

INTELLECTUAL PROPERTY POLICY

Policy Name:	Intellectual Property		
Policy Number:	SITD-1001		
Contact	Office of Technology Development in the Division of		
Dept/Title:	Strategy, Innovation, and Technology Development (SITD)		
Sponsors:	SVP, Technology Development (Gregory Raskin)		
	Executive Vice President and General Counsel		
	(Jorge Lopez, Jr.)		
Content Experts:	VP, Technology Management and Commercialization		
	(Yashodhara Dash)		
	VP, Associate General Counsel and Chief Intellectual		
	Property Counsel (Hilary J. Libka)		
Effective Date:	January 1, 2024		
Last Updated:	April 2, 2024		
Last Reviewed:	April 2, 2024		
Approved By:	Joint Committee on Technology Transfer (March 6, 2024)		
	Boards of Governing Trustees of Memorial Sloan-Kettering		
	Cancer Center, Memorial Hospital for Cancer and Allied		
	Diseases, and Sloan-Kettering Institute for Cancer Research (March 13, 2024)		

I. PURPOSE

Memorial Sloan-Kettering Cancer Center, Memorial Hospital for Cancer and Allied Diseases, and Sloan Kettering Institute for Cancer Research (collectively "MSK") seek to promote public dissemination of new research, innovations, and technologies while adhering to all applicable laws, regulations, and Third-Party obligations. Key among these is the Bayh-Dole Act, which created a uniform intellectual property policy and legal framework among the U.S. federal agencies that fund research. Bayh-Dole enables MSK to retain title to inventions conceived or first reduced to practice in the performance of work under federally funded research programs and seek further development, patent protection, and commercialization. If Bayh-Dole requirements are not satisfied, MSK may forfeit ownership of such inventions and associated rights.

This policy ("Policy") sets forth the responsibilities of all Workforce Members to disclose and safeguard MSK Intellectual Property ("MSK IP") as defined in Section IV ("Definitions") of this Policy. This Policy also describes how MSK administrative departments like the Office of Technology Development ("OTD") will satisfy Bayh-Dole requirements; evaluate MSK IP

disclosures; obtain timely legal protection for MSK IP; facilitate collaborations and other technology transfer; market and commercialize MSK IP on fair and reasonable financial terms; secure funding for further scientific research and education; and share revenue with contributing Workforce Members – all in the pursuit of opportunities that maximize the value of MSK IP and ensure MSK IP has the greatest chance of helping patients.

II. SCOPE

This Policy applies to all Workforce Members, including, but not limited to, graduate and other students and visiting scientists whose primary affiliation is another institution or research organization.

III. POLICY

A. Ownership of MSK IP.

- 1. Reservation of Rights. All MSK IP is the property of MSK. MSK reserves all rights in MSK IP unless and until expressly granted in writing by the MSK President and Chief Executive Officer or his or her delegate. Notwithstanding the rest of this Policy, MSK hereby waives copyright ownership of Scholarly Works, as defined herein, but retains a right to royalty-free use of all Scholarly Works (other than books and materials available from a publisher through normal distribution channels). For clarity, such waiver is limited to the copyright in and to the text of any journal article, conference paper, book or book chapter, student thesis, or other work of an academic nature. MSK reserves all rights in any other MSK IP used, described, or referenced in a Scholarly Work, including, without limitation, to illustrations or other images, inventions, Tangible Materials, Software, or confidential or proprietary data. See also Section III(C)(2)(b) ("Copyright Notices and Registration") and the definition of "Scholarly Work" in Section IV of this Policy.
- 2. <u>Duty to Assign and Cooperate</u>. To ensure compliance with all applicable laws, regulations, and Third-Party obligations, MSK requires all Workforce Members to assign to MSK their entire right, title, and interest in and to all MSK IP by written agreement (either an "Employee Agreement" or a "Nonemployee Agreement"). In such Employee or Nonemployee Agreement, Workforce Members also agree to execute all necessary papers and otherwise provide proper assistance, promptly at MSK's request and expense, during and after the period of their employment or association with MSK, to enable MSK to perfect, for itself or its nominees, MSK's title to MSK IP. These assignments and obligations are partial consideration for continuing or anticipated employment by or association with MSK; performance of research, services, or other employment- or association-related activities at MSK; opportunities made or to be made available to access or use MSK Resources; or eligibility to share revenue from MSK IP. Once executed, Employee and Nonemployee Agreements are tracked and stored centrally by the MSK Human Resources Department.
- 3. Consequences of Not Assigning. If these assignment requirements are not satisfied, MSK may forfeit ownership of Subject Inventions and associated rights under Bayh-Dole. Similarly, failure by Workforce Members to assign their entire right, title, and interest in and to MSK IP arising under a government grant, foundation grant, collaboration agreement, sponsored research agreement, clinical trial agreement, material transfer agreement, or other Third-Party arrangement may affect or negate MSK's ownership of the MSK IP and/or may amount to a breach of MSK's

Third-Party obligations. In either case, a Workforce Member who refuses to assign MSK IP to MSK in accordance with this Policy will forfeit any right to share in revenue from MSK IP under this Policy and may be subject to disciplinary action or personal liability or lose access to MSK Resources.

4. Multiple or Conflicting Assignments. If a Workforce Member has assignment obligations to a Third Party (e.g., a graduate or other student or visiting scientist whose primary affiliation is another institution or research organization, or a professional or medical staff member with multiple affiliations), OTD will use its best judgment to reach out to the Third Party to determine ownership of any MSK IP and cooperate as appropriate in protection and commercialization efforts. Principal Investigators intending to host a visiting student or scientist who will conduct research at MSK must contact the MSK Human Resources Department promptly and at least thirty (30) days in advance of such student's or scientist's access to MSK Resources to ensure that any Nonemployee Agreements and/or other necessary agreements are promptly prepared and executed. Likewise, any Workforce Member intending to engage with a Third Party to perform research, services, or other activities at MSK must contact OTD promptly and at least thirty (30) days in advance of any performance or access to MSK Resources to ensure that any necessary agreements are prepared and executed such that all MSK IP developed in the Third Party's performance is assigned to MSK.

B. Disclosure of MSK IP.

- 1. <u>Duty to Disclose</u>. All Workforce Members have a duty to disclose MSK IP to OTD both during and after the period of their employment or association with MSK.
- 2. Form of Disclosure. MSK requires all Workforce Members to report MSK IP promptly in writing to OTD by completing and submitting an online Intellectual Property Disclosure Form ("IPDF") to promote public dissemination and ensure compliance with all applicable laws, regulations, and Third-Party obligations. Each IPDF must identify any contributing Workforce Members or Third-Party participants; any related government grants, foundation grants, collaboration agreements, sponsored research agreements, clinical trial agreements, material or data transfer agreements, or other Third-Party arrangements; any publications, presentations, or other disclosures or uses of the MSK IP outside MSK; whether a manuscript describing the MSK IP has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. Once accepted, IPDFs are tracked and stored centrally by OTD.
- 3. Timing of Disclosure. To allow OTD adequate time to evaluate and seek legal protection of MSK IP, Workforce Members must submit IPDFs to OTD at least thirty (30) days prior to any public or Third-Party disclosure (e.g., abstract, poster, scientific presentation, manuscript, preprint, publication) of MSK IP. Workforce Members must share with OTD copies of any planned publications, presentations, or other materials including the MSK IP as soon as available and preferably thirty (30) days in advance of disclosure publicly or to a Third Party. For example, if a Workforce Member plans to present an abstract at the American Society of Hematology (ASH) Annual Meeting, the Workforce Member must submit all such information in advance so that OTD can file a patent application before the ASH abstract is published online. While this Policy is not intended to limit the academic freedom of Workforce Members to publish Scholarly Works, MSK and Third-Party research sponsors may require that a Workforce Member delay public disclosure for a reasonable period of time to allow MSK to seek appropriate legal protection (e.g., file a patent application). OTD will instruct Workforce Members through suitable

- educational programs on the importance of disclosing MSK IP in sufficient time to permit evaluation and protection prior to any U.S. or foreign statutory bars.
- 4. Consequences of Not Disclosing. If these disclosure requirements are not satisfied, MSK may forfeit ownership of Subject Inventions and associated rights under Bayh-Dole. Similarly, failure by Workforce Members to promptly report MSK IP arising under a government grant, foundation grant, collaboration agreement, sponsored research agreement, clinical trial agreement, material transfer agreement, or other Third-Party arrangement may affect or negate MSK's title to or rights in the MSK IP and/or may amount to a breach of MSK's Third-Party obligations. A public disclosure of MSK IP may materially affect MSK's ability to obtain specific rights and protections for and/or reduce the likelihood of internal MSK or Third-Party investment to further develop or commercialize the MSK IP. If a Workforce Member fails to disclose MSK IP to OTD in accordance with this Policy or elects to publish, present, or otherwise disclose the MSK IP publicly or to a Third Party without informing OTD, the Workforce Member will forfeit any right under this Policy to share in revenue from MSK IP and may be subject to disciplinary action or personal liability or lose access to MSK Resources.

C. Strategy for MSK IP.

1. Evaluation. OTD will review all IPDFs promptly, and all Workforce Members will cooperate with OTD at its request to evaluate any MSK IP disclosed therein and the potential commercial value thereof. OTD will consider the views of contributing Workforce Members in determining what strategies to take, if any, to protect, market, and commercialize MSK IP, including whether to create a new company around MSK IP, license MSK IP to a Third Party, or even sell some or all of MSK's rights under a license to receive future royalties or other payments (a "Royalty Monetization"). If OTD finds, in its sole discretion, a sound basis for pursuing specific legal rights and protections (e.g., filing patent applications), marketing, and/or commercializing MSK IP, OTD will take necessary steps at no expense to the contributing Workforce Members. At any time, OTD may determine, in its sole discretion, that the potential commercial value of certain MSK IP does not justify further pursuit or management of specific legal rights and protections (e.g., patents, trademarks, copyrights, and related rights). In such event, OTD may choose to license such MSK IP to one or more contributing Workforce Members or a Third Party to pursue or manage at their or its expense and subject to any reserved rights and other terms negotiated with OTD.

2. Protection.

- a. Patent Filings.
 - i. <u>General</u>. A patent is a time-limited territorial right to exclude others from making, using, offering for sale, selling, or importing an invention. OTD will decide whether and where to pursue patent protection for an invention. When OTD decides to pursue patent protection, OTD will instruct counsel at an MSK-approved law firm to prepare, file, and prosecute U.S. and/or foreign patent applications in conformance with applicable law.
 - ii. <u>Inventorship</u>. Contributing Workforce Members will cooperate fully with OTD, and OTD will coordinate interactions of contributing Workforce Members with patent counsel. OTD and patent counsel will determine who should be listed as Inventor. Unlike authorship of a Scholarly Work, inventorship is a legal determination based on contributions to at least one of the patent claims as granted (i.e., inventorship may change

over the course of prosecution). If inventorship is incorrect, MSK may lose the patent rights, including the right to receive and share revenue with any Inventors.

b. Copyright Notices and Registration.

- i. General. A copyright is a bundle of time-limited exclusive rights to reproduce an original work of authorship, prepare derivative works based upon the work, distribute copies of the work, and perform or display the work publicly. Copyright protection exists as soon as the Author fixes the original work in a tangible form of expression (i.e., can be communicated to others via visual or audio means). Although registering a copyright is not mandatory, U.S. registration is necessary to enforce the exclusive rights of copyright through litigation in the United States and puts Third Parties on notice. OTD will decide whether to register a copyright to reduce the likelihood of infringement and increase MSK's recovery of damages and expenses from infringement.
- ii. Notice. Workforce Members will consult with OTD and apply a copyright notice to any work that comprises MSK IP prior to disclosing the work publicly or to a Third Party. The copyright notice must include the copyright symbol or the word "Copyright," the name of the copyright owner (solely MSK in the following example), the year of first publication (designated as 2023 in the following example), and the statement "All rights reserved."

Example:

Copyright © 2023 Memorial Sloan-Kettering Cancer Center, Memorial Hospital for Cancer and Allied Diseases, and Sloan-Kettering Institute for Cancer Research. All rights reserved.

- iii. Scholarly Works. Publishers may require Authors and copyright owners to assign some or all of their rights in and to Scholarly Works prior to publication. If a Workforce Member wants to retain rights in and to a Scholarly Work submitted for publication, the Workforce Member must submit a written proposal to OTD for review and approval prior to making any arrangement with a publisher. MSK hereby waives ownership of Scholarly Works as defined herein but retains a right to royalty-free use of any Scholarly Works (other than books and materials available from a publisher through normal distribution channels).
- iv. <u>Software</u>. Workforce Members must have prior written permission from OTD to publish any Software comprising MSK IP or distribute such Software to a Third Party. Workforce Members must submit a written proposal to OTD for review and approval prior to posting or making available such Software on an external-facing website or creating an external-facing website to display or distribute Software. Among other things, OTD will confirm whether proper disclaimers are provided to limit MSK's liability to any Third Party. All such Software must include the following copyright notice (with the year adjusted to that of the first publication of the Software):

Example:

Copyright © 2023 Memorial Sloan-Kettering Cancer Center, Memorial Hospital for Cancer and Allied Diseases, and Sloan-Kettering Institute for Cancer Research.

ALL RIGHTS RESERVED. No part of this program may be reproduced or transmitted by any form or means, electronic or mechanical, including photocopying and recording, or by any information storage and retrieval system, except with prior written permission of Memorial Sloan-Kettering Cancer Center, Memorial Hospital for Cancer and Allied Diseases, and Sloan-Kettering Institute for Cancer Research.

If such Software is in source code form, the copyright notice must appear in the file headers. If such Software is in object code or executable form, the copyright notice must appear on: (1) the first screen of the user interface that appears when the Software is activated or, if not appropriate, in an "About" or similar menu item made available from a home screen; (2) any documentation for the Software; and (3) any place where the Software is made available (e.g., for download).

c. <u>Trademark Notices and Filings.</u>

- i. General. A Trademark right is a territorial right to exclude others from using a Trademark (see definition in Section IV of this Policy) in association with specific goods or services. Trademark protection may exist solely through use in commerce in a specific geographical area (e.g., a common law trademark). Although registering a Trademark is not mandatory, U.S. registration is necessary for protection across the geographical area of the United States and puts Third Parties on notice. Trademark registration may be mandatory for protection in foreign jurisdictions. When OTD or other MSK departments decide to pursue registration of a Trademark, OTD will instruct counsel at an MSK-approved law firm to prepare, file, and prosecute U.S. and/or foreign applications in conformance with applicable law.
- ii. Notice. Workforce Members will use a Trademark notice with MSK Trademarks in accordance with the MSK Brand Portal. For example, Workforce Members will apply a Trademark symbol, preferably in superscript manner, following a MSK Trademark as appropriate. Until an MSK Trademark is registered in the United States, Workforce Members will apply the symbol TM for goods and the symbol SM for services. Once a Trademark registration has been issued for an MSK Trademark, Workforce Members may apply the symbol ® but only in association with the goods or services listed in the Trademark registration. Workforce Members should consult with the MSK Department of Marketing & Communication or OTD regarding how to refer to Trademarks including MSK Trademarks. Workforce Members must consult with the MSK Department of Marketing & Communication or OTD regarding the development or legal protection of new MSK Trademarks.

Examples:

Memorial Sloan Kettering Cancer Center®

The PRISSMMTM cancer data modeling system...

MEMORIAL SLOAN KETTERING CANCER CENTER and its logos are registered service marks of Memorial Sloan-Kettering Cancer Center.

d. Controlled Access and Distribution.

- i. General. Certain MSK IP may not be eligible for specific legal rights and protections. In other cases, MSK IP may be eligible for specific legal rights and protections, but OTD may decide against seeking such legal rights and protections because the MSK IP is so unique or difficult to replicate that simply controlling access and distribution to the MSK IP is sufficient protection. Examples may include, without limitation, certain Know-How, Tangible Materials, Software, and confidential or proprietary data (e.g., genomic sequencing data, radiology images). Workforce Members must have prior written permission from OTD to provide a Third Party with access to or distribute such MSK IP, regardless of its eligibility for specific legal rights and protections.
- ii. <u>Confidential Disclosure</u>. A Confidential Disclosure Agreement ("CDA") is required prior to sharing confidential or proprietary information about MSK IP with a Third Party. All Workforce Members involved in such discussions are responsible for promptly disclosing the nature and details of such discussions to OTD by submitting an CDA request in <u>MSK eContracts</u> (or its successor) <u>and to other MSK stakeholders as may be directed</u>. Prior to any discussions, OTD must prepare, negotiate, and execute a CDA with the Third Party. OTD is responsible for maintaining a record of all CDAs. See also Section III(C)(8) ("Consequences of Not Adhering to this Policy") of this Policy.

iii. Material Transfer.

- (a) General. A Material Transfer Agreement ("MTA") or equivalent agreement is required prior to transfer of any Tangible Materials between MSK and a Third Party, whether for Third Party Tangible Materials to be transferred in from the Third Party to MSK or Tangible Materials to be transferred out from MSK to the Third Party, regardless of ownership or control of the Tangible Materials or any commitment or obligation to share Tangible Materials with the Third Party, for example, as required by a source of research funding (e.g., the National Institutes of Health). Prior to transfer of any Tangible Materials, OTD must prepare, negotiate, and execute an MTA (or the equivalent) with the Third Party. See also Section III(C)(8) ("Consequences of Not Adhering to this Policy") of this Policy.
- (b) <u>Prior Approval</u>. Each Workforce Member involved in any distribution or receipt of any Tangible Materials is responsible for fully complying with the procedures described herein, including promptly disclosing the nature and details of such activities to OTD by submitting an MTA request in <u>MSK eContracts</u> (or its

successor) and to other MSK stakeholders as may be directed. For example, Workforce Members must obtain OTD's review and approval prior to depositing any Tangible Materials in a repository outside MSK (e.g., American Type Culture Collection), instead of using an MSK core facility (preferred). OTD will coordinate with other MSK stakeholders as appropriate to ensure proper stewardship of Tangible Materials.

- (c) OTD Responsibilities. OTD will identify the appropriate agreement to cover a transfer of Tangible Materials. For example, a license (and not an MTA) may be more appropriate for transfer of Tangible Materials to a for-profit organization. MSK has agreements with certain Third Parties (e.g., the Howard Hughes Medical Institute, the Ludwig Institute, and the National Institutes of Health) that require use of special MTAs. A research agreement or other special agreement may have terms that provide for transfer of certain classes of Tangible Materials, and a transfer of Tangible Materials covered thereunder will not require a separate MTA. OTD is responsible for maintaining a record of all such agreements and complying with legal and contractual matters regarding distribution and receipt of Tangible Materials.
- (d) Compliance. Transfers of Tangible Materials must comply with all applicable laws, regulations, Third-Party obligations, and MSK policy. In particular, transfer of human tissue samples must comply with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and have the appropriate Institutional Review Board ("IRB") and/or Human Biospecimen Utilization Committee ("HBUC") approval. Workforce Members are responsible for consulting with the IRB, HBUC, and OTD to ensure the distribution or receipt of any human tissue samples is approved and covered under an MTA. Should a Third Party require a term or condition that MSK cannot accept, OTD will advise the requesting Workforce Member accordingly.

iv. Data Transfer.

- (a) General. A Data Transfer Agreement ("DTA") or equivalent agreement is required prior to transfer of any confidential or proprietary data (e.g., preclinical or clinical) between MSK and a Third Party (including another non-profit or academic collaborator), in either direction, regardless of ownership or control of such data or any commitment or obligation to share such data with a Third Party, for example, as required by a source of research funding (e.g., the National Institutes of Health). Prior to transfer of any material, OTD must prepare, negotiate, and execute a DTA (or the equivalent) with the Third Party. See also Section III(C)(8) ("Consequences of Not Adhering to this Policy") of this Policy.
- (b) Prior Approval. Each Workforce Member involved in any distribution or receipt of confidential or proprietary data, including as required for acceptance or publication of a Scholarly Work, is responsible for fully complying with the procedures for data transfer described herein or as otherwise directed by MSK, including promptly disclosing the nature and details of such activities to OTD by submitting a DTA request in MSK eContracts (or its successor) and to other MSK stakeholders as may be directed. For example, Workforce Members must obtain OTD's review and approval prior to depositing confidential or proprietary data in a

- repository outside MSK (e.g., European Genome-Phenome Archive); OTD will coordinate with other MSK stakeholders as appropriate to ensure proper data stewardship.
- (c) OTD Responsibilities. OTD will identify the appropriate agreement to cover a data transfer. For example, a license (and not a DTA) may be more appropriate for transfer of confidential or proprietary data to a for-profit organization. A research agreement or other special agreement may have terms that provide for transfer of certain classes of data, and a transfer of data covered thereunder will not require a separate DTA. OTD is responsible for maintaining a record of all such agreements and complying with legal and contractual matters regarding distribution and receipt of confidential or proprietary data.
- (d) Compliance. Data transfers must comply with all applicable laws, regulations, Third-Party obligations, and MSK policy. In particular, transfers of personal health data must comply with HIPAA and, depending on the sources and/or locations where data will be processed or maintained, transfers of personal data must comply with the General Data Protection Regulation ("GDPR"), among other data protection or privacy laws. Should a Third Party require a term or condition that MSK cannot accept, OTD will advise the requesting Workforce Member accordingly.

3. Transactions.

- a. General. OTD will obtain the best and fairest deal through good faith negotiations on behalf of MSK in licensing, sale, or other disposition of MSK IP or related rights. This may include, without limitation, reasonable financial terms such as license fees, royalties, milestone payments, and equity as appropriate and in OTD's discretion. For clarity, only OTD—not individual Workforce Members—will determine whether to monetize an existing royalty stream or any portion or aspect thereof. Any related party transaction, as defined under New York Not-for-Profit Corporation Law, will be subject to additional reviews as required by applicable law and MSK policy.
- b. <u>Licenses in Research Agreements</u>. In any research agreement, whether preclinical or clinical, under which a Third Party obtains rights to MSK IP (e.g., Know-How, Tangible Materials, Software, confidential or proprietary data), OTD will require appropriate value (e.g., license fees, royalties, milestone payments, equity) in exchange for such rights.
- c. External Funding and Support. To accept external sponsorship, funding, or other support from any non-profit foundation, corporation, government, or other Third Party seeking in exchange rights to any resulting MSK IP, revenue derived therefrom, or reports on intellectual property protection or commercialization efforts), MSK will ensure that a written agreement with the Third Party unambiguously addresses the following (as applicable):
 - i. The scope of what constitutes any "funded" MSK IP versus non-funded MSK IP (e.g., conceived or first actually reduced to practice in the performance of the funded research);
 - ii. The scope of any shareable revenue (e.g., limited to net revenue attributable to the funded MSK IP versus non-funded but potentially related MSK IP);

- iii. The proportion of any revenue sharing (e.g., based on the ratio of funds actually paid to the total costs);
- iv. The cap on any revenue sharing (e.g., a single-digit multiple of the funds actually paid);
- v. The treatment of any equity consideration (e.g., that the consideration be paid at the value of and only after the liquidation thereof); and
- vi. The scope of any reporting requirements (e.g., reasonable and limited to the funded MSK IP).
- d. Reservation of Rights. MSK must reserve certain rights to MSK IP, including, without limitation, any rights of the U.S. government under Bayh-Dole, rights for MSK and other non-profit organizations to use the MSK IP for research purposes, rights to control use of MSK names and other MSK Trademarks, and rights for Workforce Members to publish on use of MSK IP and related technology. Regarding the latter, MSK (for itself or on behalf of a Third Party) may require that Workforce Members delay publication, presentation, or other public disclosure to first seek patent protection. Under no circumstances will the delay be unreasonable (e.g., greater than sixty (60) calendar days).
- e. <u>Financial Terms</u>. OTD will inform Workforce Members of any relevant obligations they may have under an MSK IP agreement. To ensure that decisions are made at arm's length from any Workforce Members who have a conflict of interest, Workforce Members who contributed to MSK IP should not request information about financial terms or their negotiation, and OTD will have no obligation to share any financial terms with contributing Workforce Members during negotiation. However, OTD will make reasonable efforts to contact contributing Workforce Members regarding possible implications for MSK IP revenue sharing before executing an IP agreement that could lead to Excluded Proceeds pursuant to Section III(E)(4)(b)(vi) ("Limits and Exceptions") of this Policy. In general, Workforce Members are expected to consult with OTD regarding possible implications for MSK IP revenue sharing before accepting stock or other equity or an option thereto in a Third Party related to their work at MSK or if they are aware that MSK has negotiated, is negotiating, or will negotiate an IP agreement with the Third Party. OTD will share finalized financial terms with contributing Workforce Members upon request and under appropriate conditions.
- f. <u>Signature Authority</u>. Generally, Workforce Members should not sign agreements on behalf of MSK. Certain OTD members have specific corporate signature authority to execute MSK IP agreements (e.g., licenses, research agreements, confidential disclosures, and material or data transfers). Once executed, MSK IP agreements are managed and stored centrally by OTD.
- 4. Company Formation and Equity. Workforce Members must submit a written proposal to OTD for review and approval prior to creating a new company (e.g., a "start-up" or "spin-off" company) in any field overlapping with MSK's research, education, or treatment of cancer and related diseases (or applying for funding that requires creation of such a company). This includes, but is not limited to, situations in which a Workforce Member wishes to further develop or translate Know-How or other MSK IP to the marketplace. OTD will consult with other internal stakeholders and determine, in its sole discretion, whether to license MSK IP (including, e.g., Institutional Works or Works Made for Hire) to a new company. While a Workforce Member may receive founder's equity in a company, OTD will ensure that the Workforce Member's

relationship with the company, including any founder's equity, does not negatively impact MSK's financial interests. If MSK licenses MSK IP to a new company and has or will play significant role in advancing the MSK IP, MSK expects to receive equity on par with the amount of founder's equity received by any Workforce Member. In cases where a Workforce Member receives significantly more equity in the new company than MSK, MSK reserves the right, in its sole discretion, to adjust revenue sharing with the Workforce Member. See also Section III(E)(5)(b)(v) ("Limits and Exceptions") of this Policy.

- 5. Outside Activities. Pursuant to the Conflict of Interest and Commitment Policy, any independent outside activities by Workforce Members with for-profit or foreign entities that involve written independent agreements for services must first be submitted in the Consulting, Advisory, Speaking Agreements ("CASA") module in MSK eContracts (or its successor) for prior review and approval. Such agreements may include consulting, founder, director, scientific advisory board, or company formation agreements. If OTD determines that proposed outside activities by a Workforce Member involve providing Know-How or other MSK IP to a Third Party or applying Know-How or other MSK IP on behalf of a Third Party, then OTD will negotiate and execute an appropriate institutional agreement to cover the activities and the transfer of MSK IP between MSK and the Third Party. If outside activities under an approved independent agreement lead to a Workforce Member providing Know-How or other MSK IP to a Third Party or applying Know-How or other MSK IP on behalf of a Third Party, then MSK reserves the right to assert ownership over any assets provided or developed by the Workforce Member under such agreement, and the Workforce Member must suspend such outside activities unless and until OTD negotiates and executes an appropriate institutional agreement to cover the transfer of MSK between MSK and the Third Party.
- 6. Online Sharing. Workforce Members must submit a written proposal to OTD for review and approval prior to uploading, posting, or otherwise making available MSK IP on an external website or creating an external-facing website to display or distribute MSK IP, regardless of whether access to the website or MSK IP is controlled. This includes, without limitation, Software or confidential or proprietary data (e.g., preclinical or clinical), even if required by the publisher of a Scholarly Work. See also Sections III(B) ("Disclosure of MSK IP"), III(C)(d)(iv) ("Data Transfers"), and III(C)(8) ("Consequences of Not Adhering to this Policy") of this Policy.
- 7. <u>Enforcement</u>. OTD will monitor for infringement of MSK IP by any Third Party. However, no Workforce Member shall initiate legal proceedings to pursue enforcement of MSK IP or defend any litigation involving MSK IP without the prior review and approval of the MSK General Counsel.
- 8. Consequences of Not Adhering to this Policy. Workforce Members are responsible for reviewing and adhering to this Policy. If a Workforce Member fails to cooperate with OTD or fails to obtain OTD's prior approval for certain activities in accordance with this Policy, or undermines OTD's efforts to protect, develop, or commercialize MSK IP by, for example, independently seeking legal rights and protections for MSK IP; electing to disclose MSK IP publicly or to a Third Party without a CDA; transferring or receiving Tangible Materials without an MTA; transferring or receiving confidential or proprietary data without a DTA; or marketing or commercializing MSK IP, including "non-commercial" or "open-source" licensing, without MSK's express permission, the Workforce Member will forfeit any right under this Policy to share in revenue from MSK IP and may be subject to disciplinary action or personal liability or

lose access to MSK Resources. See also Sections III(A)(3) ("Consequences of Not Assigning") and III(B)(4) ("Consequences of Not Disclosing") of this Policy.

D. Bayh-Dole Compliance.

- 1. Subject Invention Disclosure. To ensure compliance with Bayh-Dole, MSK requires OTD to evaluate and determine whether any IPDF includes a Subject Invention. OTD will comply with all Bayh-Dole reporting requirements for identified Subject Inventions, specifically via Interagency Edison ("iEdison"). OTD will disclose each Subject Invention to the Federal agency via iEdison within two (2) months of receiving an IPDF disclosing a Subject Invention. The disclosure to the Federal agency will be in the form of a written report and will be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention. The disclosure will identify the contract under which the Subject Invention was made; the Inventor(s); any publication, on-sale, or public use of the Subject Invention; whether a manuscript describing the Subject Invention has been submitted for publication and, if so, whether such manuscript has been accepted for publication at the time of disclosure. OTD will promptly notify the Federal agency of the acceptance of any manuscript describing the Subject Invention for publication or of any on-sale or public use planned by MSK.
- 2. Election of Title. OTD will notify the Federal agency via iEdison as to whether or not MSK will elect to retain title to any such Subject Invention within two (2) years of the disclosure to the Federal agency in iEdison. However, in any case where a patent, a printed publication, public use, sale, or other availability to the public has initiated the one (1) year statutory period wherein valid patent protection can still be obtained in the United States, OTD will notify the Federal agency via iEdison as to whether or not MSK will elect to retain title to the Subject Invention no more than sixty (60) days prior to the end of the statutory period.
- 3. Patent Filings. OTD (or its agent) will file MSK's initial patent application on a Subject Invention to which MSK elects to retain title within one (1) year after election of title or, if earlier, prior to the end of any statutory period during which valid patent protection can be obtained in the United States after a publication, sale, or public use. If OTD files a provisional application as MSK's initial patent application, OTD will request from the Federal agency within eight (8) months of the filing of the provisional application an extension to file a non-provisional application. Unless the Federal agency denies the request for an extension, OTD will file the non-provisional application within one (1) year of the filing of the provisional application. If the Federal agency denies the request for an extension, OTD will file a non-provisional application within ten (10) months of the filing of the provisional application. OTD will file patent applications in additional countries or international patent offices within either ten months of the first filed patent application or six months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where a Secrecy Order has prohibited such filing.
- **4.** Government Support Clause. OTD will include, within the specification of any U.S. patent application and any patent issuing thereon covering a Subject Invention, the following statement, "This invention was made with government support under [identify the contract] awarded by [identify the Federal agency]. The government has certain rights in the invention."
- **5.** <u>Notice of Abandonment</u>. For each Subject Invention, OTD will, no less than sixty (60) days prior to the expiration of the statutory deadline, notify the Federal agency of any decision: Not to

continue the prosecution of a non-provisional patent application; not to pay a maintenance, annuity or renewal fee; not to defend in a reexamination or opposition proceeding on a patent, in any country; to request, be a party to, or take action in a trial proceeding before the Patent Trial and Appeals Board of the U.S. Patent and Trademark Office, including but not limited to postgrant review, review of a business method patent, inter partes review, and derivation proceeding; or to request, be a party to, or take action in a non-trial submission of art or information at the U.S. Patent and Trademark Office, including without limitation a pre-issuance submission, a post-issuance submission, and supplemental examination.

- 6. <u>Utilization Reports</u>. For each Subject Invention, OTD will report to the Federal agency via iEdison within two (2) months after the end of each Federal fiscal year on the utilization of the Subject Invention or on efforts at obtaining such utilization that are being made by MSK or its licensees, including information regarding the status of development, date of first commercial sale or use, gross royalties received by MSK, and such other data and information as the Federal agency may reasonably specify. OTD will timely invoice licensees and track revenue and other commercialization activities related to Subject Inventions to enable annual submission of such utilization reports.
- 7. Close-out Report. The MSK Office of Research Project Administration ("ORPA") will submit a report to the Federal agency prior to the close-out of a funding agreement listing all Subject Inventions or stating that there were none. ORPA will coordinate with OTD to provide the patent and/or application number, title, filing date, grant date if applicable, and a copy of the patent or patent application for any Subject Invention in any country in which MSK has applied for a patent.

E. Revenue Sharing.

- 1. General. Under Bayh-Dole, MSK must share royalties from a Subject Invention with the Inventor and use the balance of any royalties or revenue earned with respect to a Subject Invention, after payment of expenses (including Inventor payments) incidental to the administration of the Subject Invention, to support scientific research or education. To meet these requirements and incentivize Workforce Members to promptly disclose all MSK IP, MSK will share a portion of Cumulative Gross Proceeds resulting from transactions for MSK IP created both with and without federal funding support (but not a Work Made for Hire or an Institutional Work) (a "Creator Share") with contributing Workforce Members as set forth below and apply the remainder of the Cumulative Gross Proceeds for scientific research or educational purposes. Cumulative Gross Proceeds do not include revenue applied to any unreimbursed IP Expenses or any payments or distributions due to a Third Party, which MSK subtracts and/or pays prior to distributing any shares of Cumulative Gross Proceeds. MSK may reserve a portion of Cumulative Gross Proceeds for additional anticipated IP Expenses. Otherwise, to the extent practicable as determined by MSK, MSK will distribute shares of Cumulative Gross Proceeds within three months of receipt by MSK; for clarity, Royalty Monetization by MSK will not affect the distribution schedule. MSK will not pay any interest on any distributions under this Policy.
- 2. Equity Proceeds. The MSK Executive Vice President, Finance will hold stock or other equity obtained directly as consideration for MSK IP rights and will manage or sell such stock or other equity according to procedures that ensure that decisions to sell are made at arm's length from any Workforce Members who have a conflict of interest. Cumulative Gross Proceeds may include proceeds from sales of stock or other equity obtained directly by MSK as consideration for MSK

IP rights but do not include proceeds from sales of stock or other equity purchased by MSK under a license or similar agreement (e.g., via a share purchase right or option).

3. No Retroactive Effect. Notwithstanding anything in this Policy to the contrary, this Policy will not affect any existing allocations or prior distributions.

4. MSK Creator Share.

a. Eligibility.

- i. Inventor. MSK will allocate a Creator Share of Cumulative Gross Proceeds resulting from transactions for patent rights to the contributing Workforce Member who is determined to be the Inventor. For cases with more than one such eligible Inventor, MSK will consider all eligible Inventors named on a nonprovisional patent application, following an objective determination of inventorship by patent counsel, to be equal contributors and therefore allocate the Creator Share equally unless all eligible Inventors agree that their relative contributions are unequal, or MSK, at its sole discretion, renders an independent judgment regarding their relative contributions and allocates the Creator Share accordingly. The percentage of the Creator Share that each Workforce Member is allocated is referred to herein as such Workforce Member's "Individual Allocation." For clarity, the sum of all Individual Allocations will equal the Creator Share. If inventorship changes during prosecution of a nonprovisional patent application or in a continuing patent application, MSK may adjust such Individual Allocations to reflect the changes and/or relative contributions of the remaining eligible Inventor(s).
- ii. Author. MSK will allocate a Creator Share of Cumulative Gross Proceeds resulting from transactions for an original work of authorship to any contributing Workforce Member whom MSK determines, at its sole discretion, to be the Author. For cases with more than one such eligible Author, MSK will consider all eligible Authors to be equal contributors and therefore divide the Creator Share equally unless all the eligible Authors agree that their relative contributions are unequal, or MSK, at its sole discretion, renders an independent judgment regarding their relative contributions and allocates the Creator Share accordingly. If the authorship changes for a revised or derivative work, MSK may adjust such Individual Allocations to reflect the changes and/or relative contributions of the remaining Author(s).
- iii. Other Creator. MSK will not allocate a Creator Share to a Workforce Member who contributed to MSK IP by merely carrying out instructions or performing assigned job duties in the regular course of business. Notwithstanding the foregoing, MSK may adjust Individual Allocations to recognize any Workforce Member whose contributions are not considered inventive under U.S. patent law or authorial under U.S. copyright law, but are found by MSK, at its sole discretion, to have been significant to the discovery, creation, reduction to practice, or development of MSK IP (e.g., patent rights, original works, Know-How, Tangible Materials) that results in Cumulative Gross Proceeds. MSK reserves the right to make a final determination regarding such Individual Allocations.
- iv. Forfeiture. Notwithstanding the foregoing eligibility criteria, any Inventor, Author, or other contributing Workforce Member who would be eligible for an Individual Allocation but refuses or fails to adhere to this Policy will forfeit such Individual

- Allocation, which MSK will reallocate for scientific research or educational purposes. See also Section III(C)(8) ("Consequences of Not Adhering to this Policy") of this Policy.
- v. <u>Refusal</u>. A Workforce Member who would be eligible for an Individual Allocation may decline, via an agreement with OTD, such Individual Allocation, which MSK will reallocate for scientific research or educational purposes.

b. Distribution and Limits.

- i. MSK IP Licensed on or After the Effective Date. For all Cumulative Gross Proceeds resulting from transactions for MSK IP executed on or after the Effective Date of this Policy, the Creator Share is thirty percent (30%) of such Cumulative Gross Proceeds. Note that MSK will monitor the effects of this distribution plan against MSK's overall financial performance, and MSK reserves the right to modify this distribution plan at its sole discretion.
- ii. MSK IP Licensed on or After April 1, 2016, and Before the Effective Date. For all Cumulative Gross Proceeds (rounded up to the next dollar) resulting from transactions for MSK IP executed on or after April 1, 2016, and before the Effective Date of this Policy, MSK will distribute the Creator Share according to the following rate table:

Cumulative Gross Proceeds		Creator Share
From	То	
\$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%

iii. MSK IP Licensed Before April 1, 2016. For all Cumulative Gross Proceeds (rounded up to the next dollar) resulting from transactions for MSK IP executed before April 1, 2016, MSK will distribute the Creator Share according to the following rate table:

Cumulative Gross Proceeds		Creator Share
From	To	
\$1	\$100,000	42.5%
\$100,001	\$200,000	28.5%
\$200,001	\$1,000,000	22.5%
\$1,000,001	\$15,000,000	20.0%
More than \$15,000,000		5.0%

iv. <u>Tax Consequences</u>. MSK will report Creator Share distributions as payment of "royalties" and not as "wages." Creator Share distributions may have tax consequences for a Workforce Member, which tax consequences will be the sole responsibility of the Workforce Member. Each Workforce Member should consult a personal tax advisor.

- v. <u>Limits and Exceptions</u>. Under no circumstances may any Creator Share distributions exceed the total amount that may be paid under applicable laws and regulations. Workforce Members must notify OTD and/or the MSK Compliance Department if they are aware, or become aware, of a proposed agreement (or a proposed amendment to an existing agreement) with a Third Party that is or becomes involved with MSK in a transaction to license MSK IP. Such agreements may include consulting, founder, director, scientific advisory board, and company formation agreements. MSK's proceeds from sales of stock or other equity and success payments based on increases in the value of a Third Party's equity are referred to herein as "Excluded Proceeds." In order to receive Excluded Proceeds from an IP agreement with a Third Party, a Workforce Member may not—during any of the time period extending from one (1) year before to two (2) years after MSK's receipt of equity under such transaction—hold or have a right to receive or purchase stock or other equity in such Third Party that reasonably relates to such transaction and exceeds the lower of the following:
 - (a) one percent (1%) of the total fully diluted outstanding shares of the Third Party; and
 - (b) the Workforce Member's prorated Individual Allocation of the Creator Share of MSK's equity stake in the Third Party.

MSK will reallocate any Creator Share distribution of Excluded Proceeds, not to any other contributing Workforce Members, but to support scientific research or education. See also Section III(C)(4) ("Company Formation and Equity") and Section III(E)(2) ("Equity Proceeds") of this Policy.

Example:

- MSK is licensing Drug X to a company, Newco. As part of the license consideration, MSK will receive 8% of the company's stock. Drug X has three Inventors: Alan, Betty, and Connie. Alan was the primary Inventor and has an Individual Allocation of 50%; Betty of 40%; and Connie of 10%. Newco wants Betty to be a founder of the company and offers to give her stock options, separate from MSK's equity consideration from the license. If Betty wants to retain rights to her share of Excluded Proceeds, she must ensure that she did not obtain (over the past year) and does not obtain (for the next two years starting the day that MSK receives its equity) options or stock that correspond >0.96% of Newco's fully diluted shares [0.96% = 40% Individual Allocation for Betty x 30% Creator Share x 8% MSK share of Newco]. Note that this threshold of 0.96% is lower than the 1% absolute cap for receiving excluded proceeds.
- For clarity, the most equity Betty can accept from Newco to be a founder is 0.96% of the fully diluted outstanding shares of Newco if she wants to also share in Excluded Proceeds from MSK.
- Before accepting any such equity, Betty should ask OTD if accepting equity might affect her share in Excluded Proceeds.

- vi. <u>Conflict of Interest</u>. Workforce Members must review MSK's <u>Conflict of Interest and Commitment Policy</u>. Workforce Members who receive or have the potential to receive Creator Share distributions may have a conflict of interest. The MSK Compliance Department will work with Workforce Members to manage such conflicts.
- vii. Departed, Deceased, or Unresponsive Creator. MSK will use diligent efforts to continue to make Creator Share distributions due to Workforce Members, even after their association with MSK ends, provided that each Workforce Member has the sole obligation to maintain current contact and beneficiary information with OTD. In the event of a Workforce Member's death, MSK will use diligent efforts to continue to make Creator Share distributions to the deceased Workforce Member's estate in accordance with this Policy and applicable law, provided that such estate has the sole obligation to maintain current contact information with OTD. If MSK has been unable to make a Creator Share distribution for three consecutive years, unless expressly prohibited by applicable law, MSK will reallocate the Creator Share distribution—not to any other contributing Workforce Members, but to support scientific research or education. If the unresponsive Workforce Member or beneficiary subsequently claims the Individual Allocation, MSK will resume Creator Share distributions to such Workforce Member or beneficiary from the time when such claim is made.

5. MSK Unit Share.

- a. <u>Eligibility and Allocations</u>. MSK will share a portion of Cumulative Gross Proceeds resulting from transactions for certain MSK IP executed on or after the Effective Date of this Policy (a "Unit Share") with contributing MSK departments, laboratories, core facilities, services, programs, or other units (each an "MSK Unit") to support scientific research or education as set forth below. If an MSK Unit is not allowed to access or apply a Unit Share under applicable law or MSK Policy, MSK will reallocate the Unit Share for scientific research or educational purposes. Likewise, if an MSK Unit is dissolved, MSK will reallocate any Unit Shares for other scientific research or educational purposes.
 - i. Patent Rights, Original Works, and Know-How. MSK will allocate a Unit Share of ten percent (10%) of Cumulative Gross Proceeds resulting from transactions for patent rights, original works, and Know-How to the MSK Unit primarily associated with the Workforce Member who would be eligible for a Creator Share under this Policy and the relevant MSK IP at the time such MSK IP was created. If the Workforce Member subsequently departs MSK or the MSK Unit, then MSK will continue to allocate the Unit Share to the MSK Unit unless and until the MSK Unit is dissolved. For cases with more than one eligible MSK Unit, MSK will allocate the Unit Share among the eligible MSK Units according to the relative contributions of the associated Workforce Members. MSK reserves the right to make a final determination regarding such allocations.
 - ii. <u>Unpatented Tangible Materials</u>. MSK will allocate a Unit Share of twenty percent (20%) of Cumulative Gross Proceeds resulting from transactions for unpatented Tangible Materials created on or after January 1, 2010, to the MSK Unit primarily responsible for creating the Tangible Materials. When applicable, MSK will allocate an additional Unit Share of ten percent (10%) of Cumulative Gross Proceeds resulting from transactions for unpatented Tangible Materials created on or after January 1, 2010, to the MSK Unit primarily responsible for collecting samples associated with the Tangible Materials. For

- cases with more than one eligible MSK Unit, MSK will divide each applicable Unit Share according to the relative contributions of the eligible MSK Units. MSK reserves the right to make a final determination regarding such allocations.
- iii. <u>Institutional Works</u>. MSK will allocate a Unit Share of ten percent (10%) of Cumulative Gross Proceeds resulting from transactions for an Institutional Work to the MSK Unit that made significant contributions to the value of the Institutional Work. For cases with more than one eligible MSK Unit, MSK will divide the applicable Unit Share according to the relative contributions of the eligible MSK Units. MSK reserves the right to make a final determination regarding such allocations.
- b. Distributions. A Unit Share will remain in MSK general funds until MSK receives a threshold amount of Cumulative Gross Proceeds resulting from a transaction for MSK IP, the threshold amount to be initially determined (e.g., \$100,000 rounded up to the next dollar) and modified at MSK's sole discretion. Once such threshold amount is met, any eligible MSK Unit may request distribution of some or all of the applicable Unit Share in its annual budget to support scientific research or education. MSK will distribute such amount to a fund designated by the eligible MSK Unit for this purpose (a "Unit Research Fund"). A Unit Research Fund may be applied to, for example, research personnel salary, research supplies, core facility services, travel to scientific meetings, and the like; but not to administrative support, marketing, nonresearch equipment, etc. MSK will cap each Unit Share at the same upper limit per transaction per year, the upper limit to be initially determined (e.g., \$500,000 rounded up to the next dollar) and modified at MSK's sole discretion. In addition, each Unit Research Fund may carry over no more than a maximum amount to the next calendar year, the maximum amount to be initially determined (e.g., \$500,000 rounded up to the next dollar) at MSK's sole discretion. In either case, any excess will remain in or be transferred back to MSK general funds for scientific research or educational purposes.
- c. <u>Indirect Costs</u>. Indirect costs will be assessed from Unit Share distributions based on actual drawdown and repaid to MSK for other scientific research or educational purposes. MSK will initially determine and may modify the indirect cost rate (e.g., MSK's most recent negotiated federal Facilities & Administrative cost rate) at its sole discretion.

IV. DEFINITIONS

<u>Author</u> means the person or, if a joint work, the persons collectively who created the original expression in a work pursuant to U.S. copyright law, including Title 17 of the United States Code. In the case of a Work Made for Hire on behalf of MSK, MSK is automatically the Author.

<u>Cumulative Gross Proceeds</u> mean all payments received by MSK from a Third Party in exchange for rights in or to MSK IP, less any unreimbursed IP Expenses and any payments or distributions due to a Third Party (e.g., a co-owner of the MSK IP or a funding organization that requires revenue sharing). Cumulative Gross Proceeds may include license fees, milestone payments, royalties, proceeds from sales of stock or other equity obtained directly as consideration for MSK IP rights, success payments based on increases in the value of a Third Party's equity, and proceeds from sales of Priority Review Vouchers, under a license or similar agreement. Cumulative Gross Proceeds do not include payments for research or project support, value of materials or other resources supplied, reimbursed IP Expenses, or other specific reimbursements of costs; MSK will consider such revenue to be institutional revenue for use in accordance with MSK policy.

<u>Intellectual Property Disclosure Form</u> means an electronic form that a Workforce Member submits to OTD to establish a record of MSK IP.

<u>Interagency Edison ("iEdison")</u> means a unified electronic data system that receives, stores, tracks, sorts, monitors, and generates reports of intellectual property resulting from awards to extramural grant or contract funding recipients across U.S. Federal government funding agency offices (available at www.iedison.gov).

<u>Institutional Work</u> means MSK IP, such as Trademarks, Know-How, Tangible Materials, Software, and confidential or proprietary data, prepared by a Workforce Member within the scope (i.e., regular duties) of the Workforce Member's employment or association with MSK. Institutional Works do not include inventions for which patent protection is sought or original works of authorship, unless an original work of authorship is a Work Made for Hire.

<u>Inventor</u> means a person or, if a joint invention, the persons collectively who invented or discovered the subject matter of an invention pursuant to U.S. patent law, including Title 35 of the United States Code.

<u>IP Expenses</u> mean out-of-pockets costs attributable to specific MSK IP, including without limitation fees and costs associated with legal protection or registration applications, prosecution, maintenance, enforcement, marketing, transactions, and project management support.

<u>Know-How</u> means any tangible or intangible asset not in the public domain and relevant or useful to the study, discovery, creation, invention, authorship, development, formulation, testing, manufacture, use, or commercialization of a product, service, or technology. Know-How includes unpublished information, documents, and materials (e.g., trade secrets, compositions, formulations, samples, specifications, methods, processes, data and results, unpublished patent applications, grant applications, study protocols, regulatory filings, and business and commercialization strategies).

MSK Intellectual Property ("MSK IP") means any creations of the intellect, including without limitation any discoveries, inventions, original works of authorship and derivative works thereof (e.g., Scholarly Work), designs, Trademarks, Know-How, Tangible Materials (e.g., drug products, reagents, biologics, cell lines, transgenic animals), algorithms, Software, confidential or proprietary data (e.g., unpublished patent applications or research results, preclinical or clinical data), tools, devices, systems, and any improvements to, new methods of making, and new uses of any of the foregoing, regardless of eligibility for specific legal rights and protections (e.g., patents, Trademarks, copyrights, and related rights), which a Workforce Member has discovered, conceived, originated, invented, authored, created, developed, or otherwise made, whether or not reduced to writing, drawing, or practice, in whole or in part, either solely or jointly with others, arising from or in the course of employment by or association with MSK, either during or up to one year following termination of employment or association with MSK, or with the significant use of MSK Resources, or ordered or commissioned by MSK, or otherwise owned or controlled by MSK.

<u>MSK Resources</u> means any funding, personnel, equipment, facilities, materials, data, or other tangible or intangible resources owned or controlled by MSK.

<u>Scholarly Work</u> means the text of any journal article, conference paper, book or book chapter, student thesis, or other work of an academic nature that comprises MSK IP (other than a Work Made for Hire). Except with prior written approval from OTD, Scholarly Work specifically excludes other MSK IP, including, without limitation, inventions, illustrations or other images (e.g.,

Works Made for Hire), Tangible Materials, Software, and confidential or proprietary data (e.g., raw preclinical or clinical data).

<u>Software</u> means any application, script, program, code, or other set of instructions used to operate or execute specific tasks on a device or any associated data or documentation.

<u>Subject Invention</u> means any MSK IP conceived or first actually reduced to practice in the performance of work under any contract, grant, or cooperative agreement entered into between a Federal agency and MSK for the performance of experimental, developmental, or research work, funded in whole or in part by the Federal government, wherein the MSK IP is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.), provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.

<u>Tangible Materials</u> mean any physical assets including, without limitation, biological materials (e.g., biospecimens, cell lines, clones, animal models, patient-derived xenografts, organoids, biologics), chemical substances (e.g., compounds, formulations, extracts, reagents, nanoparticles, biosynthetics, culture media), technical drawings, and prototypes (e.g., tools, devices, systems, equipment).

<u>Third Party</u> means any person who is not a Workforce Member or any entity or other organization other than MSK or its affiliates.

<u>Trademark</u> means any word (e.g., name), phrase (e.g., slogan), symbol (e.g., logo), device (e.g., sound, color, shape), or a combination thereof that either (i) identifies a source of goods or services and distinguishes that source from others or (ii) certifies the quality or accuracy of goods or services or that work or labor on goods or services was performed by a particular organization or according to particular standards or tests of competency. In this Policy, Trademark may refer to a trademark, service mark, collective mark, or certification mark.

Work Made for Hire means MSK IP specially ordered or commissioned by MSK.

<u>Workforce Member</u> means any person who is hired, appointed, designated, selected, or otherwise associated with MSK, including an employee, trainee, volunteer, graduate or other student, postdoctoral researcher, visiting scientist, provider, clinical fellow, rotating house staff, and/or consultant, whether compensated or not, who is involved in any activities supported in whole or in part by MSK Resources.

V. PROCEDURES

MSK may revise this Policy at any time and without prior notice. OTD will review this Policy on a regular basis and maintain detailed standard operating procedures to effectuate this Policy. OTD should be contacted with questions or requests for procedures applicable to this Policy. To appeal any interpretation or application of this Policy, a Workforce Member must submit to OTD a written request along with any supporting documentation for review and resolution. In the event of any unresolved dispute or unusual circumstances, OTD will make a recommendation to the MSK President and Chief Executive Officer, or his or her delegate, whose decision regarding OTD's recommendation will supersede any inconsistent provisions of this Policy.

VI. PREVIOUS POLICIES

This Policy replaces and supersedes any prior MSK policy on this subject matter.

VII. OTHER APPLICABLE POLICIES

Conflict of Interest and Commitment Policy (available at https://www.mskcc.org/teaser/conflict-interest-commitment-policy.pdf).

VIII. REFERENCES

- Bayh-Dole Act or Patent and Trademark Law Amendments Act, 35 U.S.C. §§ 200–212 (1980) (Pub. L. No. 96-517) (implementing regulations at 37 C.F.R. §§401.1–401.17).
- Extramural Invention Reporting Compliance Responsibilities (available at https://public.era.nih.gov/iedison/public/timeline.jsp).
- Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (implementing regulations at 45 C.F.R. §§ 160, 162, 164).
- MSK Brand Portal (available at https://brand.mskcc.org/).
- MSK eContracts (available at https://econtracts.mskcc.org).
- MSK Intellectual Property Disclosure Form ("IPDF") (available at https://mskcc.sharepoint.com/sites/pub-RTM/SitePages/otd/Invention-Disclosure.aspx).
- New York Consolidated Laws, Not-For-Profit Corporation Law NPC § 715. Related party transactions.
- Regulation 2016/679 of the European Parliament and of the Council of Apr. 27, 2016, on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation or GDPR), art. 9(1), 2016 O.J. (L 119) 38 (EU).