

Please contact Ryan Davis at Ryan.Davis7@va.gov for information and application

POSITION DESCRIPTION

Program Specialist, GS-0301-12

INTRODUCTION

The position is located at the VA Ann Arbor Healthcare System in the Office of the Associate Chief of Staff for Research, who is responsible for managing and directing the Research and Development Service Line. The Service Line supports one of the primary missions of VA, Research and Development, and provides integrated and comprehensive services to each medical center service line, employees, patients and families, and other stakeholder groups. As part of this mission, the Service Line administers research programs conducted by VA investigators, interacts extensively with the affiliates involved in research and ensures that compliance is met so that programs are run effectively. The position manages translational technology from a research portfolio of over \$25 million in direct expenses and over 400 projects servicing approximately 150 Principal Investigators and numerous research personnel. The incumbent will also work closely with the Technology Transfer Program (TTP), Office of Research and Development (ORD), Veterans Health Administration (VHA), Department of Veterans Affairs (VA). TTP has the principal responsibility for the implementation for the Federal Technology Transfer Act (FTT A) of 1986.

The Position:

1. Develops, proposes, and implements innovative business and commercial development strategies for licensing and partnerships of technology and inventions made by VA employees.
2. Coaches and guides VA employees to identify potentially patentable inventions.
3. Develops and implements business strategies for the licensing of patents, including the identification of prospective licensees, the valuation of patents, the development of business terms and the negotiation of patent licenses.
4. Provides advice, guidance and assistance to ORD on such things as the development and management of intellectual property; registration and management of patents, terms and negotiation of licensing and collaborative agreements, management and administration of royalties; transfer of research materials and other related matters.
5. Serves as the focal point within ORD, for the implementation of pertinent legislation, rules, and regulations, and the administration of activities relating to collaborative agreements, inventions, patents, royalties, and associated matters.
6. Proposes and assists in the development of TTP policy and prepares and disseminates operating procedures and guidelines for VHA staff on matters related to the areas of responsibility assigned to TTP.
7. Reviews and analyzes collaborative agreements to ensure that they are in accordance with applicable ORD, VHA, and VA policy and procedures, and federal laws.
8. Prepares or coordinates the preparation of regular and special reports on matters falling within the purview of TTP; including an annual report to congress.
9. Serves as liaison with individuals, committees, and organizations within and outside federal government who are interested or involved in matters relating to TTP. In addition to the VA Ann Arbor Healthcare System, the incumbent will be responsible for providing

technology transfer support for the Saginaw, Detroit, and Battle Creek Medical Centers.

Occasional travel is expected to Washington, DC, the assigned VA Medical Centers, conferences, or to other locations deemed essential by the Director or team lead.

Technology Transfer 55%

- With guidance from senior technology transfer staff and the Director, acts solely and independently, utilizing expert knowledge in biomedical technologies, knowledge of industry needs and practices to work closely with industrial, academic, and federal scientists to:
 - Identifies potentially patentable inventions that result from work performed at VA.
 - Develops and implement marketing plans to identify prospective industry development partners for VA owned inventions
 - Use a variety of resources to analyze the business practices and financials of interested prospective business partners
 - Use analysis results together with knowledge of industry needs and practices to develop negotiating strategies for the negotiation of business terms, including product development objectives and financial terms for the licensure of VA owned inventions.
 - Participates in negotiations of patent licensing agreements, with the legal assistance of OGC.
 - Monitors the activities of licensees after execution of licenses, to ensure compliance with license provisions, adequate development progress, and proper payments to VA.
 - Negotiates amendments to existing patent licensing agreements when justified by circumstance.
 - Makes the recommendation if patent applications should be filed on inventions based upon their commercial, scientific and technical merits and their importance to Veterans, the public and the Government and to ensure that the interests of the VA and their investigators are represented.
 - May serves as primary negotiator on matters relating to licensing VA patents. The position negotiates business terms, including financial terms (royalties) and discusses the language of the license agreement with an interested party.

Management of Regulatory Documents 30%

- With assistance from senior technology transfer staff, acts solely and independently in matters relating to originating, drafting, negotiating, and managing a portfolio of agreements including but not limited to, Material Transfer Agreements (MTAs), Confidential Disclosure Agreements (CDAs), Data Use Agreements and licenses.
- Originates drafts of the agreements as needed to address the specialized needs of TTP or ORD.
- Serves as a liaison to regional Academic Affiliates, responsible for communicating with the Tech Transfer office of the academic affiliates, compliance within agreements,

commercialization efforts of jointly owned IP, and assistance with distribution of royalties received.

- Solely conducts invention evaluations for commercial, scientific and technical merit and makes recommendations to General Counsel for the Government to assert rights.
- Develops and conducts educational programs designed to train VA employees, including VHA intramural investigators, administrative officers for research, Associate Chiefs of Staff (ACOS) for research, and medical center directors, about technology transfer issues such as invention disclosures, patents, licensing, confidential information, and collaborative agreements.

Conflict of Interest Administration 15%

- Serves as the Research Conflict of Interest Administrator for VA Ann Arbor Healthcare System. Reviews and advises on conflict of interest matters and serves as liaison with the Office of General Counsel Ethics team to ensure that financial conflict of interest with investigators is addressed.
- Advises investigators and administrators on matters involving both domestic and foreign patent rights, policies and procedures.
- This includes but is not limited to promoting increased awareness of the importance of patents and encouraging submission of invention disclosures at an early state of development, evaluating inventions and their marketability; the use of provisional applications; and the timing and ramifications of foreign filing decisions.
- Occasionally makes presentations and conducts seminars for these purposes throughout the country at varying medical centers.

Participates or completes special projects as assigned.

Performs other related duties as assigned.

FACTOR LEVEL DESCRIPTIONS

Knowledge required by the position

Expert knowledge of biomedical industry business practices, including (1) industry financial decision making, (2) research and development goal setting, management and milestone setting, (3) commercialization practices, including distribution channels, market segmentation, product position and reimbursement strategies, as applicable. Uses this expert knowledge of industry practices to plan, develop and negotiate term sheets, which describe key business terms that will be further developed in patent license agreements. Works closely with Office of General Counsel to develop and negotiate patent license agreements based on agreed business term. Experience and expertise in negotiating complex agreements in the private sector. Uses this expertise to serve as the lead for VA in the negotiation of patent license agreements and successfully negotiates and conclude agreements such as research agreements, licenses, MTAs, and CDAs. Expert professional or industry knowledge from among a broad spectrum of scientific disciplines (e.g., biology, microbiology, chemistry, biotechnology, biochemistry, animal science genetics, bioengineering, electronics, physics, mathematics, allied health, computer science and others). The level of technology in any discipline spans the full range of research technology levels conducted in VHA, much of which is highly advanced and rapidly changing. In such technologies, the principles, concepts and theories involved either are new, or represent radical

departure from those more commonly accepted and associated with the art. Advances in the field and the inventions arising there from frequently represent a major departure from the concepts, principles, and theories associated with the field, or represent principles, concepts and theories not previously known as such as in the many pioneering fields of study at VHA and ORD.

Knowledge of the administrative laws, policies, rules, methods and procedures of VHA and ORD as they relate to the technology transfer and typically represented by an advance degree in law, public health, business administration, chemical or biological science or other scientific discipline related to the mission of the VHA and ORD. This level of knowledge is employed to plan and carry out long-term actions and develop new strategies for problems which have not been susceptible to treatment by accepted methods. This includes expert knowledge and application of: 1) the laws and procedures; 2) the Stevenson-Wydler Technology Innovation Act and the Federal Technology Transfer Act, and the Cooperative Research and Development Agreements which they created; also, knowledge of the above laws and procedure will allow the incumbent to make educated and pertinent decisions relating to technology transfer with ORD, VHA and VA.

Working knowledge of the legal concepts of patentability, such as anticipation, obviousness, unexpectedness, synergism, abandonment, and distinctiveness of invention. Awareness of and working understanding of the Title 38 United States Code (Patent Laws), Section 37 of the Federal Technology Transfer Act, and the Cooperative Research and Development Agreements which they created; also, knowledge of the above laws and procedure will allow the incumbent to make educated and pertinent decisions relating to technology transfer with ORD, VHA and VA.

Awareness of and working understanding of the Title 38 United States Code (Patent Laws), Section 37 of the Federal Regulations, rules and procedures of patent prosecution set forth in the Manual of Patent Examining procedure, and by the Paris Convention, The Patent Cooperation Treaty, the European Patent Convention, and generally off of the legislative and judiciary regulations and decisions set down by the Executive Order, Congress, and the Courts, particularly the Court of Appeals for the Federal Circuit, The District Courts, the U.S. Court of Appeals, and the U.S. Supreme Court. This knowledge is utilized to aid in deciding on whether to patent VA technologies or not. Substantive knowledge of VHA and ORD organization and procedures. Knowledge of the scientific goals, priorities, duties and commitments of ORDs intramural programs. Substantive knowledge of the many research projects underway in ORD and VHA medical center laboratories to facilitate technology transfer with industry. Uses such knowledge to identify researchers with potentially inventive work to facilitate the transfer of these research ideas to the private sector for further development.

Supervisory controls

Works under the broad administrative and policy direction of the TTP Director and regional team lead, who provides broad program guidelines and objectives. Supervision is primarily for general guidance in new ORD and TTP goals and policies regarding the administration and management of its intellectual property. Exercises considerable initiative, originality and sound professional judgment in determining whether to broaden or narrow the scope of projects or studies to ensure that ORD goals and objectives are met. The position is granted wide latitude of independence

and plans, organizes, and schedules the work of the position, including the negotiation of all technology transfer agreements, directing outside legal counsel in patenting, managing marketing and directly handling licensing activities. Issues which are unusually complex or set precedents are discussed with the Director and team lead. The position is the authority for the business and technical aspects of technology transfer issues and actions. Decisions and recommendations are reviewed primarily for results obtained in achieving the goals and objectives of TTP and ORD. Findings and recommendations are normally accepted without significant change.

Guidelines

Written guidelines consist of Federal statutes and regulations, procedural manuals, policy issuances, scientific and medical reference books, program guidelines, etc., which cover activities with which the incumbent is involved. Other guidelines consist of formal and informal office policies, precedents and procedures which emphasize matters relating to judgment, efficiency and priorities. From an expert knowledge of business operations within companies, related laws, regulations and policies, the incumbent applies and interprets existing guidelines to develop modus operandi for the execution of work for which specific guidelines are not developed. The position functions as expert and uses judgment and discretion in determining intent, and in interpreting and revising existing policy and regulatory guidance for use by others. Utilizes the U.S. Code of Regulation (including Title 5, Title 15, Title 17, Title 21, Title 35 and Title 38) Code of Federal Regulations (including Title 21, Title 37 and Title 38), the Federal Acquisition Regulation, and professional Directors and journals as sources of established current information. Makes judgment as to the applicability of a procedure, regulation, or precedent decision to the particular situation. Makes reference to business resources such as Securities and Exchange Commission filings, company annual reports and press releases, business publications, technical materials including journals and reprints, science and engineering Directors and textbooks, the vast body of prior patent disclosure, as well as to general, legal and technical dictionaries and encyclopedias. In highly advanced and rapidly developing technologies, the surrounding literature is sparse, and the body of applicable prior art is not extensive.

Complexity

The position utilizes expert business process and scientific knowledge of the programs in ORD and their relationship to other parts of VHA and VA. Assignments are usually without precedent and often cover a wide range of issues which affect the Program. The level of difficulty and complexity of assignments is such as to require independent judgment and decision making, capacity for teamwork and a comprehensive knowledge of the scientific and administrative aspects of ORD activities and the ability to act solely to negotiate complex research and development agreements and intellectual property licenses independently and in opposition to corporation lawyers, managers and scientists. Work effectively with both senior and support staff and interacts successfully on a continuing basis with professional members and business representatives from industry and academia.

Independently performs a variety of duties encompassing the business, technical, scientific, legal and procedural aspects of the position including for example, advising inventors on patent matters, reviewing documents for inventive subject matter, and evaluating inventions for commercial value as well as patentability, and ensuring all appropriate provisions are included in agreements. Work is often complicated by the need to consider and evaluate the impact of

changes in the business environment, changes in medical reimbursement policies, legislative and regulatory requirements; long-range Program goals and objectives; political, economic, and social consequences of changes; or the changing nature of the Program's clients and beneficiaries. Advises ORD and VHA inventors and collaborates on a vast array of tasks relating to patent preparation and prosecution. Exercises a high order of perception, skill, ingenuity, judgment and creativity in comprehending highly advanced and abstract concepts, in identifying the most important elements of the invention, in identifying the commercial value of the invention, in visualizing alternative embodiments, in anticipating potential future uses for the purpose of drafting claims, and in combining legal and technical principles for the purpose of formulating arguments in support of unobviousness and general patentability. Correlates the several rules, regulations, procedures and policies of the TTP, ORD, VHA, OGC, VA, the PTO (Department of Commerce), the Paris Convention, the Patent Cooperation Treaty, and the European Patent Convention, all with one another and the guidelines established by Executive Order, the Congress, and the Courts.

Scope and Effect

The purpose of this position is to use expert industry knowledge and technical expertise to act as a "one stop" expert resource person for ORD and TTP with regard to the management of intellectual property. This includes identification of inventions, developing commercialization strategies for inventions for the benefit of veterans, providing advice regarding intellectual property and other activities as already described. Tact and diplomacy are absolutely essential to the program performance of this job. Assignments are related to government programs that are of significant interest to the public and Congress and are of major importance to several Departments and Agencies. Applies technical, scientific, and legal expertise in providing protection of the intellectual property arising from patentable developments at the ORD and VHA laboratories, and in providing a vehicle for technology transfer. Patents may be available for both domestic and foreign licensing to private industry with an ultimate return of royalties to the U.S. Treasury, VA and cash awards to inventors.

The position solely negotiates licenses including financial terms (royalties) and language of the agreement. Royalties have a direct long-term impact on the ability to reward (and retain) skilled researchers and the funding of research within VHA. Work facilitates partnership with a variety of academic, non-profit and commercial organizations to advance research and generate discoveries and inventions to benefit Veterans. Commercial interest in patents from ORD and the number of licenses granted thereon provide a measure of research importance and a guide to its future direction. Licensing worthy VA technologies can have a profound impact on improving veterans and general public lives. The patent disclosure is also a technical publication which contributes on a worldwide basis to the body of art in the subject technology, provides background and expertise for future developments.

Personal Contacts

Personal contacts include written (including facsimile and e-mail transmissions), telephonic and extensive in-person communications. These contacts are with attorneys, scientists, and business representative, industry and academic. Intra-agency contacts include all levels of research personnel in the ORD/VHA laboratories, information officers, OGC, and other administrative personnel. Inter-agency contacts include attorneys and executives for VA. Non-Government

contacts include contractors, grantees, and industrial and community representatives negotiating agreements with or requesting information about the TTP, ORD, VHA, VHA scientists, agreements, and ORD patents. All the above contacts may be face-to-face, telephonic, or written, as the situation warrants.

Purpose of Contacts

The purpose of the personal contacts is to facilitate the planning, negotiation and execution of complex, scientific research and development agreements between or among ORDNHA scientists, industry and academia, the protection and effective exploitation of the Government's intellectual property rights arising there from, and the management of inventions jointly owned with VA's academic affiliates. Contacts with the personnel at the intra-, inter-, and non-governmental level are for the purpose of exchanging information, negotiating terms of agreements, resolving unusual problems, and resolving problems related to identifying unreported inventions, title ownership, domestic and foreign rights, inventorship, and problems related to trademark registration and infringements. Contacts are also for the purpose of discussing rules, regulations, procedures and policies in regard to ORD patents and technology transfer agreements with VA researchers, V AMC leadership and academic affiliates.

Physical Demands

The work involves mostly office posture, entailing long periods of sitting in one position, intense concentration, and job-related pressure to meet critical legal deadlines. The position's work, while primarily sedentary, requires some walking, standing, bending and carrying of items such as papers, books and files, but normally places few physical demands on the incumbent. The position also includes the occasionally physical ability to meet with scientists and other staff including travel to and from VA medical center and prospective licensees.

Work Environment

The work is routinely performed in an office setting.

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