



SUBJECT: Intellectual Property Procedure

POLICY: CNMC:A:08BP

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I. PROCEDURE

See Appendix Detail to Follow, pages 2-15.

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III. REFERENCES

CNMC:A:08B - Intellectual Property Policy

(prior to 11/04, was CNMC:FI:06B - Intellectual Property Policy)

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I. GENERAL INFORMATION

A. OBJECTIVE

Children's National Medical Center and its subsidiaries and affiliates, collectively represented herein as "Children's National", strive to support its faculty and employees in securing commercial development of intellectual property resulting from their research so that society may benefit at the earliest opportunity. Faculty and staff who make discoveries and inventions as part of their academic work are encouraged to develop their inventions consistent with the academic mission of Children's National. Children's National has policies and guidelines that provide incentives for its researchers while protecting the integrity of research emanating from the institution. Moreover, Children's National provides an array of administrative services to its inventors to assist them in protecting rights to intellectual property, in satisfying requirements imposed by sponsors of the research, and in fostering commercial development.

B. IMPLEMENTATION

1. The Children's National President and CEO shall cause the establishment of the Intellectual Property Committee (IPC) for the purpose of advising the President and CEO, and the Board of Directors, of the appropriate entity(s) on all matters pertaining to any discoveries, inventions, trademarks or servicemarks, or works of authorship of commercial value by Children's National staff or anyone utilizing Children's National resources.

IPC members will include the Chairperson appointed by the President and CEO, the Chief Legal Officer who will serve as Vice-Chair, the Chief Academic Officer (CAO), the Director of Children's Research Institute (CRI), the CRI Scientific Director, one CRI Center Director, the Vice-President of the Sheikh Zayed Institute for Pediatric Surgical Innovation, the Director of Research Finance, the Director of the Office of Innovations, the Director of Innovation Development, and one staff attorney. The IPC may invite others, e.g. Directors of other Centers or Divisions to participate as necessary in its deliberations.

2. The policies set forth herein have been reviewed and approved by the IPC. The Children's National Office of Innovations (OI) is charged with the administration of these policies relating to Intellectual Property (IP) management including but not limited to patenting, technology transfer and commercialization activities. Issues not expressly addressed herein or matters unresolved by OI will be referred to the IPC for further action. The Children's National Code of Conduct and policies related to Conflicts of Interest are companions to this policy and should be read and consulted. Approved policies and documents related to IP as well as those related to Conflict of Interest (COI) and the Code of Conduct may be found on the Children's National Intranet in Policy and Procedures and are also available on the OI website.
3. Children's National may use a law firm or technology transfer consultant to evaluate, protect, and/or market works of authorship, discovery, trademarks or other servicemarks, or other inventions as the Chief Legal Officer and Vice Chair of the IPC deem advisable under the circumstance.

4. Children's National shall comply with the requirements of OMB Circular A-124 and all other applicable Government policies regarding the prompt disclosure of information on patentable discoveries or inventions resulting from Government-sponsored programs.
5. Intellectual property assets are important to Children's National, and it will vigorously enforce its rights in appropriate circumstances against all infringements. Information concerning unauthorized use of or other possible infringement shall be referred promptly to the Legal Department of Children's National.
6. Disputes on intellectual property matters not resolved by the IPC, including the interpretation of this policy, shall be referred to the President and CEO of Children's National for resolution.

C. PERSONS COVERED

This policy governs all persons employed at Children's National and its subsidiaries and affiliates, including full- and part-time faculty, visiting faculty, full- and part-time agents and employees (staff), full- and part-time students, medical interns and residents, and fellows (pre- and post-doctoral), whether or not they receive all or any part of their salary or other compensation from Children's National.

D. INTELLECTUAL PROPERTY

Intellectual property, as used in this policy, includes not only technology such as inventions, discoveries, creations, or authored works which may be protected legally, such as patents and copyrights, but also the physical or tangible embodiment of the technology, such as biological organisms, plant varieties, or computer software.

E. INTELLECTUAL PROPERTY AGREEMENTS

Children's National requires everyone who has technical responsibilities to the institution or who participates in an internally or externally sponsored research program at Children's National to execute an Intellectual Property Agreement (IPA) assigning rights to intellectual property to Children's National (see also Section II.A.). Each Center Director or Clinical Division Head is responsible for securing execution of the IPA at the outset of the individual's employment or other association with Children's National. For non-student employees, the Human Resources (HR) Office will assist in this process at the time of hire. Electronic copies of the completed forms should be forwarded to OI within two (2) weeks of the time that the individual begins work and the originals retained by the appropriate Center or Division in which the individual has primary assignment as determined by HR. Children's National will provide neither institutional endorsement, sign proposals or grant awards for any individual named in an application for research if the appropriate Center or Division to which the individual has primary assignment has not received a signed IPA from that individual.

F. DISCLOSURE

1. **Internal.** It is the responsibility of the Inventor that all Intellectual Property subject to Children's National ownership under the policies set forth herein is to be disclosed to

OI using an Invention Disclosure Form (IDF) as soon as possible but no later than sixty days of the date that a determination is made that a potentially protectable creation, discovery, or invention as prescribed in this section exists. Failure to do so may result in the forfeiture of all or part of the monies payable to the inventor(s) under the terms of the Distribution of Royalties (Section VI.B.4 and 5).

2. **External.** Disclosure to OI must be made well in advance of any scheduled or anticipated disclosure, presentation, display, performance, or publication of the work to any public audience. Failure to do so may result in loss of rights and subsequent commercial potential both in the U.S. and internationally. Additionally, individuals should consult with OI regarding the need to discuss prospective intellectual property with third parties to ensure that appropriate Confidential and Non-Disclosure Agreements are in place.
3. **Action.** Once notified, through the completion and submission of the IDF, OI will make its best efforts to review the submitted material in a timely manner and, upon receipt of all relevant documentation and in consultation with the inventor or investigator, advise of its decision regarding the disposition of the trademarks, servicemarks, work of authorship, discovery, or invention.
4. **Obligations & Rights.** In the event that OI determines additional information is required, the inventor(s) shall be obligated to provide the requested information before a decision can be made to present such disclosures before the IPC in order to determine intent to pursue intellectual property rights on behalf of Children's National. If the IPC decides to pursue prosecution of disclosed intellectual property, the inventor(s) agrees to provide all requested documentation and other information deemed relevant and necessary by the IPC in a timely fashion. If at such time that the IPC reaches a decision not to continue to pursue or preserve the intellectual property rights, the inventor(s) shall be entitled to appeal if s/he disagrees.

In the event that the IPC chooses not to pursue intellectual property protection on behalf of Children's National, the IPC shall re-assign all rights to the inventor(s) or author(s) according to Section VII below and subject to certain conditions set forth by the regulations appearing in 35 U.S.C. Section 202(d) and 37 CFR 401.9 regarding intellectual property developed with publicly funded sources (e.g. NIH). Inventor(s) and author(s) agree that, upon re-assignment, no Children's National resources (e.g. infrastructure, material resources, research funding, etc.) will be used to continue development of the intellectual property without the expressed written consent of the IPC and subject to terms, conditions and considerations set forth by mutual agreement of the parties in advance.

G. EXTERNAL SPONSORSHIP

When intellectual property is developed under research sponsored by external sources (including federal and state agencies), the research agreement typically provides the sponsor with certain rights to that material and may impose other duties, such as advance notice of publication. The IPC should be consulted for assistance in understanding and complying with such terms.

H. INDEPENDENTLY OWNED PROPERTY

Persons who wish to pursue the development of their independently owned intellectual property may offer it to Children's National by disclosure to OI (Section I.F). OI will evaluate the commercial potential of the work disclosed and determine whether or not it will be accepted for licensing. Acceptance for licensing will require assignment of the property rights to Children's National. Persons covered by this policy (Section I.C) are equally free to choose some other method for commercializing their independently owned works, but they should first ensure that these are, in fact, independently owned, i.e., not subject to Children's National's rights under one or more of the provisions set forth below. Persons electing to pursue independent development and commercialization of their intellectual property are not allowed to use Children's National resources (defined in Section II.B.1).

I. CONSULTING AND OTHER AGREEMENTS

Consulting and other agreements must be reviewed by the Legal Department at Children's National and a copy registered with OI and other offices of Children's National as appropriate. To avoid conflicts with third parties, persons covered by this policy (Section I.C) should carefully examine the intellectual property provisions in agreements with third parties and should seek assistance from OI if problems arise or issues are not clear. Researchers should not sign any agreement with a third party which is inconsistent with the provisions of this policy. For instance, assigning ownership of inventions in a consulting agreement is problematic when the consulting services overlap with research conducted at Children's National and its research institutions.

J. RIGHTS OF OTHERS

Everyone at Children's National is asked to observe the rights of other owners of intellectual property. With very limited exceptions, use of protected intellectual property without the permission of the owner is unlawful and can result in substantial civil and/or criminal penalties.

II. CHILDREN'S NATIONAL MEDICAL CENTER OWNERSHIP RIGHTS

A. POLICY STATEMENT

Works of authorship, technical discoveries, inventions, marks or other items of commercial interest created by or resulting from research or investigations conducted by Children's National staff (including employees, faculty members, fellows, residents, consultants, trainees, students, and volunteers) on Children's National time or by anyone utilizing Children's National resources shall become the property of Children's National (or other appropriate Children's National subsidiary and affiliate) or its assignee. Children's National reserves the right to protect, by patent, copyright, servicemarks, trademarks or other appropriate intellectual property protection such discoveries or inventions and works of authorship.

B. DEFINITIONS

1. **Significant use of Children's National resources:** Any substantial use of Children's National and its research institutes' laboratories, equipment, funds, personnel, or facilities,

except those resources provided generally to all faculty and staff, such as the use of libraries and offices. Questions of whether someone has made a significant use of CRI resources will be resolved by the Chief Legal Officer and the Chief Academic Officer (CAO) of Children's National after reviewing recommendations by the IPC.

2. **Institutional works:** Works created under the auspices of Children's National by employees or contractors as Children's National rather than through personal efforts. All "works for hire" as that term is defined under copyright law are included (Computer programs written by hired programmers are a good example). Works which Children's National commissions non-employees to prepare, such as Children's National publications, architectural designs, engineering studies, and consultants' reports, are also within the meaning of this term. In order to fully protect its interests, Children's National's policy is to obtain an agreement in writing whenever Children's National has an interest in owning a commissioned work.

3. **Mask works:** Two or three-dimensional layouts or topography of an [integrated circuit](#) (IC or "chip"), i.e. the arrangement on a chip of [semiconductor devices](#) such as transistors and passive electronic components such as [resistors](#) and interconnections as designs protected under a federal law administered by the Copyright Office.

C. COPYRIGHTS

1. **General Rule.** In keeping with academic tradition, Children's National generally does not claim for itself copyrights in those books, articles, theses, papers, novels, poems, musical compositions, and similar works which are intended to disseminate the results of the academic research, scholarship, and artistic expression of its faculty, staff, and students.

2. **Exceptions.** Excepted from the general rule above are works which are produced with the significant use of Children's National resources, are institutional works, works subject to license, or are subject to contractual obligations, such as a sponsored research agreement. Ownership of such works vests in Children's National.

D. MASK WORKS

Children's National policy on the ownership of mask works is the same as for copyrightable works under Section II.C.2 above.

E. PATENTS

Ownership of a discovery of invention will vest in Children's National if it results from (1) the efforts of applicable Children's National employees or others as defined in Section I.C above, (2) the significant use of Children's National resources, (3) is an institutional work, or (4) arises out of an externally sponsored research project, consistent with the agreement(s) governing such research.

F. COMPUTER SOFTWARE

Children's National policy on the ownership of computer software is the same as for copyrightable works under Section C.1 and 2 above. In instances where software can be licensable or is part of a patentable invention, Children's National policy concerning ownership of patents is applicable, see Section E above.

III. PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

A. COPYRIGHTS AND MASK WORKS PROTECTION

1. **Copyright Notices.** If materials are published (including any printed, photocopied, typed, microfilmed or otherwise fixed communication such as conventional academic publications, abstracts, master's theses, Ph.D. dissertations, presentation overheads, poster sessions and taped recordings of speeches) without a proper notice as noted below, full protection against infringement is jeopardized. Prior to any publication the following notice should be placed on all materials in which Children's National owns the copyright: Copyright © [year] Children National Medical Center (and /Children's Research Institute or /Sheikh Zayed Institute, if applicable). All rights reserved.
2. **Mask Notices.** To protect mask work rights, the following notice should be applied on all Children's National-owned semi-conductor chip products which incorporate mask works: Mask Work *M* [year] Children National Medical Center (and /Children's Research Institute or /Sheikh Zayed Institute, if applicable). No other institutional, center or division name is to be used in the notice, although the name and address of the appropriate institution, center or division to which readers can direct inquiries may be listed below it. The date in the copyright notice should be the year in which the work is first published (i.e., distributed to any sizable audience).
3. **Registration.** Additional rights and protection for copyrightable material and mask works require registration with the U.S. Copyright Office, which will be coordinated through IPC after disclosure (Section I.F).

B. PATENTS

Recognizing that patent rights can be lost if patent applications are not filed in a timely manner, Children's National will make all reasonable attempts to not delay publication to pursue intellectual property protection. Patent applications for Children's National-owned discoveries and inventions are coordinated through OI. A percentage of all net income from licensing activity as outlined in Section VI.B.5 will be retained by OI to subsidize the support of IP management infrastructure, patent processing, marketing and other related administrative expenses.

C. TRADEMARKS TM AND SERVICEMARKS *SM*

1. **Notice.** To protect trade and service marks, they should be accompanied by the TM or *SM* designations respectively.
2. **Registration.** Additional rights and protection are afforded to trade and service marks if they are registered. Registration should be coordinated through OI. Only registered marks are accompanied by the ® symbol.

IV. TRADE SECRETS

Commercial enterprises which sponsor or are otherwise involved in Children's National research may seek to protect their trade secrets (i.e., proprietary information giving rise to a competitive commercial advantage) with agreements requiring the maintenance of confidentiality. Children's National will not generally enter into such agreements involving Children's National research because of the resultant conflict with Children's National policies of requiring the free and open publication of academic research.

V. TANGIBLE RESEARCH PROPERTY

Intellectual creativity and invention often produces a physical embodiment of the effort. Examples include integrated circuit chips, computer software, biological organisms, engineering prototypes and drawings. The following policies govern the distribution of such Tangible Research Property (TRP) for research and other non-commercial purposes. Commercial licensing of TRP is covered together with the commercialization of intangible intellectual property in Section VI.

A. DISTRIBUTION FOR SCIENTIFIC RESEARCH

The traditions of academic science compel Children's National and its research institutes to make available the results of scientific research promptly and openly. This is no less so for TRP than for intangible results which can be disseminated through ordinary scholarly discourse and publication. Accordingly, TRP should also be promptly and openly made available to other academic scientists for their research, once the TRP has been sufficiently characterized and developed, unless there exist countervailing safety considerations or conflicting legal obligations.

B. CONTROL OF TRP

Control over the development, storage, distribution, and use of TRP is the responsibility of the principal investigator(s) if the research giving rise to the TRP was externally sponsored, and by the CAO if the research was not externally sponsored, but significant Children's National resources (Section II.B.1) were used in the development. This responsibility includes determining if and when the TRP is to be made available to other researchers pursuant to this policy. Principal investigators, division, center, or institute directors should seek advice from OI, the Office of Research Administration or the CAO on all matters of control over TRP.

TRP may only be distributed through a properly executed Material Transfer Agreement (MTA) registered with OI and the Office of Research Administration.

Similarly, TRP to be acquired from external sources must be registered with OI and the Office of Research Administration using either an appropriate accompanying MTA form from the external source or one provided by OI. MTA forms may be obtained from OI, its intranet webpage or through the Office of Research Administration.

C. TRP WITH COMMERCIAL VALUE

Whenever TRP has potential commercial as well as scientific value, persons controlling that TRP should seek guidance from OI on ways to make it available for scientific use without diminishing its commercial value or inhibiting its commercial development.

(Commercialization of intellectual property, both tangible and intangible, is discussed in Section VI.)

D. IDENTIFICATION

Each item of TRP should have an unambiguous name, description and identification code sufficient to distinguish it from other similar items developed at Children's National or elsewhere. OI will work with the Office of Research Administration and investigators to develop a uniform structure of identification.

E. CONDITIONS OF DISTRIBUTION TO RESEARCHERS

Children's National-owned TRP may be distributed to academic researchers at other institutions in many cases without significant preconditions. However, OI should be consulted for appropriate preconditions to be incorporated into MTAs whenever one or more of the following applies:

- a. The TRP is susceptible to commercialization, further transfer, or other inappropriate use so that restrictions on use and transfer are needed.
- b. The recipient is expected to defray the costs of materials and handling incurred in the distribution.
- c. There is a possibility of biohazard or other risk associated with the transport, storage, or use of the TRP, or the recipient might expect to use the TRP in clinical research or some other application posing significant health or safety considerations.
- d. The TRP was developed under a sponsored research agreement or is part of a pending or potential patent application.
- e. Third party restrictions apply to components of the TRP with regard to transfer and use.
- f. The Public Health Service has developed a standard agreement for transfer of biomaterials between academic institutions and OI will develop other situation-specific TRP material transfer agreements upon request.
- g. All TRP transfers subject to the conditions outlined above require pre-authorization from OI or the CAO and appropriate transfer agreements must be completed and recorded with OI.

VI. COMMERCIALIZATION

A. GENERAL

1. **Commercial development through licensing encouraged.** Children's National encourages the commercial development of creative works and inventions for the public use and benefit. Typically this requires that Children's National grant one or more enterprises a license to further develop, use, or sell those works and inventions.

2. **Non-exclusive licensing favored.** Whenever possible, Children's National endeavors to make its creative works and inventions available on a non-exclusive basis; however, in many cases an exclusive license may be necessary to make it economically feasible for an enterprise to undertake commercial development and production.
3. **Costs.** Costs associated with commercialization, such as securing patent or copyright protection, are the ultimate responsibility of the division/center/institute of the individual inventor or author. The IPC will consult with and gain approval from the appropriate Director or Chair, in agreement with the CAO, prior to incurrence of such costs.

B. LICENSING

1. **Initial IPC Action.** After an invention or creation is disclosed to OI and presented before the IPC (Section I.F), OI and the IPC will review such, possibly with the assistance of an outside expert source, with the inventor(s) or author(s) and evaluate its potential for licensing. If it is concluded at that time that its novelty, commercialization and royalty potential are sufficient to justify further efforts toward filing a patent application or securing other appropriate legal protection, an executed assignment agreement (the IPA) by the inventor(s)/author(s) must be in place and on file with OI to proceed.
2. **Third Party Commercialization Assistance.** Children's National may retain third party firms to assist it in the administration and commercialization of its technology. After consultation with the inventor(s) or author(s), IPC may submit the disclosure to such third party firms for review, evaluation and possibly filing of patent applications or other legal protection. If such third party commercialization entity accepts a disclosure for development, Children's National may enter into contractual and financial arrangements with the third party to commercialize the technology and return a share of any financial reward from such commercialization to Children's National. If such financial reward is generated, and income is returned to the Children's National, the income will be distributed in accordance with the formula set forth in Section VI.B.5.
3. **Inventor/Author Assistance.** In order to license inventions or creative works successfully, it is often necessary that the inventor or author work jointly and cooperatively with IPC and the licensee. In all instances, IPC will attempt to minimize the assistance required and, in some cases, the inventor or author is compensated by the licensee for giving assistance.
4. **Distribution of Royalties.** Royalties received by Children's National from license agreements signed on or before June 30, 2011 shall be distributed according to the royalty distribution rules in effect at the time the license was signed. Royalties received by Children's National/ from license agreements signed on or after July 1, 2011 shall be distributed as specified below and shall continue to the heirs/survivors of the inventor or discoverer. Any obligation on the part of Children's National to make payments to the creator, inventor, discoverer, or author's heirs/survivors shall transfer to Children's National or Children's National's designate. Unless otherwise determined, the aggregate share to Center/Division (defined below) will be divided equally among the Center/Division(s) of appointment of record of the inventor(s)/author(s) at Children's National at the time of invention disclosure.

5. **General Rule.** Children's National will deduct non-reimbursed legal and direct administrative expenses incurred in the commercialization of intellectual property from all Royalties resulting in Distributable Net Income (DNI). DNI shall be distributed according to whichever of the following schedules applies:

For intellectual property disclosed before July 1, 2011	
Distributed according to the royalty distribution rules in effect at the time the license was signed.	
For intellectual property disclosed on or after July 1, 2011	
First \$100,000 DNI	
Inventors ¹	50.0%
CRI/CNMC ²	20.0%
Center/Division(s) ³	20.0%
OI ⁴	10.0%
Subsequent \$100,001 to \$250,000 DNI	
Inventors	45.0%
CRI/CNMC	22.5%
Center/Division(s)	22.5%
OI	10.0%
Subsequent \$250,001 and above DNI	
Inventors	40.0%
CRI/CNMC	22.5%
Center/Division(s)	22.5%
OI	15.0%

- ¹ Children's National Inventor(s)'s share of DNI will be divided equally between personal distribution(s) and distribution(s) into an Inventor Research Reserve Fund for allocation specifically to the inventor(s) for supplemental research expenditures. Non-Children's National Inventor(s)'s share of DNI will be distributed directly to the responsible office at their Institution or in the case of Non-Institutional Affiliated Inventors as a personal distribution. Non-Institutional Affiliated Inventor(s)'s share of DNI will be subject to an additional 5% administrative fee.
- ² This share of DNI is distributed to the general budget of CRI or CNMC as determined by the appointment status of the inventor(s) (Section VI.B.4).
- ³ The appropriate Center or Division of the Inventor(s) as defined by his/her appointment status (Section VI.B.4).
- ⁴ The Office of Innovations' (OI) allocation of DNI will be used for the support of IP management infrastructure, patent processing, marketing and any additional administrative expenses associated with technology licensing and commercialization not covered by expenses in VI.B.5.
6. **Exceptions.** DNI generated by institutional works (Section II.B.2) are retained 100% by Children's National, unless there is a written agreement to the contrary. Royalties are allocated by the CAO in consultation with the IPC.

7. **Frequency of Distribution.** DNI received by Children's National will be distributed to inventors/authors and appropriate Children's National's Centers or Divisions on no less frequently than a semi-annual basis. Promptly following January 1 and July 1, the previous period's revenue and expenses will be summarized with the balance distributed to the respective accounts as indicated.
8. **Equity.** Technologies disclosed by Children's National, its research scientists and other staff are offered to potential licensees for commercial evaluation, often during the early stages of developmental research. These early-stage technologies typically require a considerable amount of additional research to prove the value of the technology or to support good patent protection if appropriate. Therefore, Children's National seeks licensees able to demonstrate that they are currently adequately financed or that adequate financing will be available, and that they are willing to focus such resources on the developmental research necessary to advance to technology to a marketable product.

Further, such licensees must be able to meet regulatory requirements for introduction of the technology into the marketplace and to satisfy adequately the market demand for the technology. These licenses are time-limited, and do not grant the right to sell the technology. Separate licensees would subsequently be required to obtain a separate license (exclusive/non-exclusive, internal use only, unpatented TRPs) for further use and development of a technology.

Children's National will generally seek from the licensee the costs of obtaining patent or other intellectual property protection and other customary financial considerations. The combination of developmental costs and risk, and uncertainty as to the potential value of the technology occasionally make it difficult for Children's National to identify a licensee possessing both the requisite capabilities and willingness to assume such financial risks.

Small or startup companies may find it particularly difficult to commit significant cash outlays for both developmental and licensing costs. Accordingly, Children's National may accept equity in a company as partial consideration for technology licensing-related transactions in appropriate circumstances pursuant to the following provisions of this policy:

When the company selected to develop, market, and deliver the technology to the marketplace is not reasonably able to provide adequate compensation for licensing in cash, Children's National may choose to accept equity in that company, in partial lieu of cash, to facilitate the practical application of a Children's National technology for the general public benefit.

Children's National may, if deemed and necessary, engage a third party for the purposes of establishing valuation of equity. Costs of such determination will be borne by the licensee.

Children's National acceptance of equity in consideration of licensing a Children's National technology shall be based upon the principles of openness, objectivity and fairness in decision-making, and preeminence of the education, research and public service missions of Children's National over financial or individual personal gain.

Children's National may retain the right to designate a representative to the board of directors of a licensee in which it holds equity.

The terms of a technology licensing-related transaction, other than those related to the acceptance of equity in the company by Children's National, shall be consistent with Children's National transactions for comparable technologies.

Children's National investigators may perform clinical trials or other comparable licensed-product development or testing for companies in which Children's National or one of its faculty members holds equity as part of the technology licensing-related transaction only after (1) written notification to OI of intent to conduct such activities, (2) review to assess any real or perceived organizational conflict of interest in the performance of such trials or human research activities by the Children's National CRI Institutional Review Board or Research Compliance Committee as appropriate, and (3) after the approval of proposed activities by the such Committees and upon authorization by the CAO.

When Children's National accepts equity in a company as partial consideration for a technology licensing-related transaction, Children's National, taking into account any legal restrictions and the wishes of each inventor involved, shall:

- a. arrange for the inventor(s) to receive his or her share of equity directly from the company upon execution of the relevant agreement; or
 - b. take all equity, including the inventor(s)' share, in the name of Children's National; in which case OI and the IPC will review the matter based upon sound business judgment and publicly available information, make decisions regarding equity disposition, and coordinate with the appropriate Children's National officials if necessary, the inventor(s)' sole right being the receipt of the appropriate share of such equity or its cash equivalent at such time and in such form as deemed appropriate.
 - c. shall determine the inventor(s)' share of equity in lieu of cash in consideration for a technology licensing-related transaction consistent with formulas established in Section VI.B.5.
9. **Inventor's Estate.** For purposes of Sections VI.B.4 and VI.B.5 of this policy, the term "Inventor" should be read to include the inventor's estate, heirs, legatees or assigns.

VII. WAIVER OF INSTITUTIONAL RIGHTS

Children's National will waive its rights to intellectual property in favor of the inventor(s) or author(s) only if Children's National determines that it has no general proprietary interest in the knowledge and that such a waiver: (i) would enhance the transfer of the knowledge into useful applications for the public benefit; (ii) does not raise a conflict of interest; and (iii) is consistent with Children's National's obligations to third parties, particularly the sponsor(s) of the research forming the basis of the intellectual property.

Federal research agreements generally require that universities take title to resulting inventions and discoveries, subject to certain obligations concerning exploitation in the public interest. Decisions by Federal sponsors to permit individual inventors to acquire ownership

are generally made on a case-by-case basis, with the Federal government retaining for itself those rights previously discussed.

Once a nonprofit grantee/contractor organization has waived rights to a particular subject invention, the Government must approve the requested assignment. As an alternative to approving the assignment, the Government may choose to retain rights if it is the opinion of the awarding agency that this is in the public's best interest. In order for an inventor(s) to receive assignment, a formal request to an Agency must be made and may include such materials to be submitted such as a copy of the original invention disclosure, a completed inventor certification form, a statement of the willingness of the grantee/contractor organization to release the rights, a completed set of invention commercialization questions and a complete copy of all patent applications and issued patents pertaining to the invention. OI will work with inventor(s) to complete any required agency forms and documents.

For non-Federal sponsors, Children's National will seek approval of the sponsor prior to releasing its ownership rights in favor of the inventor(s) or author(s).

VIII. DISCLOSURE FORMS

The following forms for disclosure are to be submitted to OI, for consideration by the IPC for subsequent action. These forms may be obtained from OI or on Children's National Intranet Website.

Invention Disclosure Form (IDF)

A document that embodies the date of conception of, a complete description of, and all potential contributors to an invention being disclosed to Children's National.

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