Lifespan Office of Research Administration

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<u>Lifespan Corporation and Affiliates</u> <u>Intellectual Property Policy</u>

I. <u>Introduction</u>.

This Intellectual Property Policy (the "Policy") applies to Lifespan Corporation ("Lifespan") and its hospital affiliates (each a "Hospital") and to any Covered Person, defined below, associated with a Hospital. The purpose of this Policy is to create a uniform rule governing the rights and responsibilities of individuals and institutions with respect to Intellectual Property, as defined below. Subject to Section III(B), below, this Policy supersedes and replaces all previously issued policies on the subject matter issued by Lifespan or any of its affiliates. The Policy serves the following important objectives: (1) to preserve academic freedom; (2) to promote efficient technology transfer and protect Hospital assets; (3) to ensure the Hospitals meet their contractual obligations to research sponsors, material providers, and other third parties when IP is developed with external support; and (4) generally to benefit the

greater community within which the Hospital, Lifespan and Inventors function (the term "Inventor" or "Inventors" as used in this Policy shall be deemed to include any creator of Intellectual Property). The "Effective Date" of this Policy is February 1, 2012

Lifespan and its Hospitals believe the encouragement of research and the discovery and creation of new techniques, methods, procedures, and processes in medicine promote the ultimate goals of providing high quality, innovative patient care, and advancing medical education. Furthermore, Lifespan and its Hospitals believe the public benefits directly from the application of such discoveries and creations, and benefits indirectly when the financial fruits of new discoveries and creations are used to further medical research and to support medical care delivery. Rewarding creative and innovative individuals is a key aspect of promoting and sharing the benefits of further discovery. To these ends, this Policy is intended to encourage and promote the appropriate creation, use and development of Intellectual Property that may benefit the public, and to allocate fairly between the Hospitals and the Inventors the rights and responsibilities arising from the creation of Intellectual Property.

Compliance with this Policy is mandatory for all Covered Persons and continued employment, funding, sponsorship, affiliation, or other support from a Hospital and/or Lifespan are conditioned on such compliance. Other Lifespan or Hospital policies may also apply and should be considered by Covered Persons involved in research and the creation of IP, including but not limited to, the policies and procedures of the Lifespan Office of Research Administration and the Lifespan Policy on Research Conflicts of Interests (CCPM-43).

II. Definitions.

- A. "Covered Person" means any full or part-time employee or member of the professional staff of the Hospital, whether or not they are paid by the Hospital, as well as anyone using Hospital Resources (for whatever purpose, and whether or not for compensation), anyone participating as a member of the research team in clinical or other research conducted at the Hospital or under its auspices, and anyone using funds from outside sources (e.g. grants) under Hospital sponsorship, including without limitation contractors, consultants, agents, visiting clinicians or scientists, fellows, students and trainees. See also Section II.E.
- **B.** "Effective Date" is defined is Section I of this Policy.
- C. "Hospital Resources" shall mean any items or persons provided by or accessed through the Hospital, including but not limited to Hospital funding, facilities (excluding space rented at fair market value from the Hospital), materials, supplies, property, ideas, data, information not in the public domain,, use of regulatory review committees, staff or patients.
- **D.** "Intellectual Property" or "IP" means: any and all patents, copyrights, trademarks, or trade secrets, as well as any and all of the following which are or

may be protected by any law, statute or regulation (including but not limited to patent, copyright and trade secret laws), by the common law, or by agreement: inventions; discoveries; works of authorship; proprietary data; novel procedures, processes, arts, methods, techniques, or designs; know how; biological organisms (including cell lines and genes); tangible research property; computer and electronic programs, technology and software (including algorithms and formulas); and improvements or new uses of any known process, design, machine, manufacture, or composition of matter or material.

Typical types of Intellectual Property covered by this Policy include, but are not limited to:

- Inventions that can be protected by patent;
- Written, visual or audible works that can be protected by copyright;
- Biological or other materials that can be protected by patents or written agreements;
- Proprietary data, ideas or other information that may not qualify for protection under patent or copyright law, but that still have competitive or commercial value.
- E. "Covered Intellectual Property" or "Covered IP" means: Intellectual Property that is made, conceived, reduced to practice, authored, created or developed by a Covered Person while engaged in activities (a) for which the Covered Person received salary or other financial support from or through the Hospital ("through" would mean, for example, that the project was funded through an external grant managed by the Hospital); (b) that involved the non-incidental use of any Hospital Resources, (c) which are related to the subject matter of the Covered Person's employment, clinical, research, scholarly or other activities conducted at, for or under the auspices of the Hospital by the Covered Person and which involve the use of Hospital Resources; or (d) which are supported by, or subject to the terms of, a project, program, collaboration, agreement or other relationship between the Hospital and a third party, including but not limited to a sponsored research agreement, clinical trial agreement, federal grant or contract, material transfer agreement, cooperative or collaboration agreement, or other such agreement or relationship. In the event the facts concerning the circumstances of an invention are in dispute, the invention shall be presumed to be Covered IP unless the Covered Person can prove otherwise. The term Covered IP shall also include any IP not covered by the above categories which was developed and is owned by a Covered Person and which the Covered Person wants to assign to the Hospital and have the Hospital treat as Covered IP subject to the provisions of this Policy. The term Covered Intellectual Property shall also include all copyright and copyrightable works of authorship falling under any of the above categories, including but not limited to a work-for-hire, but shall generally exclude Scholarly Works (e.g., works of authorship customarily recognized as academic or scholarly in nature, such as scholarly books or articles written for journal publication,

scholarly presentations, or scholarly papers prepared for professional conferences), except in cases where substantial Hospital Resources are involved. The exception for Scholarly Works shall not include any Hospital-commissioned works intended for use by the Hospital which are prepared by a Covered Person upon the specific request of the Hospital or under special arrangement between the Hospital and the Covered Person.

F. "Inventor" shall have the meaning set forth in Section I of this Policy.

III. Scope of the Policy.

A. To Whom Does This Policy Apply?

This Policy applies to all **Covered Persons** as defined above. In the event of uncertainty as to whether an Inventor is a Covered Person with respect to an item of IP, the Hospital will make a good faith determination based on information provided by the Inventor. If a Covered Person is also subject to the intellectual property policy of another institution with respect to a particular piece of Intellectual Property, the Hospital President/CEO or his or her designee shall work with the appropriate official at the other institution to resolve the matter, with the goal of working out an equitable split based on relative contributions.

B. To What Does this Policy Apply?

This Policy applies to all Covered Intellectual Property conceived and/or reduced to practice by a Covered Person on or after the Effective Date. Any Intellectual Property disclosed to the Hospital's Office of Research Administration ("ORA") prior to the Effective Date of this Policy shall be governed by the terms of the policy that was in effect for the Hospital at the time of receipt of such disclosure, unless the Inventor or Inventors opt(s) in writing to be bound by the terms of this Policy.

IV. Ownership.

All Covered IP is owned by the Hospital and is covered by this Policy. However, pursuant to the terms of this Policy and unless an exception applies, the Hospital will share with the Covered Person and his or her laboratory, research group or department, any net licensing, royalty, or other fees or revenue derived from commercialization of the IP. See Section VII of this Policy. By virtue of being bound by this Policy, Covered Persons hereby assign all Covered IP to the Hospital. Covered Persons have **no** right to enter into agreements concerning the Covered IP and any such agreement shall be considered null and void; furthermore, if a Covered Person enters into such a prohibited agreement it shall constitute non-compliance with this Policy and may put continued employment, funding, sponsorship, affiliation, or other support from a Hospital and/or Lifespan at risk.

Additionally, the Hospital may permit an Inventor to offer IP to the Hospital even if the Inventor is not otherwise subject to the terms of this Policy. In such a case, if the Hospital

accepted the offer, the IP would be considered Covered IP and it and the Inventor would become subject to the terms of this Policy. An inventor might decide to offer IP in this way if he or she wanted the Hospital's assistance in commercializing the IP.

In some cases, Covered IP may be subject to the terms and conditions of agreements entered into by the Hospital and third parties, such as clinical trial or sponsored research agreements with private drug or device companies, which grant certain rights in Covered IP to those third parties. The Hospital has exclusive authority to enter into such agreements, on terms it considers reasonable in its sole discretion, and nothing in this Policy shall be understood to give Covered Persons any rights with respect to establishing the terms of such agreements, or the disposition of Covered IP developed under such agreements. Covered IP developed in connection with activities funded by the federal government, such as activities funded under NIH research grants, are also subject to the retained rights of the federal government (e.g. government use licenses, march-in-rights) and other regulations of the federal government pertaining to such IP.

V. <u>Disclosure of Inventions</u>; Publications.

Each Covered Person who makes, conceives, reduces to practice, develops or generates any article or item of Covered IP (or an item or article of IP other than Covered IP which the Covered Person developed and owns and wishes to have treated like Covered IP under this Policy) must promptly submit a completed Disclosure Form relating to such IP to the Director of the Office of Research Administration (ORA). Forms are available from the ORA or at http://www.lifespan.org/research/administration/intellectual-property. In cases where the Covered IP is a creative work that may best be protected through the copyright laws, the Inventor should also send a copy of the Disclosure Form to the Lifespan Office of the General Counsel.

In cases where a Covered Person is not certain whether the IP he or she has developed falls within the definition of Covered IP, the Covered Person is strongly encouraged to submit a Disclosure Form to ORA, along with a request that the Hospital confer with him/her and advise as to whether or not the Hospital considers the IP to be Covered IP. In instances where there is a question of whether IP was developed in whole or in part by the Covered Person under a private consulting arrangement with a company, and there are concerns about the possible or perceived sharing or disclosure of company confidential information to the Hospital, the Hospital is willing to enter into reasonable confidentiality agreements that would allow its consideration of the IP and the circumstances leading to its development.

The description of the IP in the Disclosure Form should provide enough detail to allow ORA or its designee to determine the most appropriate steps, if any, to protect and commercialize the IP. If applicable, the Disclosure Form should also document the source of written records on the invention, as documentation is critical to patent success. If the Covered Person is a consultant engaged by an employee or staff member of the Hospital, then the employee or staff member is responsible for ensuring that the Disclosure Form is completed and submitted to ORA.

Under the patent law, prompt and full disclosure of new IP is essential to protect the value of the IP and to prevent outside parties from using it without compensating the Hospital and the Covered Person. If IP is disclosed outside the Hospital before appropriate steps are taken to protect the IP--such as in a publication or oral presentation, by use, or by public sale--the Inventor's and the Hospital's rights in the IP may be lost. Therefore, an important goal of the disclosure process is to allow ORA or its designee to assess the IP and to make a prompt decision about whether and how best to protect it. In the interest of academic freedom and in order to promote timely publication of research results, the Hospital agrees to use best efforts or to cause its designee to use best efforts to assess IP within a reasonable period of time after disclosure. Furthermore, Covered Persons must consult with the ORA to protect the IP before agreeing to any publication, including oral publication, regarding Hospital-owned IP. Temporary delays in publication or disclosure, when necessary for the patent filing process, are considered acceptable in both the hospital and university research settings, and may occasionally be required.

If a Covered Person disagrees with any decisions made with respect to ownership or protection pursuant to this Policy, the Covered Person should present his or her position in writing to ORA within 10 business days of receipt of notification from the Hospital. The opinion of the Hospital President may be sought if necessary.

ORA or its designee will maintain central records of the Hospital's invention disclosures and all subsequent transactions.

VI. <u>Commercialization Options</u>.

IP can often best be protected with a patent, or, in cases where a patent is not a possibility, through other protective arrangements such as copyright, trademark, licensing agreements, materials transfer agreements, or confidentiality agreements. The Hospital shall have sole and exclusive authority to make all decisions about the protection and commercialization of Covered IP, including whether or not to pursue protection or commercialization at all. However, the Hospital will generally consult with the Covered Person(s) who developed the Covered IP about significant decisions relating to protection and commercialization, and will generally keep such Covered Person(s) reasonably advised about its significant actions and progress in those areas such as: (1) issuance of a patent; (2) licensing of IP; and (3) terms of the licensing agreements. However, such notification shall not give the Covered Person any right to negotiate or exercise decision-making responsibilities with respect to the Covered IP. The costs of all IP protection and commercialization activities shall be borne by the Hospital, which also may decide to protect and commercialize Covered IP through a recognized patent management company or through another appropriate entity.

At the same time, the Covered Person is expected to, and shall be required to, fully cooperate in all of the Hospital's IP protection and commercialization efforts relating to Covered IP by, including but not limited to: providing upon request of Hospital or its agents all relevant technical information and documentation relating to the Covered IP; executing an assignment to the Hospital of all of the Covered Person's rights in the IP; and executing all other agreements, acknowledgements, applications and other documents which the Hospital deems necessary and

appropriate for its protection and commercialization activities; assisting the Hospital and its agents in preparing technical documents and patent applications or other IP related applications; and helping the Hospital and its agents identify potential markets for the IP and potential licensees who might be interested in licensing or acquiring the IP, and providing information and demonstrations to potential licensees and commercial partners, as requested by the Hospital.

However, if a Covered Person wishes to develop Covered IP at his or her own expense (or, if the Hospital declines to pursue commercialization), the Covered Person may, in writing, request a written waiver of the Hospital's Intellectual Property rights. This waiver request should be coordinated through ORA. The Hospital shall decide, in its sole discretion, whether such waiver should be granted, with reversion of ownership of Covered IP back to the Covered Person, keeping in mind the best interests of the Hospital and the public, and the applicable requirements of law as well as the terms of any applicable agreements. In cases where the IP was developed with federal financial assistance, the Hospital shall consider whether approval (or a waiver of federal rights) is required from the federal funding agency prior to a transfer of ownership of the IP, and shall obtain any such required federal waiver or approval prior to the transfer back to the Covered Person. If the Hospital decides to release the Covered IP to the Covered Person, the ORA, on behalf of the Hospital, may ask the Covered Person for reimbursement for patent expenses or other research costs. In such cases, the Hospital shall also retain a royalty-free right to use the IP for research purposes.

VII. Income and Distribution

- A. <u>IP Income</u> If the Hospital retains ownership of the Covered IP, the Hospital will endeavor to generate income from the IP by licensing (or in some appropriate and permissible cases, by selling or assigning) the Covered IP in exchange for appropriate consideration such as fees, up-front payments, milestone payments, dividends, royalties and other income or compensation. The Hospital shall share Net Income (as defined below) from technology transfer as follows; provided, that distributions may be reasonably postponed if the Hospital anticipates future expenses such as patent prosecution expenses or an infringement suit:
 - 1. "Net Income" Defined. "Net Income" related to Covered IP is defined as gross income from the Covered IP (including, but not limited to, gross royalties, licensing fees or similar income actually received from the sale, assignment, licensing or other exploitation of the Covered IP) cumulatively, minus all expenses of Hospital and Lifespan in evaluating and protecting the Covered IP and in bringing the Covered IP to market and maintaining it in market, including, but not limited to all legal and administrative expenses as well as any and all expenses and payments associated with the utilization of a licensing agent or other organization that the hospital may rely on to assist with this process. Net Income shall not include any compensation received by the Hospital in the form of equity. Furthermore, in cases where the research or program funding agreement requires payment of certain IP related income to the research or

- program sponsor, all such payments shall be considered Hospital expenses and deducted from Net Income.
- 2. <u>Distribution of Net Income</u>. Unless an exception applies, Net Income shall be distributed in accordance with the following Table A; provided that all distributions to Covered Persons shall be subject to the limits described in Section VII(A)(3) of this Policy:

First \$1MM of	Net Income in
Net Income	excess of \$1MM

Inventor(s)*	50%	35%
Inventor's lab or		
research group **	25%	25%
Hospital Department		
of the Inventor(s) **	15%	15%
Hospital	10%	25%

- 3. <u>Limits on Income Distributions</u>. If reasonably required to ensure compliance with IRS standards, Lifepan reserves the right to defer or restructure the amount of distribution to an inventor in a particular year. If a Covered Person leaves the Hospital or is deceased, personal royalty shares will still be payable to him or her or their estate; shares for their department or laboratory would revert back to the Hospital.
- 4. Exceptions. The distribution schedule in Table A shall not apply to any income from copyrighted/copyrightable "works made for hire" or "Hospital-commissioned works" intended for use by the Hospital which are prepared by a Covered Person upon the specific request of the Hospital, under special arrangement between the Hospital and the Covered Person. All income arising from such endeavors shall accrue to the Hospital.
- **B**. Transactions or Agreements with Third Parties/Sponsors/Grantors. In situations where a commercial sponsor is involved in funding of research and/or commercialization of IP, the Hospital shall designate a member of the ORA staff to negotiate a sponsored research agreement or license agreement on behalf of the Hospital and the Covered Person. The Hospital representative shall consult regularly with the Covered Person during this process and the Covered Person may offer guidance on business terms, but shall not have final decision-making authority. The director of the ORA shall have signature authority for all agreements.

The Hospital shall endeavor to secure broad rights in the invention for the Hospital, consistent with the public interest. For example, the Hospital shall endeavor to control prosecution of patents, obtain reimbursement, ensure broad publication rights, and ensure a wide distribution of products. Achievement of these goals also benefits the Covered Person pursuant to the royalty provisions of this Policy.

C. <u>License Agreements/Equity</u>. Depending on the technology and field, license agreements with third parties typically include: a license issue fee; license maintenance fees; royalties on net sales by licensee, its affiliates and, in the case of exclusive licenses, sublicensees; in the case of exclusive licenses, an agreed upon percentage of non-royalty sublicense income. License agreements with start-ups might include equity, as well, in lieu of a part of the license issue fee.

Transactions involving the issuance of equity require additional scrutiny and must be approved by the Office of the Vice President for Research and by the Research Conflict of Interest Committee. In general, equity should only be accepted when a start-up company is cash poor and lacks significant revenues, and represents the best opportunity for the development of early-stage technology. Stock should not be taken in preference for cash, but rather in the absence of sufficient cash compensation and when the best possible cash terms have already been negotiated. While there is no prohibition against such arrangements, the Research Conflict of Interest Committee should exercise particular scrutiny in cases where Lifespan or a Hospital proposes to exercise management or governance authority over the start-up. Additionally, the Research Conflict of Interest Committee should consider requiring the Hospital and/or Lifespan to cash out equity upon the first liquidation event or sooner.

Lifespan and its affiliate hospitals prefer not to own equity in companies conducting research studies at a Hospital, although occasional exceptions might be made by the Research Conflict of Interest Committee. Any license agreement involving equity should include provisions obligating the company to repurchase Lifespan or Hospital equity at fair market value before a research study is begun at a Hospital.

Covered Persons who own equity in companies seeking to conduct clinical trials at a Hospital must disclose such interest as a conflict and such conflict will be managed in accordance with Lifespan's policies and procedures in this area.

VII. General.

The Lifespan ORA, in consultation with the Lifespan Legal Department, shall be responsible for interpreting this policy and resolving questions and disputes concerning it. ORA may also make and implement procedures necessary to effectuate this Policy. Lifespan may make changes to this Policy at any time and such changes would take effect upon approval by the Vice President for Research. Any such changes would apply only to Covered IP developed after the effective date of the revision.