



Policy on Intellectual Property

March 2020

I. Goals of Intellectual Property Management at Memorial Sloan Kettering Cancer Center (MSK)

The mission of MSK's Office of Technology Development (OTD) is to ensure that MSK's intellectual property has the greatest chance of helping patients. OTD is also committed to creating maximum value from technology transfer to support further scientific research at MSK. To that end, OTD will make every effort, as appropriate, to pursue patents, licenses, and other opportunities that encourage the development and commercialization of MSK's intellectual property. These efforts include a thorough review of each disclosure of Intellectual Property, submission of timely patent applications, securing funding as needed for further technology development, marketing IP to potential licensees, identifying and facilitating start-up opportunities, and executing license agreements that include fair and reasonable financial terms.

II. Definition and Ownership of Intellectual Property

A. Definition of Intellectual Property

For the purposes of this policy, Intellectual Property (IP) shall include inventions, discoveries or know-how, whether patentable or not; copyrightable materials (other than journal publications), such as software; and tangible property. Know-how is defined as information in the form of unpatented inventions, including formulae, designs, drawings, procedures and methods, together with accumulated skills and experience which could assist in the development or manufacture of a product or its use. The creators of IP shall be known as inventors.

It is the policy of MSK that all rights to IP resulting from research or other work that is conducted by employees of MSK within the scope of their employment – or is in any way connected with employees' work at MSK – shall be the property of MSK. In addition, any work specifically ordered or commissioned by MSK – or conducted by any person(s) making significant use of MSK resources – shall also be the property of MSK. Such persons may include graduate students, postdoctoral researchers, clinical fellows, rotating house staff, and visiting scientists. Note that this applies to all IP that is conceived or reduced to practice during, or up to one year following the termination of employment or association with MSK.

IP shall be owned by MSK unless and until expressly released in writing by the President of MSK. All releases are reported to the Board of Managers of MSK.

B. Staff's Responsibility of Disclosure

All MSK employees are required to sign an Employee Agreement that assigns all IP to MSK and obligates them to promptly disclose in writing all IP without delay, at least in advance of its disclosure to third parties. All staff who are not MSK employees are required to sign a Non-Employee Agreement that assigns all IP to MSK and obligates them to promptly disclose in writing all IP without delay, at least in advance of its disclosure to third parties. Such disclosures during or after the employee's term of employment or non-employee's term of association with MSK shall be submitted to OTD.

C. Assignment of Rights

MSK is hereby assigned all rights, title and interest in any IP arising from employment-related activities and the use of MSK Resources. MSK Resources means MSK's facilities, funds, equipment, or other tangible and intangible properties.

III. Evaluation and Protection of Intellectual Property

A. Evaluation

Inventors need to disclose IP to OTD through an online Invention Disclosure Form, attaching all supportive scientific, technological, and other related information. OTD will review all disclosures in order to determine the potential commercial value of the IP. When, in the judgment of OTD, there appears to be sound basis for pursuing commercialization of the IP, OTD will take necessary steps to protect it at no expense to the inventor(s). In the event that the inventor(s) disagrees with OTD's decision not to protect the IP, the decision may be appealed (see RTM-4001, Intellectual Property Review Process).

B. Protection

1. Patenting

When OTD decides to seek patent protection, it retains patent attorneys to prepare, file, and prosecute the applications in conformance with applicable patent law and procedures. The inventors will be expected to cooperate fully with OTD in defining the rights to such IP (e.g., joint ownership with another institution) and in the preparation and prosecution of any patent application. OTD coordinates the interaction of inventors with patent counsel. Note that the criteria for determining inventorship are not the same as those for determining authorship of research publications. The inventors on a patent application will be determined according to patent law. Naming the wrong inventors can jeopardize the validity of a patent. The individual contributions of each inventor must be the subject of specific claims in the patent application.

2. Copyright Protection

Copyright protection is in place the moment the work is created and fixed on a tangible form that is perceptible either directly or with the aid of a machine or device. There is no obligation to register a work unless the owner intends to bring a lawsuit for infringement. In some cases, it will be appropriate to register a copyright to reduce the likelihood of infringement and increase MSK's recovery of damages and expenses from infringements. Notice of a copyright should be given to the public when a work is published. The copyright notice must include either the word "copyright," or the symbol "©," accompanied by the name of the copyright owner and the year of first publication (designated as 2015 in the following example).

Example:

© 2015 Memorial Sloan Kettering Cancer Center

The author(s), MSK, and/or the sponsor(s) are sometimes requested to relinquish rights to copyrighted articles submitted to scholarly and professional journals. If the author(s), MSK, or the sponsor(s) are to retain title or other rights to copyright of the material in these cases, advance arrangements, approved by Research and Technology Management, should be made with the publisher.

For information about copyrighting software, see Section III F. below, "Software Copyright Protection."

3. Trademark Protection

A trademark or service mark includes any word, name, symbol, or any combination thereof, used, or intended to be used to identify and distinguish the goods or services of one seller or provider from those of others. A trademark or service mark also indicates the source of the goods or services. OTD will assist employees in registering trademarks and obtaining protection as necessary.

4. Tangible Property

Tangible property for purposes of this policy is defined as tangible or physical items resulting from research or other work. Such items could include biological materials (e.g., cell lines, clones, tissues, animal models), chemical compounds, formulations, extracts, engineering drawings, and prototype devices and equipment.

Tangible property may be patentable and/or copyrightable, but patent protection is not always sought. Often, tangible property is so unique and difficult to replicate that it is protected simply by controlling its distribution. Biological materials may be deposited in a repository such as the ATCC. Tangible property may be transferred to non-commercial or academic users under Material Transfer Agreements or to commercial entities under a license.

For information about transferring tangible property, see Section III, E, "Material Transfer Agreements."

IV. Commercialization of Intellectual Property

A. Marketing

OTD shall identify and evaluate potential and preferred licensees (e.g., companies, investors, entrepreneurs, executives) for IP. OTD shall also generate and disseminate marketing materials including marketing sheets and scientific and business presentations; and work with inventors to identify appropriate venues to present IP.

B. Licensing

In licensing, sale, or other disposition of rights, OTD shall seek the best and fairest deal it can obtain through good faith negotiations on behalf of MSK and the inventors. This includes, but is not limited to, reasonable financial terms such as license fees, royalties, milestone payments and equity as appropriate. OTD will supervise and manage all license agreements throughout their duration.

C. Release of Ownership Rights

MSK may determine that neither the potential contribution to the public good nor commercial possibilities warrant either managing or pursuing specific IP. In this event the employee, as the inventor, may petition OTD for a license to such IP, or the reassignment of the rights. If such license or reassignment of the rights is approved, the employee will assume all future expenses related to the IP, pay a portion of any future revenues resulting therefrom to MSK, and will allow MSK to retain a license for its own purposes.

D. Income Sharing

All income derived from IP in which MSK has proprietary rights, and that is received under a license, shall be distributed to inventors as defined in Section II A above in accordance with the following guidelines. Income will not be distributed to those who are not inventors, but who contribute to the creation of the IP through the regular course of business performing their assigned job duties.

1. Cumulative Gross Proceeds

Cumulative Gross Proceeds shall mean the sum total of all payments received under a particular license, such as license fees; milestone payments; royalties; proceeds from sale of stock or equity obtained under the license; Success Payments (payments to MSK based on increase in value of licensee's equity); and proceeds from sale of Priority Review Vouchers or similar rewards. Cumulative Gross Proceeds shall not include payments for research support, value of materials supplied, reimbursed patent expenses, or other specific reimbursements of expenses or costs.

The Cumulative Gross Proceeds shall be assigned to MSK, unless determined otherwise by the President of MSK. The Cumulative Gross Proceeds shall then be shared with the inventor(s) according to the rate table below:

Cumulative Gross Proceeds

<i>From</i>	<i>To</i>	<i>Inventors' Share</i>
\$1	\$ 200,000	40.0%
\$ 200,001	\$1,000,000	30.0%
\$1,000,001	\$250,000,000	20.0%
More than \$250,000,000		10.0%

Distribution of the remaining income will be directed toward meeting the needs of the MSK research enterprise. On a case-by-case basis, distributing a portion of the remaining income to the program/service/department(s) of the individuals who have contributed to the creation of the IP will be considered by senior leadership. In the case of disputes or unusual circumstances, the President of MSK will determine the distribution.

This policy will apply to the distribution of any Cumulative Gross Proceeds from all licenses executed after the effective date of this policy. For clarity, this policy will not affect proceeds from licenses executed before the effective date of this policy: proceeds from those licenses will be distributed according to the policy in effect at the time the license was executed.

As defined above, Cumulative Gross Proceeds derived from licensing agreements of IP may include the sale of stock or other equity in a company. Such stock or equity will be held by the Executive Vice President, Finance, and will be managed and sold according to procedures that ensure that decisions to sell are made at arm's length from those MSK employees who are inventors of the licensed IP.

2. Other Income

Other income received such as payments to support collaborative work in the development of IP, research support, patent expenses, and license management fees will be considered institutional revenue, and shall be used in accordance with institutional and corporate policies.

3. Limits on Distribution

a. Under no circumstances may any royalty or other form of compensation (including financial awards, bonuses, annuities, etc.) exceed the total amount that may be paid under applicable federal and other laws and regulations (including those applicable to organizations exempt from taxes under Section 501(c)(3) of the Internal Revenue Code).

b. In the event that there are multiple inventors, the inventors' share of Cumulative Gross Proceeds will be distributed among the inventors according to a written allocation agreement executed by the inventors. If there is no written allocation agreement, all inventors will receive equal portions of the inventors' share. In case of disputes or unusual circumstances, the distribution will be determined by the President of MSK.

c. All agreements related to IP will be negotiated and entered into by OTD. An inventor should notify OTD if he or she becomes aware of a proposed agreement (or a proposed amendment to an existing agreement) that has not been negotiated and entered into by OTD (e.g., consulting agreement, founder's agreement), but is with an entity that is or becomes involved with MSK in a license transaction concerning the inventor's IP.

Should an inventor have, received or have a right to receive equity in such an entity through said agreement or amendment, OTD will recommend to the President of MSK that such inventor should not receive a share of certain proceeds from the license, including proceeds from sale of stock or equity obtained through the license, Success Payments and proceeds from sale of Priority Review Vouchers or similar rewards. As needed, OTD may consult with the Committee on Technology Transfer of the Board of Managers in developing its recommendation. The President's decision regarding OTD's recommendation will supersede any

inconsistent provisions set forth herein. Such revenue not distributed to inventors due to the provisions in this Section IV.D.3.c will be retained by MSK and not redistributed to any other inventors of the IP. This retained revenue will be utilized by MSK as described in Section IV.D.1.

4. Time of Payment

Each inventor's share in the Cumulative Gross Proceeds shall be calculated and paid to the extent practicable (as determined by MSK), within three months of the receipt of funds by MSK.

5. Abandoned Cumulative Gross Proceeds

If after diligent efforts MSK has been unable to deliver to an inventor his or her share of Cumulative Gross Proceeds for three consecutive years, such money will henceforth become the property of MSK and will be treated in the same manner as MSK treats its own share of Cumulative Gross Proceeds. If the inventor subsequently claims his or her share of Cumulative Gross Proceeds, MSK will resume distributing his or her share from the time when such claim is made.

V. Related Matters

A. Sponsored and Collaborative Research, Foundation Grants, and Federal Grants

In cases of sponsored or collaborative research and clinical trials, special arrangements regarding IP may be necessary. Research and Technology Management manages all awards for projects sponsored by external agencies including, but not limited to, foundations, corporations, and the federal government. MSK may have certain obligations to a foundation (e.g., sharing of income from IP) when a grant from such foundation results in the generation of IP. IP arising from sponsored or collaborative research and clinical trials may result in additional obligations to the funding source. The source of funding used to create IP must be disclosed on the Invention Disclosure Form.

IP arising from research funded by US government agencies will be controlled by the terms of the applicable grant or contract and statutes, specifically the Bayh-Dole Act of 1980. All licenses granted for such IP will also be subject to these terms. Grants from the NIH, and generally those from other government agencies, require MSK to disclose all patentable IP to the funding agency. MSK may then elect to retain ownership of patents issued for such IP, subject to rights retained by the government such as (i) a nonexclusive license to use the IP for its own purposes and (ii) the right to "march in" and license such patents. The government also requires that preference be given to small businesses, and that patented products be manufactured substantially in the United States.

B. Delay of Publication

Employees should be aware that public disclosure prior to the filing of a patent application could prevent MSK from securing IP rights. Employees must notify OTD in advance of any type of public disclosure (abstracts, texts, posters, scientific presentations) that is related to IP disclosed to OTD. For example, if an inventor plans to present an abstract at the American Society of Hematology (ASH) Annual Meeting, OTD needs to have received all such information in advance of the date on which the ASH abstracts will be published online, so that OTD can file a patent application before such public disclosure.

MSK, and other entities providing funds or materials for an employee's research, may request that the employee delay a publication or presentation of any research that discloses IP until a patent application has been filed. It is important to disclose IP to OTD promptly, and to provide drafts of any proposed publications or presentations as soon as possible. This policy is not intended to limit the right of individuals to publish or to make other types of public disclosures.

C. Conflict of Interest

An employee may have a financial conflict of interest when they receive or have the potential to receive income or equity under an option or license agreement. MSK's Compliance Office will work with

employees to manage such conflicts. Employees should review MSK's Conflict of Interest Policy at <https://one.mskcc.org/sites/pub/Compliance/Policies/COMP-COO1.pdf>.

Any license agreement that is a related party transaction, as such term is defined under New York Not-for-Profit Corporation Law, shall also be subject to all additional reviews as required by applicable law and MSK policy.

D. Commissioned Works of Nonemployees

Employees who intend to contract with or otherwise engage third parties to perform services or conduct research at MSK should contact OTD or the Human Resources Department in order to put in place a Nonemployee Agreement. This agreement will ensure that all IP generated by such contractors are assigned to MSK.

E. Material Transfer Agreements

Material Transfer Agreements (MTAs) are required for all tangible property, such as cell lines, clones, tissues, chemicals, and other reagents that are sent from or received by MSK. MTAs are required regardless of any commitment or obligation to share resources with other institutions as may be required by a source of research funding (e.g., NIH grants). Employees have an obligation to use the procedures described in these guidelines to send or to receive tangible property.

Procedures for Sending or Receiving Tangible Property

1. All employees who are involved in the exchange of tangible property are responsible for promptly disclosing the nature and details of such activities to OTD and their laboratory head, and for complying fully with procedures for material transfers described herein.
2. All MTAs, whether for sending or receiving tangible property, must be signed by OTD prior to exchange of the tangible property. Most MTAs are handled using OTD's electronic MTA system (eMTA), which can be accessed through MSK's intranet.
3. OTD is responsible for maintaining a record of all MTAs and complying with legal and contractual matters regarding distribution and receipt of tangible property, and will assist employees in any matter relating to tangible property.
4. MTAs as well as research agreements from provider organizations may contain conditions that MSK cannot accept. For example, MSK is required, per MSK policy and, in certain instances, federal law, to own rights to any IP made using the provider's tangible property and to retain unrestricted rights to publish results of MSK research.
5. Transfer of human tissue samples must always be in compliance with the Health Insurance Portability and Accountability Act of 1996, and have the appropriate Institutional Review Board (IRB) and/or Human Biospecimen Utilization Committee (HBUC) approval.
6. An MTA might not be appropriate for the transfer of tangible properties to commercial, for-profit organizations. OTD will identify the appropriate agreement to cover such transfer.
7. In some instances, a research agreement or other special agreement will have terms that provide for transfer of certain classes of tangible property. In such cases, transfers of covered materials will not require separate MTAs. Agreements have been made with certain organizations to use special MTAs. Examples include the Howard Hughes Medical Institute, the Ludwig Institute, and the National Institutes of Health.

F. Software Copyright Protection

All computer software should contain the following notice:

“© 2015 Memorial Sloan Kettering Cancer Center. All rights reserved. The computer program contained herein is the property of Memorial Sloan Kettering Cancer Center and cannot be reproduced, copied, or used without written consent of Memorial Sloan Kettering Cancer Center.”

The reference should be adjusted to the year in which the software is first published.

If the software is in source code form, this notice should appear in the file headers. If the software is in a binary or executable form, the notice should be included in all of the following places: on the first screen that appears when the software is engaged or, if not appropriate, in an About or similar menu item made available from the home page; in the documentation for the software; on the web page from which the software is made available for download.

Prior written permission is required for the distribution of any MSK software to anyone outside of MSK, including but not limited to distribution of software in source or object code form from a webpage. Among other things, proper disclaimers are required to limit MSK's liability for any code that may be made available to third parties.

Employees should inform OTD before creating an external facing website containing or displaying MSK IP or other proprietary information.

G. Confidentiality

In the course of evaluating the commercial potential of IP owned by MSK, it is often necessary to provide prospective licensees with specific information about the property to determine if there is commercial interest. In order to protect MSK's ownership and other rights, disclosure of unpublished IP or other pertinent information to third parties should be made only after the third party has signed a confidentiality agreement negotiated by OTD.

H. Litigation

MSK will not bring, prosecute, or defend any litigation in court involving IP, or any patent or patent applications relating thereto, without the prior approval of the General Counsel.