

STANDARD OPERATING PROCEDURE FOR THE JOINT USUHS-FOUNDATION TECHNOLOGY TRANSFER PROGRAM

This Standard Operating Procedure (SOP) has been mutually agreed between the Uniformed Services University of the Health Sciences (USUHS or the “University”) and the Henry M. Jackson Foundation for the Advancement of Military Medicine (the “Foundation”). It implements the Subagreement on Technology and Patents entered into by the University and the Foundation, dated 15 June 1994, as the same may be amended or replaced from time to time. This SOP may be modified or amended by written agreement signed by the respective Presidents of the University and the Foundation.

I. AGREEMENTS

A. Material Transfer Agreements (MTAs)

The University hereby delegates to the Foundation blanket authority to negotiate and execute all MTAs for University researchers subject to review and acknowledgement by the University's General Counsel. The University hereby acknowledges that the Foundation has negotiated and executed MTAs in the past based on an informal understanding between the University and the Foundation. Within one year of the effective date of this agreement, all such previously executed MTAs that have neither expired nor been terminated are to be included in the data base described in section II.A.1 below.

University researchers and their research sponsors should submit requests for MTAs directly to the Technology Transfer Manager of the Foundation, who will coordinate with the University researcher as the MTA is negotiated. The University researcher(s) will sign an acknowledgement agreeing to be bound by the terms of the MTA. The Technology Transfer Manager of the Foundation will provide to the respective general counsel of the University and the Foundation a monthly report of MTAs negotiated; the report will identify the material involved, the grantor of the material, and the University researcher(s) involved.

B. Cooperative Research and Development Agreements (CRADAs)

CRADAs may be entered into by either the University or the Foundation acting alone. When either party considers it appropriate to involve the other in a CRADA, the general counsel of the University and the Foundation shall consult with one another. If both general counsel agree that the Foundation should negotiate a CRADA to benefit both the University and the Foundation, the general counsel may (but are not required to) refer the matter to the Joint Patent and Technology Review Group (discussed in section II below) to provide guidance to the Foundation. CRADAs involving University researchers will conform to applicable Department of Defense regulatory requirements

and will be coordinated with the affected departmental chair(s) and with the general counsel of the University.

C. Agreements Controlling Disclosure of Proprietary Information

Confidential Disclosure Agreements (CDAs), Nondisclosure Agreements (NDAs), and other agreements controlling disclosure of confidential or proprietary information may be entered into by either the University or the Foundation acting alone. Employees of the University should submit requests for such agreements to the general counsel of the University. Foundation employees should submit requests for such agreements to the general counsel of the Foundation.

Generally, where University technology or research by a University employee is involved, the general counsel of the University will forward requests for such agreements to the general counsel of the Foundation for action on behalf of the University. The University hereby delegates to the Foundation blanket authority to negotiate and execute all CDAs, NDAs, and similar agreements forwarded to the Foundation by the University subject to review and acknowledgement by the University's General Counsel. The University hereby acknowledges that the Foundation has negotiated and executed such agreements for the University in the past based on an informal understanding between the University and the Foundation. Within one year of the effective date of this agreement, all such previously executed agreements that have neither expired nor been terminated are to be included in the data base described in section II.A.1 below.

When the Foundation is entering into a CDA, NDA, or similar agreement on behalf of the University and the Foundation so requests, the affected University departmental chair(s) and researcher(s) will sign an acknowledgement agreeing to be bound by the terms of the agreement. The Technology Transfer Manager of the Foundation will provide to the respective general counsel of the University and the Foundation a monthly report of such agreements negotiated; the report will identify the other party to the agreement and the University department(s)/researcher(s) principally involved.

II. INVENTION DISCLOSURES

A. Establishment of JOTT and JPTRG

1. *JOTT*

There shall be a Joint Office of Technology Transfer (JOTT) staffed by employees of the Foundation, including the Foundation's Technology Transfer Manager and Technology Commercialization Associate, who shall operate the office in a collaborative manner with appropriate officials of the University, including the Vice President for Executive Affairs, the General Counsel, affected Department Chairs, the Director of the University's Center for Technology Transfer, and inventors. Failure of

any of the listed University personnel to provide input when requested will not preclude JOTT action.

The Foundation's Technology Transfer Manager shall maintain a data base of relevant agreements (including MTAs, CRADAs, CDAs/NDAs), invention disclosures, pending patent applications, issued patents, patent license agreements, and technology licenses. The data base shall be used for tracking of actions and agreements and generation of reports. *No action or agreement shall be commenced by the JOTT or the Foundation for any University researcher until the Foundation's Technology Transfer Manager has logged the action in the data base and assigned it a tracking number.*

2. JPTRG

There shall be a Joint Patent and Technology Review Group (JPTRG) constituted to review and make recommendations to the President of the Foundation with respect to (i) invention disclosures and (ii) other technology-related matters of joint interest to the University and the Foundation (*e.g.*, CRADAs, licenses, and other agreements that the Foundation is to negotiate on behalf of itself and the University). The JPTRG shall be chaired on a rotating basis by the University's Vice President for Research Administration and the Foundation's Vice President for Scientific Affairs. Membership in the JPTRG shall be as follows:

Ex Officio Members:

Foundation Vice President for Scientific Affairs (Co-Chair)
University Vice President for Research Administration (Co-Chair)
Chairperson, USUHS Faculty Senate Research Committee
University General Counsel
Foundation General Counsel
Director, University Center for Technology Transfer
Foundation Technology Commercialization Associate
Foundation Technology Transfer Manager (Recorder)

Appointed Members

Five (5) members to serve for three-year terms appointed by the University President, after consultation with the Foundation President.

B. Routing of Invention Disclosures

JOTT personnel will address all initial patent inquiries from University employees or Foundation employees working at the University.

An inventor who is a University employee, a federal employee at the University, or a Foundation employee at the University shall file an Invention Disclosure with the JOTT. JOTT personnel and the Director of the University's Center for Technology

Transfer will meet at the University with University inventors and potential inventors and educate them on the proper procedure for filing Invention Disclosures; JOTT personnel will meet at the Foundation with Foundation inventors.

The Foundation will be the patent management organization for all inventions by employees described in this section II.B.

C. Processing Through the JPTRG

Invention Disclosures and related information shall be processed by the JPTRG. The JOTT shall provide the JPTRG with:

- the inventor's completed Invention Disclosure form;
- relevant excerpts from any applicable agreements (grants, cooperative agreements, etc.) and proposals under which the invention arose or will be further developed;
- other data, if any, provided to the JOTT by the inventor or by the University's Center for Technology Transfer;
- proposed or past publications by the inventor, if any, relevant to the invention; and
- a preliminary report on patentability and commercial potential.

Other technology-related matters referred to the JPTRG by the general counsel of the University and the Foundation (*e.g.*, CRADAs, licenses, and other agreements that the Foundation is to negotiate on behalf of itself and the University) shall be processed by the JPTRG. The JOTT shall provide the JPTRG with:

- the draft CRADA, license, or other agreement, if any; and
- the JOTT's proposed draft of the JPTRG recommendation to the Foundation President (*e.g.*, desirable technical terms, business terms, or other aspects of the contemplated agreement that the Foundation should seek in negotiations).

The JPTRG shall:

- meet monthly (except in months in which there have been no Invention Disclosures or other new business) or as otherwise scheduled;
- consider and discuss each Invention Disclosure and other matter referred to it;

- in the case of Invention Disclosures, make a recommendation to the Foundation President whether to proceed or not to proceed with patenting; and
- in the case of other matters referred to the JPTRG, make such recommendation to the Foundation President as the JPTRG deems appropriate, keeping in mind (i) the interests of both the Government and the Foundation and (ii) applicable federal statutes and regulations, if any.

The Chair of the JPTRG, assisted by the Recorder of the JPTRG, shall issue a Report to the President of the Foundation recording the recommendations of the JPTRG and noting any dissenting votes and summarizing the reasons therefor. The Report shall be submitted to the Foundation President, with a copy furnished to the University President. The Foundation will proceed pursuant to the JPTRG recommendations, unless the University President or the Foundation President objects within ten (10) calendar days, or, in the case of recommendations to proceed with patenting, within such shorter time frame as may be necessary to protect the invention(s).

D. Post-JPTRG Processing of Inventions

No later than thirty (30) days after receiving the Chairman's report on the JPTRG recommendations, the Foundation shall complete its review of the patentability and commercial viability of each technology/invention and inform the Chairs in writing of the results of its review. If the Foundation review concluded that an invention recommended by the JPTRG is not patentable or is not commercially viable and the University Co-Chair of the JPTRG (the University's Vice President for Research Administration) believes patenting nevertheless should be pursued, the matter shall be resolved by mutual agreement between the University's General Counsel and the Foundation's General Counsel. Failing agreement, the matter shall be referred to the Presidents of the University and the Foundation for resolution, which may include University prosecution of the patent at its expense either with or without Foundation assistance.

No later than seven (7) calendar days (or sooner if required to protect the patent) after the Foundation has informed the Chairs of the JPTRG that the Foundation will proceed, the University shall execute an assignment, in substantially the form set forth in Attachment 1 hereto, to enable the Foundation to fully prosecute the patent applications in the U.S. and foreign patent offices.

III. PATENT PROSECUTION

JOTT personnel will consult with outside patent counsel on timing and strategy for prosecuting patents. The Foundation's Technology Transfer Manager will maintain appropriate patent records at the Foundation's Office of Technology Transfer and will manage the University/Foundation's patent portfolio, including maintenance of the data

base described in section II.A.1 above. JOTT personnel will monitor relevant deadline dates for patent filing, prosecution, and maintenance activities.

The Foundation will supervise outside counsel's prosecution of patents on inventions recommended (i) by the JPTRG, or (ii) pursuant to section II.D above, by the mutual agreement of (A) the University's General Counsel and the Foundation's General Counsel or (B) the University President and the Foundation President.

The Foundation will recoup fees and expenses in accordance with section IV.C below. The University, in its discretion, may reimburse the Foundation for fees and expenses not expressly recoverable under this SOP (*e.g.*, for fees and expenses incurred in patenting inventions that are not producing royalties). The agreed policy of the parties is that patent fees and expenses, and expenses incurred for commercialization of inventions, shall be recouped from royalties or other license payments received on patentable inventions, but not from payments received pursuant to research agreements and the like. Although the University and the Foundation intend that all aspects of the Joint USUHS-Foundation Technology Transfer Program ultimately will be self-supporting financially, both parties recognize that in some instances funds expended for patent fees and expenses and for commercialization efforts may not be fully recouped under the aforementioned policy.

Nothing in this SOP shall preclude the University and the Foundation from agreeing on a case-by-case basis to alternative arrangements for payment of patent prosecution costs or expenses of commercializing an invention or inventions (*e.g.*, as part of an agreement entered pursuant to section II.D above).

IV. COMMERCIALIZATION OF INTELLECTUAL PROPERTY

A. Analysis of Commercial Potential

Within thirty (30) days of the Foundation agreeing to patent the technology, Foundation technology commercialization personnel will meet with the inventor(s) to identify potential markets for the technology and possible collaborators to further the development of the technology. In the case of University inventor(s), Foundation technology commercialization personnel shall also coordinate with the Director of the University's Center for Technology Transfer regarding potential markets and possible collaborators. Failure of the Director to provide input when requested will not be a basis for inaction by Foundation technology commercialization personnel. After the initial meeting with the inventor(s), Foundation commercialization personnel will consult the inventor(s) on an as-needed basis.

Considering the relevant information provided by the inventor and the University, the Foundation will estimate the value of the technology and an appropriate royalty or other remuneration. The Foundation will develop its commercialization strategy based on the type of, development of, interest in, value of, and preexisting commitments to the technology.

Foundation commercialization personnel will endeavor to identify:

- other Foundation or University researchers with experience and research interests that may make them good collaborators to further the development of the technology;
- companies that may be interested in licensing the technology, taking into consideration the companies' needs and interests, including but not limited to established pharmaceutical companies, start-up companies, venture capitalists, and partnered groups of start-up companies and venture capitalists;
- other technologies that, if bundled with the technology to be commercialized, could make an attractive package; and
- other similar ongoing research within the University, the Foundation, other research institutions, and federal agencies.

As necessary and appropriate, discussions of technology between the Foundation and the potential licensee, collaborator, sponsor, or other partner shall be subject to a confidential disclosure agreement protecting the intellectual property rights of the University and Foundation. Foundation commercialization personnel will market the technology, using active and passive approaches as appropriate, by employing various methods including the following (depending on the nature of the technology, the status of development, and any pre-existing commercial commitments):

- soliciting interest via the internet;
- preparing and distributing brochures;
- attending, and networking at, industry and professional conferences;
- attending and making presentations at meetings held in conjunction with local and national biotech associations;
- approaching intermediaries (commercialization or teaming partners); and
- conducting direct discussions with pharmaceutical companies, start-up companies, venture capitalists, and partnered groups of start-up companies and venture capitalists.

Foundation personnel will work closely with Research Administration at the University and the Office of Sponsored Programs at the Foundation to explore the research interests of the inventor and identify other Foundation or University researchers who may want to collaborate to further the development of the technology. Foundation

commercialization personnel will also seek additional research and development funds, as appropriate, to further the development of the technology.

Once a commercial licensee, collaborator, sponsor, or other partner has been identified, the Foundation will perform reasonable due diligence to evaluate the commercial strength of the proposed relationship. Before commencing negotiations, the Foundation will present the proposed license, collaboration agreement, research and development agreement, or other arrangement to the University's General Council for concurrence (in the case of an agreement being proposed by the Foundation) or comment (in the case of an agreement proposed by the potential licensee, collaborator, sponsor, or other partner).

The Foundation shall report the results of commercialization efforts to the University's General Council in a monthly meeting with JOTT representatives.

B. Licensing of Technology

As a preliminary matter, the University and Foundation, supported by outside patent counsel of the Foundation as appropriate, shall develop a standard license agreement to be used by the Foundation in its license negotiations, either as an initial draft license agreement (in cases where the Foundation proposes the initial draft) or as a guideline (in cases where the licensee has proposed its draft license).

After the Foundation and the University, pursuant to IV.A above, have approved the proposed license, collaboration, research and development agreement, or other arrangement (or, in the case of a license proposed by a commercial licensee, collaborator, sponsor, or other partner, have approved the proposed response thereto), the Foundation will negotiate the necessary agreements. The Foundation will apprise the University General Council of the status of the negotiations for each agreement, as needed, but no less frequently than weekly. The Foundation will provide the University's General Council with copies of proposed drafts received from the other party and all proposed Foundation drafts.

C. License/Agreement Administration

The Foundation shall maintain relationships with licensees and parties to the Agreements and follow up and monitor licensee performance. The Foundation will monitor the performance of the licensee, collaborator, or other partner by scheduling meetings on an as-needed basis and by ensuring:

- that the required progress reports are sent to the Foundation on a timely basis; and
- that the required royalty, milestone, or other payments are made on a timely basis.

The University and the Foundation shall jointly share the royalties and licensing fees generated from inventions covered by this SOP in the manner specified in an applicable

CRADA or license agreement, if any, or in the absence of any agreement so specifying, in the following manner: from the royalties and licensing fees received for a particular invention

- (i) each year the first \$2,000.00 times the number of inventor(s) plus 20% of the balance shall be paid to the Inventors account maintained by the Foundation, such amount to be paid promptly thereafter from said account (in the case of University inventors, at the direction of the University President) to the sole-inventor, or collectively to be shared by joint-inventors, or as otherwise required by law, subject to the limitation that royalties or other payments from inventions to any one person shall not exceed \$150,000 for each year without the approval of the President of the United States;
- (ii) from the balance remaining, an amount equivalent to the previously unreimbursed fees and expenses incurred for patentability assessments and patent filings and prosecution attributable to such invention shall be paid to reimburse the incurring party or parties for such fees and expenses incurred consistently with this SOP;
- (iii) from the balance remaining thereafter, an amount equivalent to the previously unreimbursed expenses (excluding labor costs for employees of the Foundation or the University) incurred for and directly attributable to commercialization of such invention (*e.g.*, travel and lodging expenses, and fees for attorneys or consultants, incurred in preparing and negotiating license agreements related to such invention) shall be paid to reimburse the incurring party or parties for such fees and expenses incurred consistently with this SOP; and
- (iv) of the balance remaining thereafter, the University shall receive sixty percent (60%) and the Foundation shall receive forty percent (40%).

The Foundation will forward copies of progress reports, relevant correspondence, and payment information to the University's Vice President for Executive Affairs and the University's General Counsel.

V. OTHER RECURRING REPORTS

The University shall promptly prepare and forward to the JOTT a written disclosure of all inventions developed at the University as a result of sponsored research. The JOTT, in turn, shall provide timely written disclosure to the research sponsor, if any.

The JOTT shall establish and maintain a data base of inventions and shall provide monthly reports in a mutually agreed format to the University's Vice President for Executive Affairs, the University's General Counsel, the Director of the University's

Center for Technology Transfer, the Foundation's Vice President for Business Development, and the Foundation's General Counsel.

The Foundation shall provide the JPTRG a quarterly statement detailing expenses, royalties, distributions, commercialization activity, licensing activity, CRADA activity, and the research dollars generated and their distribution.

This SOP is effective immediately.

/s/

Dr. James A. Zimble
President
Uniformed Services University
of the Health Sciences

/ 6/30/2000 /

Date

/s/

John W. Lowe
President
Henry M. Jackson Foundation for the
Advancement of Military Medicine

/ June 30, 2000 /

Date

ASSIGNMENT

WHEREAS , the UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES, a United States Government Agency (hereinafter referred to as Assignor), by virtue of an assignment from an inventor executed on _____, has right, title, and interest in an invention entitled:

which was filed as a provisional application on _____ (Serial No. _____);
and

WHEREAS, the HENRY M. JACKSON FOUNDATION FOR THE ADVANCEMENT OF MILITARY MEDICINE, a corporation of Rockville, Maryland, whose post office address is 1401 Rockville Pike, Suite 600, Rockville, Maryland 20852 (hereinafter referred to as Assignee), is desirous of securing the right, title, and interest in and to this invention in all countries throughout the world, and in and to the application for United States Letters Patent on this invention and the Letters Patent to be issued upon this application; and

WHEREAS, Congress envisioned that the Assignor, should be, among other things, at the forefront of medical teaching, research and care, and, in 1983, in order to facilitate the carrying out of these purposes, established the Assignee; and

WHEREAS, accordingly, the Assignor and the Assignee have entered into an agreement on Technology and Patents whereby the Assignee is the Assignor's primary patent management organization, and this Assignment is in furtherance of this agreement.

NOW THEREFORE, be it known that in return for good and valuable consideration the receipt of which from Assignee is hereby acknowledged, the Assignor does hereby sell, assign, transfer, and set over unto the Assignee, its lawful successors and assigns, its entire right, title, and interest in and to this invention, and this application, and all divisions, and continuations thereof, and all Letters Patent of the United States which may be granted thereon, and all reissues thereof; and all rights to claim priority on the basis of such application, and all applications for Letters Patent which may hereafter be filed for this invention in any foreign country and all Letters Patent which may be granted on this invention in any foreign country, and hereby authorizes and requests the Commissioner of Patents and Trademarks of the United States and any official of any foreign country whose duty it is to issue patents on applications as described above, to issue all Letters Patent for this invention to Assignee, its successors and assigns, in accordance with the terms of this Assignment.

THE ASSIGNOR DOES HEREBY covenant that it has the full right to convey the interest assigned by this Assignment, and has not executed and will not execute any agreement in conflict with this Assignment; and

THE ASSIGNOR DOES HEREBY further covenant and agree that it will, without further consideration, communicate with Assignee, its successors and assigns, any facts known to it respecting this invention, and testify in any legal proceeding, sign all lawful papers when called upon to do so, execute and deliver any and all papers that may be necessary or desirable to perfect the title to this invention in said Assignee, its successors or assigns, execute all divisional, continuation, and reissue applications, make all rightful oaths and generally do everything possible to aid Assignee, its successors and assigns, to obtain and enforce proper patent protection for this invention, it being understood that any expense incident to the execution of such papers shall be borne by the Assignee, its successors and assigns.

IN TESTIMONY WHEREOF, I have hereunto set my hand.

STATE OF MARYLAND, COUNTY OF MONTGOMERY, SS.

DR. JAMES A. ZIMBLE, PRESIDENT
UNIFORMED SERVICES UNIVERSITY
OF THE HEALTH SCIENCES

Subscribed and sworn to before me this
____ day of _____, 20____.

Notary Public