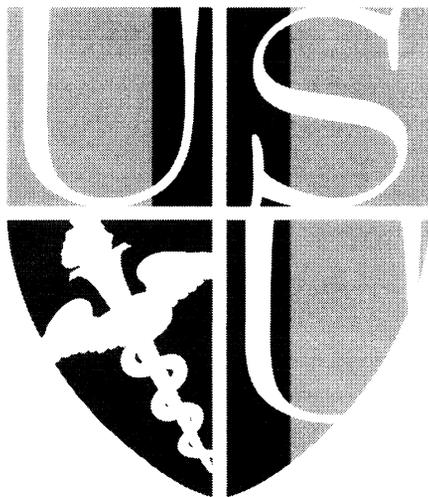


**USUHS
INSTRUCTION
5537**





UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

SUBJECT: Technology Transfer Activities – Invention Disclosures and Patent Consideration – and Related Intellectual Property

Instruction 5537

NOV 17 2006

(VEA)

ABSTRACT

This Instruction establishes policies, responsibilities, and procedures to be followed for technology transfer activities and the submission of invention disclosures for patent consideration at the Uniformed Services University of the Health Sciences (USUHS). Technology transfer activities are integral to educational activities and scientific research at USUHS, which is both a federal laboratory and public university. It is incumbent on USUHS, in this regard, to ensure that all ideas and discoveries generated by USUHS faculty members, researchers, and students are properly disclosed and utilized for the greatest possible public benefit. This includes protecting USUHS patent rights and related intellectual property and full compliance with U.S. and DoD patent, technology transfer, and related intellectual property requirements.

A. Reissuance and Purpose. This Instruction reissues USUHS Instruction 5537a and prescribes the procedures for submitting invention disclosures at USUHS and follow-on technology review, preparation of patent applications, and appropriate management of related intellectual property.

B. References. See Enclosure 1.

C. Applicability.

1. This Instruction is applicable to all inventions and related intellectual property conceived and/or generated:

a. At USUHS by USUHS employees and non-employees who utilize information,

equipment and/or funding made available to them by USUHS (regardless of source of funding).

b. By USUHS employees on activities or studies conducted by the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF) at USUHS or on behalf of USUHS.

c. At sites other than USUHS on activities or studies:

(1) Funded through or by USUHS.
(2) Conducted by USUHS faculty members, staff, or students who are acting in connection with their responsibilities or relationship to USUHS.

(3) Involved with the records or other materials of USUHS.

2. This Instruction is primarily concerned with inventions in USUHS laboratories leading to patents and commercialization (technology transfer). Reference (f) provides additional guidance on technology transfer; on the respective rights of USUHS and USUHS faculty members, researchers, and students; and on related areas of intellectual property (e.g., copyrights and trademarks).

D. Definitions. See Enclosure 2.

E. Policy.

1. All USUHS faculty members, researchers, and students who make inventions and discoveries during the performance of their official duties are required to (a) submit invention disclosures for patent consideration and (b) complete assignment of rights to the government unless it is determined that the government is not entitled to rights under criteria included in 37 CFR, Section 501.8. Non-government faculty members, researchers, and students are required to complete assignments of rights in accordance with individual agreements. (See Enclosures 4 and 5.)

2. USUHS will arrange for collaborative services to secure patent protection on inventions directly related to the USUHS mission. This includes taking the necessary steps to file or have filed patent applications that are the most useful, or are likely to be most useful, in carrying through its teaching and research mission. If a decision is made not to exercise the option of obtaining patent protection on particular inventions, or to transfer them to an interested federal agency, USUHS may authorize individual inventors to pursue patent protection at their own expense.

3. To make the best possible use of scientific and technical capabilities to enhance its effectiveness, USUHS has formed a collaborative alliance with HJF, a non-federal intermediary to provide additional support for its technology transfer programs. This is consistent with DoD Instruction 5535.8, references (e), (h), and (i).

F. Responsibilities.

1. Individual Inventors. Inventors who are USUHS employees, federal employees at USUHS, or HJF employees at USUHS shall file Invention Disclosures with the JOTT for evaluation and recommended action.

2. Department Chairs, Institute Directors, and Principal Investigators. Department Chairs, Institute Directors, and Principal Investigators will ensure that (a) non-government USUHS faculty members, researchers, and students complete agreements acknowledging that inventions made during the course of research supported by USUHS belong to the United States (Enclosures 4 and 5), (b) all USUHS faculty members, researchers, and students promptly submit invention disclosures through the Joint (USUHS and HJF) Office of Technology Transfer (JOTT) to the Joint Patent and Technology Review Group (JPTRG) for appropriate review and patent consideration, and (c) faculty members, researchers, students, and support staff who make successful contributions to technology transfer receive appropriate recognition.

3. JOTT/JPTRG. JOTT/JPTRG will (a) provide education and training on technology transfer policies and procedures to faculty members, researchers and students, (b) promptly process and evaluate invention disclosures, and (c) coordinate patent protection and commercialization of USUHS inventions.

4. VPR, VPC, and OGC. The Vice President for Research (VPR), Vice President for Finance and Administration (VPF), and General Counsel (OGC) will:

- (a) Ensure appropriate oversight for technology transfer.
- (b) Advise the President, USUHS, on appropriate allocation of technology transfer income, with priority to supporting laboratories generating income and to emerging technologies.

G. Procedures.

1. JOTT personnel will meet with USUHS inventors and potential inventors and educate them on the proper procedures for filing Invention Disclosures.

2. The JOTT shall provide the JPTRG with:

- (a) The inventor's completed Invention Disclosure form.
- (b) Relevant excerpts from any applicable agreements (grants, cooperative agreements, etc.) and proposals under which the invention arose or will be further developed.
- (c) Other data, if any, provided to the JOTT by the inventor.
- (d) Proposed or past publications, if any, by the inventor, relevant to the invention.

(e) Any preliminary report on patent ability and commercial potential.

3. The JPTRG will evaluate the invention and make a recommendation to the HJF.

4. HJF may elect to file a patent application or return the invention to USUHS. If the invention is returned to USUHS, USUHS will process the invention (i.e. file a patent application, transfer custody of the invention to another government agency, or release the invention to the inventor(s)). A final decision will be made by the President, USUHS.

5. The JOTT will follow up to ensure that:

- (a) The invention is marketed and made available for licensing by the public.
- (b) The filed patent applications are pursued to obtain available patent protection through the issuance of patents by the U.S. and/or foreign countries.

H. Effective Date. This Instruction is effective immediately.



Charles L. Rice, M.D.
President

Enclosures:

- 1. References
- 2. Definitions
- 3. Invention Processing Flow Chart
- 4. Non-government USUHS Faculty Member/Researcher Agreement
- 5. Non-government USUHS Student Agreement

REFERENCES

- (a) USUHS Instruction 5537, "Submission of Invention Disclosures and Preparation of a Patent Application," dated August 24, 1989 (hereby cancelled)
- (b) Title 10, United States Code, Section 2113, "Administration of University" (USUHS)
- (c) Title 35, United States Code, Section 171, "U.S. Design Patent Application"
- (d) Title 35, United States Code, Section 101, "U.S. Utility Patent Application"
- (e) EO 10096, dated 23 January 1950, as amended and as implemented by 37 CFR, Part 501
- (f) DoD Directive 5535.2, "Delegation of Authority to the Secretaries of the Military Departments-Inventions and Patents," 16 October, 1980 (certified current as of 11/21/2003)
- (g) DoD Directive 5535.3, "DoD Domestic Technology Transfer (T2) Program," May 9, 2000
- (h) DoD Instruction 5535.8, "DoD Technology Transfer (T2) Program," May 14, 1999
- (i) USUHS PPM-001-2004, "Technology Transfer Income"
- (j) "Memorandum of Understanding Between the Uniformed Services University of the Health Sciences and the Henry M. Jackson Foundation for the Advancement of Military Medicine," October 28, 1987
- (k) USUHS Standard Operating Procedure (SOP), "The Joint USUHS-Foundation Technology Transfer Program," February 24, 2006

DEFINITIONS

A. Copyright and Public Domain.

Protection for an original work of authorship “fixed in a tangible medium of expression.”

A work prepared by a government employee as part of that person’s official duties is in the public domain and no copyright arises in such a work. Such a work is, however, protected by copyright law to the effect that copyright may not be asserted by others.

B. Intermediary. Private entity facilitating and supporting technology transfer by a government laboratory or university (e.g., The Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF)).

NOTE: Under certain circumstances, and with the approval of the VEA, other not-for-profit organizations may be substituted for HJF in this Instruction, as provided for in 10 USC 2113(J).

C. Invention. A discovery and reduction to practice of a new product, apparatus, process, composition of matter or living organisms, or improvements to existing technologies in those categories, whether patentable or non-patentable.

D. Investigators. USUHS faculty members conducting work in pursuit of the aims of a research/clinical investigation project. Investigators are expected to conduct all research according to accepted scientific and resource management principles.

E. Intellectual Property. Inventions, discoveries, know-how, processes, methods, materials, copyrightable works, original data, and other creative or artistic works (which may have value). Intellectual property includes that which is protectable by statute or legislation (e.g., patents, copyrights, trademarks, service marks, trade

secrets, mask works, and plant varieties). It also includes the physical embodiments of intellectual effort (e.g., models, machines, devices, designs, apparatus, instrumentation, circuits, computer programs, visualizations, biological materials, chemicals and other compositions of matter, plants, and records of research). At USUHS, intellectual property most frequently refers to patentable inventions created by faculty, students, and staff in the course of their research or scholarly activities.

F. Patent Application. A document filed with a national government requesting that a patent be granted covering a particular invention. Filing a patent application allows an invention to be marked “Patent Pending.”

G. Principal Investigator. Investigator who is responsible for directing a project.

H. Provisional Patent Application. A relatively new form of protection for an invention, which is very simple, inexpensive to file, and allows the owner to use the term “Patent Pending” for a period of one year. However, a Provisional Patent application CANNOT become a patent, expires at the end of one year, and CANNOT be renewed or extended.

I. Scientific Research. Systematic, studious inquiries undertaken to produce knowledge and conducted in a way that provides a rational basis for conclusions. At USUHS this includes both basic science and clinical investigations. The result of the planned inquiries could reasonably be expected to be published in the scientific literature.

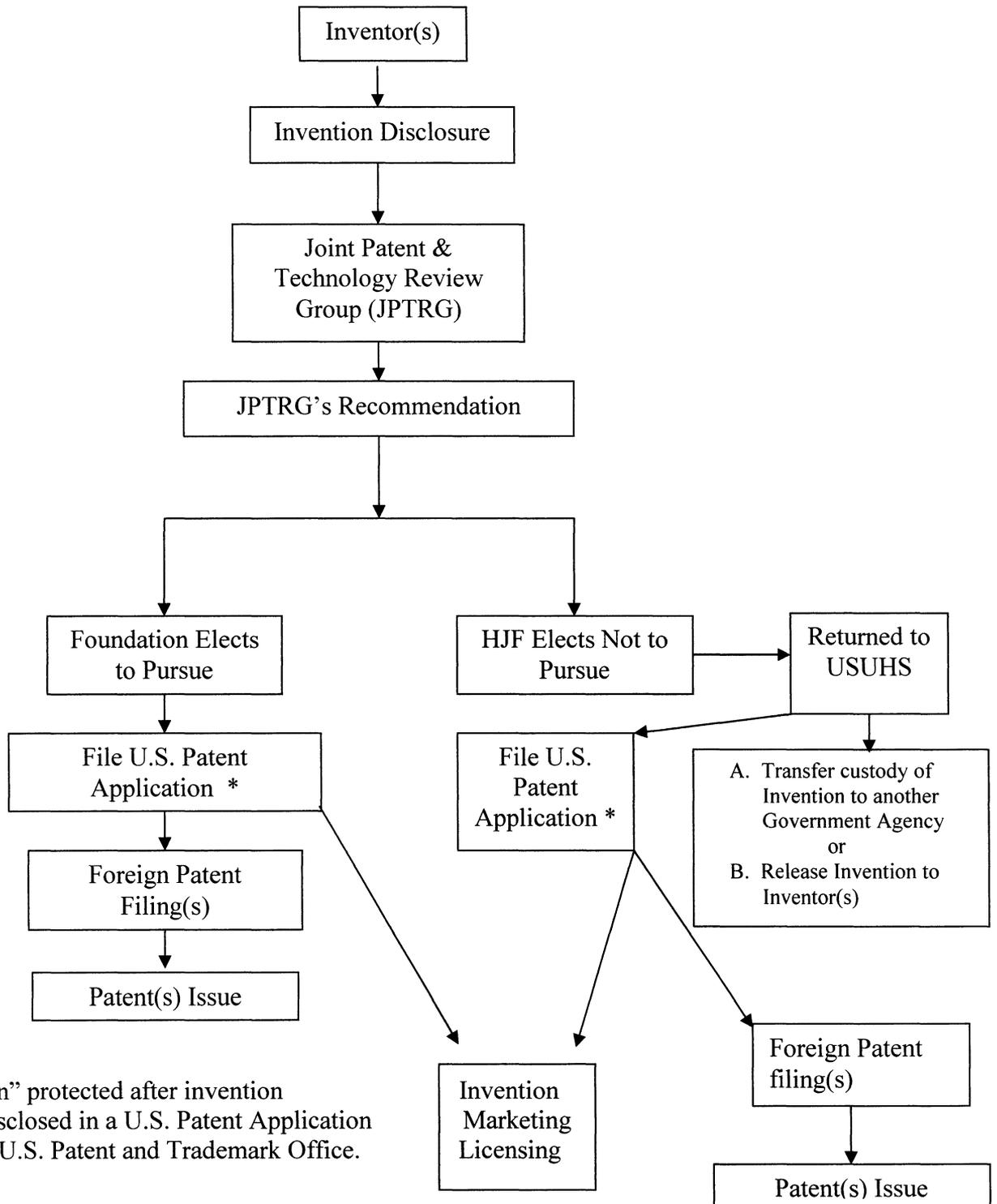
J. Trade Secret. Anything that a disclosing party desires to keep secret. Trade secrets usually include such things as the

manufacturing details for a product, variations, or alternative uses.

K. Trademark. Word, name, symbol, device or any combination thereof, which is used to identify and distinguish the goods or services of one company (or organization (e.g., USUHS)) from goods or services of another. In order to qualify as a trademark, the mark must be used in federally regulated commerce, and the mark must be distinctive. In a nutshell, the distinctiveness requirement means that a mark cannot describe the underlying product, or if it does describe the product, the mark must have been used extensively enough in commerce to acquire a certain level of market recognition (i.e. secondary meaning). Some marks will not be protected as trademarks, even though they are well recognized by consumers as trademarks (e.g., forbidden marks).

L. Utility Patent. Intellectual property right relating to advances made in a technical field. A patent for an invention is granted by the government to the applicant, and gives the applicant the right to stop others from making, using or selling the invention without permission for a limited period. In return for this right, the applicant must disclose how his invention works in sufficient detail to enable it to be produced by others. When a patent is granted, the applicant becomes a named inventor, but may or may not be the owner of the patent. Currently in the United States, the grant runs for 20 years from the filing date. Like any other form of property, a patent can be bought, sold, licensed or mortgaged. Patents are territorial - a United States patent will only give the owner rights within the United States, to include the right to stop others from importing certain products into the United States.

SCHEMATIC SUMMARY OF THE PATENT PROCESS



* "Publication" protected after invention has been disclosed in a U.S. Patent Application filed in the U.S. Patent and Trademark Office.

Non-Government USU Faculty Member/Researcher Agreement

This agreement is made by me, a non-government faculty member/researcher at the Uniformed Services University of the Health Sciences (USU), a “federal laboratory” operated by the United States Department of Defense (DoD), in consideration of my utilization of USU information, facilities or other resources and, further, USU’s agreement to consider me as a USU inventor for purposes of inventor(s)’ rights and monetary benefits.

I understand and agree that every possible Invention (as such term is defined in Patent, Invention and Technology Transfer policies of USU) which I conceive, develop, make, produce or reduce to practice as a result of my utilization of USU information, facilities or other resources will belong to the United States and will be promptly reported to USU.

I understand that each Invention will be reviewed by USU and appropriate action thereon will be taken in accordance with the Patent, Invention and Technology Transfer policies of USU.

I further agree that, in the event USU deems any such Invention is patentable, I will execute any document and do all things necessary, to assign to USU all rights, title and interest therein and to assist USU in securing patent protection thereon.

I further agree that I will do all things necessary to enable USU to perform its obligations to grantors or granting agencies which provide funds for research.

By execution of this agreement, I understand that I am not waiving any rights to a percentage of royalty payments received by the USU as set forth in the Patent, Invention and Technology Transfer policies of USU.

I agree to be bound hereunder for any period during which I conceive or develop any Invention in the course of my utilization of any USU information, facilities or other resources.

I am signing this agreement in my own right. If my employer has separately agreed or contracted with USU or otherwise made me available to pursue research using USU information, facilities or other resources, a representative of my employer has acknowledged this agreement. If I am working with a specific USU Department or Institute, the appropriate chair has acknowledged this agreement.

This Agreement supersedes and replaces any prior Patent Agreements with USU which may have been signed by me.

_____ FACULTY MBR SIGNATURE	_____ PRINTED NAME/TITLE	_____ DATE
_____ EMPLOYER SIGNATURE	_____ PRINTED NAME/TITLE	_____ DATE
_____ DEPT CHAIR SIGNATURE	_____ PRINTED NAME/TITLE	_____ DATE
_____ FOR USU	_____ PRINTED NAME/TITLE	_____ DATE

Non-Government USU Student Agreement

This agreement is made by me, a non-government student at the Uniformed Services University of the Health Sciences (USU), a “federal laboratory” operated by the United States Department of Defense (DOD), in consideration of my utilization of USU information, facilities or other resources and, further, USU’s agreement to consider me as a USU inventor for purposes of inventor(s)’ rights and monetary benefits.

I understand and agree that every possible Invention (as such term is defined in Patent, Invention and Technology Transfer policies of USU) which I conceive, develop, make, produce or reduce to practice as a result of my utilization of USU information, facilities or other resources, will belong to the United States and will be promptly reported to USU.

I understand that each Invention will be reviewed by USU and appropriate action thereon will be taken in accordance with the Patent, Invention and Technology Transfer policies of USU.

I further agree that, in the event USU deems any such Invention shall be patentable, I will execute any document and do all things necessary, to assign to USU all rights, title and interest therein and to assist USU in securing patent protection thereon.

I further agree that I will do all things necessary to enable USU to perform its obligations to grantors or granting agencies, which provide funds for research.

By execution of this agreement, I understand that I am not waiving any rights to a percentage of royalty payments received by the USU as set forth in the Patent, Invention and Technology Transfer policies of the Department of Defense and USU.

I agree to be bound hereunder for any period during which I conceive or develop any Invention in the course of my utilization of any USU information, facilities or other resources.

I am signing this agreement in my own right. If I am working with a specific USU Department or Institute, the appropriate chair has acknowledged this agreement.

This Agreement supersedes and replaces any prior Patent Agreements with USU which may have been signed by me.

STUDENT SIGNATURE PRINTED NAME/TITLE DATE

DEPT CHAIR SIGNATURE PRINTED NAME/TITLE DATE

FOR USU PRINTED NAME/TITLE DATE