

INTELLECTUAL PROPERTY POLICY

New York Medical College for its School of Medicine, Graduate School of Basic sciences, and Graduate School of Health Sciences (hereinafter called the “College”) supports research relating to the advancement of medical knowledge and the publication and the use of the results of such research. This is consistent with the College’s mission of advancing knowledge and facilitating the practical application of such knowledge for the benefit of the public. The College recognizes that the research conducted by its faculty, its technical staff and its students may lead to inventions and discoveries which should be patented or licensed for one or more of the following reasons:

1. To serve the public interest;
2. To comply with the requirements of sponsored research grants, fellowship awards and contracts for research;
3. To promote the developments of useful apparatuses, processes or drugs which would not be developed without patent protection;
4. To encourage invention and ensure rewards for the Inventor as herein provided;
5. To support the research and education program of the College by means of its share of income derived from commercial licensing and royalties paid for the use of inventions and patents, and;
6. To provide for the general welfare of the College.

Accordingly, the College has adopted the following Intellectual Property Policy, consistent with its overall educational objectives. The Intellectual Property Policy is applied on a College-wide basis and all employees and students of the College are required to accept it as a condition of employment or enrollment.

I. Intellectual Property: Definition

For purposes of this policy, Intellectual Property is defined as any new and useful process, machine, composition of matter, life form, article of manufacture, software, copyrighted work or tangible property. It includes, but is not limited to, such things as new or improved devices, chemical compounds, drugs, genetically-engineered biological organisms, data sets, software, or unique and innovative uses of existing inventions. Intellectual property may or may not be patentable or copyrightable, and it can be created by one or more persons, each of whom, to be an Inventor, must have conceived of an essential element or have contributed substantially to its conceptual development. For the purposes of interpreting and applying the College’s rights hereunder, faculty, staff, postdoctoral trainees, residents, visiting scientists, external collaborators and students who make such inputs are referred to as “Inventors” throughout this policy.

In some instances, such as patents, distribution and commercialization of technology may be accomplished by the transfer of licensing of the intellectual property right. In other instances, distribution and commercialization of the intellectual property may be aided by or depend upon access to the physical or tangible embodiment of the intellectual property, as in the case of biological organisms. Therefore, this policy will define not only the ownership, distribution and commercialization rights associated with the technology in the form of an invention, but will also define policies and procedures which govern use and distribution of the intellectual property in its tangible form.

II. Ownership of Intellectual Property

- A. The College has title and ownership to Intellectual Property which either (1) results from the use of funds, either directly from or channeled through College, (2) results from other support from the College (e.g., College resources or facilities), or (3) was developed in a field relating to the Inventors' activities at the College whether or not disclosed while the Inventor was at the College. College support is defined as funds, regardless of origin, or other support, including, but not limited to, resources or facilities, which are used in the discovery or development of Intellectual Property and provided through College channels. In the absence of the foregoing involvement of the College, rights to intellectual property remain with the Inventor. With the approval of the Provost, an invention, software or tangible research property may be considered not to have been developed with College funds or support if:
1. only a minimal amount of College funds have been used; and
 2. only a minimal amount of time has been spent using College resources or facilities; and
 3. the development has been made on the personal, unpaid time of the Inventor.
- B. Intellectual property resulting from inventions carried out by a student in fulfillment of course requirements or other requirements for a degree; in connection with a formal training program including the preparation of a thesis or dissertation; or in connection with work conducted with funds channeled through the College, shall be construed as making use of College resources, and, hence, shall be owned by the College.
- C. Intellectual Property resulting from research performed under grants or contacts with the federal government, state, municipalities, public agencies or other parties, are subject to patent agreements with or legal requirements of these agencies. Where some option exists, the College may choose to retain all patent rights and issue nonexclusive, nontransferable licenses to the sponsor.

- D. College Inventors involved in consulting work, a business, or other outside activity are responsible for insuring that any agreement which properly they have or may enter into does not conflict with the College's Intellectual Property Policy. The College's rights and the individual's obligation to the College will in no way be abrogated or limited by the terms of such consulting work, business or other outside activities or agreements in connection therewith. In accordance with policies hereafter approved by the Board of Trustees, non-College entities conducting research in College facilities which pay for the use of space and other resources may retain rights of ownership to inventions developed in whole or in part at the College. In accordance with such policy relating to the subject as may be approved by the College's Board of Trustees, the College retains rights and a share of any revenues and profits resulting from the practice, licensing or other exploitation of inventions mentioned in the preceding sentence consistent with the contribution of the members of its faculty and students to the development in accordance with an agreement between the College through its Division of Technology Development and the non-College party(ies).
- E. Upon written approval of the Provost, the College may return its rights in an invention to the Inventor.
- F. Copyrights on, and royalties from, literary or scholarly works in tangible or electronic form (e.g., textbooks and other curricular materials, reference works, journal articles, novels, music, photographs, etc.,) except for patentable computer software, produced by faculty members as part of their usual teaching, service, and research activities, and which do not result directly as specified deliverable from projects funded in whole or in part by funds channeled through the College or by a sponsored research agency shall belong to the faculty who prepared such works and may be assigned or retained by them, (unless these are related to intellectual property to which the College has title.)
- G. Each member of the faculty and student who contributes toward an invention to the extent that he/she should have the rights of a co-inventor and/or to share in royalties or any other proceeds attributable to exploitation of the invention shall, when the invention is a joint product of persons subject to this policy and others not subject hereto, notify the College Division of Technology Development of the invention or impending invention at the very earliest opportunity and cooperate with the College so that the rights of the College faculty member or student and of the College may be protected by an appropriate agreement developed by the Division of Technology with the non-College party(ies). In cases of joint development of inventions such as the foregoing, the College and its faculty and students retain their rights, including rights to future shares of revenue generated thereby, consistent with the contributions of the members of its faculty and students to its development, which may be modified only by an agreement between the College through its Division of Technology Development and the non-College party(ies), and in accordance with any policies hereafter approved by the College Board of Trustees.

III Management of Intellectual Property

The College has established the Division of Technology Development and Industry Sponsored Research, hereinafter called “Technology Development,” within the Office of Research Administration, to provide delegated leadership and oversight of the College’s technology development program including implementation of the College’s Intellectual Property Policy. The Director of Technology Development, hereinafter called “Director” facilitates the transfer of the College’s technology to the public use and benefit in compliance with institutional applicable sponsor policies to:

- A. Create awareness of the intellectual property policies, procedures, and achievements throughout the College and with external constituents;
- B. Encourage and facilitate disclosure of intellectual property;
- C. Evaluate intellectual property and recommend patent filing;
- D. Market technologies world-wide;
- E. Identify licensees or other third parties to commercialize College intellectual property;
- F. Draft, negotiate and recommend execution of agreements, including, but not limited to license, option, equity, copyright, material transfer and nondisclosure (confidentiality agreements);
- G. Distribute royalty and other revenues in accordance with the Royalty Income Distribution Schedule of Provision VIII (B) and all other applicable College Policies;
- H. Monitor the performance of licensees and enforce the provisions of their licenses;
- I. Ensure compliance with Federal Technology Transfer Regulations;
- J. Recommend relationships with biomedical companies and the venture capital community to commercialize College intellectual property;
- K. Recommend new ventures to commercialize the College’s intellectual property such as spin-off companies and business incubators.

IV. Advisory Committees

The Provost of the University appoints the chair and the members of the Intellectual Property Committee and the Technology Advisory Board to advise the Director on the direction and implementation of the College’s technology development program. These advisory bodies may also meet in joint sessions or form working groups constituted of

members of both the Intellectual Property Committee and the Technology Advisory Board as the need arises to effectively address issues relevant to both bodies.

A. The Intellectual Property Committee

As specified in the Faculty bylaws, the Intellectual Property Committee (hereinafter called the “Committee”) is composed of a minimum of five faculty members, representing the basic and clinical sciences, including a chairperson. The Director of the Office of Research Administration and the Director of Technology Development shall serve as additional *ex-officio* members. The Committee will:

1. Review and make recommendations for changes in all policies for the ownership, distribution and commercial development of the College’s intellectual property;
2. Initiate approved policies and approved changes in such policies on ownership, distribution and commercial development of the College’s intellectual property;
3. Advise the Director on specific issues of program implementation, where guidance is sought, such as ownership of a given invention or allocation of royalties among Investors; and
4. Serve as an appeals committee in the event of a disagreement between the Inventor and the Office of Technology Development concerning pursuit of patent protection, subject to final approval of any resolution by the Provost of the University. (See VI.D.)

B. Technology Review Panels

The Director may convene Technology Review Panels, composed of experts in the technical, patent and market aspects of the particular technology. Additionally, the Technical Review Panel will include at least one faculty member. The Director may also utilize full, or part-time College employees, independent contractors, or companies or organizations providing such services, or a combination of them, as the Director determines to be appropriate with regard to a particular intellectual property and within approved budgetary limits.

C. Technology Advisory Board

The Technology Advisory Board provides input to the Director on strategic plans for maximizing the value of the College’s intellectual property. The Board is constituted of a minimum of three representatives of biomedical companies from both large and small firms, at least two members or designees of the College’s Board of Trustees, at least one representative from a government economic development agency, and at least one member from the College administration, namely the head of Research Administration, and the Chairperson of the Intellectual Property Committee. The Director serves as an *ex-officio* member. The Board will be called upon to guide and assist in such things as:

1. Developing recommendations for structuring nontraditional arrangements for financing the development of College intellectual property, e.g., equity participation in start-up companies, spin-off companies and business incubator facilities;
2. Recommending strategic alliances with companies to benefit both the College and the firm;
3. Identifying industry partners for collaboration on government-funded technology transfer programs;
4. Developing financing opportunities in the venture capital, investment banking and equity markets to support development of the College's intellectual property which has commercial potential, and recommending technologies to be supported by such funds.

V. Responsibilities of the Inventor and the College

- A. An Inventor shall notify Technology Development promptly of any intellectual property to which the College has the right to obtain title according to "*Section II, Ownership of Intellectual Property.*" The Inventor should promptly seek the advice of Technology Development before taking any steps to publish or declare a discovery publicly. Any publication describing an unpatented intellectual property may make it impossible to secure a valid patent and thereby reduce any benefit that may accrue to the Inventor and the College from the intellectual property. A U.S. filing prior to publication is necessary to secure the option for foreign patent rights. The Director, in turn, will advise the Office of Public Relations for purposes of coordinating any external publicity that may be appropriate.
- B. An inventor who believes that an item of intellectual property has been conceived should prepare and submit an Intellectual Property Disclosure form (hereinafter called the "Disclosure") at least 60 days in advance of printed or oral disclosure to permit timely filing of any patent application in the United States. The Disclosure is a document used to describe the intellectual property and to establish the name of the Inventor and the date of the first conception. An Intellectual Property Kit which includes a Disclosure form is available from Technology Development.
- C. At the request of the Director, the Inventor shall execute all documents necessary to reflect assignment to the College, or its nominee, of any and all rights to the intellectual property, including rights to patent applications and patents, and to do everything that may be reasonably required to assist all assignees to obtain, protect and maintain patent rights.
- D. Upon receipt of a Disclosure, the director shall determine the rights and obligations of the College in the intellectual property. Under normal circumstances the Director shall complete an evaluation of the intellectual property and determine whether to seek patent protection with input from sources

- such as the Technology Review Panels within three months after receipt of the Disclosure. The Director shall notify the Inventor of any patent action.
- E. In the event the College elects to proceed with commercial development, the College shall use appropriate efforts to obtain a patent and effect its commercial development. In order to guarantee the greatest possible utilization of any intellectual property, the Director may recommend entering into agreements with licensees or outside management organizations, covering any intellectual property in which the College has an interest. Any income derived from the commercial development of such intellectual property shall be distributed according to the Net Royalty Income Distribution Schedule of Provision VIII (B).
 - F. For intellectual property supported in whole or part by federal funds, the College shall abide as applicable by the regulations contained in 37 Code of Federal Regulations 401 "Rights to Inventions made by Nonprofit Organizations and Small Business Firms" including granting the federal government a nonexclusive, paid-up license to practice the federally funded invention. The College will include in all relevant patent applications and resultant patents, the statement "This invention was made with government support under (agreement number) awarded by (federal agency). The government has certain rights in the invention."

VI. Where the College Declines to Patent

- A. In the event the College or its licensee or assignee, such as an outside management organization, declines to file a U.S. patent application or to proceed with commercial development, under normal circumstances within three months after receipt of a Disclosure, it shall upon the request of the Inventor and with written approval of the Provost of the University, but subject to any prior commitment to a sponsor, execute a formal waiver of rights to the intellectual property in favor of the Inventor who shall thereafter be the sole owner of the patent rights in the intellectual property. The College will have no claim to revenue resulting from the future commercialization of the intellectual property but will retain a royalty-free, irrevocable, non-exclusive license to make or use the intellectual property for non-commercial use.
- B. In the event the College, its licensee or assignee, with the approval of the Provost of the University, permanently abandons U.S. patent prosecution or maintenance of an issued patent, the Director shall notify in writing the Inventor within 15 days of such a decision and execute a formal waiver of rights to the intellectual property in favor of the Inventor upon written request of the Inventor.
- C. In the case of intellectual property made under a funding agreement from a federal agency, Technology Development must first offer the federal government title to the intellectual property and obtain express permission from the federal agency and the Provost of the University before returning title to the College Inventor. The Director will request such approval from

the sponsoring federal agency and the Provost within one month after the College declines to patent; assignment to the Inventor will be made upon receipt of approval from the federal agency and the Provost.

- D. Should a disagreement arise between Technology Development and the Inventor concerning pursuit of patent protection or commercial development of an invention, the Inventor may appeal the decision to the Intellectual Property Committee. The Intellectual Property Committee upon review shall make a recommendation to the Provost on resolution of the disagreement.

VIII. Tangible Research Property (“TRP”)

The following policy and procedures are directed toward the administration and distribution of tangible research property which is owned and/or controlled by the College.

A. Definition of TRP

The term “tangible research property” refers to those research results which are in tangible form as distinct from intangible property. Tangible research property (TRP) including, but not limited to, such things as biological materials, software and copyrightable materials, are frequently licensed for commercial purposes.

B. Control of TRP

It is the responsibility of the Inventor to control the development, storage, use and distribution of TRP made in the course of research activity subject to provisions of applicable grants or contracts. Such control includes determining if and when distribution of the TRP is to be made beyond the laboratory for scientific use. Technology Development should be contacted to advise on possible contractual obligations with respect to the TRP prior to distribution.

C. TRP Procedures

The following procedures for identification and distribution of TRP are designed to aid the traditional open distribution and exchange of TRP for research purposes, preserve the potential commercial value of TRP, assist the further development of TRP for public use, and protect the College and its employees from liability claims arising from the use of College TRP by others.

1. Identification of TRP

Each item of TRP should have an unambiguous identification code and name sufficient to distinguish it from other similar items developed at or by the College or elsewhere.

2. Distribution of TRP for Research Purposes

a. Biological TRP

Biological materials owned by the College may usually be distributed for research purposes only, and subject to an agreement by the recipient that commercial development or commercial use or further transfer of the biomaterials shall not be undertaken. A standard transmittal letter for biological materials is available from Technology Development. Costs of materials handling may be recovered from the recipient, and returned to the account that funded those costs. When costs are charged for TRP distribution, adequate documentation must be maintained for audit purposes.

If there is a possibility of biohazard or other risk, associated with the transport, storage, or use of a particular biological TRP, or if the recipient is likely to use the TRP for clinical research, Technology Development must be contacted in advance for the appropriate disclaimer and protective agreement.

b. Software TRP

Distribution for research purposes only of computer software owned (and not merely licensed by the College) by the College may be made without restrictions unless subject to a preexisting agreement or unless eventual return or control of subsequent use by the Inventor is desired. For example, the Inventor may wish recipients to follow a specific research protocol. Any such distribution is subject to the applicable contract or grant provisions and an agreement by the recipient that commercial development of the software is not to be undertaken.

3. Distribution of TRP for Commercial Purposes

Scientific exchanges should not be inhibited due to potential commercial considerations. However, since TRP may have potential commercial value as well as a scientific value, the Inventor may wish to make TRP broadly available for other scientists by means which do not diminish its value or inhibit its commercial development.

Commercial distribution of College owned TRP is managed by Technology Development. Biological materials and software are disclosed to Technology Development in the same fashion as patentable inventions, for which the

first step is preparation and submission of an Intellectual Property Disclosure Form.

a. Distribution Agreement

If TRP developed by the College as a result of research activities is to be distributed to outside users for commercial purposes, the distribution agreement must contain provisions negotiated by Technology Development covering the terms under which the property may be used, limits on the College's liability for the TRP or products derived therefrom, and other conventional license agreement terms including those relating to any intangible property rights (such as patents) which also may be associated with the use of the tangible property.

b. Income Distribution

Any TRP-related royalty income will be distributed according to the Net Royalty Income Distribution Schedule of Provision VIII (B).

VIII. Revenues from Intellectual Property

A. All revenues derived from intellectual property will be received by and administered by Technology Development consistent with all applicable College policies. Each Inventor shall receive a portion of any funds, in excess of expenses, which the College collects as a result of the invention. College costs for patent prosecution, licensing, and license maintenance, shall be reimbursed by gross revenues. The Schedule for Distribution of Net Revenues is designed to provide personal incentives to Inventors. The royalty distribution in effect at the time of the invention shall be applied in calculating the inventor's share as long as revenue is generated.

B. Net Royalty Income Distribution Schedule

Technology Development distributes net royalty income according to the following schedule:

Inventor ^{1,2}	Inventor's Research ³	Inventor's Department ⁴	Intramural Research Fund	Research Development Fund ⁵	<u>College General Fund</u> ⁶
50%	15%	5%	10%	20%	
(45%)					(5%)

¹ 50% of first \$500,000; 45% above \$500,000.

² The Inventor has the option to allocate funds from this category to other categories subject to the approval of the Dean.

³ Funds allocated to the Inventor's research will be placed in a designated research account. Should the Inventor leave New York Medical College, two-thirds of the funds will be transferred to the Intramural Research Fund, and one-third will be transferred with the Inventor to another non-profit entity for his or her research.

⁴ These funds will remain with the Department should the Inventor leave.

⁵ An Inventor's department may pay patenting costs out of a designated purpose or private practice fund. In this case, the Inventor's department would receive an additional 5% from the College's Research and Development Fund which would then receive 15% of net royalty revenue.

⁶ 5% of income over \$500,000.

DEFINITIONS:

Net Royalty Income: Gross invention income received by New York Medical College on account of the patenting, licensing or other commercialization of a patented invention less the costs of the College for patenting; exploiting, protecting, and preserving patents, maintaining patents; the licensing of patent and related property rights; legal fees; any fees or share of patent income paid management or product development organization and such other costs and reimbursements as may be required by law or are otherwise necessary or appropriate.

Intramural Research Fund: Monies set aside for direct faculty research project support, allocated by the Dean and/or by the Dean upon recommendation of the Intramural Review Committee.

Research Development Fund: Monies to be set aside for development of the general research resources of the College, to be allocated by Administration for purposes such as facilities, equipment or technology administration.

IX. Dispute Resolution

Any disagreement on any area covered by this policy shall be resolved through institutional mechanisms culminating as necessary in a final decision by the Provost of the University.

X. Modification of Policy

All modifications of this policy shall require approval of the Provost, the President and the Board of Trustees of the College.

- This Intellectual Property Policy of October 1, 1998 supersedes and replaces the Patent Policy of October 19, 1989 and all prior policies.

Approved: Board of Trustees October 1, 1998