



North Shore-LIJ Health System is now Northwell Health

POLICY TITLE: Policy on Technology Licensing and Distribution of Royalty Income	ADMINISTRATIVE POLICY AND PROCEDURE MANUAL
POLICY #: 100.027	CATEGORY: Administrative
System Approval Date: 4/17/15	Effective Date: 4/15
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Prepared by: Office of Technology Transfer Office of Legal Affairs	Superseded Policy(s)/#: GR017 – Policy on Intellectual Property

GENERAL STATEMENT of PURPOSE

Northwell Health (“Health System”) recognizes and supports technology licensing as an integral component of the mission of the Health System and Feinstein Institute for Medical Research (“Institute”). The objectives of technology licensing include the facilitation of the transfer of knowledge and technology from the Health System to the private sector in support of patient care and the public interest; support for the discovery of new knowledge and technology; and the attraction of resources for the support of the programs of the Institute.

POLICY

The licensing of Inventions (as defined below) to parties outside the Health System and the sharing of revenues derived from such licensing is the focus of this Policy. As set forth herein, the Health System and the Institute shall share revenues received from commercialization with Inventors (as defined below). The Office of Technology Transfer (“OTT”) of the Institute shall have the responsibility for overseeing and implementing this Policy.

SCOPE

This policy applies to all members of the Northwell Health workforce including, but not limited to: employees, medical staff, volunteers, students, physician office staff, and other persons performing work for or at Northwell Health; faculty and students of the Hofstra Northwell School of Medicine conducting Research on behalf of the School of Medicine on or at any Northwell Health facility; and the faculty and students of the Hofstra Northwell School of Graduate Nursing & Physician Assistant Studies.

DEFINITIONS

“**EOE**” shall mean an Employee-Owned Entity as described in the Policy on Employee-Owned Entities (Policy 100.026).

“**Institute Inventor**” shall mean an Inventor who is (i) an employee at the Institute who is hired to perform research and who makes an Invention in the course of performing his or her duties and activities or (ii) an employee of the Health System who makes an Invention while performing research at the Health System or at the Institute or (iii) a student of the School or a student of the Elmezzi Graduate School of Molecular Medicine (the “Elmezzi”) who makes an Invention while conducting research at the Institute or the School or the Health System or by utilizing the resources of the Health System and/or the Institute.

“**Inventor**” shall mean (1) any employee of the Health System who makes an Invention in the course of performing his or her duties and activities for the Health System or by utilizing the resources of the Health System and/or the Institute, and (2) any non-employee of the Health System (including voluntary staff, volunteers, and those holding visiting or guest appointments) who makes an Invention utilizing the resources of the Health System and/or the Institute, and (3) any Health System or Institute student or trainee, including but not limited to students of the School and students of the Elmezzi, who makes an Invention while conducting research at the Institute or the School or the Health System or by utilizing the resources of the Health System and/or the Institute.

“**Invention Request**” shall have the meaning ascribed in the IP Policy.

“**Invention**” shall mean any idea or its expression that is, or may be, subject to patent or copyright protection, or is otherwise protectable under law.

“**IP Committee**” shall be those individuals appointed by the President and CEO of the Health System and the President of the Institute (the “President”), including the President (or a designee), a representative from the Office of Legal Affairs of the Health System, the Vice President, Technology Transfer of the Health System, the Director of the Office of Technology Transfer (the “OTT”) of the Institute, two representatives of the Health System and at least one member of the research staff of the Institute.

“**IP Policy**” shall refer to the Policy on Intellectual Property (Policy 100.024).

“**NIH**” refers to the National Institute of Health of the United States Department of Health and Human Services.

“**Non-Institute Inventor**” shall mean all Inventors other than Institute Inventors.

“**PHS**” refers to the Public Health Service of the Department of Health and Human Services.

PROCEDURE/GUIDELINES

1. License Agreements

Whenever possible, licenses for commercial development of Inventions (each, a “License Agreement”) shall be sought to ensure that useful Inventions shall be made available in products or services beneficial to the public. In cases involving substantial development expenditures by the licensee, or for other special reason, an exclusive license may be given, subject to the terms of an applicable grant or contract. All License Agreements shall be negotiated by the OTT or as otherwise assigned by the IP Committee. Upon approval of the IP Committee, an appropriate officer of the Institute or Health System may execute a License Agreement.

2. Royalty Income for Institute Inventors

In the event that an Invention is licensed for use other than by the Institute, the Institute Inventor thereof shall share in any income derived by the Institute from such Invention in accordance with the formula set forth below. “Royalty Income” upon which the Institute Inventor’s share is calculated, shall include all sums payable as consideration for the transfer of the Invention regardless of how it is designated (*e.g.*, whether as a royalty, license signing fee, milestone payment, minimum royalty payment or otherwise), less (i) any amounts due and payable to other entities which may have an ownership interest in the Invention, (ii) any transaction costs payable to third parties in connection with earning such Royalty Income, and (iii), for any Invention disclosed after February 1, 2012, an additional amount of up to twenty-five (25%) percent deducted from such Royalty Income to reflect the costs of work performed by Health System strategic partners who assist in the commercialization of Inventions. Royalty Income shall not include any sum paid to the Institute or Health System for a particular use, such as laboratory support, sponsored research, patent costs or as reimbursement of other costs.

3. Distribution of Royalty Income for Institute Inventors

All Royalty Income received by the Institute will be distributed to the respective Institute Inventor by the Director of the OTT as follows:

- a) Until such time as all otherwise unreimbursed legal and other out-of-pocket expenses incurred by the Institute or Health System (or paid by the Institute or Health System to or on behalf of third parties) for (x) the preparation and negotiation of the license, (y) the filing, prosecution and maintenance of patents, or (z) specifically designated technology maturation or product development activities (collectively, “Expenses”) are one hundred percent (100%) recovered, Royalty Income received by the Institute shall be distributed as a twenty percent (20%) share to the Institute Inventor and an eighty percent (80%) share to the Institute.
- b) Once all Expenses have been so recovered, Royalty Income thereafter shall be divided between the Institute and the Institute Inventor as follows:

The Institute Inventor shall be paid a share equal to forty percent (40%) of the remaining Royalty Income realized, and the remaining Royalty Income shall be retained by the Institute.

- c) Fifty percent (50%) of the Institute's retained share shall be paid to the Department or business unit from which the Institute Inventor is employed as an incentive to conduct further research which may lead to additional Inventions.
- d) In cases where there is more than one Institute Inventor (for the purposes of this section 3, "Co-Inventors"), the Co-Inventors shall be required to establish in writing the percentage distribution to each Co-Inventor with respect to any Royalty Income that might be realized on the Invention being disclosed. The aggregate amount payable to all Co-Inventors shall be limited, nevertheless, to the Institute Inventor's share as calculated above, which aggregate amount shall be divided in accordance with the percentages agreed to in advance by the Co-Inventors or, in the absence of such agreement, distributed among the Co-Inventors in a manner determined by the IP Committee.
- e) In cases where the Institute has granted an Invention Request, all such grants shall be subject to the following conditions: (i) the Institute Inventor may be required to reimburse the Institute for past Expenses relating to such Invention; (ii) the Institute Inventor shall become responsible for all future Expenses relating to such Invention; (iii) responsibility for patent prosecution and maintenance of such Invention shall thereafter rest with such Institute Inventor; (iv) responsibility for identification to the Institute of commercial partners shall thereafter rest with such Institute Inventor, (v) ownership of the Invention shall remain with the Institute, and (vi) the distribution of any compensation, in any form, that thereafter results from commercialization of such Invention shall be amended from the standard provisions of this Policy such that the Institute (A) shall distribute ninety percent (90%) of such compensation to the Institute Inventor, and (B) shall retain ten percent (10%) of such compensation, wherein such ten percent (10%) amount retained by the Institute shall not be deemed to be Royalty Income subject to distribution to such Institute Inventor pursuant to this Policy.
- f) The following exception to the Royalty Income distribution formula described in this Policy shall apply in the case of an EOE or other entity in which an Institute Inventor has a "significant financial interest" as such term is defined in the PHS and as applied in the Policy concerning the Review and Management of Financial Conflict of Interest in Research (Individuals) (GRO65). No distribution of Royalty Income shall be made to such an Institute Inventor until such time as (i) all Expenses incurred by the Institute and/or Health System and (ii) all other payments due from the EOE to the Institute and/or Health System in respect of any licensing or other agreement between them are one hundred percent (100%) recovered by, or paid to, the Institute, as the case may be.
- g) In the event of the death of an Institute Inventor, that Inventor's share thereafter shall be made payable to the Inventor's estate (subject to the distribution of royalty income provisions herein).

4. Equity Participation

- a) Technology transfer arrangements sometimes involve proposals for the issuance of equity securities to the Institute, either in addition to, or in lieu of, other forms of Royalty Income. The Institute is open to such arrangements in appropriate circumstances that will be considered on a case-by-case basis. Where such equity arrangements are made by the Institute, the Royalty Income sharing formula noted above shall apply to the liquidation value realized by the Institute at such time as the equity is liquidated by the Institute, except that there shall be no sharing of:
 - (i) equity received by the Institute in consideration for sponsored research at the Institute; or
 - (ii) equity received by the Institute as consideration for (x) cash paid by the Institute for such equity, (y) provision by the Institute of research space or services, or (z) reimbursement to the Institute of Expenses.
- b) The Institute's equity position in any entity shall be overseen and managed by the IP Committee in its sole discretion.

5. Royalty Income for Non-Institute Inventors

In the event that an Invention is licensed for use other than by the Institute, the Non-Institute Inventor thereof shall share in any income derived by the Institute from such Invention in an amount to be determined by the IP Committee taking into account, for instance, whether the Non-Institute Inventor was hired expressly for the purpose of making, or was directed in the context of his or her employment to make, the Invention, and taking further into account the amount of Health System or Institute resources used in making the Invention, and other relevant factors.

Auditing and Monitoring

The Office of Research Compliance or Internal Audit may conduct periodic routine and for cause auditing and monitoring. It is the responsibility of all members of the Health System workforce to conduct themselves in compliance with this Policy. Employees may report incidents of non-compliance via the Corporate Compliance Help Line 1-800-894-3226 or by web-based reporting at www.northshore-lij.ethicspoint.com.

Non-compliance with this policy may lead to disciplinary action, up to and including termination of employment.

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

- Northwell Health Policy 100.024: Policy on Intellectual Property
- Northwell Health Policy 100.026: Policy on Employee-Owned Entities
- Northwell Health Policy GR065: Review and Management of Financial Conflict of Interest in Research (Individuals)
- Northwell Health Policy 800.04: Gifts and Interactions with Industry

CLINICAL REFERENCES

N/A

FORMS

N/A

<u>APPROVAL:</u>	
System Administrative P&P Committee	3/26/15
System PICG/Clinical Operations Committee	4/17/15 (electronic vote)

Standardized Versioning History:

*=Policy Committee Approval; ** =PICG/Clinical Operations Committee Approval