

CATHOLIC HEALTHCARE WEST
ADMINISTRATIVE POLICY AND PROCEDURE

FROM: CHW Legal

SUBJECT: Intellectual Innovation Network

EFFECTIVE DATE: January 26, 2009

REVISED: January 20, 2009, January 9, 2009; August 26, 2008

ORIGINAL EFFECTIVE DATE: May 15, 2007

REPLACES:

APPLIES TO:	System Offices:	<u> X </u>
	Acute Care Entities:	<u> X </u>
	Non-acute Care Entities:	<u> X </u>

I. Policy:

It is the policy of CHW to:

1. Maximize CHW's intellectual assets and property, making certain of those available to the general public while also safeguarding the interests of CHW, inventors and sponsors (whether or not CHW).
2. Establish equitable guidelines for the sharing of related proceeds from commercialization between and among CHW, its employees, physicians and others.
3. Provide professional support and consultation services throughout CHW in this area.
4. Identify and share "best practices" for identifying and disseminating innovation within CHW.
5. Develop and implement procedures for the disclosure, protection, procurement, development and commercialization of intellectual assets, consistent with applicable laws, regulations and CHW policies.

II. Purpose:

Consistent with its value of excellence, Catholic Healthcare West (CHW) encourages the advancement of science and creativity that could lead to patient care benefits, contribute to the professional development of CHW employees and staff, enhance the organization's effectiveness, provide new opportunities for inventors and promote the public welfare. Through this policy, CHW intends to foster a better workplace by promoting ingenuity and innovation, focusing on health care products and services that benefit the public.

Consistent with its value of stewardship, CHW's goal is to capture and utilize the workplace activity and tools that are converted into ideas, inventions and know-how by CHW employees, and individuals associated with CHW, in a manner that balances the equitable rights of the inventor/innovator, sponsor and CHW. Intrinsic in the management of CHW's intellectual assets is the recognition of inventorship and innovation within CHW as well as the sharing of financial rewards from commercialization.

The purpose of CHW's Intellectual Innovation Network ("CHW *iin*") is to identify, track, protect and commercialize CHW's intellectual assets, consistent with this Policy, and to have staff available to consult and support the creative efforts of those covered under this Policy. CHW has established an Office of CHW *iin* to administer and be responsible for the administration of this Policy. The operations and effectiveness of CHW *iin* and this Policy will be evaluated annually.

III. Definitions:

1. Disclosure Statement - A hard copy or electronic statement on an approved form (available through the CHW's *iin* Office) for identifying and providing necessary background information on invention/innovation. A copy of the current form can be found at the webportal "CHWiin.org".
2. Employees - Nurses, resident and certain other physicians, technicians, scientists, researchers, clinical fellows, administrators, and all other professional and non-professional staff governed by CHW's human resource policies as employees. Medical Staff appointees may or may not be employees and are addressed, under Non-Employees.
3. Facilities – Buildings, equipment and/or materials (including electronic or hard copy data, servers, software, etc.) belonging to or controlled by CHW or an affiliate of CHW that are available to Participants as a result of a formal or informal affiliation or arrangement with CHW.
4. Invention – Any idea or its embodiment that has been reduced to practice, or has the potential to be reduced to practice and which is, or may be, patentable

or otherwise protected under Title 35 United States Code, or its successor.¹ An idea alone cannot be legally protected, via patent, copyright or trademark.

5. IP – Intellectual Property including all Invention(s), copyright protected work, or patentable works, trademarks, trade secrets, methods or processes, data (including patient data and data derived from health care operations) and other intellectual, intangible or tangible property, created or developed by Participants (i) in the course of employment or other association with CHW; or (ii) using CHW Facilities, information, Substantial Use of Resources or other CHW support. For purposes of clarity, IP includes, but is not limited to, research notebooks, data, databases, photographs, original drawings and diagrams, computer software and algorithms, as well as chemical and biological materials (such as proteins genes, gene products, cell lines etc). Patient data and tissue are CHW resources and are subject to HIPAA and other applicable privacy or confidentiality laws, regulations and policies.
6. Non-Employees - Third-party contractors, students and all others who are not governed by CHW’s human resource policies as Employees but who provide services to, at or for CHW Facilities or with CHW support. The activities of Medical staff members, visiting or collaborating researchers and students may, or may not, be covered under this Policy, depending upon CHW support and a Substantial Use of Resources determination. Non-Employees whose inventions/ innovations arise as a result of (a) CHW funding, whether cash or in kind, or (b) by virtue of being associated with or related to CHW are covered under this Policy as Participants.
7. Participants – Together, all Employees and Non-Employees covered under this Policy.
8. Substantial Use of Resources – The use of CHW Facilities, CHW Personnel or CHW resources to create and develop an Invention in more than an incidental or nominal manner constitutes a Substantial Use of Resources. This is a fact specific determination; see Exhibit A for examples and guidance on Substantial Uses. Medical staff members, at a minimum, are required to reimburse CHW for all of the costs associated with their use of CHW Facilities for their private research purposes, even if a Substantial Use does not arise.
9. Scholarly Works - Written, visual and/or auditory material developed for textbooks, monographs or treatises and for which the primary or intended use is academic or scholarly.

¹An invention may be legally protected only when it is reduced to practice (or has the potential to be reduced to practice) and is patentable only if novel, non-obvious and useful. A U.S. patent application must be filed within 1 year after public disclosure of an invention. However, if public disclosure precedes the patent filing, foreign patent rights are lost. **A patent application should be filed prior to the public disclosure of the invention.** Prior to public disclosure, a Disclosure Statement should be submitted to the CHW *in* Office.

IV. Principally Affected Department:

The following department in all CHW facilities including, but not limited to, hospitals, ambulatory surgery centers, home health agencies, physician practices and sites are principally affected by this policy and should receive necessary training:

- Administration
- Legal Department
- Compliance Department and Facility Compliance Liaisons
- Facility Privacy Officials
- Research
- Other departments and/or individuals involved in the creation or development of Intellectual Property

A CHW Facility may, in the exercise of its reasonable judgment, determine that other departments are affected by this policy and provide necessary training to the workforce in those departments.

V. Guidelines:

1. IP Management and Administration

1.1 IP assigned to, developed or owned by CHW will be secured, managed and commercialized by CHW *iin*. Participants are not to enter into Material Transfer, Confidentiality, Research or other types of agreements that could affect CHW's rights without authorization from the CHW *iin* Office, which operates in coordination with the CHW Legal Department on all such matters.

1.2 If CHW seeks to file for registration of or for its IP, including registration of patents or copyright protected works, CHW shall bear the costs. The inventor, however, shall cooperate fully, including signing all necessary or desirable agreements, applications, assignments and other forms.

1.3 Should CHW no longer seek such legal protection in or for an Invention, it will notify the inventor in writing, who shall be free, at his/her own expense to assume the patent prosecution subject to: (i) any prior rights of a funding agency, (ii) future use of the Invention within CHW without charge and (iii) an agreed upon payment mechanism to CHW reflecting its prior contribution.

1.4 With software programs, CHW may choose to rely on unregistered copyright or trade secret protection. Computer programs, databases, and other data should not be distributed publicly without notice of copyright.

2. Responsibilities

2.1 Participants will be introduced to the CHW *iin* intellectual asset management function when joining CHW and will acknowledge this as part of the orientation process. They are also required to sign and deliver any and all documents (e.g. applications, registrations, powers of attorney, assignments, and sworn statements) related to IP created by them as requested during their association with CHW.

2.2 Participants are to give CHW's *iin* Office prompt notice of any invention s/he has made covered under this Policy by completing a Disclosure Statement. The responsibility to disclose arises when a Participant has reason to believe an Invention has patient care, scientific, or educational value. Timely disclosure is important and prompt disclosure is encouraged.

2.3 Within thirty (30) days following the submission of a Disclosure Statement, the CHW *iin* Office staff will contact the Participant(s) to ascertain what, if any additional information is needed to make a determination whether rights of ownership to the invention will be retained by CHW or released to the inventor(s), or to a third party if so obligated by a contract or grant. Within ninety (90) days following the submission of an accurate and complete Disclosure Statement, the Participant(s) will be notified in writing of CHW's determination.

2.4 All research must be reviewed and approved by CHW in accordance with its Federal Wide Assurance, be consistent with the DHHS Office of Human Research Protection requirements as well as CHW's policies and procedures for human subjects and data research.

3. Ownership and Distribution

3.1 CHW owns all Inventions and all other IP, whether tangible or intangible developed or otherwise created by Participants if the Invention is:

3.1.1 Developed in or at its Facilities by its Employees,

3.1.2 Developed by Employees or Non-Employees via a Substantial Use of Resources,

3.1.3 Resulting from research sponsored by CHW performed by a Participant,

3.1.4 Resulting from research supported by federal funds and performed at a CHW Facility (to the extent not committed to a third party and not sponsored by an independent third party),

- 3.1.5 Developed under a contractual relationship with CHW, whether within the scope of employment or otherwise,
- 3.1.6 Commissioned by CHW pursuant to a signed contract,
- 3.1.7 Otherwise developed by virtue of opportunities arising from employment with or sponsorship by CHW, or
- 3.1.8 Considered works made for hire under U.S. copyright law²

3.2 This Policy applies to Participants (including but not limited to research staff, employees, students, residents, fellows, visiting scientists and volunteers) regardless of such person's obligations to other institutions. This policy may apply to Medical Staff members depending upon the specific circumstances.

3.3 Unless authorized in writing by CHW in advance, IP is not to be removed from the Facilities or transferred to other parties by Participant(s).

3.4 This policy does not intend to inhibit the communication of ideas and research results through teaching, research collaboration and publication; however, inventors are cautioned to communicate research findings only after the rights to commercialize these findings have been protected through disclosure to CHW's *in* Office.

3.5 While retaining ownership, CHW agrees in advance that all rights to commercialize Scholarly Works authored by Non-Employees and non-CHW funded Participants will be transferred to the authors by license or other appropriate mechanism.

3.6 CHW reserves the right to use all IP at any time, for all purposes, including but not limited to internal research, clinical and educational purposes, without cost, at any or all CHW Facilities.

3.7 Developed Software and similar Work Product may be protected by unregistered copyright or trade secret protection. Computer programs, databases and other data should not be distributed publicly without appropriate notices attached and may be subject to HIPAA and/or other research requirements.

4. Financial Distribution

4.1 The Net Proceeds (gross receipts from the commercialization, by sale or license, less direct legal or other costs/expenses incurred by CHW in developing, protecting, maintaining, marketing and commercializing the IP, and a 20%

² “work made for hire” is (1) a work prepared by an employee within the scope of employment; or work ordered or commissioned for contribution to a collective work, as a supplemental work” or as part of an “instructional text” if, absent the employment relationship, the parties expressly agree in writing that the work shall be considered a work made for hire. ”Supplementary work” is work prepared for publication as adjunct to a work by another. An “instructional text” is a literary, pictorial, or graphic work prepared for systematic instructional activities. (See 17 USC, sec 101 for further information).

withhold by CHW for administration and further innovation development) from commercialized IP shall be distributed not less than annually as follows:

50% to the inventor(s) in the Disclosure Statement filed with CHW *iin*³

50% to the CHW originating Facility

4.2 The inventor share shall continue for so long as CHW receives royalty income from the specific IP, and shall accrue to the estate of the inventor if the inventor is deceased.

4.3 If the inventor(s) are no longer affiliated with CHW, the inventor(s) share of net proceeds of the royalty income will follow that inventor but the portion assigned to the lab or department shall remain with CHW.

4.4 Proceeds distributed to any/all inventor(s) shall not be deemed salary or wages but, rather, shall be treated solely as royalty income. Tax consequences for all such additional income shall be the responsibility of the individual inventor(s).

5. **Exceptional Circumstance**

An exceptional circumstance may arise warranting an assessment of whether and/or how this Policy does or should apply. In such event, both the CHW Legal Department attorney responsible for IP (or, alternatively, the General Counsel) and the applicable Chief Operating Officer (or alternatively the CHW CFO) will determine the interpretation and application of this Policy (and make related decisions to its operationalization if and as needed) and shall notify the EMT in writing of the exceptional circumstance, the action taken and reasoning.

Replaces April 17, 2007 original

³ The inventor's share of the Net Proceeds is to be distributed equally among all inventors unless each inventor signs and submits a letter to CHW *iin* agreeing to a different distribution.

ATTACHMENT A

Representative Examples of Substantial Use of Resources

The following examples generally define a Substantial Use of Resources, individually or in combination. It is the responsibility of CHW's *in* staff to evaluate situations and determine if a Substantial Use of Resources has occurred; Participants have an obligation to promptly notify their supervisor or administrative representative if they believe that their work involves more than nominal use.

1. The use of time by the Inventor(s) when being paid by CHW, regardless of whether to create, develop or promote the Invention.
2. Any use of CHW Facilities, including equipment and staff of more than a nominal or incidental nature. The use will be deemed more than nominal or incidental if the use of CHW's resources or Facilities was more than on a one-time limited duration basis (such as one hour or one day) and such use was intentional and was significant to or advanced the development of the invention. This includes, for example, "data downloads" or significant access that may not be of long duration but would have meaningful/significant effects.
3. Use of CHW or a CHW Foundation funding, in cash or in kind, to (a) support the creation and/or development of an Invention or work that otherwise results in inventions/innovations or (b) if not funded by CHW, by virtue of being associated with or related to CHW.
4. Direction by or from CHW to Inventor(s) to develop an Invention or work leading to the Invention.
5. Use of CHW Facilities under sponsored research agreements, grants or contracts.
6. Development of Scholarly Work, but only if requested by CHW.
7. In addition to Facilities, the use of CHW support services such as computers, servers, software, employees, operating rooms, imaging equipment or services, laboratories and graphics or illustration, etc. utilized in the creation or development of Invention.