# Intellectual Property Policy (Effective Date: January 20, 2015)

# **Table of Contents**

- I. Introduction
- II. Definitions
- III. Ownership of Intellectual Property Ownership of Intellectual Property Copyrightable Works
- IV. Disclosure of Inventions and Commercialization and Distribution Process Submission and Review of Invention Disclosures Filing Patent Applications and Registering Copyrights Commercialization and Distribution Release of Inventions
- V. Disclosing or Transferring Intellectual Property Distribution of Materials Disclosure of Intellectual Property
- VI. Intellectual Property Revenue Distribution Policy
- VII. Formation of Start-up Companies based on Children's Intellectual Property

Decision to Accept Equity Management of Equity

- VIII. Consulting Arrangements
  - IX. Foundation and Department Investment Policy
  - X. Other Governing Policies

Resolution of Disputes

Effective Date

XI. Participation Agreement

# I. Introduction

This Intellectual Property Policy of Boston Children's Hospital ("Children's") is designed to promote the development of Children's research and clinical discoveries in order to benefit the public, to encourage inventorship, and to build Children's research endowment. The Technology and Innovation Development Office ("TIDO") administers the Policy on behalf of the Chief Executive Officer and Trustees.

The mission of Children's is to translate the excellence of the laboratory and clinical research and clinical care at Children's into lifesaving biomedical products, devices and procedures for the public benefit. Through active partnering with biotechnology, pharmaceutical and medical device companies at all stages (e.g. research, development, pre-clinical and clinical investigation), Children's works to translate the world-class, cutting edge research, discoveries and innovations conducted at Children's into new therapies, diagnostics and devices that can benefit the public.

This Policy recognizes the challenges of these collaborations and relationships and the importance of specifying the ownership of the intellectual property developed at Children's or with Children's resources, as well as how any monetary gain from Children's intellectual property is distributed. The Policy sets forth the procedures for disclosing intellectual property, how Children's will commercialize and distribute such assets and how intellectual property may be distributed outside Children's by its faculty, employees and staff.

With the increasing complexity of bringing intellectual property to the public, many of Children's faculty and staff are interested in forming companies to commercialize intellectual property. Children's recognizes that this strategy may provide an effective vehicle to further develop and bring new therapies, diagnostics and devices to the public benefit, but also has, among other issues, inherent conflict of interest concerns. This Policy sets forth policies to guide Children's faculty and staff in the formation and participation in new companies.

Further, this Policy recognizes the breadth and importance of copyrightable works created by Children's faculty and staff and sets forth the mechanism for distributing this valuable asset to the public.

Children's recognizes that engaging in outside consulting activities may further our faculty and staff's knowledge and perspective, and allow the individual to make contributions outside his/her Children's roles to further scientific and clinical advancement in healthcare. Consulting arrangements occasionally present issues that must be addressed prior to the individual entering into any agreement. This Policy sets forth Children's policy regarding consulting arrangements of its faculty and staff.

This Policy applies to all Covered Persons, as defined below.

## II. Definitions

Academic Works: Written works and oral works of authorship in recorded form that communicate or share for the benefit of the public or the field an activity or accomplishment within the scope of a faculty member's research, education or academic clinical activities undertaken at or in connection with their Children's or any other related academic appointments at any institution (e.g. to other Harvard-affiliated hospitals, or the joint programs with MIT), but excluding private activity that is disclosed and approved as required under this Policy and excluding works created for Children's operational, administrative or other internal or external business purposes. Academic Works may take the form of articles, books, commentaries, blogs or websites, to name some examples. Their characterization as Academic Works does not turn on that form, but on the relationship of the action to the academic appointment, and its purposes.

**Children's**: The Children's Hospital Corporation, d/b/a Boston Children's Hospital, and Children's Medical Center Corporation and any of their respective subsidiaries, affiliates and related Foundations.

**Covered Person**: A member of the medical staff or research staff of Children's and each employee, faculty member, fellow, resident, student, visiting faculty or scientist, consultant, and volunteer of Children's, whether compensated or not, who are involved in any activities supported in whole or in part by funds, personnel, facilities, materials or other resources of Children's, or administered by Children's. Covered Person includes any person, including those primarily affiliated with another institution or entity, whether non-profit or for-profit, who performs educational, research, clinical or other activities at and/or for Children's.

**Copyrightable Work(s):** Any original work of authorship that is fixed in any tangible medium of expression. Examples of Copyrightable Works include but are not limited to journal articles and other scholarly or scientific papers, books, photographs, drawings and diagrams, software, video materials (any visual, audio or audio-visual work), audio files and web content, including text, images and multi-media of any kind.

**Department:** An unincorporated division of Children's relating to a clinical specialty and headed by a chief or acting chief.

**Foundation:** Any of the faculty practice plans of Children's that are organized as non-profit corporations exempt from federal income tax under section 501(c)(3) of the Internal Revenue Code.

**Intellectual Property:** Inventions, patents, Copyrightable Works, Trademarks, Materials, and any other intellectual or intangible property. Further, Intellectual Property includes, but is not limited to, research notebooks, data, databases, photographs, original drawings and diagrams, computer programs.

**Invention**: Any creation, innovation, enhancement, improvement, alteration, approach or process, in the form of composition of matter, design, device, manufacture, or method, that is made, conceived or reduced to practice for any purpose, whether or not patentable.

Inventor: A Covered Person who makes, conceives, or reduces to practice an Invention.

**Materials:** Chemical and biological materials including but not limited to reagents, proteins, genes, gene products, DNA probes, vectors, cell lines, transgenic animals and human or animal blood and tissue samples; devices; instruments; equipment; or other tangible objects.

**Program:** A multi-disciplinary research program of Children's including, without limitation, the existing programs in Vascular Biology, Genomics, Bio-Informatics, Stem Cell Biology, Neuroscience, and Cellular and Molecular Medicine.

**Software:** Computer or computer-based materials in the broadest sense, including but not limited to computer programs, user interfaces, users' manuals and other accompanying explanatory materials or documentation, mask works, firmware and computerized databases. It includes, for example, microcode, subroutines, operating systems, high level languages, and application programs in whatever form expressed (e.g., machine or assembly language, source or object code) or embodied (e.g., chip architecture, ROM, disk or tape storage, program listing). While some materials defined here as Software may not be covered by United States copyright laws (mask works, for example, are protected separately under the Semi-Conductor Chip Protection Act), for convenience all Software is treated as Copyrightable Works for purposes of this Policy.

TIDO: The Technology and Innovation Development Office at Children's.

**Trademarks**: A brand name associated with a specific good or service. A trademark or service mark includes any word, name, symbol, device, or any combination, used or intended to be used to identify Children's or the services provided by Children's.

## III. Ownership of Intellectual Property

#### **Ownership of Intellectual Property**

Except as otherwise set forth in this Policy, Children's owns all Intellectual Property discovered, created or developed by a Covered Person, and Covered Persons hereby assign such Intellectual Property to Children's. All Covered Persons must sign a Participation Agreement, in effect from time to time, the current version of which is attached as Exhibit A. Under the Participation Agreement the Covered Person assigns, and/or confirms the assignment of, all Intellectual Property to Children's, agrees to cooperate fully with Children's by promptly disclosing Inventions, executing and delivering assignments with respect to all Inventions, complying with all relevant policies and procedures, and maintaining all appropriate research records. Failure of a Covered Person to sign a Participation Agreement does not affect the applicability of this Policy to the Covered Person or the assignment of Intellectual Property under this Policy.

Covered Persons who, by virtue of their professional relationship with another institution, are also obliged to execute that institution's participation agreement, will inform, as soon as practical, TIDO, their Department Chief or Program Director and Human Resources of this fact,

and provide the name of the institution, as well as their professional relationship with the institution. As appropriate, TIDO will work with the other institution to clarify the assignment obligations of the Covered Person and will so inform the Covered Person. The Covered Person shall thereafter assign his/her rights in Intellectual Property in accordance with any subsequent agreement reached between TIDO and the other institution.

Covered Persons are not permitted to sign any agreements, including, for example, confidentiality agreements, license agreements, assignments, material transfer agreements, or research agreements, that restrict, commit, or affect Intellectual Property. Only agreements approved and signed by an authorized representative of Children's shall be valid and binding upon Children's.

## **Copyrightable Works**

In the course of their relationship with Children's, Covered Persons may create copyrightable material that Children's wishes to distribute to the broader community to further our academic teaching, clinical and research missions. Children's owns all Copyrightable Works, subject to the discussion below regarding Academic Works.

All Covered Persons must disclose the creation of Copyrightable Works to TIDO. TIDO will maintain an inventory of all such Copyrightable Works in order to coordinate the licensing and distribution of Copyrightable Works in a consistent and effective manner that supports the overall mission of Children's.

Covered Persons may not display or distribute Copyrightable Works through a website that has not been approved by Children's for the purpose of distributing Copyrightable Works. Children's does not endorse commercial entities or products. Neither Copyrightable Works nor Academic Works may be displayed in a manner that suggests such endorsement.

Royalties received from the licensing and distribution of Copyrightable Works will be distributed as set forth in this Policy.

<u>Academic Works</u>. In accordance with the uniform practice of academic institutions, Children's grants to the author(s) of an Academic Work a perpetual, royalty-free, non-exclusive right to: assign the Children's copyright to an Academic Work or, alternatively, to license any copyrights thereunder where a license suffices, and to execute any permissions for others to anthologize or extensively incorporate all or part of an Academic Work, with acknowledgement. This right only exists where such assignment or license is for an academic or charitable purpose, and personal compensation is zero, *de minimis*, or limited to a reasonable honorarium or royalties. For private works of authorship (such as textbooks) both permitted and disclosed as required that do not arise from or relate to Children's Intellectual property or resources, Covered Persons may retain the copyright in their own name and contract personally, subject to the rules on consulting and other institutional policies.

In exercising these prerogatives, authors should find out if any reservation of rights for use by Children's and their Departments and Programs is negotiable, and if feasible attempt to obtain a

reservation such as the following: "Nontransferable rights are reserved for the author's personal and academic use, to the author's Department or Program for promotional and academic purposes, and to Children's for any noncompetitive not-for-profit purposes.

<u>Trademarks</u>. All Trademarks, whether registered or not, are Children's Intellectual Property. In furtherance of Children's mission, Children's has an interest in ensuring that its Trademarks are distinctive and are not infringed or diluted and are appropriately monitored and managed. Only Trademarks approved by Children's may be used by Covered Persons to identify or describe Children's, Children's programs or Children's services.

## IV. Disclosure of Inventions and Commercialization and Distribution Process

## Submission and Review of Invention Disclosures

Each Covered Person who makes, conceives, or reduces to practice an Invention shall promptly submit a completed Children's Invention Disclosure Form to TIDO. All Inventions must be disclosed even if the Covered Person believes it may not be owned by Children's solely or jointly. The Disclosure Form is available at <u>www.childrensinnovations.org</u>. The Disclosure Form serves as the basis for an evaluation by TIDO of the Invention's patentability, protectability, and potential for commercial application. The description of the Invention in the Invention Disclosure Form should provide enough detail to determine the most appropriate steps, if any, to protect and commercialize the Invention. To the extent reasonably possible, in the event of joint invention, Children's will coordinate efforts to protect and commercialize Inventions with other institutions/collaborators.

Covered Persons are encouraged to make disclosures as early as possible, preferably as soon as they believe they have created an Invention to allow maximum lead time to evaluate and, where appropriate, file patent applications, and develop a commercialization and distribution strategy. To maximize the potential breadth and usefulness of patent protection, Covered Persons must make disclosures prior to publication or other public presentation.

## Filing Patent Applications and Registering Copyrights

After consultation with the Inventor(s) and others as appropriate, Children's, through TIDO, shall be responsible for making the final determination as to whether protection of an Invention shall be pursued by Children's (e.g., patent application or copyright). Such determinations will be made on the basis of United States patent and copyright law, commercial potential, obligations to and rights of third parties, or other relevant considerations. When Children's determines to seek the patenting or copyrighting of any Invention which Children's owns in whole or in part, (a) TIDO shall, without expense to the Inventor, provide such professional services as it shall deem to be necessary or desirable to patent or copyright the Invention, and (b) the Inventor(s) shall cooperate fully in such effort, including promptly executing all necessary or desirable agreements, applications, assignments and other forms and instruments.

### **Commercialization and Distribution**

Children's shall be responsible for the commercialization and distribution of Inventions. Where an Invention is subject to an external agreement with a third party (for example, the federal government or other funding sponsor), Children's, through TIDO, shall make decisions consistent with that agreement. TIDO shall make reasonable efforts to keep Inventor(s) involved and informed of its commercialization and distribution efforts. Final decisions about commercialization and distribution of Inventions shall be made by TIDO, on behalf of Children's.

#### **Release of Inventions**

TIDO may decide not to file to protect an Invention, including the decision not to file a patent application on an Invention, or abandon a patent application on an Invention prior to issuance of the patent, or abandon an issued patent on an Invention. These decisions will, if feasible, be made in consultation with the Inventor(s), but the final decision will be made by TIDO, on behalf of Children's. In such cases TIDO will make reasonable efforts to inform the Inventor(s) of this decision and the Inventor(s) may request Children's to release the Invention, or issued patents or patent applications or other legal protections to the Inventor(s). Upon determining that releasing the Invention or issued patents or patent applications to the Inventor(s) will not violate the terms of an external funding agreement, and that such release will not interfere with future funded research, and is in the best interests of Children's and the public, Children's may agree to a release and in such case will assign or release all interest which it holds or has the right to hold in the Invention or issued patents or patent applications to the Inventor(s) in equal shares, or such other shares as the Inventors may all agree.

Children's is under no obligation, however, to release any Invention and its related patent or other legal protection, to any Inventor(s). As part of the release of issued patents or patent applications, Children's may require that appropriate compensation be provided to Children's, such as for its un-reimbursed out-of-pocket expenses associated with the issued patents or patent applications including, without limitation, attorney's fees and other costs incurred in obtaining legal protection for the issued patents or patent applications. If required, such compensation shall be paid to Children's once licensing or other revenue has been realized by the Inventor. Children's may also elect to retain a non-exclusive, transferable right to use any released Invention or issued patents or patent applications or other legal protections for Children's research and business purposes. Children's may impose other requirements of the Inventor(s), including but not limited to, requiring the Inventor(s) to agree to certain limitations on Children's liability and indemnification.

## V. Disclosing or Transferring Intellectual Property

## **Distribution of Materials**

In keeping with the traditions of academic science and its fundamental objectives, it is the policy of Children's that results of scientific research are to be promptly and openly made available to others. This policy applies equally to research results that are defined as Materials under this

Policy. Furthermore, the dissemination of Materials raises other issues such as the safety of the Materials; the need for Materials to be more fully characterized or developed prior to distribution; for human tissue and other bodily samples, the need for appropriate consent and compliance with applicable policy regarding transfer of human samples; and the need to ensure that dissemination of Materials is consistent with applicable policies, laws and regulations as well as contractual obligations to third parties.

Materials that are chemical and/or biological may usually be distributed for non-commercial research purposes with only minimal conditions attached consistent with or under the terms of the Universal Biological Materials Transfer Agreement providing that commercial development or commercial use or further transfer of the Materials is not to be undertaken. In addition, the Inventor may wish to control subsequent use, for example, by requiring recipients to follow a specific research protocol in the use of the Materials.

Materials which constitute human tissue or other bodily samples, or which raise safety concerns, or the distribution of which may be subject to contract, policy, law or regulation (such as export control laws, or laws pertaining to special agents) must be subject to an agreement that is reviewed, negotiated and approved by TIDO, and which contains the provisions and restrictions deemed appropriate by Children's for the particular distribution.

Without limiting the generality of the foregoing, in order to protect the faculty and Children's, Materials that are intended to be distributed for commercial research purposes or to a for-profit entity must be under the terms of an agreement negotiated and approved by TIDO, on behalf of Children's.

## **Disclosure of Intellectual Property**

All Intellectual Property (including data), invention disclosures, license agreements, and research reports and documents pertaining thereto shall be treated as confidential, proprietary information belonging to Children's until public release. If Intellectual Property is disclosed outside Children's (such as in a publication or oral presentation, by use, by public offer for sale, or by public sale), before appropriate steps are taken to protect the Intellectual Property, such as filing a patent application, certain legal rights may be lost. Therefore, prior to any proposed publication of Intellectual Property or other disclosure of the Intellectual Property outside Children's, Covered Persons must advise TIDO of the intended disclosure in sufficient time to permit Children's to take steps necessary to protect Children's rights in the Intellectual Property. In many cases, TIDO may determine that a Confidential Disclosure Agreement must be obtained from a recipient before information about the Intellectual Property is disclosed to that party.

## VI. Intellectual Property Revenue Distribution

#### **Proceeds for Inventions**

Children's shall act to bring to the public all Inventions which Children's owns in whole or in part, by such means Children's deems appropriate under the circumstances. The cumulative net revenue received by Children's for the sale or licensing of an Invention shall be distributed as

shown in the table below. Cumulative net revenue includes all income received by Children's from the sale or licensing of an Invention less all out-of-pocket costs attributable to patenting, copyrighting, litigation, marketing, and other related expenses incurred by Children's including any obligations to third party sponsors, co-owners and/or co-inventors of such Invention.

Inventor	Inventor's Research or Education	Inventor's Dept. and/or Program	Children's	TIDO
	Endeavor			
30%	12.5%	12.5%	30%	15%

The 12.5% share between the Department and Program will be decided by the Chief and the Program Director, with the approval of the Chief Executive Officer, recognizing the relative contribution of each party. It is expected that the share will be split evenly and only adjusted if the contributions of each party are materially different.

In Children's discretion, distribution of revenue from Copyrightable Works and Materials may be handled separately with the revenue going to the Inventor's research or education endeavor, and Department or Program.

Income shall be distributed for the lifetime of the license (or in accordance with such other agreements Children's shall make, such as a sale of a royalty stream) according to the terms of the Intellectual Property Policy in effect on the effective date of the license agreement, or on the date of signing if no effective date is stated. In the event Children's adopts a new Intellectual Property Policy and all the parties (Inventors, Department/Program and Children's) agree, then an existing license may be handled under the terms of a new policy.

The determination that an Inventor is to be listed on a patent application is governed by patent law and may differ from academic standards of authorship. If there is more than one Inventor, the Inventor's share will be distributed equally among the co-Inventors, unless Children's has been instructed otherwise in writing by all of the co-Inventors.

Children's pays royalties only to its own Inventors. However, when a Children's Inventor makes an Invention with a co-inventor at another academic or non-profit institution, and the institutions agree to market the Invention jointly, Children's may authorize an agreement whereby each institution pays all inventors according to the terms of its own intellectual property policy.

Children's may agree to distribute royalties from an Inventor's share to other Children's employee(s), who has/have made a substantial contribution to the Invention even if such contribution does not rise to the level of inventorship, provided all Inventor's agree in writing to such distribution and describe the substantial contribution of such employee to TIDO.

If an Inventor dies, then Children's will distribute the Inventor's individual share to the Inventor's estate or heirs. Children's will make reasonable efforts to inform the estate or heirs of any net revenue available for distribution, however, it will be the responsibility of the executor or legal representative of the Inventor's estate to notify Children's in writing, as to where future payments should be sent.

If an Inventor dies or if an the Inventor leaves Children's, the Program Director or Department Chief will decide on the allocation of the Inventor's research or education endeavor share and the use of any current balance available from the Inventor's research or education endeavor.

Royalty shares will be distributed by TIDO no less frequently than quarterly.

Children's share of net license revenues will be placed in two funds to support research programs of Children's. First, funds from Children's share of annual revenues will establish and maintain a Technology Development Fund, to be managed by TIDO for support of developmental activities that enhance the marketability of early stage technologies. The Technology Development Fund will receive up to \$450,000 per year with the remainder of Children's share of annual revenue allocated to the General Research Endowment Fund to support Children's research and education.

In certain cases, a Department or Program or Children's itself may wish to make an extraordinary investment in the development of the research of a faculty member with the goal of furthering the research so that it results in Intellectual Property that can then be licensed to a third party. An extraordinary investment is generally above \$100,000 and does not include government, corporate, Foundation grants, philanthropic gifts, start-up or recruitment packages or Children's resources, cores or facilities that are generally available to researchers at Children's.

In the event that Children's or a Department or Program wishes to make such an extraordinary investment, the other party (i.e., Children's or the relevant Department/Program) may choose to split the investment. In this situation, the revenue distribution set forth above will be modified such that there will be a 50% reduction of the Inventor share until the investment of the investing party(s) is repaid with interest at prime plus 1%. In the situation where either Children's or the relevant Department/ Program makes an extraordinary investment in the development of research and the other party chooses not to split the investment, then the revenue distribution set forth above will be modified such that there will be a 50% reduction of the Inventor share and a 50% reduction of the non-investing party share (i.e., Children's or the Department/Program as the case may be) until the investing party is made whole with interest at prime plus 1%; provided, however, that if Children's is the non-investing party, it will share in the repayment of out of pocket expenses on equal footing with the investing Department/Program.

Prior to making an extraordinary investment, the Department Chief/Program Director, Children's Chief Executive Officer (or designee), the General Counsel (or designee), and the Director of TIDO will meet with the faculty member and discuss and agree as to how the investment will be used to further the research and Intellectual Property and review how the future revenue distribution will be altered as set forth in this section.

# VII. Formation of Start Up Companies Based on Children's Intellectual Property

In some cases, Children's may determine that the most appropriate method to bring a technology to the public may be to license the Intellectual Property to a newly formed company and to receive stock, stock options, warrants or similar ownership interests (hereinafter "equity" or "stock") in the company as consideration or partial consideration for the license. In such situations, the new company may wish to execute founder, consulting or scientific advisory agreements with key individuals who contributed to the development of the transferred Intellectual Property. Taking equity in companies to which Children's transfers technology, however, raises serious questions of conflicts of interest both for the institution and individuals. This Policy addresses Children's receipt of equity under license agreements and sets forth steps to guide Covered Persons in the formation and participation in new companies and in the receipt of any equity for founding, consulting or advisory agreements.

Covered Persons may not form or hold equity investments in companies that receive a license of Children's Intellectual Property without prior notification to, and written approval from, his/her Chief or Program Director, the General Counsel and TIDO. Any Covered Person considering forming or receiving equity in such a company must discuss his/her business plans in advance with the Director of TIDO and his/her Chief or Program Director. Upon approval by the Chief/Program Director, TIDO and General Counsel, TIDO will work with the Covered Person to assist in determining if the company in question is the most appropriate method for commercializing the technology and, if so, will provide advice and guidance in the appropriate structure of the company. TIDO will also ensure that the confidential information of Children's is not shared without sufficient protection.

The Foundations and the Departments/Programs are prohibited from making equity investments in any company that receives a license of Children's Intellectually Property without the permission of Children's.

#### **Decision to Accept Equity**

To minimize the possible divergence of the separate interests of the Inventor and Children's, the following will apply. Normally, Children's will acquire equity at the time of licensing, and future equity may be received by Children's as developmental milestones are achieved by the company. Proceeds from equity received by Children's, both upon licensing and as milestones are reached by the company, will be distributed to Inventors, in accordance with this Policy. In this manner, Inventors benefit from the equity received by Children's under licensing agreements for Children's Intellectual Property.

In addition, Inventors may wish to receive equity as a founder of a company or under contractual relationships to provide consulting or scientific advisory functions. Any Covered Person who wishes to take equity from a company that receives a license to Children's Intellectual Property must give prior notice, and receive written approval from, his/her Chief, Program Director, TIDO and the General Counsel. Such review and approval is intended to maintain a fair balance between compensation given under a license and separately to an individual and to ensure compliance with all applicable Children's, Harvard Medical School and Public Health Service policies. The review will include a consideration of the fairness of anticipated revenue to the Inventor and Children's and Inventor's Department and/or Program.

#### **Management of Equity**

Equity received by Children's will be managed in the same way all stock is managed by Children's and may be sold when deemed appropriate in the sole discretion of Children's and in accordance with policies approved by the Children's Medical Center Corporation Investment Committee and Board of Trustees. In choosing the appropriate equity management mechanism, Children's will endeavor to ensure that the designation is consistent with the protection of its academic principles. To this end, Children's will take measures to isolate individuals responsible for equity management from the Inventors who have relationships with industry. Further, Children's believes that if a decision regarding institutional equity presents a conflict between the objectives of protecting academic principles and making sound financial decisions, the protection of academic principles will prevail over Children's opportunity for financial gain.

Once the equity is liquidated by Children's, the cash proceeds (net of expenses and investment costs) will be distributed according the distribution mechanism set forth in Article IV of this Policy.

The decision to accept equity in addition to or in lieu of cash in exchange for the transfer of an Invention, and the management thereof, shall be governed by Children's Guidelines for Managing Equity Obtained in the Transfer of Children's Owned Technology, as the same may be amended from time to time.

## **VIII.** Consulting Arrangements

Children's recognizes that engaging in outside consulting activities may further the Covered Person's knowledge and perspective, and allow the Covered Person to make contributions outside his/her Children's roles to further scientific and clinical advancement and the aims of healthcare. Children's further endorses the Harvard Medical School ("HMS") conflict of commitment policy and acknowledges that, with the permission of a faculty member's Chief or Program Director, (or from the Chief Executive Officer in the case of a Chief/Program Director) a faculty member may devote up to 20 percent of his/her professional time to outside activities, provided that such activities do not compromise the faculty member's responsibilities to Children's or HMS.

Consulting arrangements often present issues that must be addressed prior to the Covered Person entering into any agreement. These issues may include but are not limited to: (a) the services contemplated by the proposed consulting arrangement may materially relate to or draw on work (i) which the Covered Person has done, is doing, or expects to do within the scope of his/her employment by or in association with Children's and (ii) for which he/she has made, is making, or expects to make substantial use of facilities by or through Children's; (b) the proposed arrangement may impose restrictions on the freedom of the Covered Person to communicate with his/her colleagues about his/her consulting work, to publish reports on such work, to establish rights to own and use the fruits of the work, or to patent discoveries and inventions resulting from it; (c) such restrictions may impinge as well on rights and duties of both Children's and

obligations to sponsors of research already under way or contracted or anticipated at Children's; and (d) the proposed arrangement may include substantial financial or equity consideration or place fiduciary obligations on the Covered Person.

Therefore, prior to agreeing to provide consulting services, the Covered Person must secure the authorization of his/her Chief, Program Director, or Vice President, as appropriate, and submit the proposed consulting agreement to the Office of General Counsel for review. The Office of General Counsel will review the proposed agreement solely to protect the interests of Children's and will advise the Covered Person with respect to his/her obligations under Children's and, if relevant, HMS related policies. The Covered Person may wish to have the agreement reviewed by his/her own counsel to protect the individual rights of the Covered Person.

In all instances, all consulting agreements must incorporate by reference and be subject to Children's Mandatory Uniform Consulting Terms, in effect at the time, and any additional terms and conditions deemed necessary.

Consulting arrangements subject to this provision do not include speaking engagements for which the Covered Person receives no or *deminimus* payment, a *deminimus* honorarium or fees for expert witness testimony. Chiefs and/or Program Directors may provide the Program or Department members with additional guidance on *deminimus* exceptions from the prior authorization requirement.

# IX. Foundation and Department/Program Policy Regarding Investment in the Translation of Discoveries/Inventions to Patients

One of the missions of Children's, its Departments, Programs, and Foundations is to translate discoveries into drugs, devices, software products, or administrative procedures that benefit patients. In some cases, this translation will require financial investments that exceed the usual support routinely provided by a Department, Program or Foundation to members of the faculty or to trainees for their work in research and innovation.

However, because the purpose of the Departments, Programs and Foundations is to support the missions of Children's, Departments, Programs, and Foundations may only invest Departmental, Program or Foundation assets in the translation of discoveries and inventions as provided in this section in order to manage (1) the substantial risk of favoritism, (2) conflict of interest if a chief has financial interest, and (3) potential conflict with Children's (e.g., if Children's licenses a technology to a third party and a Foundation or Department/Program is an investor in that party, actions of a Foundation or Department/Program could adversely affect the other – for example, if Children's decided to terminate a license for failure to meet milestones, the Foundation or Department/Program could be financially harmed).

## **Principles:**

1. Departments or Programs may not make any investments of any discretionary funds except by direction from Children's CEO or chief financial officer, and no such investments may be in any entity in which the Department Chief, or Program Director, or a Department/Program faculty member has, or may in the future have, a financial interest. Foundations may not make an investment of Foundation assets, as investors, in any entity in which the Foundation Chief or a faculty member has, or may in the future have, a financial interest.

- 2. Foundation or Department/Program assets may not be used to support advancement of a project in which the Chief is an inventor or in which the Chief claims any intellectual property rights. If the Chief is willing to forego any potential financial interest in the project, Foundation or Department/Program support of the project must be approved in advance by the CEO of Children's.
- 3. Foundations and Departments/Programs may use their assets to support a faculty member to create or advance an idea or technology that will further the missions of Children's. Any support in excess of \$100,000 must be approved in advance by the CEO of Children's. In the event the idea or technology of the faculty member is commercialized by Children's, the Foundation or Department or Program will be entitled to a return of its cash support in excess of \$100,000 plus interest on such excess above \$100,000 at prime plus 1%, subject to the same expenses and requirements as apply to other investments made by the Children's (e.g., legal fees, patent fees, etc.). The Foundation or Department or Program shall receive no equity interest or other return for its support. Support in the form of faculty time, or administrative time, or in-kind support shall not be counted in arriving at the Foundation support for the idea or technology.
- 4. All royalty income, license income, and proceeds of equity resulting from the commercialization of a technology in which Foundation or Department or Program funds in excess of \$100,000 were used will be divided according to the current Children's intellectual property policy. Shares of Children's and its Departments/Programs will go into a current use or endowment fund to be used for the furtherance of academic, clinical, or research missions. A Foundation or Department/Program may, as a condition of providing such support, require the faculty member to agree to relinquish up to 50% of his or her share of any proceeds due under this Policy. Any such interest relinquished will be added to the applicable Departmental/Program share under this Policy and will not go to the Foundation. This includes relinquishing his or her share in licensing fees, royalties and proceeds of equity.

# X. Other Governing Policies

Code of Conduct Conflict of Interest Social Media Policy Use of Name Policy Guidelines for Managing Equity Obtained in the Transfer of Children's Owned Technology Guidelines on Department and Foundation Investment in the Translation of Discoveries/Inventions to Patients

## **Resolution of Disputes**

Any disputes or problems of interpretation that arise in connection with this policy shall be resolved by the Chief Executive Officer with the advice of such persons as he or she may deem appropriate.

## **Effective Date**

This Policy is effective as of the date written below and governs all Covered Persons activities in relation to the subject of this Policy from the Effective Date forward.

Effective Date: January 20, 2015

## XI. Participation Agreement

#### PARTICIPATION AGREEMENT

In consideration of my anticipated/current employment by or association with The Children's Hospital Corporation ("CHILDREN'S"), I hereby agree as follows:

1. I have read, understand and shall comply with the terms of CHILDREN'S Intellectual Property Policy, as amended or supplemented from time to time. I understand that I am a Covered Person, as defined in the Policy. I understand that terms in this Participation Agreement have the meaning assigned to them in the "Definitions" section of the Intellectual Property Policy, a copy of which is attached.

2. CHILDREN'S owns all Intellectual Property developed by me as a Covered Person, subject to any existing obligations that I have identified on Exhibit A.

3. I shall comply with every obligation of CHILDREN'S that applies to me pursuant to any contract, grant or commitment relating to research or other work covered by the Intellectual Property Policy.

4. As required by the terms of the Intellectual Property Policy, I agree to disclose and shall promptly disclose all Inventions, whether or not patentable, copyrightable or otherwise entitled to legal protection, to the Technology Innovation and Development Office ("TIDO") on the appropriate CHILDREN'S Invention Disclosure Form.

5. I further agree to assign and do hereby assign to CHILDREN'S all Intellectual Property developed by me as a Covered Person, subject to any existing obligations that I have identified on Exhibit A, and I shall promptly execute and deliver assignments, and other documents requested by CHILDREN'S, with respect to all such Intellectual Property (except as set forth in paragraph 6), and I shall take all other action pertaining to the Intellectual Property as CHILDREN'S may, from time to time, request of me.

6. Notwithstanding the provisions of paragraph 5, in accordance with the Intellectual Property Policy, CHILDREN'S will grant, and hereby grants, me the right to assign CHILDREN'S copyright (or alternatively, to license such copyright where a license suffices) in any Academic Works that I author; provided, however, that this right only exists where such assignment or license is for an academic or charitable purpose, and my personal compensation is zero or *de minimis*, or limited to a reasonable honorarium or royalties. I understand that the Intellectual Property Policy sets forth my rights and obligations with respect to such Academic Works.

7. I agree to identify and have identified on Exhibit A hereto all agreements I have with other institutions regarding assignment of Intellectual Property. I further agree that, if I am later requested to sign an agreement relating to assignment of Intellectual Property, that I will inform

TIDO and my Department Chief prior to signing such an agreement and inform the other institution of my obligation to CHILDREN'S under this Participation Agreement. I understand that, as appropriate, TIDO will work with the other institution to clarify my assignment obligations and will inform me of any agreement reached. I agree that I shall thereafter assign my rights in Intellectual Property in accordance with such subsequent agreement reached between CHILDREN'S and the other institution.

8. Prior to agreeing to provide consulting services, I will secure the written approval of my Vice President or Chief and submit the proposed agreement to the Office of General Counsel for review. I understand and agree that all consulting agreements must include, at a minimum, Children's Mandatory Uniform Consulting Terms.

9. I agree that all Intellectual Property are the property of CHILDREN'S and are subject to the restrictions on use and disclosure set forth in the Intellectual Property Policy. I agree that all originals of Intellectual Property are to remain at CHILDREN'S, unless otherwise agreed to in writing by CHILDREN'S.

10. I understand that at termination of my employment or association with CHILDREN'S, I may request a copy of data and/or the right to remove tangible material, which CHILDREN'S will consider and may grant. I understand that CHILDREN'S ability to approve such requests may depend on the written consent of a third party. At the request of CHILDREN'S, I shall deliver promptly to CHILDREN'S copies of all written, electronic or other records describing or referencing Intellectual Property, whether or not I am still employed by or otherwise engaged at CHILDREN'S.

Signature:\_\_\_\_\_

Title:\_\_\_\_\_

Depa	artment	:		

Date Signed and Effective:\_\_\_\_\_

## Exhibit A

I hereby identify the following institutions with which I have agreements regarding the assignment of intellectual property, consulting arrangements or other agreements that may relate to my responsibilities to Children's:

Institution	Professional	Describe	Dates of
	Relationship	Arrangement/Agreement	Relationships