

DETERMINATION OF RIGHTS FOR INVENTIONS AND DISCOVERIES

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive provides revised policy and instruction for the timely and complete reporting of inventions made by Department of Veterans Affairs (VA) employees and managing inventions to facilitate the transfer of VA inventions to partners for development and commercialization to benefit Veterans and the public.

2. SUMMARY OF MAJOR CHANGES: This VHA directive updates training requirements and responsibilities of the Associate Chief of Staff for Research (ACOS/R) for each VA medical facility to reflect current VHA procedures. Major changes include:

a. Amends paragraph 5 to clarify that the ACOS/R must ensure that all VHA research employees complete the Technology Transfer Program (TTP) online course in the Talent Management System (TMS) annually, and must also maintain a registry of personnel authorized to participate in VA research at the VA medical facility. The registry must include the start and end dates of the research employment or appointment as well as the employees' affiliation(s) for dual appointment personnel (DAP), as applicable.

b. Updates paragraph 11 to clarify that all VHA employees involved in research are required to complete the TTP online course in TMS on an annual basis.

3. RELATED ISSUES: VHA Directive 1206, Use of a Cooperative Research and Development Agreement (CRADA), dated June 19, 2018.

4. RESPONSIBLE OFFICE: The Office of Research and Development (14RD) is responsible for the content of this directive. Questions may be referred to vattid@va.gov or 202-443-5600.

5. RESCISSIONS: VHA Directive 1200.18, Determination of Rights for Inventions and Discoveries, dated January 11, 2017, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of October 2028. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

October 6, 2023

VHA DIRECTIVE 1200.18

**BY DIRECTION OF THE OFFICE OF
THE UNDER SECRETARY FOR HEALTH:**

/s/ Carolyn Clancy, M.D.
Assistant Under Secretary for Health for
Discovery, Education and Affiliate Networks

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publications Distribution List on October 12, 2023.

CONTENTS

DETERMINATION OF RIGHTS FOR INVENTIONS AND DISCOVERIES

1. PURPOSE..... 1

2. BACKGROUND..... 1

3. DEFINITIONS 1

4. POLICY 4

5. RESPONSIBILITIES 4

6. GENERAL PROCEDURES FOR REPORTING AND DETERMINING RIGHTS IN INVENTIONS 6

7. INTELLECTUAL PROPERTY MANAGEMENT AGREEMENTS..... 8

8. PATENTS..... 8

9. COMMERCIALIZING VA INVENTIONS..... 9

10. ROYALTIES 9

11. TRAINING 9

12. RECORDS MANAGEMENT..... 10

13. REFERENCES..... 10

DETERMINATION OF RIGHTS FOR INVENTIONS AND DISCOVERIES

1. PURPOSE

This Veterans Health Administration (VHA) directive provides policy and guidance regarding the timely and complete reporting of inventions made by Department of Veterans Affairs (VA) employees and VA's management of such inventions to benefit Veterans and the public. Inventions made by VHA employees, including dual appointment personnel (DAP) and those having without compensation (WOC) or Intergovernmental Personnel Act (IPA) appointments, will be reported and managed according to this directive. **AUTHORITY:** 15 U.S.C. § 3710c; 35 U.S.C. §§ 207, 209; 38 C.F.R. §§ 1.650-1.663.

2. BACKGROUND

a. Executive Order 10096 expressly recognizes that inventive advances in science and technology often result from Government expenditures and activities carried out by Government employees, and that rights in and to these inventions should be evaluated pursuant to a uniform patent policy to determine the rights of the Government and employee-inventors. Furthermore, Government policy, reflected in laws and regulations, is to use the patent system to promote the use, commercialization and public availability of inventions resulting from Government expenditures and activities.

b. Accordingly, Federal regulations implementing Executive Order 10096 require the reporting of inventions made by any VA employee(s), including inventions made while off duty and without any contribution from VA, whether or not the VA employee is employed to perform VA research, and that VA determine the respective rights of the Government and of employee-inventors in and to such inventions. This directive provides policy and guidance consistent with Federal regulations regarding the timely and complete reporting of inventions made by VHA employees and VA's management of such inventions.

3. DEFINITIONS

a. **Determination of Rights.** Determination of Rights (DOR) means a decision made by VA pursuant to Federal regulations regarding the legal rights to inventions between the Government and VA employee-inventors.

b. **Determination of Rights Letter.** A DOR Letter means a formal communication on behalf of VA from VA's Office of General Counsel to a VA employee-inventor stating the DOR decision and the inventor's rights and obligations with respect to the invention.

c. **Dual Appointment Personnel.** Dual Appointment Personnel (DAP) are individuals who hold simultaneous appointments at both VA and another institution, to which the employee may have obligations with respect to intellectual property (IP), regardless of whether the appointments are full-time or part-time or are compensated or uncompensated.

d. **Employee or Government Employee.** Employee or Government employee, whether or not capitalized, means any officer or employee, civilian or military, of VA. Part-time, WOC employees and part-time consultants are included (38 C.F.R. § 1.651(b)). Additionally, the term “employee” or “Government employee” includes, but is not limited to 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) and 7406(a)); and a consultant (5 U.S.C. § 3109).

e. **Government Use License.** The Government Use License (GUL) means reservation to the Government of a nonexclusive, irrevocable, royalty-free license in an invention with the power to grant licenses for all government purposes.

f. **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 laws, and includes primarily patents, trademarks, copyrights and trade secrets.

g. **Invention.** Invention, whether or not capitalized, means any invention or discovery which is or may be patentable or otherwise protected under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (15 U.S.C. § 3703(7)). The subject matter of an invention under Title 35 may include any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. See 35 U.S.C. § 101.

h. **Invention Certification.** Invention Certification is a confidential written statement prepared and signed by an employee and provided to VA to formally disclose the employee’s understanding of VA’s involvement in the making of an invention. Instructions for completing an Invention Certification are available at this link: https://www.research.va.gov/programs/tech_transfer/disclosure_certification.cfm.

i. **Invention Disclosure.** Invention Disclosure means a document that formally describes an invention and includes the following:

(1) A detailed description of the invention.

(2) A listing of possible inventors and their affiliations.

(3) Supporting data or documents.

(4) Any manuscript intended for publication which incorporates a description of the invention.

NOTE: Instructions for submitting an Invention Disclosure to VA are available at the following link:

https://www.research.va.gov/programs/tech_transfer/disclosure_certification.cfm.

j. **Invention Submission.** Invention Submission means the entire set of documentation required by Federal regulations that must be submitted to VA to issue a DOR for an invention, including one Invention Disclosure, and a separate Invention Certification from each VA employee who is an inventor or possible inventor, per invention. See 38 C.F.R. § 1.656 and 37 C.F.R. § 501.6.

k. **Inventor.** Inventor means the individual or, if a joint invention, one of the individuals collectively, who invented or discovered the subject matter of an invention. Inventorship is determined according to legal requirements after considering each individual's contribution to the invention claimed in the patent application.

l. **Patent.** Patent means a property right granted for an invention, for a limited time by the U.S. or a foreign government to the patent owner(s). A patent provides the owner(s) a right to exclude others from making, using, offering for sale or selling the subject matter claimed in the patent throughout the applicable jurisdiction or importing the invention into the jurisdiction.

m. **Public Disclosure.** Public Disclosure means any written or oral description of an invention made to any person who is not a VA employee or otherwise subject to confidentiality obligations to VA or the inventor(s). Public Disclosure of an invention prior to filing a patent application may prevent obtaining patent protection for the invention. Examples of a Public Disclosure of an invention include describing the invention in an abstract, manuscript, poster or on a website that is publicly accessible; making public presentations at meetings, on radio or online; demonstrating how the invention works or describing it orally or in writing to a friend, colleague or potential business contact who has no confidentiality obligation to VA or the inventor(s); and offering to sell or selling the invention even if the offer or sale is confidential.

n. **License.** License means an agreement in which a patent owner agrees not to sue the licensee (e.g., for patent infringement) as long as the licensee complies with the terms of the agreement.

o. **Royalty.** Royalty means consideration (e.g., money) paid according to the terms of a license.

p. **Without Compensation Employee.** Without Compensation employee (WOC) means an individual that has an official VA appointment, but does not receive any salary from VA. 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 Employees, including, but not limited to, Government ethics laws, reporting inventions, standards of conduct, and VHA Directive 1100.20, Credentialing of Health Care Providers, dated September 15, 2021.

q. **Without Compensation Employee Intellectual Property Agreement.** A Without Compensation Employee Intellectual Property (WOC IP) Agreement is an agreement directed to reporting and managing inventions that must be signed by VA and the VA

WOC appointee prior to the WOC appointee providing services. See: https://www.research.va.gov/programs/tech_transfer/for_wocs.cfm.

4. POLICY

It is VHA policy that each VHA employee, including compensated, DAP, WOC and IPA appointee must self-report inventions in accordance with this directive and Federal regulations, including inventions made while off duty or without any VA contribution. VA is responsible for issuing a DOR Letter when requested by an employee-inventor and managing inventions according to this directive. Federal regulations require the reporting of inventions made by VA employees and provide the process for determining rights in and to such inventions. See 37 C.F.R. part 501 and 38 C.F.R. §§ 1.650-1.663.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks.** The Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks is responsible for supporting the Office of Research and Development (ORD) with implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **VA Office of General Counsel.** VA Office of General Counsel (OGC) has responsibility for reviewing initial DOR recommendations made by TTP and issuing DOR Letters pursuant to 37 C.F.R. 501 and 38 C.F.R. 1.650-1.663. OGC will not make a DOR decision or issue a DOR Letter without information required to determine rights pursuant to 37 C.F.R. 501 and 38 C.F.R. 1.650-1.663. OGC is also responsible for providing legal review and approval of license agreements directed to the development and commercialization of VA inventions.

e. **Technology Transfer Program Director, Office of Research and Development.** The Technology Transfer Program (TTP) Director, ORD is responsible for facilitating the commercialization of VA inventions to benefit Veterans and the public. This includes:

(1) Educating VA employees concerning their rights and obligations regarding inventions, as set forth in this directive, and in applicable Federal regulations and statutes.

(2) Providing technical assistance to VA employees relating to the Invention Disclosure and Invention Certification forms.

(3) Evaluating Invention Submissions for completeness, returning incomplete Invention Submissions to the VA medical facility ACOS/R for resubmission, and providing recommendations and supporting documentation to VA's OGC for their use in making DOR decisions and issuing DOR Letters.

(4) Advising VA employees regarding IP rights and obligations that arise out of their VA employment duties.

(5) Managing VA inventions, including assessing the commercial potential and pursuing patent protection for an invention; overseeing any patent application filings, prosecution and patent maintenance; and coordinating patent matters with internal and external legal counsel, as necessary.

(6) 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 primarily include the active marketing and licensing of VA inventions to industry, or partnering with industry to further develop VA inventions through a Cooperative Research and Development Agreement (CRADA).

(7) Developing and implementing policies and agreements that govern relationships among employee inventors, academic affiliates, VA medical facilities and private industry.

(8) Working with each ACOS/R to assess VA medical facility compliance with this directive, and to annually report any noncompliance with this directive to each ACOS/R and VA medical facility Director and the Under Secretary for Health.

f. **Veterans Integrated Services Network Director.** The VISN Director is responsible for ensuring that all VA medical facilities comply with this directive and informing leadership when barriers to compliance are identified.

g. **VA Medical Facility Director.** The VA medical facility Director is responsible for ensuring overall VA medical facility compliance with this directive and that appropriate corrective action is taken if non-compliance is identified.

h. **VA Medical Facility Associate Chief of Staff for Research.** The VA medical facility ACOS/R is responsible for:

(1) Ensuring that all VHA employees involved in research at their VA medical facility are educated about, and comply with, this directive and Federal regulations directed to

VA's Invention Disclosure process, and complete the TTP online course each fiscal year. See paragraph 11.

(2) Reviewing and approving all Invention Disclosure and VA Invention Certification forms submitted by VA employees at the VA medical facility along with the supervisor(s) of the inventor(s).

(3) Maintaining a registry of personnel authorized to participate in VA research at the VA medical facility, including start and end dates of research employment or appointments and the academic affiliation(s) for DAPs, as applicable.

(4) Compliance with IP-related Records Management requirements in paragraph 12.

(5) Ensuring a WOC IP Agreement is signed by the VA and each WOC employee prior to initiation of WOC duties.

i. **VHA Employees.** VHA employees are responsible for:

(1) Submitting a complete Invention Submission according to the instructions at https://www.research.va.gov/programs/tech_transfer/disclosure_certification.cfm, to their immediate supervisor, for any invention made by the employee and for ensuring the complete Invention Submission is submitted to medical facility leadership (e.g., ACOS/R) for submission to TTP, via instructions provided at the link above. See 38 C.F.R. § 1.656. **NOTE:** *VHA employees (including DAP, compensated, WOC, and IPA) must disclose all inventions to VA, including inventions made while off-duty or without any contribution of VA.*

(2) Completing the training requirements in paragraph 11 of this directive.

(3) Cooperating with VA in any patent prosecution, commercialization, or licensing activity relating to inventions made by the employee.

(4) Notifying TTP of any and all patent applications filed by a third party (e.g., an affiliate) relating to the disclosed invention(s) made by the employee, including the patent application number.

(5) If employed as a VHA WOC employee, signing the WOC IP Agreement prior to engaging in VA research. VHA WOC employees and their inventions are subject to VA's DOR process and the provisions of this directive. The WOC IP Agreement must be signed upon appointment and prior to engaging in official VA duties, and any VHA WOC employee who has not previously signed a WOC IP Agreement is required to sign a WOC IP Agreement when the employee discloses an invention to TTP. A copy of the WOC IP Agreement and additional guidance is available at the following link: https://www.research.va.gov/programs/tech_transfer/for_wocs.cfm.

6. GENERAL PROCEDURES FOR REPORTING AND DETERMINING RIGHTS IN INVENTIONS

a. **Invention Disclosure.** Each VHA employee who contributes to the making of an invention must disclose the details of the invention to VA. See 38 C.F.R. § 1.656. Instructions for completing a VA Invention Disclosure can be found at https://www.research.va.gov/programs/tech_transfer/disclosure_certification.cfm. If an Invention Disclosure meeting VA's Invention Disclosure requirements has already been completed for submission to an academic affiliate or other institution, a copy of this Invention Disclosure form may be uploaded for submission to TTP according to the instructions provided at the preceding link.

b. **Invention Certification.** Each VHA employee who contributes to the making of an invention during their VA employment or appointment must complete a VA Invention Certification. Instructions for completing a VA Invention Certification can be found at https://www.research.va.gov/programs/tech_transfer/disclosure_certification.cfm.

c. **Invention Submission.** VHA employees must timely submit a complete Invention Submission, which includes both an Invention Disclosure (unless an invention disclosure meeting VA's Invention Disclosure requirements has already been submitted on their behalf) and an Invention Certification, for each invention to which the employee has contributed, whether or not the employee believes a VA interest exists in the invention. The employee's immediate supervisor, the ACOS/R or the VA medical facility head must review, approve and submit the complete Invention Submission, including the Invention Disclosure and VA Invention Certification forms, according to the instructions at https://www.research.va.gov/programs/tech_transfer/disclosure_certification.cfm.

d. **Determination of Rights Recommendation.** TTP will review the complete Invention Submission, make a DOR recommendation and provide the complete Invention Submission, DOR recommendation and any other invention-related information used to make the DOR recommendation to OGC for review.

e. **Determination of Rights Decision.** OGC is responsible for determining, subject to appeal to the Under Secretary of Commerce for Standards and Technology, the respective rights of the Government and the inventor in and to any invention made by a VA employee. VA's decision whether to take title to an invention is made based upon a review of the facts and circumstances of the invention, including the complete Invention Submission, and applicable laws and regulations. See 37 C.F.R. 501 and 38 C.F.R. 1.650-1.663. OGC issues a DOR Letter to the employee summarizing the facts considered in reaching the conclusion. See 37 C.F.R. § 501.7 and 38 C.F.R. § 1.657.

NOTE: *Inventions can be made during a period in which the employee is both employed by VA and another institution. VA's DOR decision is only with respect to the employee's role at VA. The DOR Letter will acknowledge that an employee may also be employed or appointed at another organization, and may have obligations to disclose and assign an invention to the organization. If another organization (e.g., an academic affiliate) has an ownership interest in an invention made by an VA employee, VA will attempt to work with the organization to manage the invention in accordance with any agreement VA may have or enter into with the organization.*

f. **Potential Outcomes of Determination of Rights Decision.** There are three ways in which invention rights may be determined by VA. See 37 C.F.R. § 501.6. VA may:

- (1) Obtain the entire right, title and interest in any invention made by a VA employee.
- (2) Leave right, title and interest in an invention to the employee subject to a Government Use License.
- (3) Leave the entire right, title and interest in an invention to the employee.

g. **Appeals.** Upon issuance of the DOR Letter, an employee who disagrees with the DOR decision may obtain a review of the DOR decision by filing an appeal, within 30 days of receipt of the DOR Letter, in accordance with 37 C.F.R. § 501.8.

h. **Novelty-Destroying Public Disclosure.** A Public Disclosure prior to patent filing may negatively affect VA's ability to obtain patent protection for an invention. **NOTE:** *Submitting an Invention Disclosure within VA is not a Public Disclosure. In order to adequately protect an invention and avoid a novelty-destroying Public Disclosure, an inventor should contact TTP as far in advance of a Public Disclosure as possible. Even if a Public Disclosure may have occurred prior to the submission of an Invention Disclosure or the filing of a patent application, VA employees must submit an Invention Disclosure to VA as soon as possible to provide TTP an opportunity to work with the inventors to determine whether patent protection may be obtained and to develop an approach that will protect the rights of the inventors and VA.*

7. INTELLECTUAL PROPERTY MANAGEMENT AGREEMENTS

In some situations, VA and an academic affiliate may jointly own an invention. VA has executed Invention Management Agreements (IMAs) or Inter-Institutional Agreements (IIAs) with many of its academic affiliates and other institutions. IMAs and IIAs are agreements that cover inventions jointly owned with a particular institution and include terms for cooperatively managing inventions, including patent prosecution, marketing, licensing and royalty sharing.

8. PATENTS

a. **Authority.** VA is authorized to apply for, obtain, maintain, license and commercialize VA-owned patents and inventions in the U.S. and in foreign countries (35 U.S.C. § 207(a)(1)).

b. **Jointly Owned Inventions.** When an academic affiliate or other institution is involved, an agreement (e.g., IMA or IIA) may determine whether VA or another institution will be primarily responsible for patenting, marketing and licensing jointly owned inventions.

c. **Employee Cooperation.** VHA employees are required to cooperate with VA in patent and invention-related matters, including filing and prosecuting patent applications

and signing any documents recognizing VA's ownership in the invention, as well as in licensing and commercializing inventions. VHA employees are also required to cooperate with outside or affiliate counsel authorized by VA to manage patent matters on VA's behalf. TTP will coordinate patent support for inventions in which VA has ownership, at no cost to the VA facility or VA employee. If it is determined that VA will leave title to an invention with the employee subject to a GUL, the employee must comply with all requirements specified in the DOR Letter. This includes identification of the GUL retained by VA in all patent applications filed. The VHA employee is also required to notify TTP of any and all applications filed relating to the disclosed inventions in which the Government retains a GUL, including the patent application number, so VA may protect those interests reserved to the Government.

9. COMMERCIALIZING VA INVENTIONS

a. **Marketing Inventions.** A critical component of any successful IP management program is marketing new inventions to prospective industry partners for licensing and further development. This facilitates timely production and introduction of inventions 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.

b. **Licensing Inventions.** VA is authorized to grant non-exclusive, exclusive and partially exclusive licenses to VA-owned inventions. 35 U.S.C. § 207(a)(2). TTP leads VA's efforts to license and commercialize VA-owned inventions with legal assistance and approval from OGC.

10. 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.

NOTE: *The Royalty Distribution procedure is available at the TTP website:*

https://www.research.va.gov/programs/tech_transfer/policies.cfm.

11. TRAINING

The following trainings are ***required***:

a. **Research Employee Training.** All VHA employees (including compensated, DAP, WOC and IPA) who are conducting research, funded to conduct research, or otherwise involved in any research activity at a VA medical facility are required to receive annual training on this directive as described under paragraphs 11.b. through d. below.

b. **TMS Course Number 131008977.** Applicable VHA employees (who are not Health Professions Trainees (HPTs) or otherwise subject to condensed training) are required annually to take TTP online course VA TMS Course Number 131008977 – VA

Technology Transfer Program Training, which is included in Curriculum VHA-071 – Technology Transfer Training – VA Research Employees.

c. **TMS ID 3185966 or TMS ID 3192008.** HPTs who are subject to condensed training are required annually to take either VHA Mandatory Training for Trainees (TMS ID 3185966) or VHA Mandatory Training for Trainees – Refresher (TMS ID 3192008).

d. **TMS ID 3192008.** Transitory, part-time, and intermittent VHA staff are required annually to take the Mandatory Training for Transitory, Part-Time, and intermittent staff (TMS ID 3192008).

12. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

13. REFERENCES

- a. Executive Order 10096.
- b. P.L. 99-502.
- c. 5 U.S.C. §§ 3109, 3371-3375.
- d. 15 U.S.C. §§ 3701-3715.
- e. 18 U.S.C. § 202.
- f. 35 U.S.C. §§ 101-102, 207-209.
- g. 38 U.S.C. §§ 7405(a)(1), 7406.
- h. 37 C.F.R. parts 404, 501.
- i. 38 C.F.R. §§ 1.650-1.663.
- j. VHA Directive 1100.20, Credentialing of Health Care Providers, dated September 15, 2021.
- k. Instructions for submitting Invention Disclosures and Invention Certifications via VA TTP's Online Portal:
https://www.research.va.gov/programs/tech_transfer/disclosure_certification.cfm.
- l. Appointee Intellectual Property Agreement and WOC IP Agreement Information:
https://www.research.va.gov/programs/tech_transfer/for_wocs.cfm.

m. Royalty Distribution Procedure:
https://www.research.va.gov/programs/tech_transfer/policies.cfm.