assist in technology assessment and/or marketing.*

b. When TTP identifies a party interested in licensing a VA solely-owned or a jointly-owned technology and VA takes the lead in commercialization, TTP will lead negotiations for a license agreement with legal assistance from OGC.

c. VA is authorized to grant non-exclusive, exclusive, or partially exclusive licenses to federally-owned inventions. See 35 U.S.C. § 209(a).

d. Employees are expected to cooperate with VA in its efforts to license and commercialize inventions.

9. ROYALTIES

Royalty income to VA is received, monitored, and distributed by TTP in accordance with federal law. See 15 U.S.C. § 3710c. Centralized handling of Royalty income allows compilation of data for reporting purposes and ensures compliance with applicable laws (e.g., the current federal royalty income cap under 15 U.S.C. § 3710c(a)(3) is \$150,000 per year per employee). **NOTE:** *The most recent Royalty Distribution procedure is available at the TTP Web site:*

http://vaww.research.va.gov/programs/tech_transfer/policies/default.cfm. **NOTE:** *This is an internal VA Web site that is not available to the public.*

10. RESPONSIBILITIES OF THE VA TECHNOLOGY TRANSFER PROGRAM

TTP is responsible for facilitating the commercialization of VA inventions to benefit Veterans and the American public. This includes:

- a. Educating VA employees concerning their rights and obligations regarding inventions, as set forth in this directive, and in applicable federal regulations and statutes.
- b. Providing technical assistance to VA employees relating to the Invention Disclosures and Invention Certifications.
- c. Evaluating Complete Invention Submissions and providing recommendations and supporting documentation regarding VA assertion of ownership rights of inventions to OGC for their use in the legal review associated with issuing DOR Letters.
- d. Advising VA employees regarding intellectual property rights that may arise out of their VA employment duties.
- e. Coordinating applications for patents, managing patent portfolios and related paper work in coordination with outside counsel.
- f. Making VA's innovations more widely available to Veterans and the general public through transfer of VA technology to private and public sector partners for development and commercialization. These efforts may include the active marketing and licensing of VA inventions.
- g. Developing and implementing policies that govern the relationships among employee inventors, academic affiliates, local VA medical centers, and industry.

11. RESPONSIBILITIES OF THE ASSOCIATE CHIEF OF STAFF FOR RESEARCH

The ACOS/R is responsible for ensuring that all VA research employees at the facility are educated about and comply with the invention disclosure process. The

ACOS/R and supervisor of the inventor(s) must review and approve all Invention Disclosure and VA Invention Certification forms submitted by VA employees at the facility.

12. RESPONSIBILITIES OF VA EMPLOYEES

VA employees are responsible for complying with all applicable VA and Federal requirements. Specific responsibilities include:

- a. Submitting completed Invention Disclosures to TTP and their supervisor and local ACOS.
- b. Submitting completed Invention Disclosure and VA Invention Certification forms for any invention made by the employee regardless of where the ownership is believed to exist. See 38 C.F.R. § 1.656.
- c. Expected to cooperate with VA in any patent prosecution, commercialization, or licensing activity.

13. REFERENCES

- a. 15 U.S.C. §§ 3701-3715, Commerce and Trade, Chapter 63-Technology Innovation.
- b. 35 U.S.C. §§ 1-212, Part II-Patentability of Inventions and Grants of Patents, Chapters 10-18
- c. 37 CFR Part 404, Patents, Trademarks and Copyright, Chapter IV, Part 404 Licensing of Government Technologies.
- d. 37 CFR Part 501, Patents, Trademarks and Copyright, Chapter V, Uniform Patent Policy for Rights in Inventions made by Government Employees.
- e. 38 CFR § 501, Veterans Benefits Chapter 5-Authority and Duties of the Secretary, Subchapter 1-General Authorities, Contracts and personal services.
- f. 38 CFR §§ 1.650-1.663, Inventions by Employees of Department of Veterans Affairs (Part 1).
- g. VHA Directive 1200, Veterans Health Administration Research and Development Program.
- h. Manual of Patent Examining Procedure