



Roswell Park Cancer Institute Policy and Procedure	Date Issued: 8/15/2010	Number: 706.1
Title: Protecting and Commercializing Roswell Park Cancer Institute Intellectual Property	Revision: 1	Effective Date: 12/3/2012
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A. GENERAL STATEMENT OF POLICY

This Policy and Procedure enables Roswell Park Cancer Institute (RPCI) to protect its legal and financial interests in intellectual property developed by its employees and employees of Health Research Inc., Roswell Park Division (HRI), as well as intellectual property developed through use of RPCI and HRI resources. This Policy and Procedure is also designed to ensure compliance with the Bayh-Dole Act of 1980.

B. SCOPE

This Policy and Procedure applies to all employees, faculty and staff members of RPCI and HRI, as well as volunteers, students, trainees, and anyone using RPCI or HRI resources who may, in the course of their activities at RPCI and/or HRI, conceive, reduce to practice or otherwise develop, in whole or in part, intellectual property ("Inventors").

C. ADMINISTRATION

This Policy is administered by RPCI's Director of Technology Transfer, with oversight by the Executive Vice President.

D. POLICY / PROCEDURE

Type of Intellectual Property Covered

This Policy and Procedure applies to all inventions, discoveries, ideas, know-how, formulas, concepts, technology, and intellectual property of any nature (regardless of whether it is protectable by or reflected in a patent, trademark or copyright) that:

- (a) arises in the course of an Inventor's employment-related activities (including but not limited to research, education, scientific, and clinical activities);
- (b) arises in the course of an Inventor's training, educational, or volunteering activities through RPCI's or HRI's formal training, education, or volunteer programs; or
- (c) is created by an Inventor using RPCI or HRI resources (including but not limited to space, equipment, personnel, and core resources).

The above-listed intellectual property (IP) shall be owned entirely by RPCI. Despite the foregoing, RPCI will not assert a claim of ownership over IP that is (a) created using RPCI or HRI resources on a fee-for-service or "work for hire" basis for a non-RPCI/non-HRI individual or entity; or (b) developed wholly without the use of RPCI or HRI facilities or resources; wholly on an Inventor's own time; and is unrelated to the mission of RPCI/HRI and the RPCI/HRI employment activities of the Inventor; or (c) is a non-software copyrighted work such as a book chapter that does not contain research results or data.

Assignment to RPCI

All employees, upon commencement of employment with RPCI and HRI, agree in writing to assign their interest in any IP to RPCI. This reflects the fact that each employee is conducting his or her research activity and/or work on behalf of RPCI. Likewise, volunteers, students, trainees, and other Inventors agree in writing to assign their interests in IP to RPCI upon the commencement of their formal programs at RPCI.

IP may be patented, copyrighted or trademarked in RPCI's discretion, in order to promote the broadest, most efficient and rapid dissemination of the benefits of such IP to the public, while protecting the rights and interests of RPCI.

Inventors of potentially patentable IP, when so instructed by RPCI, shall make application for patent(s) at RPCI's expense through RPCI's Technology Transfer Office (TTO), and shall then assign the patent application to RPCI or HRI, as directed by RPCI. HRI is engaged by RPCI through a contract to serve as the administrator of RPCI's IP.

Other IP Rights

Outside parties, including commercial sponsors occasionally have certain interests in IP developed at RPCI where, for example, they engage RPCI in collaborative or sponsored research agreements. Federal research sponsors, such as NIH, may also reserve limited IP rights to IP resulting from such federally sponsored research. All IP shall be subject to such contractual obligations negotiated and finalized by the Office of General Counsel.

HRI as IP Administrator

Generally, RPCI IP that is submitted for a patent will be assigned to HRI to be administered. There are instances in which the assignment is implemented directly from the employee to HRI, for administrative convenience. Matters related to patents and other IP administration will be coordinated by the TTO, typically in collaboration with HRI. HRI may be asked by the TTO or the Office of General Counsel to assist with licensing or other commercialization efforts, and administer distribution of income, equity or other returns from the commercialization process.

RPCI may pursue commercialization efforts for its IP at any point in its development. These efforts are geared toward negotiating licensing agreements with commercial organizations such as pharmaceutical or biotechnology companies or, where appropriate, start-up companies. (See Policy regarding Employee Affiliated Companies). These activities are pursued by RPCI through the efforts of its TTO, with input from Technology Transfer Committee of the Board of Directors and the Office of General Counsel.

IP Review Process

The TTO is responsible for coordinating patent, technology transfer and related matters, and is supervised by RPCI's Technology Transfer Director (Director). The TTO and its Director report to RPCI's Chief Institute Operations Officer and receive oversight and counsel from the Technology

Transfer Committee of the Board of Directors. Technology Transfer is a specialized field encompassing aspects of scientific research, business and intellectual property law. Decisions as to patenting, commercialization, distribution of royalties or other financial returns, and related matters, are often complex and require the expertise of skilled and experienced technology transfer professionals. Therefore, it is imperative that careful consideration be given to each case by the TTO staff in consultation with RPCI/HRI scientific and management personnel.

Inventors, who develop or contribute to IP, shall promptly file a written Invention Disclosure form with the TTO (Attachment A to this Policy and Procedure). It is imperative and thus required that this Disclosure be completed sufficiently in advance of any publication (oral or written) of the IP by the employee/inventor, to allow the TTO to assess the IP for possible patenting. Valuable international patent rights can be lost or compromised where publication of the IP takes place prior to filing of a patent application. Loss or diminution of patent rights can severely limit or eliminate commercialization potential and value of IP.

After receiving a completed Invention Disclosure, the TTO will promptly evaluate the IP disclosed, utilizing consultations with scientists and other staff at RPCI and outside the institution, including outside consultants and legal advisors. The review process will cover the following issues:

- i. The advisability of pursuing a patent;
- ii. Commercial prospects for the IP;
- iii. The estimated cost of patent prosecution;
- iv. The probability of patent issuance; and
- v. The possibility of international patent coverage.

The TTO shall determine if a provisional patent application should be pursued, and if so, shall facilitate the filing of such application by the Inventor(s), and the assignment of the IP ultimately to HRI to administer on behalf of RPCI. RPCI may, at its sole option, return the proprietary rights in such IP to the Inventor if RPCI decides not to pursue a patent, subject to any retained rights of research sponsors or collaborators pursuant to contractual obligations.

Commercialization Initiatives

RPCI, through its administrator/agent, HRI, has the right to pursue commercialization of its IP, and such efforts shall be carried out by RPCI's TTO. This policy includes guidelines for such commercialization efforts. The financial benefits of such efforts (such as development milestone payments, royalties, equity or other financial interests) are owned by RPCI and administered on its behalf by HRI. Employees who invented, discovered, or are otherwise credited with having contributed to the IP, might receive a portion of the financial return from commercialization, in accordance with the guidelines in this Policy and Procedure and other relevant Policies. ([See Policy 119.1 Regarding Employee Affiliated Companies](#)).

The TTO shall facilitate the evaluation and implementation of appropriate commercialization efforts with respect to all IP subject to this Policy and Procedure and other relevant Policies. Such efforts may include, for example, licensing agreements with third parties such as established companies or start-ups whereby RPCI IP is to be further developed and commercialized in exchange for financial return to RPCI in the form of direct payment or equity. In its evaluation, the TTO shall consider all relevant information including, among other considerations, the: (i) development stage of the IP; (ii) projected cost of and resources needed for further development; (iii) length of time it will take to further develop the IP; (iv) potential for

development of the IP in the Western New York region; and (v) relative value to RPCI of a licensing income stream as compared to the potential growth value and risks involved with equity investment by RPCI in spin-off ventures. ([See Policy 119.1 regarding Employee Affiliated Companies](#))

Decisions as to whether particular RPCI IP will be licensed or perhaps considered for a spinoff/start-up venture shall be made by the TTO in consultation with RPCI's senior management, including the Executive Vice President and General Counsel and the Technology Transfer Committee of the Board of Directors and the Board itself. The TTO Director shall facilitate that evaluation process.

Distribution of Income

Income derived from the patenting, licensing, or other method of disseminating IP shall be distributed as follows: All income shall first be used to offset any expenses incurred by RPCI/HRI in the patent prosecution, issuance, maintenance and enforcement and licensing efforts (including but not limited to attorneys fees, consultant fees, and patent expenses). After all expenses are recouped, the remaining income (if any) shall be divided as follows: sixty percent (60%) shall be allocated to RPCI and forty (40%) percent shall be allocated proportionately among all of the Inventors of the particular IP, based upon their respective contributions to the IP. This right to share in License Fees or other IP income to RPCI will not apply if the Inventor creates or founds a company which licenses the IP at issue from RPCI. Such arrangements are covered by RPCI's separate Policy and Procedure regarding faculty/employee start-ups. ([See Policy 119.1](#) regarding Employee Affiliated Companies).

E. DISTRIBUTION

This Policy and Procedure will be distributed to all Institute Managers via the RPCI internal web page and to holders of backup hard copies of the manual. Managers are responsible for communicating policy content to pertinent staff.