Policy Title: Intellectual Property Policy

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Approver:
Dr. Douglas Reding
Vice President, Marshfield Clinic
Date

Approver:
Dr. Robert Steiner
Executive Director, Marshfield Clinic Research Foundation
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Applied Sciences
1. SCOPE

1.1 System Wide (with exemption for Marshfield Clinic Information Systems Specific to Cattails Software Suite of Services).

The term "Intellectual Property" (IP) is synonymous with and includes by way of example, but not by way of limitation; information, discoveries, inventions and any creation, conception, or production of something or some process, which did not previously exist, whether as a product or mental process or as a result of scientific investigation and experimentation. Intellectual Property shall encompass, by way of examples; trademarks, service marks, and/or associated good will; copyrightable works, trade secrets or other confidential or proprietary information, business or pedagogical concepts or methods; drugs or other medicaments; electrical or mechanical devices; methods of healing or promoting the healing arts; know how or show how; chemical, biological processes or methods; computer software algorithms or code (except that created by Information Systems which is governed by a separate MCIS IP agreement); video or multimedia works; illustrations or animations; cells, organisms, or chemical or biological compounds; combinations of matter; electrical circuits; and any improvements, additions or modifications to the foregoing.

Property shall also include literary contributions and anything deemed to have value to the organization, whether formerly protectable as IP or not, if it confidential or propriety.

Property created by Marshfield Clinic Information Systems, Inc. and products or developments specific to the Cattails MD Suite of Software Services shall be governed by the IP Policy of Marshfield Clinic Information Systems. IP created by both Marshfield Clinic and Marshfield Clinic Information Systems, Inc. shall be governed by both this policy and the IP policy of Marshfield Clinic Information Systems and shall be jointly owned unless otherwise agreed in a joint operating agreement.

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1 Purpose

To encourage discovery, invention, and innovation; to clarify the responsibility and expectation of Marshfield Clinic (MC) employees; to clarify procedures for disclosing and protecting intellectual property; and to manage distribution of royalties resulting from licensing or other commercialization of MC or Marshfield Clinic Research Foundation (MCRF) intellectual property.

Discoveries from medical research, as well as other forms of innovation and creation in the workplace, may result in intellectual property that has commercial value. The protection and commercialization of such discoveries, creations, and improvements not only enhance healthcare by bringing new technologies and processes to the clinical and public health areas, but also generate revenues to support research, education, and other purposes consistent with MC’s not-for-profit status. Thus, it is important for MC inventors and affiliates to understand their rights and responsibilities concerning the generation, protection, and commercialization of intellectual property. This revised policy replaces the Intellectual Property Policy made effective 8/16/04. The new policy, which is comparable to intellectual property policies of many top-tier universities and academic medical centers, addresses percentage of net revenue distributed to
inventors and their laboratories or departments when intellectual property is commercialized by MC; clarifies ownership rights and related key concepts; provides guidelines on inventors’ obligations to protect both MC’s rights to intellectual property and the rights of research sponsors; clarifies the rules governing publication of medical and scientific articles; and assigns administrative responsibilities.

2.2 Definitions

a. “Marshfield Clinic” is defined as Marshfield Clinic and any of its affiliates, divisions, or operating units including but not limited to joint ventures, the Marshfield Clinic Research Foundation and hospitals, and other such affiliates.

b. “Marshfield Clinic Research Foundation” (MCRF) is defined as the Research Division of Marshfield Clinic, supporting research discoveries by MCRF scientists and physicians in multiple fields of human health and reducing the burden of disease and disability. MCRF has offices and laboratories in the Lawton Center for Research and Education and the Laird Center for Medical Research in Marshfield and also has clinical research staff supporting physician-led research at medical centers in each of the Clinic’s regional divisions.

c. “Marshfield Clinic Applied Sciences” (MCAS) is defined as the Division of MC responsible for protecting intellectual property; developing technology or fostering discovery to stage of commercialization; and managing distribution of royalties resulting from licensing or other commercialization of MC/MCRF intellectual property.

d. “Marshfield Clinic affiliate” is defined as any entity, which is now, or hereafter owned or controlled by, controlling or under common ownership or control with, managed by or under contract with (such as a joint venture or partnership) MC, together with those entities owned, operated or managed by or in connection with the foregoing. An entity will be deemed to control another entity if it is a corporate member holding at least 51% of the corporate membership units or shares of the entity or has the power to direct or cause the direction of the management or policies of the entity, whether through the ownership of voting securities, the right to appoint at least 51% of the board of directors, by contract, or otherwise. Notwithstanding the foregoing, Marshfield Clinic Information Systems is excluded from the definition of a “Marshfield Clinic affiliate” under this policy.

e. “Marshfield Clinic Technology Transfer Committee” (TTC) is defined the committee which evaluates MC/MCRF developed technologies and opportunities for non-patient commercial ventures and makes recommendations to the leadership of Marshfield Clinic for managing efforts of technology transfer and commercialization.
f. "Clinic Intellectual Property" is defined as any invention, creation, innovation, discovery, or improvement produced in whole or part 1) by a MC employee during working hours at Marshfield Clinic, 2) by an Inventor with a contribution by Marshfield Clinic of Clinic Resources, or 3) as a consequence of which bears a direct relationship to the employee's duties at MC. Clinic Intellectual Property may include but is not limited to works that are patentable, copyrightable (including but not limited to books, treatises, training materials and chapters), or are trade secrets as well as improvements or enhancements of existing Clinic Intellectual Property. All references herein to intellectual property refer by default to Clinic Intellectual Property unless otherwise specified.

g. "Clinic Resources" are defined as all tangible resources provided by MC to Inventors, including but not limited to salary, insurance, or retirement plan contributions paid to or for the benefit of Inventors; office, lab, and studio space and equipment; computer hardware, software, and support; administrative services; research, teaching, and lab assistants; supplies; utilities; funding for research and teaching activities, travel; and other funding or reimbursement; and all intangible resources, including but not limited to know how, trade secrets, and other Clinic Intellectual Property.

h. "Inventor" (or "Inventors") is defined as a physician, researcher, staff, and other person employed by Marshfield Clinic, whether full- or part-time (except employees providing information services - see Section 1, "Scope," above); a visiting researcher; and any other person, including residents, interns and students, who invents, authors, discovers, or contributes to the invention, authorship, or discovery of another individual in whose work product the Clinic has rights, or who is otherwise responsible for the creation of Intellectual Property.

i. "Net Revenue" is defined as revenue remaining after deducting for all of MC's expenses incurred in obtaining protection for, defending, commercializing, or licensing the applicable Clinic Intellectual Property. Such expenses may include but shall not be limited to legal, development, and marketing costs. Such expenses also include any investment into technology or product development, financial assistance and support from outside entities for technology transfer for commercialization and consulting services.

j. "Disclosure" is defined as any tangible form of evidence including, but not limited to, e-mails, filing of provisional patent applications, submittal of MC invention disclosure forms, and queries made to MCAS or designated representative.

k. "Research Article" is defined as any medical or scientific paper or article authored by such MC/MCRF employee or affiliate or affiliate's employees.

l. "Third Party" is defined as any non-affiliate entity that provides products or services to Marshfield Clinic, assists MC in the commercialization of Clinic Intellectual Property, or otherwise does business with Marshfield Clinic, including any vendors, suppliers, professional service firms, and third parties having a common client/customer/patient with MC; any client/customer/patient that orders or purchases products or services from MC; and any collaborative institution or consortium of which Marshfield Clinic is a member or otherwise involved, as employee may be also be exposed to Confidential Information owned by related affiliates and unrelated third parties during the course of employment. For example,
by way of illustration but not limitation, affiliate may provide its own Confidential Information to support and develop Marshfield Clinic’s business or a third party customer may expose its Confidential Information to MC for the limited purpose of Marshfield Clinic adapting or tailoring its product(s) and/or service(s) to work effectively in customer’s environment or infrastructure.

m. “Confidential Information” is defined as any and all data or information and documentation relating to MC’s Business or to the businesses or activities of any MC affiliates or third parties that is not generally known to the public or readily obtainable from outside sources, irrespective of whether owned by or licensed to MC, an MC affiliate, or a third party. Confidential Information includes, by way of example and without limitation, the following: financial information, including but not limited to earnings, assets, debts, prices, cost information, budgets, sales and profit projections or other financial data; marketing information, including but not limited to details about ongoing or proposed marketing strategies, marketing forecasts, or information about impending transactions; product information, including but not limited to development plans, product designs, product costs and pricing policies; information regarding actual or potential customers; intellectual property, including but not limited to trade secrets, know-how, unpatented Inventions, and unpublished patent and trademark filings with any patent office anywhere in the world; employee information, compensation information and recruiting plans. Employees acknowledge that such information is confidential whether or not such information is labeled as such by MC.

3. POLICY BODY

Marshfield Clinic’s comprehensive approach to health care expands upon the Clinic’s mission to provide outstanding patient care to include extensive research that provides valuable insight into the prevention, diagnosis and treatment of major human health conditions and the quality and cost-effectiveness of care. Marshfield Clinic Applied Sciences (MCAS) and Marshfield Clinic Research Foundation (MCRF) exchange knowledge between patient care services and research programs, and determine the commercial potential of advances in research and technology. Together, they align research projects with health care needs to transform human health through scientific discovery, thus meeting the Clinic’s mission to serve patients through accessible, high quality health care, research and education.

MC is committed to commercializing any intellectual property (“IP”) developed by its professional staff, agents, students, trainees, interns (collectively, “MC Personnel”). MC invests the net income from commercializing IP into additional areas of opportunity for research, development, discovery and translation for improved health care, sharing a portion of the net income with the creator(s) of the IP to promote continued creation and development of medical innovations. MCAS was established with responsibility to protect, manage, and commercialize MC/MCRF IP and is authorized to implement and enforce the following policy on behalf of MC.

The following policy governs all scientific, technological, or business-oriented IP that (i) is conceived, developed, and/or otherwise reduced to practice by MC Personnel; or (ii)
relates directly or indirectly to the business of MC or its actual or demonstrably anticipated research or development activities; or (iii) is conceived, developed, and/or otherwise reduced to practice during participation in any MC-associated activities; or (iv) is conceived, developed, and/or otherwise reduced to practice using MC resources of any kind; or (v) is conceived, developed, and/or otherwise reduced to practice in MC owned or operated facilities; or (vi) is an improvement, addition, or modification to existing MC-owned IP; as well as its subsequent commercialization.

MC is hereby assigned all rights, title and interest in any scientific, technological, or business-oriented IP arising from the employment-related activities of MC Personnel, except for certain activities specifically identified in the MC IP Policy relative to IT development. MC is also hereby assigned all rights, title, and interest in any IP arising or derived from the use of funds, equipment, rooms, laboratories, facilities, buildings, or other tangible or intangible property of MC (hereafter “MC Resources”). The “Data Sharing for Genome-Wide Association Studies” Policy will govern requirements for certain NIH studies (GWAS studies), investigators who submit grants or proposals to NIH regarding certain restrictions on intellectual property rights by NIH policy.

3.1 Policy Body

a. Statement of Ownership Rights - MC owns all rights to MC/MCRF IP and any IP in other areas to which only MC employees have made a contribution. MC shall have the sole right to determine the disposition of Clinic Intellectual Property under this Policy. Inventors shall promptly disclose to Marshfield Clinic Applied Sciences all Clinic Intellectual Property produced by them and shall hereby assign rights in all such Clinic Intellectual Property to MC without further consideration and in accordance with the disclosure rules referred to in Section 7 of this agreement and as otherwise amended or established by MC/MCRF. Inventors may not assign, or license rights in, Intellectual Property to third parties without the written consent of MC. Inventors of MC Intellectual Property shall assist as reasonably necessary in MC and its appointed agents’ efforts to obtain statutory and other protection for and perfection of MC’s ownership interest in Clinic Intellectual Property and company start-up including, but not limited to, executing appropriate assignments and other documents. Due to the prolonged nature of some types of intellectual property prosecution, the inventor’s duty to assist shall survive termination of employment, whatever the cause, provided prosecution is at the expense of MC.

b. Limited Exceptions to Ownership Rights - MC, from time-to-time, may decline to commercialize IP because the IP is not MC-associated IP; or determine, in its sole discretion, that the market potential for a specific MC-associated IP does not warrant the expense of legal protection (if available) and/or Commercialization; or decide, in its sole discretion, to cease either patent prosecution or maintenance or ongoing commercialization efforts regarding a specific MC-associated IP. MC-associated IP declined due to a lack of market potential remains the property of MC, but the creator(s) may choose to pursue commercialization of the MC-associated IP on the creator(s)’ own accord. The creator(s) are encouraged to then re-involve MC if commercial interest in the MC-associated IP is generated. The creator(s) of the affected MC-associated IP can request that such MC-associated IP be re-assigned to the creator(s) to commercialize or subsequently abandon as the creator(s) desire. If MC, in its sole discretion, agrees to such re-assignment, then the creator(s), in exchange for such re-assignment, must agree that MC shall (a) first be
fully reimbursed for any and all costs incurred by MC relating to the protection and/or commercialization of the MC-associated IP, e.g., personnel or marketing costs and out-of-pocket patent-related expenses, and (b) it shall retain a royalty-free, irrevocable, worldwide, perpetual license to use the applicable Clinic Intellectual Property for any purpose within the Marshfield Clinic organization. Any ensuing MC-associated IP developed by such creator(s) will remain subject to this Policy.

c. Joint Ownership - In the event MC employees invent or develop IP together with employees of any other entity joint ownership shall result, shared by the employers of the employee inventors unless otherwise agreed in a joint operating agreement.

d. Required Initial Disclosures - All preexisting IP must be fully disclosed to MCAS and MCRF by its creator before its creator’s employment or association with MC. All disclosures must include summary statements outlining the work with an explanation of any planned continuation of work during employment at MC. Plan should also define any proposed MC time or resource which is expected to be utilized for project continuation. Any IP not disclosed will be presumed to be MC-associated IP after its creator’s employment or association with MC and will be subject to this policy. A statement by its creator that a specific IP predated its creator’s employment or association with MC must be supported by clear and convincing evidence, e.g., properly authenticated laboratory notebook entries or previously filed patent application(s), that such IP was actually conceived and reduced to practice prior to its creator’s employment or association with MC. If so supported, then such IP shall not be subject to this policy. Finally, if IP is either (i) conceived prior to employment or association with MC, but then developed and/or otherwise reduced to practice after employment or association with MC or (ii) conceived and reduced to practice prior to employment or association with MC, but then improved, added to, or modified, after employment or association with MC, then MC is hereby assigned all rights in newly developed MCRF/MC, title, and interest in and to such IP or such improved, added to, or modified IP, respectively, by its creator (or creators), unless its creator or creators is/are legally unable to do so or if such IP is otherwise exempt from this Policy.

e. Confidential Information - In the course of developing and commercializing intellectual property, MC employees may be exposed to various forms of confidential information including that of MC, affiliates, and third parties. Employees shall maintain the confidentiality of such information regardless of whether formal intellectual property protection is pursued.

f. Affiliations - In support of its mission of education, research, and patient care, MC may sponsor, directly or with the help of affiliates or other entities, the commercialization of MC-associated IP by establishing or expanding corporations, partnerships, or other commercial enterprises via MCAS. In such cases, MC may receive and hold equity shares in companies as consideration for authorizing the use of MC-associated IP or for investments (including cash and in-kind investments) made by MC in spin-off companies. MC shall solely hold such shares until such shares are liquidated, at which time the proceeds related to the MC-associated IP will be distributed according to the IP Policy.
g. Conflict of Interest - MC personnel may consult or otherwise participate in a commercial interest in exchange for equity or other consideration so long as such participation has been disclosed to and reviewed according to MC’s ICOI Policy and a management plan has been executed for governing any identified conflict. Any consulting or other participation in a commercial interest in exchange for equity or other consideration must be wholly consistent with the individual’s MC employment obligations, MC’s business interests, and MC’s Conflicts of Interest Policy, Investigator Conflict of Interest in Research Policy, Institutional Conflict of Interest Policy, and other relevant policies.

h. Organizational Structure and Procedure Governing Commercialization - MC, in its need to provide organizational structure and procedures through which inventions and discoveries made in the course of Clinic research are made readily available to the public through channels of commerce, will recognize efficient and effective means of commercializing technology, at times through start-up companies by MC. When such companies are formed, conflict of interest, conflict of commitment and other issues related to assuring the most effective and rapid development of technology into products benefiting the public must be addressed through MC’s New Ventures Company Start-Up Policy.

3.2. Distribution of Net Revenue

a. In the event MC receives revenue from MC Intellectual Property, Net Revenue will be divided as follows:

1. to the Inventor or Inventors (in the event there is more than one Inventor) - 30%. In the event there is more than one inventor, all royalties shall be split evenly among the partner investigator unless otherwise agreed to by the inventors and through formal approval of the TTC.

2. to the Inventor’s designated MC department or research area consistent with MC’s not-for-profit mission - 10%. (Inventors are hereby advised that certain designations may result in an assignment of the applicable Net Revenue distribution to a MC cost center that does not rollover on an annual basis.)

3. to MCAS as the administrative support for technology transfer efforts and overseeing entity of Intellectual Property and commercialization – 25%

4. to MCRF for research related support efforts - 25%

5. to a fund designated toward efforts of technology development and commercialization to be overseen and awarded by MC’s TTC – 10%. (Fund shall be a rolling balance not subject to annual budgetary constraints.)

b. Such Net Revenues shall further be distributed in accordance with the Distribution Rules set forth in Section 5(A) of this Policy.

c. Notwithstanding this paragraph, individuals who retire from MC remain eligible for the royalty distribution. In the event of a death, all enhanced royalty distribution will be assigned to the estate of the investigator.
3.3 Prior Rights of Research Sponsors or Third Party Research Partners

a. At MC’s election, intellectual property created in other contractual arrangements approved by MCAS and MCRF, and governed by a cooperative research and development agreement executed between MC and a party external to it may be governed by this policy. (MC physicians, researchers, and other employees are specifically prohibited from negotiating and/or executing agreements with third parties that in any way involve MC Intellectual Property; all such agreements must be negotiated by the MCRF, MCAS, or through MC’s customary contracting procedures.)

b. Intellectual property ownership and related issues such as distribution of royalties shall be determined in accordance with the terms and conditions of the applicable agreement with such external parties. Intellectual property created while working under federal and state grants and contracts will be treated in accordance with the particular agency’s regulations covering intellectual property ownership.

c. Discovery from grant funds awarded by foundation or other such non-government related entities will be governed by MC’s Intellectual Property Policy, unless otherwise approved by MCAS.

d. To the extent that any of these agreements with research sponsors or third party research partners are not inconsistent therewith, any net revenues received by MC will be distributed according to the divisions set forth in Section 5(A).

3.4 Disclosure and Protection Rules

a. Failure to Disclose and Protect
In order to preserve MC’s rights in Clinic Intellectual Property, disclosure to MC must occur no less than thirty (30) days before first publication or public use of an invention or creation. (Inventors who fail to: 1) disclose to MC, MC Intellectual Property produced by them, 2) cooperate with MC to secure, protect, and commercialize Clinic Intellectual Property, or 3) cooperate with MC in administrative or legal proceedings with regard to infringement matters, shall forfeit their rights to their distribution of Net Revenue provided for under Section 5 of this Policy.)

b. Disclosure and Protection Rules
Additional disclosure and protection rules relating to MC Intellectual Property shall be established by and administered by the MC’s TTC and approved by MC’s Board of Directors as necessary.

3.5 Medical/Scientific Article Publishing Rules

a. Exception to Ownership Rights
MC hereby grants MC employees the limited right to publish or submit to a publisher for publication medical or scientific papers or articles authored by such employees (hereafter, “Research Article(s)”). In such instances, MC employee authors are also granted the limited right to assign copyright in a Research Article to the applicable publisher. (Other works of authorship that constitute MC
b. Notice to Marshfield Clinic Prior to Publishing

In the event a Research Article contains MC Intellectual Property (other than the copyright in the Research Article itself), the employee author shall provide MCAS and MCRF with notice of intent to publish no less than thirty (30) days in advance of submission for publication of a Research Article or abstract thereof. Unless otherwise designated, such notice shall be provided to MCAS. Thereafter, MC shall determine the appropriate actions required to protect MC Intellectual Property, which may include filing one or more patent applications preferably prior to publication. The employee author shall promptly cooperate with all such efforts to procure patent protection as MCAS determines is necessary to protect MC Intellectual Property in furtherance of MC’s mission.

3.6 Approvals

Wherever approval or consent by MC is required in this Policy, including approval of a governing body such as MC’s Board of Directors, the decision whether or not to grant such approval or consent shall be at MC’s sole discretion.

3.7 Expense Reimbursement

Inventors of MC Intellectual Property may be reimbursed for all reasonable personal costs incurred in developing MC Intellectual Property or assisting MC in perfecting its ownership interest in MC Intellectual Property as approved by the MC President, Vice President, or Executive Director of the MCRF.

3.8 Administration of this Policy

This Policy shall be administered by the Marshfield Clinic Applied Sciences Division, subject to the approval of the Marshfield Clinic Board of Directors.

a. Distribution Rules

Rules are set forth herein and as also further established by the MC Board of Directors and administered by the Marshfield Clinic’s Applied Sciences Division.

b. Inventor’s 10% Designation

With regard to the Inventor’s 10% designation set forth in Section 5(A) (2) of this Policy, such designation shall be subject to department or research area consistent with MC’s not-for-profit mission. In the event the Inventor’s employment is terminated with MC, the right to designate the 10% distribution to any area of Marshfield Clinic shall vest in MC’s Finance Committee with recommendation by the TTC, as of the effective date of such Inventor’s termination of employment.

3.9 Forms

Invention Disclosure Forms (2) – MC/MCRF Personnel who, alone or with others, create, develop, and/or otherwise reduce to practice MC-associated IP must timely submit to MC Applied Sciences a completed Confidential Invention
Disclosure Form regarding such MC-associated IP. Such Forms are available on MC’s Intranet Website.

3.10 Keywords

Marshfield Clinic, Marshfield Clinic Applied Sciences, Marshfield Clinic Research Foundation, Technology Transfer & Commercialization Committee, intellectual property, disclosure, inventor, patent, copyright, royalty, technology, creation, discovery, research articles

4. ADDITIONAL RESOURCES

4.1. References:
- Authorship
- Compensation for Physicians Conducting Funded Research
- Conflict of Interest
- GWAS policy:
- Institutional Conflict of Interest in Research:
- Investigator Conflict of Interest in Research:
- Investigator Research Accounts:
- MCRF Emeritus Clinician-Researcher Program:

4.2 Supporting documents available:
## 5. DOCUMENT HISTORY

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