

	MOREHOUSE SCHOOL OF MEDICINE	POLICY NUMBER	
	INTELLECUTUAL PROPERTY	EFFECTIVE DATE	16 December 2010
	POLICIES AND PROCEDURES	PAGE (S)	11
	<u>SUBJECT</u> PATIENTS AND ROYALTIES	SUPERSEDES	

## I. PURPOSE

To establish Morehouse School of Medicine (MSM) policy for patenting any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereon made by MSM faculty, staff, and/or students, while using MSM facilities and/or funds, and to establish policy for the distribution of patent income (the "Policy").

## II. ACCOUNTABILITY

Under the direction of the President, the Senior Vice President and Chief Financial Officer shall ensure compliance with this policy. The Vice President and Senior Associate Dean for Research Affairs shall implement this Policy.

## III. APPLICABILITY

- A. All MSM personnel, including every person holding any form of teaching or research appointment, fellows, and non-academic staff, holding appointments at or employed by MSM.
- B. All students enrolled at MSM.

## IV. DEFINITIONS

- A. **Copyrightable Material** - Material that is subject to U.S. copyright laws, including, but not limited to, literary works, musical works, dramatic works, choreographic works, graphic works, Software, photographic works, cardiographic, radiographic and pictorial works (e.g., - x-rays, images), sculptural works, audiovisual and videotaped works, sound recordings, films, theses, and works in electronic media (e.g., digitized works and network transmission of digitized works, multimedia broadcast, web-based products, recorded materials, remote transmission of information, instructional software, CD/DVD-ROMs).
- B. **Equity** - Stock, stock options, or a contractual or other right to acquire stock or options or interests as an owner, proprietor, partner, or beneficiary, or a beneficial interest in any of the foregoing.
- C. **Income** - From the licensing or other utilization of Inventions, Intellectual Property, or Tangible Research Property, income means sale proceeds, license fees, royalties, and other such revenues attributable to the use or sale of the property, but does not

include revenues explicitly earmarked in the license or distribution agreement to reimburse patent, development or other costs incurred by MSM, to fund future research or other activity, or to compensate MSM for providing training or other benefits other than the property or property rights themselves.

- D. **Intellectual Property** – includes, but is not limited to, Inventions (whether patentable or not), patents, patent applications, Copyrightable Material, Trademarks, service marks, domain names, Trade Secrets, trade dress rights, formulas, designs, Software, programming code, New Media, intangible rights in machines, compositions of matter and devices, techniques, processes, procedures, systems, or formulations.
- E. **Invention** – Any discovery of a subject matter that is humanly made, whether patentable or not, including any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereon. Examples of Inventions include but are not limited to new and improved devices, systems, circuits, and compounds; novel biological materials such as proteins, genes, DNA constructs, cell lines and transgenic animals, diagnostics, immunoassays, and therapeutics; new uses of known articles or substances; new methods of producing or manufacturing any articles or substances; algorithms; Software; and any other Tangible Research Property.
- F. **Inventor** - Any individual as referenced in Article III above who makes or develops any. Invention. An Inventor is further defined as an individual who has provided critical intellectual contribution that in its absence would not have resulted in the particular Intellectual Property. An author of a manuscript that describes the Invention may or may not appear as an Inventor, as determined by the Intellectual Property Committee in consultation with the MSM Office of General Counsel.
- G. **Invention Developed With MSM Support** - Any Invention made or developed upon the time of and while in the pay of; or during appointment by or enrollment as a student; in the laboratory of or with space, facilities, materials, or other resources of MSM (including resources provided in-kind by outside sources); or through use of direct or indirect financial support from MSM, including funding from any outside sources awarded to or administered by MSM.
- H. **Net Income** - The Income received by the MSM in each fiscal year from the licensing or other utilization of any Invention, Intellectual Property, or Tangible Research Property owned in whole or in part by it after deduction of all unreimbursed costs reasonably attributable to protecting such Intellectual Property and making it available to the public. These deductions shall include any expense of patent prosecution and interference, copyright registration, litigation, marketing, licensing, acquisition of related rights or permissions needed to license or utilize the Invention, and the like incurred prior to the end of such fiscal year.
- I. **New Media** - means digital or electronic media, including but not limited to software, video/audio tapes, CD-ROM, DVD-ROM, Internet-based media, and other multimedia materials that are used for the purpose of education or the dissemination

of knowledge, but does not include technology that may be embodied in the New Media.

- J. **Patent** - A patent is an intellectual property right granted by the Government of the United States of America to an inventor "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited time in exchange for public disclosure of the invention when the patent is granted. The term of a new patent is 20 years from the date on which the application for the patent was filed in the United States or, in special cases, from the date an earlier related application was filed, subject to the payment of maintenance fees. US patent grants are effective only within the US, US territories, and US possessions.
- K. **Patent Management Organization** - A corporation or foundation which may be designated by MSM from time to time as MSM's agent in the handling of certain patent matters.
- L. **Service mark** - is the same as a trademark, except that it identifies and distinguishes the source of a service rather than a product. The terms "trademark" and "mark" are commonly used to refer to both trademarks and servicemarks.
- M. **Software** – All computer-readable, computer-based, or computer-related materials as determined in the broadest sense, including but not limited to computer programs, user's manuals and other accompanying explanatory materials or documentation, mask works, firmware and computerized databases. "Software" includes, for example, micro code, subroutines, operating systems, high-level languages, and application programs in whatever form expressed (e.g., machine or assembly language, source or object code) or embodied (e.g., chip architecture, ROM, disk or tape storage, program listing). While some materials defined here as Software may not be covered by United States copyright laws (mask works, for example, are protected separately under the Semi-Conductor Chip Protection Act), any and all Software is treated as Copyrightable Material for purposes of MSM's Copyrights and Royalties Policy (the "Copyrights Policy"); in many cases, however, Software will constitute or embody Inventions as well as Copyrightable Material and shall be subject to this Policy as well as the Copyrights Policy. The Intellectual Policy Committee shall have the sole authority to clarify, modify, or define this term at its discretion from time to time.
- N. **Tangible Research Property** - means biological materials, Software, and any other tangible results of research conducted at MSM.
- O. **Trademark** - means any word, phrase, logo, design, or other symbol used to identify and distinguish the source of goods or services of one party from those of others. As used here, the term includes any trademark, service mark, trade name, or trade dress.
- P. **Trade Secret** - means any scientific or technical information, know-how, design, process, formula, listing, or other information of MSM that is kept reasonably

confidential and that has economic value. A Trade Secret may, but need not, be patentable or copyrightable.

## V. POLICY

### A. Requirements:

1. MSM is committed to fostering research, educational and technical endeavors related to the advancement of scientific knowledge and to the publication and the use of the results of such research. While such research activities performed with the facilities and/or funds of MSM by faculty, staff and students are not intended to be profit making, MSM recognizes that some activities may lead to Inventions which should be patented for one or more of the following reasons:
  - a. to protect the public interest;
  - b. to comply with the requirements of research grants, awards, and contracts for research;
  - c. to comply with the requirements agreed upon by MSM and non-research entities;
  - d. to promote the development of useful apparatus and processes which would not be developed without patent protection;
  - e. to encourage the making and development of Inventions and assure adequate rewards as incentive for Inventors; and
  - f. to support facilities and programs at MSM for research, education, and advance technology by means of income derived from royalties.
2. This Policy is intended to be consistent with these principles and philosophy and with the purposes of MSM. It is intended to encourage patenting of potentially valuable Inventions made by members of the MSM community while using MSM facilities, resources, and/or funds. Inventors shall take all steps necessary to make this Policy effective, including executing all necessary or desirable agreements, applications, assignments, or other documents if requested or required by MSM. A failure by an Inventor to execute such a document shall not in any way affect the applicability of this Policy.
3. Nature of Inventions; Protection and Licensing

Inventions that are "new," "non-obvious," and "useful" may be protected under the patent laws of the United States and other countries. To obtain a patent, the inventor – or, in some countries, the institution that owns the invention – must promptly file a patent application describing the invention in each country where patent protection is desired.

Many Inventions, including but not limited to biological materials and Software, are protectable under other legal doctrines even if they are not patentable. When Inventions are likely to be useful to the public, MSM may be able to license, sell, or otherwise utilize them to selected companies to develop them

into products and market them to others, in exchange for royalties and other benefits to MSM and its Inventors.

#### 4. Ownership of Inventions

- a. A condition of appointment or continued employment by or enrollment in MSM is the agreement to assign to MSM in accordance with this Policy all Inventions Developed with MSM Support, or otherwise subject to MSM ownership pursuant to this Policy. Notebooks, electronic files, and other documents pertaining to research activities and all data (including written and computerized material and photographs, etc.) leading to an Invention must be maintained by the Principal Investigator and copies made available to MSM.
- b. Rights in Inventions and Patents
  - a. Inventions and patents not owned by MSM or a third party, as provided below, may be owned by their Inventors (as defined by U.S. patent law). If no part of an Invention is owned by MSM, the Inventor shall be free to take any actions on his or her own initiative and at his or her own expense, and to keep all royalties and other proceeds. Before beginning to patent or commercialize any Invention, the Inventor must first have met the disclosure requirements of this Policy and received notice from MSM that it does not claim ownership in the Invention.
  - b. Inventions that are subject to any grant, contract, or other arrangement with a third party, such as the federal government, a foundation, or a corporate research sponsor ("Sponsored Inventions"), will be owned as agreed upon in that arrangement.
  - c. Subject to Sections A,4,b(1) and (2) above of this Article V, MSM shall own all Inventions, and patents claiming them, in the following categories:
    - (a) Inventions conceived or reduced to practice by one or more Inventors in performing activities that either:
      - (i.) received direct or indirect financial support from MSM, including funding from any outside sources awarded to or administered by MSM;
      - (ii.) made substantial use of any space, facilities, materials, or other resources of MSM including resources provided in-kind by outside sources (use of office space and word processors alone shall not be considered "substantial use" for purposes of this Subsection); or
      - (iii.) are otherwise an Invention Developed with MSM Support, as defined under this Policy.
    - (b) Inventions conceived or reduced to practice by one or more Inventors that are not Sponsored Inventions, or that are not subject to MSM

ownership pursuant to Section A, 4, b(3)(a) above of this Article V, but that arise out of or relate to the administrative, clinical, research, educational or other activities of the Inventor at MSM.

- d. The Intellectual Property Committee shall be responsible for considering disputes regarding ownership of Inventions and patents, including whether a particular Invention is related to the Inventor's activities at MSM, and shall make recommendations to the Senior Associate Dean for Research Affairs, who will make the final determination in consultation with the MSM Office of General Counsel.
5. Administration of Patents and other Intellectual Property
    - a. The Office for Sponsor Research Administration ("OSRA") shall be responsible for providing information and assistance on patent matters to Inventors, and for managing the patenting, licensing, and other use of Inventions under this policy after consultation with the Inventors.
  6. Disclosure Responsibilities of Inventors
    - a. Each and every Inventor shall promptly disclose to OSRA as described under Article VI, "PROCEDURE" all Inventions in order that such Inventions may be evaluated as to patentability and commercial and scientific utility so that timely decisions can be made regarding the filing of patent applications and/or other protections existing under international, federal, or state laws. Any Inventor who makes an Invention shall disclose it under the following conditions (which may overlap). Note that under some circumstances this Policy requires disclosure of Inventions that may not be owned by MSM.
    - b. In the case of any Invention that an Inventor believes is not owned by MSM, if the Inventor wishes to make or permit use of such Invention for commercial purposes or private gain, he or she must first disclose the Invention in accordance with Article VI, PROCEDURE of this Policy.
    - c. In the case of Inventions that are owned by MSM under this Policy –
      - (1) If the Invention is or may be patentable or otherwise protectable under statutory rights existing under international, federal, or state laws, the Inventor shall disclose it to OSRA.
      - (2) If the Invention is owned by MSM but is not included in category (i) above, the Inventor shall disclose it to OSRA if he or she desires to have MSM commercialize it or believes it is likely to have some commercial value.
    - d. If an Invention, whether patentable or not, is subject to any grant, contract, or other arrangement between MSM and a third party, the Inventor shall disclose it as necessary to carry out the terms of that arrangement.
    - e. An **Intellectual Property Disclosure Form** will be filed in accordance with the provisions set forth below under PROCEDURE. Such Intellectual Property Disclosure Form shall be completed and filed by the applicant/Inventor and

reviewed by the Intellectual Property Committee in accordance with this Policy before any provisional or full patent application is filed. In completing the Intellectual Property Disclosure Form, the applicant/Inventor will indicate the novelty of the potential Invention, and any and all obligations or collaborations made by the Inventor(s) that may have directly or indirectly led to the invention, including the intellectual contribution (percentage) made by the Inventors (i.e., % inventorship).

7. Inventions made Jointly with Outside Inventors

- a. Where an invention covered by this Policy has been developed jointly with individuals not covered by this Policy, the terms of any contractual agreement previously entered into by MSM with the non-MSM inventors will govern. If no agreement exists or the terms of the existing agreement are not complete, an agreement regarding patent rights and obligations, at MSM's discretion, shall be negotiated with the co-inventor(s)'s or the appropriate institution or corporation by the Associate Dean for Sponsored Research Administration.

8. Compliance with Contractual Patent Restrictions

- a. All Inventions or disclosures thereof resulting from research performed under grants or contracts entered into by MSM with specific patent restrictions shall be subject in the first instance to the restrictions, but, even when governed by contract or grant, all Inventions must be submitted for review and evaluation as provided in Section A, 6, e above of this Article V.

9. Distribution of Royalty Income

- a. A portion of royalty income shall be paid to the Inventor(s) according to the schedule set forth in Section C, 1 of Article VI below.
- b. In the event of more than one Inventor, the distribution of royalty income among such Inventors shall be determined in accordance with Section C, 3 of Article VI below.

## VI. PROCEDURES

### A. Disclosure of Inventions

1. Inventors shall submit a full disclosure of any Invention to OSRA using the Intellectual Property Disclosure Form.
  - a. Intellectual Property - ORD is responsible for all Technology Transfer/Intellectual Property related issues. Any questions or concerns related to such issues should be directed to this office. **It is extremely important that Intellectual Property not be presented, discussed, published, or disclosed prior to completing and filing an Intellectual Property Disclosure Form and receiving a written determination**

**from the Intellectual Property Committee indicating its intentions regarding the subject Intellectual Property.**

b. Process for Submitting Invention Disclosure

- Obtain, complete and return Intellectual Property Disclosure Form from the OSRA.
  - OSRA will forward the completed Intellectual Property Disclosure Form to the Intellectual Property Committee for review. The review process takes up to 30 days.
  - If the Intellectual Property Committee does not have proper representation for evaluating a given technology being disclosed, an ad hoc committee member with appropriate qualifications will be brought in for the review and will be required to submit confidentiality agreement substantially in the form of Exhibit II.
  - Once the Intellectual Property Committee reviews the disclosure, it will make a decision as to whether the disclosure should be submitted to the MSM Office of General Counsel based on its potential or returned to OSRA with reviewer's comments.
  - Requester will be notified in writing of the decision.
2. Disclosures by Inventors to OSRA must be made as early as possible in the development of an Invention.
  3. When any question exists as to whether an Invention is covered by this Policy, the Invention must be disclosed through the disclosure mechanism described above, with a request for a determination of whether the Invention is covered. In cases where an Inventor seeks to establish that an Invention is not covered by this Policy, the burden of proof shall be with the Inventor. The final determination shall be made in accordance with Section A,4,b,(4) of Article V above.
  4. Prior to an Inventor initiating any negotiations with outside companies with regard to further support or licensing of an Invention, an Intellectual Property Disclosure Form must be completed and submitted in accordance with the procedures outlined above and a determination made by the Intellectual Property Committee in support of such negotiations. This process shall be strictly adhered to even if the Inventor seeks additional support to complete the Invention or to enter into a collaborative arrangement to complete the Invention. This process is imperative in order to ensure confidentiality of the Invention or potential Invention.
  5. A **Confidentiality Agreement** must be completed and submitted to ORD when MSM or the applicant/Inventor wishes to have an Invention externally evaluated for commercial purposes or to gather expertise about the proposed Invention from an external expert.

## B. Patent/Intellectual Property Protocol

1. Once the Invention disclosure has been made to the ORD in accordance with the foregoing process, ORD shall promptly submit the disclosure to the Intellectual Property Committee for review. Upon a disclosure containing sufficient technical information to permit an effective patent study or other determination, and upon completion of such determination in accordance with the foregoing process, ORD shall notify the Inventor in writing of MSM's intentions regarding the Invention (for example, whether to seek a full or provisional patent and/or other statutory protections under international, federal, or state law).
2. Options Available to MSM. MSM may, after consultation with the inventor:
  - a. undertake the filing of patent prosecution within 30 days, development, and marketing of the Invention and shall bear all related costs;
  - b. seek support for the costs of patent prosecution through a licensing or other agreement;
  - c. cause the Invention to be assigned to a Patent Management Organization. The domestic or foreign patent rights, or both, may be assigned to a Patent Management Organization;
  - d. take other actions as it deems appropriate in its discretions, such as promoting, selling, and/or licensing the Invention to make it available to the public;
  - e. release to the Inventor all rights to the invention unless such rights revert to the sponsor of the program or the Federal Government; or if, for any reason, MSM is unwilling or unable to take appropriate steps to commercialize the Invention within 18 months following disclosure, offer to release the Invention to the Inventor(s), as in Section B, 2, e above of this Article VI, under **conditions acceptable** to both parties.
3. Continuing Option
  - a. Notwithstanding any previous decision to support an Invention, MSM, at its discretion, may at any time elect to release all rights to the Invention to the Inventor, as in Section B, 2, e above of this Article VI. If ownership in the Invention is relinquished, MSM is deemed to have at least a royalty-free non-transferable license for research, clinical, and educational purposes within MSM unless the parties agree otherwise.

## C. Distribution of Invention Related Income

1. Formula for Distribution of Annual Net Income
  - a. 60% of the net patent income and/or milestones to the Inventor(s); and
  - b. 40% of the net patent income and/or milestone to the Institution.

The Institution's distribution shall be divided:

    - i. 50% to the Office of the Dean; which shall be distributed at the discretion of the Dean to support the research infrastructure; and
    - ii. 50% to the Research Development to help defray the cost of administrating Intellectual Property related activities (i.e., provisional patents, full patents, legal services, marketing, etc.).

2. Income from Other Research Results, Trademarks, Trade Secrets, and Other Intellectual Property. Income from the use of the name MSM shall belong to MSM and shall not be distributed to individuals. Otherwise, in the case of Trademarks, Trade Secrets, Tangible Research Property, or other research results or Intellectual Property that are not covered by Section C, 1 of this Article VI, any Net Income received by MSM shall belong to MSM and shall be distributed or not distributed as determined by the Intellectual Property Committee.
3. Determination of Shares among Multiple Inventors. If the Intellectual Property Committee determines that more than one Inventor was involved in the creation of an Invention, the Inventor's share of Income shall be divided among the multiple Inventors as determined by the Senior Associate Dean for Research Affairs. If requested by any Inventor, the determination of the Senior Associate Dean for Research Affairs will be reviewed by the Intellectual Property Committee.
4. Departure from MSM. Should any or all of the Inventors leave MSM, the allocation and payment of Income shall remain the same as if the Inventors were still at MSM, unless otherwise approved by the Intellectual Property Committee. In the event of the death of an individual entitled to receive a share of Income, his or her share shall inure to his or her estate.

#### D. Exceptions to Income Distribution Rules

1. Grant-Related Conditions. Income generated under grants from federal agencies and some other sources may be subject to conditions in the grant or grant-related regulations, which must be complied with before any Income can be distributed. For example, in some cases license income produced under a grant must be applied against the amount of the grant. Inventors are encouraged to consult with ORD to be sure they are aware of any applicable conditions.
2. Anticipated Expenses. If MSM anticipates incurring unreimbursable expenses in connection with any Invention (such applicable costs to be determined by the Intellectual Property Committee and may include costs of patent prosecution or litigation, or other expenses of a type that are deductible from Income under the definition of Annual Net Income), it may hold in reserve all or a portion of any Income derived from such Invention to the extent deemed necessary by the Intellectual Property Committee to cover such anticipated expenses. In such a case, the relevant Principal Investigator or Inventor will be notified of the amount being held in reserve and the reasons for holding it in such manner.
3. Waivers. Any Inventor or other party entitled to receive any share of Income under this Policy may waive that share with the approval of the Senior Associate Dean for Research Affairs or Intellectual Property Committee or in accordance with guidelines established by the Intellectual Property Committee.

