

**Wake Forest University Baptist Medical Center
Intellectual Property Policy¹
October 2017**

1. GENERAL POLICY STATEMENT

The mission of Wake Forest University Baptist Medical Center (the “Medical Center”) is to improve the health of our region, state and nation by generating and translating knowledge to prevent, diagnose and treat disease; training leaders in health care and biomedical science; and serving as the premier health system in our region, with specific centers of excellence recognized as national and international care destinations. Stewardship of intellectual property arising at the Medical Center is in furtherance of this mission.

Widespread dissemination of ideas and information is fundamental to generating and translating knowledge and training leaders in medicine and science. In certain circumstances, widespread dissemination may be realized by utilizing intellectual property protection to encourage the development of products that are available to the public through established channels of commerce. Appropriate intellectual property protection and commercialization can promote the Medical Center’s mission by improving the public health and welfare, encouraging the open dissemination of research results, bringing recognition to the Medical Center and individual researchers, and providing a source of revenue to support further research and education at the Medical Center.

A. Scope

Persons Covered. This Intellectual Property Policy (this “Policy”) is applicable to all Medical Center full-time, part-time and adjunct faculty, staff and employees; students, residents and postdoctoral fellows; and non-employees who use Medical Center funds, facilities or other resources, or participate in Medical Center-administered research, including visiting faculty and scientists, fellows and industry personnel, regardless of obligations to other companies or institutions. A separate, but substantively similar, policy covers persons associated with Wake Forest University other than the Medical Center.

Intellectual Property Covered. This Policy sets forth general principles applicable to the ownership and disposition of the Medical Center’s intellectual property, including inventions, copyrights (including computer software), and tangible research property such as biological materials. Certain types of intellectual property may also be the subject of other policies of the Medical Center, Wake Forest University Health Sciences, or North Carolina Baptist Hospital.

Entities. In general, references in this Policy to the “Medical Center” include the Medical Center, Wake Forest University Health Sciences, North Carolina Baptist Hospital, and the subsidiaries and affiliates (other than Wake Forest University) of each.

B. Responsible Department/Party/Parties

Policy Owner: Chief Executive Officer, Wake Forest Baptist Medical Center
Procedure: Wake Forest Innovations
Supervision: Medical Center Legal Department
Implementation: Wake Forest Innovations

2. DEFINITIONS

A. Intellectual Property

Innovations: Inventions, Tangible Research Materials, Device-Like Copyrightable Materials and other copyrightable works excluding Traditional Works of Scholarship, and Institutional Works.

¹ Adopted by Wake Forest University Baptist Medical Center on August 23, 2017 and by Wake Forest University Health Sciences on October 4, 2017

Device-Like Copyrightable Materials: software or other copyrightable material that, like a device, is intended to or likely to execute a task or application or to allow the user to produce, manage, analyze, or manipulate a product, such as data, text, a physical object or other software.

Inventions: (i) patentable or potentially patentable inventions, discoveries, materials or know how, regardless of whether reduced to practice or actually patented; and (ii) Device-Like Copyrightable Materials, whether or not patentable or patented.

Tangible Research Materials: research resources and tools including biological materials, such as cell lines, organisms, proteins, plasmids, DNA/RNA, transgenic animals, antibodies and chemical compounds and other tangible materials useful for research or for commercial purposes.

Institutional Works: Works specifically commissioned by the Medical Center or created pursuant to a specific direction from the Medical Center, whether protectable by patent, copyright or otherwise. Institutional Works include work for hire, as that term is used in the Copyright Ownership Policy.

Traditional Works of Scholarship: copyrighted scholarly and creative works that are defined in and governed by the Copyright Ownership Policy. Examples of Traditional Works of Scholarship include scholarly publications, journal articles, research bulletins, monographs, books, play scripts, theatrical productions, poems, works of music and art, instructional materials in print or electronic format.

B. Individuals

Faculty and Trainees: Faculty, residents and postdoctoral fellows.

Innovator: Any person covered by this Policy who individually or jointly with others creates an Innovation.

C. Institutional Resources

Incidental Use: de minimis or incidental use of Medical Center facilities or funds. Examples of Incidental Use include ordinary use of computers, or office and library facilities generally made available to Medical Center faculty, staff, or students, as the case may be.

Medical Center Support: (i) financial support of research, clinical and teaching activities, whether from Medical Center funds or third party funds administered by the Medical Center; (ii) support from Medical Center clinical or technical staff; or (iii) use of Medical Center materials and space other than Incidental Use.

D. Financial

Net Proceeds: consideration, including equity (as described in Section 5.1.D), received by the Medical Center in connection with licensing (or other intellectual property related transaction) of a specific Innovation for commercialization, less contractual amounts due to third parties and, except in the case of equity, Specific Expenses previously incurred or reasonably anticipated. Net Proceeds expressly excludes any consideration received by the Medical Center for the reimbursement of Specific Expenses or for the performance of research or services by the Medical Center, even if such research or service is related to an Innovation.

Specific Expenses: out-of-pocket expenses of the Medical Center related to the protection and commercialization of and attributable to a specific Innovation, including (i) costs of securing, maintaining and enforcing intellectual property protection such as legal fees, including patenting and litigation expenses; (ii) costs of activities undertaken at the Medical Center's direction to enhance the commercial value of the Innovation, for example, prototype build, proof-of-concept studies, or other technology development; (iii) marketing and licensing costs; (iv) expenses related to initiating startup companies, for example incorporation or the recruitment of management team members; and (v) expenses in making, shipping or otherwise distributing Tangible Research Materials.

3. OWNERSHIP AND DISPOSITION OF INTELLECTUAL PROPERTY

3.1 Ownership Generally

A. Medical Center Ownership. The following Innovations are the property of, and are hereby assigned to, Wake Forest University Health Sciences or North Carolina Baptist Hospital, as applicable. Innovators will promptly confirm such assignment in writing upon request.

(i) In the case of Faculty and Trainees: Innovations developed (a) in the course of an Innovator's employment; or (b) within or useful within the Innovator's normal field of employment; or (c) with more than Incidental Use of Medical Center funds or facilities.

(ii) In the case of employees other than Faculty and Trainees: Innovations developed (a) in the course of an Innovator's employment; or (b) within the scope of the Innovator's job responsibilities; or (c) with more than Incidental Use of Medical Center funds or facilities.

(iii) In the case of students: Innovations developed (a) in the course of or within the scope of research programs supported by Medical Center funds or third party funds administered by the Medical Center, in which the student is engaged; (b) in the course of or within the scope of the Innovator's duties when the student is engaged as a teaching assistant or research assistant; or (c) in the course of the Innovator's academic program.

(iv) In the case of non-employees other than students: Innovations developed with Medical Center Support.

B. Individual Work. Innovations developed outside the scope set forth in Section 3.1.A are the property of the individual Innovator(s) and are not subject to this Policy. To make clear what constitutes individual work, employees are required to obtain approval in advance for specific consulting or contractual arrangements in accordance with the Consulting, Outside Activities, Conflict of Commitment and Conflict of Interest policy, and other applicable policies.

C. Research Sponsored by Third Parties. It is the policy of the Medical Center that Innovations arising under sponsorship or under contract with a third party (including government or private grants, sponsorship of targeted research, consulting arrangements, or otherwise) are the property of Wake Forest University Health Sciences or North Carolina Baptist Hospital, as applicable. Biomedical Research Services & Administration is responsible for review of all sponsored research arrangements and, in consultation with appropriate academic and administrative officials, will endeavor to ascertain that the terms and conditions of the proposed research program will foster the research and educational purposes of the Medical Center, are consistent with the Medical Center practices and policies, and protect the interests of the Medical Center and its stakeholders including researchers. Upon determination that doing so is in the best interests of the Medical Center, these ownership provisions may be modified by written agreement between the Medical Center and the third party.

3.2 Tangible Research Materials

A. Distribution for Scientific Research. Tangible Research Materials are recognized as a form of research results and as such should be promptly and openly made available to other scientists for their non-commercial scientific research, unless special circumstances make such distribution inappropriate or impractical. Principal investigators are primarily responsible for decisions regarding the development, storage, and distribution and use of Tangible Research Materials for scientific research.

B. Commercialization. The Medical Center may make appropriate distribution of Tangible Research Materials in the public interest, including licensing or transferring Tangible Research Materials for commercial purposes. Potential commercial considerations should not inhibit scientific exchanges of Tangible Research Materials.

3.3 Traditional Works of Scholarship

Ownership and disposition of Traditional Works of Scholarship are governed by the Copyright Ownership Policy.

3.4 Institutional Works

A. Ownership. Institutional Works are the property of Wake Forest University Health Sciences or North Carolina Baptist Hospital, as applicable, which retains all rights to use and commercialize Institutional Works. To the extent

that Institutional Works do not qualify under U.S. copyright law as “works for hire,” Institutional Works are hereby assigned to Wake Forest University Health Sciences or North Carolina Baptist Hospital, as applicable. Persons producing Institutional Works will promptly confirm such assignment in writing upon request.

B. No Right to Proceeds. Persons producing Institutional Works will have no right to any share of any proceeds resulting from Institutional Works.

C. Right to Use. In the absence of contractual or legal restrictions to the contrary, the Medical Center generally grants persons producing Institutional Works non-exclusive rights for non-commercial use of Institutional Works they have created and consents to continued use of such works by them at another nonprofit institution for teaching, research, and other non-commercial purposes should they leave the Medical Center. For clarity, no right to use the name or trademarks of the Medical Center or its affiliate institutions or employees is granted under this Policy.

3.5 Release of Rights

The Medical Center may, if requested by the Innovator(s) and at the Medical Center’s discretion, release its rights in an Innovation in those situations in which the Medical Center, acting through its authorized representatives, determines that doing so is in the best interests of the Medical Center and the public, and would not violate the Medical Center’s obligations under federal regulations or contractual obligations to third parties. The Medical Center will provide a timely response to Innovator requests for release of rights.

Release of Innovations will generally be conditioned upon written acceptance by the Innovator(s) of certain obligations to the Medical Center including reservation of rights to practice the Innovation for nonprofit purposes; the Innovator’s return to the Medical Center of a portion of future proceeds, if any, from the Innovation (without a right to the Innovator’s share of the payments to the Medical Center), and the Innovator’s compliance with the applicable policies.

Innovators are not permitted to further develop released Innovation(s) at the Medical Center without the approval of the heads of the Wake Forest School of Medicine (for Medical Center faculty related issues and for the School of Medicine), or of Wake Forest Baptist Health (for North Carolina Baptist Hospital). Release of existing Innovation(s) conveys no rights to any improvement or modification to the Innovation(s) or to Innovations derived from or based on such Innovation, which are subject to this Policy.

4. FACULTY, STUDENT, STAFF AND VISITOR OBLIGATIONS

4.1 Disclosure and Cooperation

The Medical Center is obligated under federal regulations to promptly report inventions conceived or reduced to practice in the course of a federally sponsored research program. The Medical Center similarly is obligated to report Innovations to other third parties that provide financial support for research. Innovators should report to Wake Forest Innovations any Innovations arising during the course of a sponsored research agreement or with Medical Center Support to enable the Medical Center to comply with these regulations and contract terms.

Innovators have a continuing duty to assist the Medical Center in the evaluation, protection, and licensing of Innovations. Such assistance includes providing information and guidance for preparation and prosecution of patent applications and executing all documents and taking such other actions as reasonably required to perfect the rights of the Medical Center. The Medical Center has a continuing duty to make reasonable efforts to communicate with Innovators and to consider Innovator comments regarding in the evaluation, protection, and licensing of their Innovations.

4.2 Intellectual Property Agreements

Federal regulations require the Medical Center to obtain assignments necessary to protect rights of the federal government in inventions conceived or reduced to practice during the course of a government-sponsored research program. Other third parties that provide financial support for research similarly require the Medical Center to secure ownership of Innovations. By accepting employment, participating in sponsored research or using Medical Center Support, Medical Center faculty, staff, students, visiting scientists and fellows evidence agreement with the terms of this Policy and thereby assign to Wake Forest University Health Sciences or North Carolina Baptist

Hospital, as applicable, title to intellectual property as provided by this Policy. Members of the Medical Center community will promptly confirm their consent to this Policy in writing upon request.

4.3 Consulting Agreements

It is the responsibility of individual members of the Medical Center community to ensure that the terms of personal consulting arrangements with third parties do not conflict with their obligations to the Medical Center. Each individual should make the nature of his or her obligations to the Medical Center clear to any third party for whom he or she expects to consult and ensure that the scope of the consulting services is clearly distinguished from the scope of commitments to the Medical Center.

Employees are required to request approval in advance for specific consulting or contractual arrangements in accordance with the Consulting, Outside Activities, Conflict of Commitment and Conflict of Interest, and other applicable policies. Each individual engaged in personal consulting will ensure that the following paragraph (adapted to the particular agreement) is included in any and all personal consulting agreements:

[Entity] acknowledges that Consultant's primary obligation is to Wake Forest Baptist Medical Center (WFBMC). It is the intent of the parties that efforts and specific responsibilities under this Agreement be separate and distinct from those duties performed for WFBMC. In the event of any conflict between this Agreement and any terms of employment between the Consultant and WFBMC, including work responsibilities and ownership of any resulting intellectual property, the terms and conditions of the Consultant's employment with WFBMC will take precedence unless specific written arrangements have been made in advance between [Entity] and WFBMC.

5. DIVISION OF PROCEEDS

5.1 Distribution of Innovator Share

A. Distributable Proceeds. The Medical Center will distribute Net Proceeds as and to the extent provided in this Policy. The Medical Center does not act as a fiduciary or agent for any Innovator concerning potential proceeds not actually received by the Medical Center and no Innovator has any interest in, or legal right to, such potential proceeds.

B. Distribution Generally. Except as otherwise provided in this Policy or unless legal requirements or contractual agreements require otherwise, the Medical Center will distribute to the Innovator(s) 50% of the first \$500,000 and 40% thereafter of the Net Proceeds arising from the applicable Innovation, except Net Proceeds attributable to Institutional Works (see Section 3.4 A). Net Proceeds will generally be distributed quarterly.

C. Alternate Distributions. Except as otherwise provided in this Policy or unless legal requirements or contractual agreements require otherwise, Net Proceeds earned from Innovations with multiple Innovators or subject to distribution other than to the Innovator(s) will be as follows.

(i) *Among multiple Innovators for a single Innovation*: Innovators may specify the division of the Innovator share among themselves by written agreement signed by all of the Innovators. In the absence of a written agreement among the Innovators, the Net Proceeds will generally be divided equally among joint Innovators. The Medical Center may, in its discretion, allocate Net Proceeds in accordance with its reasonable determination of the relative contributions of the Innovators to the Innovation.

(ii) *For multiple Innovations generating Net Proceeds as a package*: Where the commercialization agreement does not assign values or otherwise allow determination of the value attributable to each Innovation, absent a written agreement among the Innovators to the contrary, Net Proceeds will generally be allocated equally among the Innovations. The Medical Center may, in its discretion, allocate Net Proceeds in accordance with its reasonable determination of the relative contributions of the Innovations to the Net Proceeds.

(iii) *To a non-Innovator*: Innovator(s) may elect to recognize significant contributions from non-Innovators with a share of Net Proceeds. Personal shares will be allocated to non-Innovators in accordance with a written designation provided to Wake Forest Innovations before any commercialization agreements are signed. Such designation will be irrevocable once made.

(iv) *To a laboratory*: If an Innovator wishes to waive his or her personal portion of the Net Proceeds, that Innovator must inform Wake Forest Innovations of this desire, in writing, before any commercialization agreements are signed. Such waiver will be irrevocable once made. The Innovator may state a preference as to the use of the funds by the Medical Center.

D. Equity. The Medical Center may accept securities or other equity shares as one form of compensation for license rights, subject to a conflict of interest review if appropriate. If the Medical Center acquires equity in lieu of compensation that would otherwise be distributable under this Policy, the Medical Center may require that the licensee distribute directly to those Innovators the percentages of equity that would have otherwise been distributed to them under this Policy if the payment had been made in cash, provided that the equity will be distributed without regard to recovery of Specific Expenses.

E. Portability of Royalty Shares. Personal shares of Net Proceeds will be payable to Innovators whether or not employed at the Medical Center and are transferable by assignment, will, or intestate succession. It is the responsibility of the Innovator to provide notice of updated contact information to the Medical Center. Notice should be sent to Wake Forest Innovations with a copy to Financial Services.

5.2 Distribution of Institutional Share

A. Allocation and Use of the Institutional Share. The institutional share of Net Proceeds will be allocated to Wake Forest University Health Sciences or North Carolina Baptist Hospital according to or proportional to the Innovator(s)'s place of employment or academic program. The institutional share of Net Proceeds is, by policy and law, to be used for educational and research purposes, including support for basic and clinical research programs, invention commercialization, and the operations of Wake Forest Innovations.

B. Allocation to Academic Units. For Innovations arising from the School of Medicine, 10% of Net Proceeds will be allocated to the academic unit (department, center, or institute) of the Innovator(s), subject to the requirement that the expenditure of Net Proceeds by the academic unit will be guided by identified strategic priorities and with approval through the standard institutional operational and financial planning processes.

(i) *Among multiple Innovators*, the academic unit shares will be allocated proportionally to the distribution of Innovator shares.

(ii) *For an Innovator with joint appointments*, the academic unit share will be allocated between the two primary academic units identified by the Innovator at the time of disclosure of the Innovation, proportional to the support provided by each academic unit for the activity in which the Innovation arose (if there is more than one academic unit providing such support).

(iii) *For Innovators who are students*, the academic unit will be deemed to be the academic unit of the student's primary advisor.

6. ADMINISTRATIVE RESPONSIBILITIES

6.1 Executive Authority

The President of Wake Forest University and the Chief Executive Officer of the Medical Center are responsible for administrative matters relating to this Policy for matters arising at the Reynolda Campus and Medical Center, respectively, which authority they may delegate in whole or in part. The President of the University and the Chief Executive Officer of the Medical Center, in consultation with the University Provost and with the Dean of the Wake Forest School of Medicine, will appoint the senior executive responsible for the oversight of Wake Forest Innovations.

6.2 Administrative Offices

Wake Forest Innovations is primarily responsible for addressing all intellectual property matters at the Medical Center. Wake Forest Innovations is charged with the transfer of the Medical Center's and University's intellectual property for public use and benefit while generating unrestricted income to support their research and education missions. Wake Forest Innovations is responsible for the administration of the invention reporting and licensing program; the commercial evaluation of Innovations; patent, copyright and trademark filing decisions; petitions to agencies for greater rights in Inventions; and negotiation of commercialization agreements with industry.

Biomedical Research Services & Administration assists Wake Forest Innovations in intellectual property matters and is responsible for reviewing terms and conditions of grants and contracts for compliance with policies on intellectual property rights and openness in research and negotiating the patent and copyright terms in arrangements with private and public research sponsors.

6.3 The Innovations Advisory Committee

A. Composition. Wake Forest Innovations will establish the Innovations Advisory Committee (the “Committee”). The Committee will consist of six faculty members, representing a variety of academic disciplines and two of whom are from the Reynolda Campus, appointed for staggered three year terms. In addition, the Associate Provost for Research of Wake Forest University, the research representative of the Dean of the Wake Forest School of Medicine, the General Counsel of Wake Forest University, the General Counsel of the Medical Center, the Medical School Controller, and the Dean(s) of the Graduate School of Arts and Sciences will serve as *ex officio* members of the Committee. The senior executive of Wake Forest Innovations will act as the chair of the Committee.

B. Duties. The Committee will meet twice a year, with ad hoc meetings as required, to receive a report of the activities and portfolio of Wake Forest Innovations and will from time to time advise Wake Forest Innovations leadership on issues of program development and implementation, situations in which problems arise in the implementation of this Policy, and specific cases for which the Committee’s guidance is sought.

6.4 Resolution of Disputes

Administrative decisions made under this Policy may be appealed by the persons affected. Appeal requests should be timely made in writing to Wake Forest Innovations. The appeal request will set forth the decision at issue, the proposed alternate course of action and relevant facts in support of the alternate action.

The senior executive of Wake Forest Innovations and the persons requesting appeal will meet promptly following the appeal request and attempt to resolve the matter. If they are unable to resolve the matter within 30 days the appeal request, the appeal will be referred to an intellectual property policy review panel appointed by the Dean of the School of Medicine (for Medical Center faculty related issues and for the School of Medicine), or the Chief Operating Officer of Wake Forest Baptist Health (for North Carolina Baptist Hospital), as applicable and including: (i) the department chair to whom the appealing party reports; (ii) the research representative of the Dean of the Wake Forest School of Medicine or the Chief Administrative Officer for North Carolina Baptist Hospital; (iii) the senior executive of Wake Forest Innovations; and (iv) non-involved representatives of the faculty. The panel will hear the appeal and provide its recommendation to the Chief Executive Officer of the Medical Center, who will render a final decision.

7. REVIEW / REVISION / IMPLEMENTATION

A. Review Cycle. This Policy will be reviewed every three years.

B. Office of Record. The Dean of the School of Medicine and the Medical Center Legal Department are responsible for reviewing and, subject to the approval of the Board of Directors of the Medical Center, revising or updating this Policy as necessary, not less than every three years. Wake Forest Innovations and Biomedical Research Services & Administration are designated as the responsible parties for implementing the Policy.

C. Applicability. This Policy is applicable to all Innovations disclosed to the Medical Center on or after the Policy’s effective date. If an Innovation has not yet generated any Net Proceeds, the Innovator(s) (unanimously if there are multiple Innovators) may request of the senior executive of Wake Forest Innovations that an Innovation disclosed prior to the effective date of this Policy fall under this Policy. The senior executive of Wake Forest Innovations will determine whether the request is appropriate after careful consideration and consultation with the appropriate Medical Center officials and administrators, and will confirm in writing to the requestor(s) whether the request is granted. The distribution policy made applicable to the Institute for Regenerative Medicine by Wake Forest University Health Sciences Board of Directors (June 6, 2003) is not superseded by this Policy.

D. Exceptions. From time to time, it may be in the best interests of the Medical Center to make exceptions to the provisions of this Policy. The Medical Center may, in its discretion, make exceptions after consultation with the appropriate Medical Center officials and administrators and only upon written agreements signed by individuals authorized to grant such exceptions on behalf of the Medical Center.

8. CROSS REFERENCES

Copyright Policy
Conflict of Commitment Policy
Consulting Policy
Conflict of Interest Policy
Human Resources policies

9. RETENTION

Wake Forest Innovations is designated as the responsible party for retention and implementation of this Policy.

10. GOVERNING REGULATIONS / REFERENCES

The Bayh-Dole Act (35 U.S.C. § 200 *et seq.*) and implementing regulations (13 CFR 401 *et seq.*)
National Institutes of Health Grants Policy Statement (available at
<http://grants.nih.gov/grants/policy/policy.htm#gps>)