

Title	RES - Intellectual Property				
Region	Carle Health East				
Scope	Research / Research				
Document type	Policy & Procedure				
Owner	Kathy Dams (Dir - Grants Admin&Research Op)				
Reviewer(s)	Amada Guerra (Grants Business Accountant), Cassandra Paul (Sr Research Award Negotiator)				
Approver(s)	APM Administrators, Jennifer Eardley (VP, Research)				
Effective Date	11/01/2010	Next Review Date:	02/10/2025	Approval Date	02/10/2023

Attachments N/A

Purpose/Scope

- A. This policy sets forth Carle's expectations for the ownership of intellectual property, the assignment of intellectual property rights, the prosecution of patent rights, the distribution of revenue produced from Carle-owned intellectual property, as well as the guidelines for disclosing research activities to Carle and working collaboratively with other institutions that share a similar vision for research, innovation and transformation.
- B. Research, invention and discovery are important components of Carle's mission. In fulfillment of its mission, Carle supports and promotes the research activities of its employees, medical staff members, students and residents. Carle also shares a vision for research with the University of Illinois at Urbana-Champaign. Consistent with this shared vision, Carle and the University entered into a unique research partnership defined by collaboration, mutual respect, and the ultimate goal of transforming health care.
- C. To further Carle's mission, it is important for Carle to clearly define its expectations for research performed for or on behalf of Carle as well as the mutual expectations of Carle and other partner institutions when representatives from both parties are involved in Collaborative Research (as defined below).
- D. This policy is intended to apply to Research activities, regardless whether the Research activities commenced prior to or after the latest Revision Date (listed above). As such, Research activities that commenced prior to the Revision Date shall be governed by this policy and any other relevant agreements related to the Research, unless otherwise requested and agreed to by Carle and Creator(s).

Definitions

- A. **Carle** The Carle Foundation and its affiliates and subsidiaries including, but not limited to, The Carle Foundation Hospital, Carle Hoopeston Regional Health Center, Carle Richland Memorial Hospital, and Carle Physician Group.
- B. **Carle Assets** Includes tangible assets, such as facilities, equipment, materials or funds, and intangible assets, including, but not limited to, Patient Medical Records, trade secrets, confidential or proprietary information, as well as the time, skill and expertise of Carle Research Institute personnel.
- C. Carle-Illinois Joint IP for purposes of this policy, any Intellectual Property that this authored, invented, discovered, conceived or developed by a Carle investigator (which shall include Creator) and a University investigator.
- D. Collaborative Research Research that involves investigators from both Carle and a partner institution.
- E. **Course of Employment** Used when the creator conducted research while providing services for or on behalf of Carle, through the use of Carle assets, or the research is considered related research.
- F. Creator The individual Carle workforce member, medical staff member, student or resident, regardless of full-time, part-time or independent contractor status, who authored, invented, discovered, conceived, developed or otherwise made a substantive intellectual contribution to the creation of the Intellectual Property at issue. As used in this policy, the term "Creator" includes the definition of "inventor" used in U.S. Patent Law and the definition of "author" used in the U.S. Copyright Law.
- G. Intellectual Property and IP All tangible and intangible conceptions, ideas, innovations, discoveries, inventions, processes, machines, formulae, formulations, compounds, compositions, equipment, improvements, enhancements, modifications, technological developments, know-how, show-how, methods, techniques, systems, designs, schematics, production systems and plans, software, documentation, data, programs and information, and works of authorship, whether or not patentable, copyrightable, or susceptible to any other form of legal protection.
- H. Intellectual Property Rights and IP Rights Any and all forms of intangible property rights in any jurisdiction throughout the world, including without limitation all rights to: (a) all patents, trade secrets, trademarks, trade names, copyrights, moral rights, rights of publicity, mask work rights, and all other industrial or intangible property rights throughout the world, including without limitation rights in inventions, technologies, designs, and utility models; (b) all

grants and registrations worldwide in connection with any of the foregoing, and all rights with respect thereto; (c) all applications for any such grant or registration; (d) all rights of priority under international conventions to make such applications and the right to control their prosecution, and all amendments, continuations, divisions and continuations-in-part of such applications; and (e) all corrections, reissues, patents of addition, extensions, and renewals of any such grant, registration, or right

- I. **Joint IP** For purposes of this policy, any Intellectual Property that this authored, invented, discovered, conceived or developed by a Carle investigator (which shall include Creator) and an investigator(s) from a partner institution
- J. **Net Revenue** All revenue received by Carle minus all out-of-pocket payments or obligations attributable to protecting (including defense against infringement or enforcement actions), marketing, licensing or administering the intellectual property, including any in-kind contributions from Carle (e.g. use of Carle Assets).
- K. **OTM** The Illinois Office of Technology Management on the University's Urbana campus.
- L. **Patient Medical Record** All information, in whatever form, documenting the provision of health care to a Carle patient and maintained by Carle.
- M. **Related Research** Research conducted by the creator outside of work hours, which is based on, related to, or furthers research performed for Carle or using Carle assets.
- N. Research A systematic investigation, inquiry, or analysis designed to develop or contribute to generalized knowledge that will primarily benefit those beyond the study participants. Research includes activities that aim to test a hypothesis, discover or collate facts, principles, or effects, reach new conclusions, or reexamine information by the critical study of a subject or by a course of scientific inquiry. Research also encompasses basic and applied product development, activities for which research funding is available from a Public Health Services component through a grant or cooperative arrangement, as well as any experiment that involves a test article and one or more human subjects.
- O. **Research Affiliation Agreement** The Research Affiliation Agreement entered into on October 30, 2015 by Carle and the University.
- P. **Revenue** Cash from payments including, but not limited to, royalties, option fees, and license fees or from the sale of Carle's equity interest
- Q. **Shared Employee** An individual who is employed by either Carle or a partner institution but who is shared with the other party for a specified percentage of time in exchange for compensation paid by the other party to the individual's primary employer.
- R. University The University of Illinois at Urbana-Champaign.

Statement of Policy

- A. Ownership of IP
 - 1. Except as otherwise stated by Carle in writing, all of a Creator's rights, title and interest in Intellectual Property developed during his/her Course of Employment shall belong to Carle.
- B. Assignment of IP
 - 1. As a condition of employment, Carle requires each Creator who: participates in Research during his/her Course of Employment; conducts Related Research; or uses Carle Assets while conducting Research to assign to Carle in writing all of his/her IP Rights arising from such Research.
- C. Disclosure Requirement
 - 1. Each Creator shall promptly disclose to the Vice President of Research, or his or her designee, in a form and format prescribed by Carle, all Intellectual Property in which Carle has an ownership interest under the provisions of this policy and that has the potential to be brought into practical use for public benefit. In the case of Collaborative Research involving the University, the Carle-Illinois Joint IP shall also be disclosed to the University Office of Technology Management in coordination with Carle.
- D. Carle Support of Research
 - 1. With the approval of the Vice President of Research and/or Chief Medical Officer, Carle may support Research activities in a variety of different ways, including, but not limited to, direct financial support, in-kind contributions (e.g. access to laboratory equipment, research staff, etc.) and covering the cost of protecting, marketing, licensing and administering the Intellectual Property. If, on the other hand, Carle chooses not to support certain Research activities, Carle shall assign its IP Rights to the Creator(s) in order to allow the Creator(s) to continue the Research activities, subject to the terms of any applicable third-party funding agreement and Carle's retention of a non-exclusive, royalty-free license to utilize the Intellectual Property for Carle's purposes.
- E. Prosecution of Patent Rights; Licensing
 - Patent. As described in the Research Affiliation Agreement, Carle will work with the OTM, to file, prosecute and
 maintain patent applications and patents arising from Carle-Illinois Joint IP. Carle may work with either the OTM,
 or another reputable vendor, to file, prosecute and maintain patient applications and patents arising from Carleowned Intellectual Property and/or Joint IP.

2. License. Carle shall have the right to license or otherwise enter into agreements to commercialize Carle-owned Intellectual Property. In no event, shall a Creator enter into or purport to enter into a license that permits another party to profit from Carle-owned Intellectual Property without Carle's express written approval.

F. Revenue Distribution

- 1. Revenue received by Carle from the transfer, commercialization or other exploitation of Carle-owned Intellectual Property will be divided among the Creator and Carle. When Revenue is received by Carle, all out-of-pocket payments or obligations attributable to protecting (including defense against infringement or enforcement actions), marketing, licensing or administering the Intellectual Property, including in-kind contributions from Carle (e.g. use of Carle Assets) may be deducted from such Revenue. The Net Revenue remaining after deductions shall be allocated as follows:
 - a. Creator Share 40% of Net Revenue
 - b. Carle Share 60% of Net Revenue
- 2. The Creator (or Creator's heirs, successors, and assigns) will, with limited exception, receive 40% of Net Revenue. If there is more than one Creator, the 40% of Net Revenue will be net divided among them as they mutually agree. If the Creator's fail to agree on a division of Net Revenue, Carle's Vice President of Research shall determine the division.
- G. University Office of Technology Management
 - 1. In the case of Carle-Illinois Joint IP, Carle has agreed to work directly with the OTM to manage, prosecute and coordinate Carle's share of related royalties and expenses as described in the Research Affiliation Agreement. Carle may also request the use of the OTM's administrative services to evaluate, market or license Carle's IP Rights according to OTM's standard processes. In those cases, it is Carle's expectation that Creator's cooperate with both Carle and the OTM to ensure the timely and appropriate use of Carle and OTM resources.

H. Shared Employment

- If a Creator is Shared Employee involved in Collaborative Research, Carle's IP Rights shall be determined by
 considering the Shared Employee's percentage of inventive contribution and percentage appointment to both
 Carle and the partner institution. In cases in which the Shared Employees between Carle and the University, the
 IP Rights of Carle and the University will be determined in accordance with the terms of the Research Affiliation
 Agreement.
- I. Preemption by Third-Party Agreements
 - Where Research is funded by a third-party, to the extent there is a conflict between the terms of the relevant third-party funding agreement and this policy, the IP Rights arising from such Research will be governed by the terms of the relevant third-party funding agreement.

Other Related Links As Applicable To Site N/A

References

Patent Law: 35 U.S.C. § 1 – 376
Copyright Law: 17 U.S.C. § 101-1332

• Illinois Employee Patent Act, 765 ILCS 1060