Relationship Disclosure and Management (Conflict of Interest)

1.0 Preamble

The Hospital for Sick Children's (SickKids or Hospital) mission requires collaboration with public and private partners, locally and globally, to improve the health of children and youth. These partnerships are critical to innovation and discovery and staff are encouraged to engage in external activities. Philanthropy is also key to an academic hospital's ability to achieve its mission and often involves individuals and organizations having relationships with the Hospital and staff.

At the same time, the Board of Trustees, Staff and volunteers must carry out their duties in accordance with high ethical standards and professional integrity in order to maintain public trust and institutional integrity. While important, relationships with third parties have the potential to interfere or be seen to interfere with these duties. The purpose of this Policy is to provide guidelines for identifying and disclosing relationships which may give rise to conflicts of interest, and to outline mechanisms for relationship management. The mere existence of a relationship is not inherently bad, and the emphasis in this Policy is on prudent management of relationship, where possible.

This Policy is complementary to other Hospital policies governing the conduct of Staff, volunteers and trustees. Everyone to whom this policy applies must comply with this Policy irrespective of any other conflict of interest policy of any other institution with which they may be affiliated.

2.0 Policy

2.1 Application

This policy (Policy) shall apply to all Staff (as defined below) and volunteers. Questions relating to the application of this Policy should be directed to the relevant Supervisor or to the Relationship Management team at <relationship.disclosure@sickkids.ca>.

Members of the Board of Trustees are governed by the Hospital's By-laws (Article 7) and the Board of Trustee Relationship Disclosure (Conflict of Interest) and Management Policy. The Hospital for Sick Children Foundation (Foundation) and its employees are governed by the Foundation's conflict of interest policy.

2.2 Failure to comply

Failure to comply with this Policy may result in disciplinary action up to and including suspension or termination of employment or appointment with the Hospital, or, where relevant, up to and including suspension or termination of Hospital privileges. Furthermore, it may be required that a serious breach of this Policy be reported to the Staff member's professional body, if applicable.

2.3 Confidentiality

Any information gathered under this Policy shall be held in confidence and used/disclosed only as required to give effect to this Policy or as required by law). See Privacy & Confidentiality of Information.

3.0 Definitions

3.1 Conflict of Interest

A Conflict of Interest exists in any situation where there is a potential divergence between a person's private interests and their obligations to the Hospital such that an independent observer would reasonably question whether the person's behavior or decisions may be motivated by considerations of personal gain, financial or otherwise, from a source other than the Hospital. A Conflict of Interest may be actual, apparent, perceived or potential.

3.2 Consulting

Consulting means providing a professional service related to a Staff member's field or discipline to a third party where the main objective is to further the interests of the third party. Consulting shall include providing advice and services to industry (e.g. a pharmaceutical or medical device company), acting as an advisory board member in a for-profit organization, acting as an expert witness, speaking engagements supported in whole or in part by a for-profit organization, and independent medical evaluations outside of SickKids.

Consulting shall not include clinical or professional services provided under a Hospital service provider contract or pursuant to the mandate of a Hospital division or department (e.g. expert witness services provided by staff of the Suspected Child Abuse and Neglect clinic).

3.3 Designated Staff and Appointees

Designated Staff and Appointees are those individuals/positions required to participate in the Annual Process set out in section 5.1.1 as recommended by the Relationships Management Committee and approved by the Senior Management Committee of the Hospital.

3.4 Executives

Executives include the Hospital's Chief Executive Officer, Executive Vice-President(s), and Vice-President(s).

3.5 External Appointments

External Appointments refer to positions or appointments held outside of SickKids where you serve as an officer, board director or trustee or have a similar duty in a for-profit or not-for-profit organization, a lobby group or industry organization. These positions may include financial benefit or ownership interest.

3.6 Financial Interest

Financial interest includes, but is not limited to, an opportunity to receive anything of monetary value, including salary, royalties, fees, work-in-kind, Gifts or other payments, dividends or distributions, including through equity, partnership or beneficial interests (e.g., stocks, stock options, or other ownership interests), or any Intellectual Property rights.

3.7 Gifts

Gifts include, but are not limited to:

- articles of value such as cash, personal loans, donations or property;
- offers of travel, conference fees, accommodation, meals, entertainment, equipment or other special considerations, including those that might be provided by commercial external sponsors of continuing education programs or conference where the Staff member is playing no other role other than that of an attendee; or
- offers of products or services related to the Staff member's profession, field or discipline.

3.8 Hospital Business

Hospital Business means having an opportunity in your role at SickKids to influence transactions affecting SickKids or the Foundation such as approving contracts, providing input on the engagement of individuals or companies, or recommending the purchase or use of goods. For clarity, this includes participation on a procurement committee evaluating a response to a vendor proposal.

3.9 Intellectual Property, or IP

Intellectual Property means inventions or discoveries (whether patentable or not), technology, technical information, know-how, trademarks, official marks, industrial designs, or literary and artistic works, and other copyrighted materials.

3.10 Non-Research Funding

Non-Research Funding means funding from any for-profit companies or private foundations, received directly or indirectly through any Hospital department or the Foundation, which supports a fellowship salary, salary for administrative roles, education or clinical activities. Non-Research Funding can be through grants, donations, other awards, in-kind support, or through any non-Consulting contracts.

3.11 Personal Associate

Personal Associate means a: (i) spouse or spouse equivalent; or (ii) immediate family member, household member or other person in a close personal relationship who could be perceived to influence your roles, responsibilities and commitments to your Hospital(s) and its patients and/or research participants.

3.12 Professional Development/Public Service

3.12.1 Professional Development/Public Service includes: activities associated with a Staff member's field or discipline undertaken to maintain professional competence and remain informed regarding contemporary developments within a discipline or profession; or activities or services in the community consistent with a Staff member's obligations to the Hospital or the public.

3.12.2 Professional Development/Public Service activities that also qualify as a Relationship requiring disclosure under another section of this Policy need to be disclosed as such.

3.12.3 Examples of Professional Development/Public Service include:

- participation (e.g., speaker, organizer, etc.) at scientific meetings or collegial seminars;
- attendance at professional or trade-related educational activities;
- serving as an editor or part of an editorial board;
- professional affiliations with governmental agencies, or with advisory groups to other nonprofit institutions;

and
- acting as a peer reviewer or participating in granting agency peer-group review panels.

3.13 Relationship

Any association, activity or situation in which a person subject to this Policy or their Personal Associate has/have personal, business, financial, professional, or other interests that may impact, or be perceived to impact, the person's roles, responsibilities and commitments to the Hospital and its patients or research participants.

Of particular importance are Relationships that result in, or may results in, the following:

- a direct or indirect financial benefit to a person or a Personal Associate;
- a gain, advantage or showing of preference to a person or their Personal Associate;
- the use of privileged or confidential information, including personal health information, for personal gain;
- a reciprocal benefit or arrangement between a person or their Personal Associate and an external organization or individual;
- outside interests, activities or commitments that impede or could be perceived to impede a person from meeting their duty to patients and/or research participants or roles, responsibilities and commitments to the Hospital;
- outside interests or activities that may erode the public's trust or the trust of staff in the integrity of the Hospital; and
- any relationship, activity or situation in which the interests of the Hospital or a Hospital decision-maker, acting within their authority on behalf of the Hospital, may impact, or be perceived to impact, the research, education, clinical care, business activities or other activities of the Hospital (Institutional Relationships).

3.14 Relationship Disclosure Form

Relationship Disclosure Form means a form approved by the Relationship Management Committee that is to be used to enable the disclosure of Relationships by Staff, as may be amended from time to time. This form may be provided through the CMaRS system, an equivalent, or any other means approved by the Relationship Management Committee.

3.15 Relationship Management Committee

The Relationship Management Committee is a Hospital committee established under the authority of the Chief Executive Officer for the purposes of assessing Relationship disclosures, and, where possible, developing plans for managing disclosed Relationships.

3.16 Research

For the purposes of this policy, Research is as defined in the Responsible Conduct of Research policy.

3.17 Researcher

For the purposes of this policy, Researcher is as defined in the Responsible Conduct of Research policy.

3.18 Staff

Staff refers to all Hospital employees, Researchers, members of the medical, dental, nursing or professional staff of the Hospital, and trainees including post-doctoral fellows, as well as house staff and students.

3.19 Supervisor

Supervisor means the individual to whom a person reports at the Hospital. In addition, where the Relationship is Research-related, Supervisor also includes the Hospital's Chief of Research (the Chief).

4.0 Requirements applicable to all Staff

Full disclosure of a Relationship, in advance, is critical to ensuring the Relationship is managed in a manner which protects the interests of both the Hospital and the Staff member. This Policy cannot deal unambiguously with every circumstance. Common sense must prevail, and any questions and/or ambiguities must be resolved through consultation with the Relationship Management office, before the Relationship is entered into. Due to the wide range of duties and responsibilities of Staff at the Hospital, mechanisms for management of Relationships will vary among groups, disciplines and/or departments. However, several principles apply to all. These include the following:

4.1 Advance disclosure of Relationships

Staff members must disclose Relationships in advance, using a Relationship Disclosure Form, unless specified otherwise in this policy.

4.2 Use of Hospital facilities, supplies or staff for privately undertaken work

Each Staff member must obtain prior approval for and reimburse the Hospital for all costs (including overhead and salary) associated with the use of Hospital facilities, supplies, or other Staff for privately undertaken work whenever that work entails more than trivial use of those facilities, supplies, or Staff. Whether or not the use of Hospital facilities is trivial shall be determined by the Staff member's Supervisor. The Supervisor may refer the matter to the Relationship Management Committee.

4.3 Personal or Financial Interest of Staff or Personal Associate in Hospital Business

No Staff member will conduct Hospital Business, hire, supervise, evaluate, purchase from, sell to, or engage in any commercial benefit, or authorize, recommend or influence a decision in that regard, with a Personal Associate or an organization in which the Staff member or their Personal Associate (i) has a personal and/or a Financial Interest, or (ii) holds a position as an officer, corporate board director, trustee or similar position, without disclosing the activity using a Relationship Disclosure and receiving prior approval from the Relationship Management Committee.

4.4 Gifts

No Staff member will accept Gifts of more than Nominal Value from individuals or business organizations doing business with the Hospital. "Nominal Value" means a gift with a value that is small and incidental in nature.

Luncheons, dinners, or business organization meetings with supplier representatives on an infrequent basis are helpful in establishing better business understanding, and are neither questionable nor unethical provided the Staff member remains free of obligations. Any Staff member who is offered or receives a gift of more than Nominal Value shall refuse or return it to the giver in a tactful and dignified manner, advising the giver of the Hospital's Policy prohibiting its acceptance.

Whether or not a gift is of Nominal Value shall be determined by the Staff member's Supervisor. In determining Nominal Value, Supervisors shall consider the frequency and nature of the gift and whether the Staff member or Hospital might be perceived to be influenced in making business or patient care decisions because of accepting such a gift. The Supervisor may refer the matter to the Relationship Management Committee.

4.5 External Appointments

There are many circumstances in which it will be beneficial for Staff to hold External Appointments at organizations outside of the Hospital. In order to ensure that such Relationships are appropriately managed, the Staff member must disclose any External Appointments using a Relationship Disclosure Form.

4.6 Consulting

4.6.1 Consulting may be permitted provided that the activity does not detract from the Staff member's primary commitment to the Hospital and that neither the Hospital nor patient care is adversely affected in any way. *Appendix A- Consulting* sets out general guidelines regarding Consulting applicable to certain categories of Staff.

4.6.2 In addition, some departments may place restrictions on Consulting activities. The Hospital's funding agreements with the Ontario Ministry of Health (MOH) restrict physicians that are full-time members of (a) the Department of Paediatrics and the Paediatric Consultants Partnership, or (b) full-time members of SickKids Perioperative Services and the Paediatric Specialties Association, from directly or indirectly billing/ claiming or accepting any payment from the Ontario Health Insurance Plan (OHIP) or any person, or authorizing or permitting any person to bill/claim or accept payment on their behalf from OHIP or any person, for any clinical activities outside of SickKids and related sites, except as expressly permitted by the agreement. All full-time members of (a) the Department of Paediatrics and Paediatric Consultants Partnership, or (b) SickKids Perioperative Services and the Paediatric Specialties Association, must disclose all other clinical activities including out-of-province and out-of-country to their Supervisor in addition to completing a Relationship Disclosure Form.

4.6.3 Insurance Coverage. Staff members should ensure that they have sufficient insurance coverage in order to protect themselves against liabilities that may arise as a result of their Consulting activities. In addition, the Staff member will defend, indemnify and hold harmless the Hospital for any such liabilities. Accordingly, it is recommended that the Staff obtain independent legal advice before pursuing Consulting activities.

4.6.4 Terms of Consulting agreement. In the event of a conflict between the provisions of any Consulting agreement between a Staff member and a third party, and the terms and conditions of a Staff member's employment or appointment at, or association with, the Hospital, the terms of employment or appointment shall prevail. Accordingly, all Consulting contracts shall contain the following paragraph: "The terms and conditions of employment/appointment at The Hospital for Sick Children and the provisions of any agreement between The Hospital for Sick Children and external sponsors of projects on which the consultant works as part of their Hospital duties shall prevail in the event of any conflict with the provisions of this agreement."

4.6.5 Hiring Hospital Staff for Consulting activities. No Staff member shall, without prior approval of their Supervisor, hire or directly supervise another Staff member for their Consulting activities while simultaneously serving as the Hospital Supervisor of the same Staff member. In any case, the work of Staff

must not be constrained by, or exploited in the course of, a Staff member's Consulting activities. Staff must maintain at all times an atmosphere free from unwarranted external influences.

4.6.6 Payment. Generally, revenue received by Staff for their Consulting activities is to be paid to them directly by the organization retaining them, and shall not be considered supplementary income from the Hospital.

4.7 Professional Development/Public Service

A Staff member, upon making a request to their Supervisor, may be granted a reasonable amount of time to participate in Professional Development/Public Service such that the level of involvement does not detract from the Staff member's primary commitment to the Hospital. The Supervisor may refer the matter to the Relationship Management Committee.

4.8 Unrelated activities

Where Staff members pursue other activities for financial or personal gain such as outside employment or conducting a business, unrelated to their professional field or discipline, such activity must take place on personal time, outside of the Hospital and not detract from the Staff member's primary commitment to the Hospital. The Staff member must disclose the Relationship to their Supervisor and comply with all Hospital and departmental policies. The Staff member's Supervisor may refer the matter to the Relationship Management Committee.

4.9 Relationships with external entities

4.9.1 Institutional Relationships. The Executive of the Hospital is responsible for identifying, disclosing, and managing all Institutional Relationships, in order to preserve the public trust, protect the integrity of the hospital's primary missions of patient care, education, and Research, and is accountable to the Board of Trustees in this duty. The CEO may refer any matters involving Institutional Relationships to the Relationships Management Committee.

4.9.2 Staff personal and/or Financial Interests in prospective Institutional Relationships. Prior to the Hospital entering into any of the following Institutional Relationships with an external entity, the involved Staff member must disclose the Relationship using a Relationship Disclosure Form:

a) Gifts to the Hospital which will be under the control of, or will directly support the clinical, teaching or Research of the Staff member and Non-Research Funding from an organization (or individual) in which they or their Personal Associate(s) (i) has a personal and/or a Financial Interest, or (ii) are an officer, corporate board director, trustee or have a similar duty;
b) business transactions, sponsored projects or Research proposals, proposals from subcontractors, vendors, or collaborators in which any of the involved Staff members or their Personal Associate(s) (i) have a personal and/or a Financial Interest, or (ii) are an officer, corporate board director, trustee or have a similar duty.

4.9.3 Support of donors. The Hospital relies on the generous support of individual donors, donor companies and other organizations to provide financial support for Hospital sanctioned activities including Staff social events. The potential or real or perceived influence by these parties, particularly if they are vendors, suppliers, contractors or potential vendors, suppliers or contractors, exists and care must be taken not to embarrass either party by allowing the circumstances for this to occur. Staff members shall ignore any donor relationship in decisions taken on contractual, financial or exchange of goods or services basis. Any attempts to influence based on a donor relationship must be reported to the Supervisor. See Code of Conduct, University of Toronto Sponsorship of Educational Events, and Supply Chain Code of Ethics.

4.10 Disclosure of funding sources and Relationships in publications

When publishing the results of Research or other Hospital projects, Staff must disclose the source of any external funding and any Relationships/activities/interests related to entities whose interests may be affected by the content of the publication. For clarity, any Relationships or interests pertaining to the subject matter of the publication should be disclosed, even if they are not mentioned in the publication.

Staff are required to comply with the requirements of the entity publishing the material, if any. If the entity publishing the material does not have any specific requirements, or where the requirements are vague, Staff should follow the International Committee of Medical Journal Editors (ICMJE) requirements outlined in their Disclosure of Interest form.

4.11 Use of Hospital name

The Hospital does not endorse services, organizations or products. Neither the name of the Hospital nor its photograph nor its logo may be used by other organizations in any way without the permission of the Director of Public Affairs. See Use of SickKids Name, Photograph and Logo.

4.12 Start-up companies

Subject to the discretion of the CEO, the management activities of a start-up company must take place outside of the Hospital. All relevant sections of this Policy (including but not limited to Sections 4.2 and 4.9.2) apply.

4.13 Use of Hospital facilities for external colleagues

Occasionally, Staff at the Hospital, because of their particular expertise and the availability of specialized equipment, are called upon to perform services for external colleagues, including, but not limited to, analyses or laboratory tests. While the provision of such services is encouraged in the spirit of collegiality, the Staff must receive prior approval, and remuneration generated from such services cannot be retained personally by Staff. All such compensation is to be deposited into a Hospital account, and used for Hospital activities as approved by the Staff member's Supervisor.

4.14 Volunteers

Supervisors are responsible for ensuring volunteers disclose all relevant Relationships.

4.15 Obligations to Research funders

In addition to disclosing Relationships through the Relationship Disclosure Form, all Researchers are responsible for being aware of and complying with the terms of the agencies and companies that support their Research activities, including but not limited to conflict-of-interest provisions (See 5.15 Other Hospital Processes). Staff conducting Research that is funded or proposed for funding by the Public Health Service of the United States Department of Health and Human Services, including the National Institute of Health, must comply with the terms set out in *Appendix B- Public Health Service (PHS) Funded Research.*

4.16 Disclosure to Research Ethics Board

All Researchers must also disclose any relevant Relationships in all Research Ethics Board application forms and in informed consent forms as required by the Hospital's Research Ethics Board.

5.0 Procedures for Managing Relationships

5.1 Disclosure

5.1.1 All Staff are required to report Relationships as soon as a requirement under this Policy is triggered and before the Relationship is entered into.

5.1.2 Annual Attestation and Disclosure. On an annual basis, Designated Staff and Appointees shall submit a Relationship Attestation and Disclosure Form in a manner approved and amended from time to time by the Relationship Management Committee.

5.1.3 Transactional Disclosure

Advance Disclosure. On an ongoing basis, Staff are required to disclose all Relationships as soon as they arise and before a commitment to the Relationship is made through the submission of a Relationship Disclosure Form or by providing an update to previously disclosed Relationships, unless specified otherwise in this Policy.

Research, Licensing Arrangements, and Purchasing. Prior to applying for Research Ethics Board approval, entering into a licensing arrangement in which you are an inventor or owner, or participating in a purchasing decision, evaluation, recommendation, or negotiation, Staff are required to affirm the accuracy and completeness of their Relationship Disclosure Form and make appropriate updates. Staff participating in procurement processes will also be required to complete conflict of interest declarations issued by the Procurement Office.

5.1.4 Urgency. Where an unforeseeable situation of urgency arises that is beyond the control of a Staff member, and urgent review of a Relationship is required which cannot wait until the next scheduled meeting of the Relationship Management Committee (where Relationship Management Committee review is required or desired), the affected Staff member shall submit a Relationship Disclosure Form and contact the Relationship Management office to advise of the urgency. Any two of a Co-Chair of the Relationship Management Committee and the Director responsible for relationship management will review and make decisions about urgent matters and report back to the Relationship Management Committee at its next regularly scheduled meeting.

5.1.5 Other Hospital Processes. Disclosure of Relationships through the submission or updating of a Relationship Disclosure Form is supplemental to other internal processes requiring the disclosure of relationships, including those related to procurement and external research grant applications. Staff must disclose Relationships in both avenues, and information collected under this Policy may be used to support other internal Conflict-of-Interest disclosures or attestations.

5.2 Review Process

5.2.1 Intake. The Relationship Management office will collect and conduct an initial review of all disclosures and consult with the Faculty Office, relevant Supervisor(s) and Department Chief(s) as appropriate.

5.2.2 Review of Relationship Disclosures. The Relationship Management Committee shall establish a framework for determining which Relationship disclosures can be handled administratively by the Relationship Management office and which Relationship disclosures will receive full consideration by the Relationship Management Committee. Where a Relationship disclosure is considered by the Relationship Management Committee, the Staff member disclosing the matter shall be given an opportunity to provide

input to the Relationship Management Committee. The Relationship Management Committee may also receive submissions from the relevant Department Chief and any other person that may, in its opinion, offer expertise on the matter.

The Relationship Management Committee shall determine the management plan for all disclosed Relationships and, where the Relationship Management Committee determines that the Relationship cannot be adequately managed, it is authorized to prohibit the Relationship.

Relationship disclosures for Executives shall be managed by the Chief Executive Officer together with the Relationship Management office and with oversight by the Board of Trustees. Trustee Relationship disclosure shall be handled in accordance with the Board of Trustee Relationship Disclosure (Conflict of Interest) & Management Policy.

5.2.2.1 Consideration of impact on Staff member's ability to meet obligations to Hospital. Consideration will be given on the extent to which the disclosed Relationship will affect the ability of the Staff member to meet their duties, responsibilities and commitments to the Hospital, and enhance, as relevant, the clinical, teaching, Research, and/or service responsibilities of the Staff member.

5.2.2.2 Consideration of impact. Consideration will be given to the importance of the Relationship to the mission of the Hospital as well as any potential consequences that might result from a Relationship. For example, the effect on public perception of the activities taking place at the Hospital, or on the practices of other Staff within the Hospital and staff at other hospitals.

5.2.2.3 Consideration of how Relationship(s) can be Managed. Where relevant, consideration will be given to the extent to which the disclosed activity can be accommodated without interfering with work being carried out at the Hospital. Emphasis will be placed on the establishment of management plans to address any concerns raised by Relationship disclosures. In some cases, disclosure alone may be adequate. In other cases, additional steps may be required. In the event that a Staff member disagrees with the plan of management proposed by the Relationship Management Committee, they may appeal the matter to the Chief Executive Officer in accordance with section 5.2.3.

5.2.2.4 Timing of Decision. The Relationship Management Committee shall consider Relationship Disclosure Forms and render a decision in writing in a timely manner.

5.2.2.5 Documentation and monitoring of approved activity. If permission to proceed with a Relationship is granted, the Supervisor is responsible for overseeing Staff compliance with this Policy, any management plan imposed and nothing in this Policy affects a Supervisor from taking steps outside those included in the management plan to ensure that the Relationship does not adversely impact the Hospital or their department goals or objectives, or where relevant subject the Hospital to any liabilities. To fulfill this responsibility, the Supervisor may attach further conditions to and restrictions on the approval as necessary in their discretion, for example, requesting periodic written reports. The basis of the permission, the written approval, and the content of any reports shall be maintained by the Supervisor, and copies shall be filed in the Staff member's file. All records shall be subject to the review by the Relationship Management office, Relationship Management committee, the relevant Division Head, Department Chief, the President and Chief Executive Officer, and the Chief of Research to the extent required to carry-out duties under this Policy.

5.2.2.6 Changes to situation. Once approval is received, the Staff member must complete a further Relationship Disclosure Form in the event there are any material changes to the information originally provided as continued approval is subject to review as the circumstances change.

5.2.2.7 Permission denied. If approval to proceed with a Relationship is denied, the Staff member shall be provided in writing with the reasons for the denial.

5.2.3 Appeals. An appeal of a decision of the Relationship Management Committee in respect of a disclosed Relationship may be made to the Chief Executive Officer. A decision of the Chief Executive Officer is final and binding.

6.0 Related Documents

Appointment and Review of Scientific Staff

Intellectual Property

Research Agreements: Eligibility, Review and Approval

Code of Conduct

Appendix A - Consulting

All Consulting activities must be identified and managed in accordance with the Policy.

1.0 Definition

The definition of Consulting set out in section 3.2 of this Policy, shall apply to this Appendix A.

1.1 Application

To assist Staff members in planning their activities, this Appendix A sets out conditions under which Consulting is generally permissible for the following categories of Staff only:

- physicians
- senior scientists
- scientists
- senior associate scientists
- associate scientists
- scientist-track investigators
- project investigators
- emeritus scientists
- team investigators

For greater clarity, these are guidelines only. Consulting activities must be disclosed regardless of value and are subject to review by the Relationship Management Committee.

1.12 Full-time Staff

Consulting on one or many occasions for up to 20 working days or 200 hours in a calendar year.

1.13 Part-time Staff

Part-time shall include Staff members who are classified as casual workers, and those who have a regular schedule of less than the full-time equivalent for their specific job at the Hospital. The limits set out in Section 1.12 shall be prorated for part-time Staff members. For example, where a Staff member holds a half-time position, their limits on Consulting during scheduled working hours will be 10 days (100 hours) for any one activity and in total per calendar year respectively before written approval is necessary.

Appendix B – Public Health Service (PHS) Funded Research

1.0 Purpose

The following is an appendix to the Relationship Disclosure and Management Policy. It applies to all research funded or proposed for funding by the Public Health Service (PHS) of the U.S. Department of Health and Human Services, including the National Institutes of Health (NIH). The purpose of this appendix is to implement the requirements of the federal regulations set forth in 42 CFR Part 50 and 45 CFR Part 94, and any additional regulations that may be in effect from time to time, governing Investigators' responsibilities for promoting objectivity in PHS-Funded Research. This policy shall be construed in accordance with such regulations and shall be deemed to include any requirements set forth in such regulations that are not expressly set forth below.

2.0 Covered Parties

This appendix applies to all persons responsible for designing, conducting or reporting PHS-Funded Research under the auspices of The Hospital for Sick Children (the Hospital).

3.0 Definitions

Designated Official: an institutional official designated to solicit and review disclosures of Significant Financial Interests from Investigators. The Designated Official shall be the Chief of Research and/or such other individual(s) as the Hospital may designate in writing. All references herein to the Chief shall be deemed to refer to such other Designated Official(s) as appropriate.

Financial Conflict of Interest (FCOI): a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-Funded Research.

Institutional Responsibilities: an Investigator's professional responsibilities on behalf of the Hospital including but not limited to research, research consultation, teaching, professional practice, and administration such as service on committees, boards and panels.

Investigator: the principal investigator or project director, or any other person, regardless of title or position, who is responsible for either the design, conduct, or reporting of PHS-Funded Research, which may include, for example, collaborators or consultants.

Manage: taking action to address a Financial Conflict of Interest, which can include reducing or eliminating the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PHS-Funded Research: Research funded by or proposed to be funded by the PHS, including without limitation NIH grants. The term includes any Research for which funding is available from a PHS awarding component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

Research: a systematic investigation to establish facts, principles or generalizable knowledge. Research uses scientific methods and standardized protocols; some studies of individual subjects, and some innovations in patient care, may also be considered to be research. The term encompasses basic and applied research as well as product development (e.g., a diagnostic test or drug), and may involve

subjects through their physical participation and/or through collection or use of personal health information, tissue or biological fluids.

Significant Financial Interest (SFI):
A financial interest consisting of one or more of the following interests of an Investigator, or the Investigator's spouse or dependent children that reasonably appears to be related to the Investigator's Institutional Responsibilities:
a. **With regard to a publicly traded entity**, a significant financial interest exists if the value of any remuneration from the entity in the 12 months preceding the disclosure of the SFI and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5000 USD. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship fees). Equity interest includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

b. **With regard to a non-publicly traded entity**, a significant financial interest exists if the value of any remuneration, as described above, received from the entity in the 12 months preceding the disclosure of the SFI, when aggregated, exceeds $5000 USD or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interests).

c. **Intellectual property rights and interests (**e.g. patents, copyrights) upon receipt of royalties or other income related to such rights and interests that exceed $5000 USD.

d. **Reimbursed or sponsored travel** (sponsored travel being that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to an Investigator's Institutional Responsibilities. Disclosures will include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The initial disclosure of reimbursed or sponsored travel must include reimbursed or sponsored travel that is received in the preceding 12 months.

Exceptions: "Significant Financial Interest" does not include:
a. Salary, royalties, or other remuneration paid by the Hospital to the Investigator, if the Investigator is currently employed or otherwise currently holding an appointment at such institution;

b. Intellectual property rights assigned to the Hospital and agreements to share in royalties related to such rights (e.g., an Investigator's royalties received under the Intellectual Property Policy.);

c. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the

Investigator does not directly control the investment decisions made in these vehicles; and

d. Income from seminars, lectures, teaching engagements, service on advisory committees or review panels, or travel expenses that are reimbursed or sponsored by U.S. Federal, state, provincial or local government agencies; institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching Hospitals, and medical centres.

4.0 Requirements

4.1 Investigator Responsibilities

This appendix requires Investigators to (i) disclose Significant Financial Interests (including financial interests of the Investigator's spouse and dependent children), (ii) comply with the Review Process, and (iii) complete training with respect to PHS-Funded Research. (Training is dealt with in section 4.6 below.)

4.1.1 Disclosure. Every Investigator must disclose all of his or her Significant Financial Interests ("SFIs"), and those of the Investigator's spouse and dependent children, that reasonably appear to be related to the Investigator's Institutional Responsibilities. The Investigator is not charged with making a determination as to whether the SFI constitutes a conflict of interest or could affect the design, conduct or reporting of the PHS- Funded Research. That determination is made by a Designated Official, as described above. Investigator disclosures are required as follows:

a. **Upon Application.** Each Investigator who is planning to participate in PHS-Funded Research must disclose SFIs to the Hospital's Research Integrity Office no later than the time of application or submission of a formal proposal for the PHS-Funded Research. This will be initiated by the Grants Management Office. With respect to SFIs of reimbursed or sponsored travel, disclosures will include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

b. **Annually.** Each Investigator who is participating in PHS-Funded Research must submit an updated disclosure of SFIs at least annually during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph "a" above, or in any subsequent disclosure of SFIs, and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

c. **New SFI.** Each Investigator who is participating in PHS-Funded Research must submit a disclosure within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI.

4.2 Process for Reviewing Investigator Significant Financial Interests

4.2.1 Initial Review and Action. Before the Hospital disburses any funds for a PHS-Funded Research project, the Designated Official will do the following directly or acting through the Research Integrity Office or the Research Institute Conflict of Interest Review Committee (the latter described in more detail in 4.2.3, below):

a. Solicit and review Investigator Significant Financial Interest ("SFI") disclosures and any other information deemed relevant (e.g. research proposal summary, IRB application, etc.). In connection with this review, the Designated Official may require the Investigator to provide additional information;

b. Using Institutional guidelines, determine (1) whether an Investigator's SFI is related to PHS-Funded Research, and if it is, (2) whether the SFI is a Financial Conflict of Interest ("FCOI"); and

c. Take such actions as necessary to manage the FCOI, including development and implementation of a management plan (see section 4.3, below).

4.2.2 Financial Conflict of Interest. An Investigator's SFI is related to PHS-Funded Research when the Institution, through its Designated Official, reasonably determines that the SFI could be affected by the PHS- Funded Research or is in an entity whose financial interests could be affected by the PHS-Funded Research. A FCOI exists when the Hospital, through its Designated Official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-Funded Research**.**

4.2.3 Review Committee on Research Conflicts of Interest ("Review Committee"). Where a FCOI is identified, the Review Committee will be asked to review the COI and develop the management plan. The Review Committee will be composed of Research Institute Associate Chiefs, the Research Integrity Advisor and either the Executive Director of Research Operations or the Chief of Research. Designated counsel from Legal Services will be involved on an as-needed basis but will not be members of the Review Committee. A majority of the committee members must be present to constitute a quorum. The Committee is empowered to act by majority vote of the members present at a meeting at which a quorum is present, or by written or electronic consent of a majority of all members.
The Review Committee will review the facts and on a case-by-case basis to determine (1) whether the Investigator's SFI is related to PHS-Funded Research and, if it is, (2) whether the SFI is a FCOI, confirming the initial review conducted by the Designated Official or the Research Integrity Office. Investigators may be required to provide additional information.
The Review Committee will prepare a report for the Chief detailing a recommended management plan, including any proposed conditions or restrictions to manage the FCOI.

4.2.4 Decision by Chief. If the Review Committee determines that a FCOI exists, it will submit a report of its determination and recommended management plan to the Chief. The Chief may return the report to the Review Committee for clarification or supplementation, and will accept, reject or modify the Review Committee's determination and recommendation. The Chief will make a final determination in writing and specify the conditions or restrictions, if any, that should be imposed to manage the FCOI. The Chief or the Research Integrity Office will provide copies of the final decision to the Investigator, the Investigator's Program Head, Chair of the Investigator's department (if applicable), the Research Ethics Board (if human subjects research is involved), and the Grants Management Office.
On occasion, normally with respect to existing management plans, the Chief may provide for administrative handling, consisting of a letter issued by the Research Integrity Office, providing appropriate guidance and, if warranted, stating that no additional safeguards or conditions are needed.
Upon receipt of the decision, the Investigator must either acknowledge it or submit an appeal. Funding will be held until the Investigator agrees to comply with the management plan.

4.2.5 Investigator Appeals. The Investigator has 10 days from receipt of the Chief's final decision to submit an appeal in writing to the Executive Vice-President, Corporate as applicable. The appeal should include the specific provisions being challenged, the reason for the appeal, and the justification for a different outcome. The Investigator may also provide an alternative management plan and any supplemental information that might be helpful to the Executive Vice-President, Corporate in making a final determination. This decision shall be final.

4.2.6 Submission of the Research Application. The Hospital will certify in the application to the Hospital's effective, implemented policy and full compliance with the federal regulations at 42 CFR Part 50 and 45 CFR Part 94, as specifically enumerated in 42 CFR §50.604(k)(1)-(5) and 45 CFR §94.4(k)(1)-(5).

4.2.7 Institutional Remedies.
a. Investigators are required to comply with the final decision of the Chief or the Executive Vice-President, Corporate. If an Investigator fails to comply, the Chief, with the aid of the Review Committee, will develop a corrective action plan.

b. The Hospital may impose sanctions for non-compliance including suspension, denial of eligibility to engage in Research, or other appropriate penalties. Such sanctions may require giving notice to professional bodies or journals, or the public.
c. If an Investigator fails to comply with this appendix or a management plan in a way that could have biased the design, conduct, or reporting of PHS-Funded Research, the Hospital shall promptly notify the PHS awarding component of the corrective action taken or to be taken (e.g., a mitigation report for the PHS-Funded Research, as further described below), and implement corrective action.

4.3 Management of Financial Conflict of Interests

4.3.1 Management Plans. Each management plan shall specify the actions that have been, and shall be, taken to manage the FCOI.

4.3.2 Conditions or Restrictions. Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:
a. Public disclosure of the FCOI (e.g., when presenting or publishing the research);
b. For PHS-Funded Research projects involving human subjects research, disclosure of the FCOI directly to the human subjects as approved by the Research Ethics Board;
c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the PHS-Funded Research against bias resulting from the FCOI;
d. Modification of the research plan;
e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the PHS-Funded Research;
f. Reduction or elimination of a financial interest (e.g., sale of an equity interest); and
g. Severance of relationships that create the FCOI.

4.3.3 Clinical Research. The existence of a FCOI related to a clinical research project creates a rebuttable presumption that stringent management of the FCOI is appropriate. In any case in which the U.S. Department of Health and Human Services determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Hospital as required, the Hospital shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

4.3.4 Monitoring Compliance with the Management Plan. The Research Integrity Office will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-Funded Research.

4.4 New SFIs during ongoing PHS-Funded Research.

Whenever, in the course of ongoing PHS-Funded Research, an Investigator who is new to participating in the PHS-Funded Research discloses an SFI or an existing Investigator discloses a new SFI, the Designated Official will do the following, acting directly or in conjunction with the Review Committee, within sixty (60) days:
1. review the SFI;
2. determine whether it is related to PHS-Funded Research;
3. determine whether a FCOI exists, and, if so;

4. implement a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI

4.5 Review of Existing SFIs and Retrospective Review during ongoing PHS-Funded Research.

The Designated Official, acting directly or in conjunction with the Review Committee, will take the following actions with respect to a Financial Conflict of Interest in ongoing PHS-Funded Research:

4.5.1 Review of Existing SFIs. Whenever the Hospital identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed during ongoing PHS-Funded Research (e.g. was not timely reviewed or reported by a sub-recipient), the Designated Official will, within sixty (60) days, undertake the same review, determinations and management plan implementation set forth in Sections 4.2 and 4.3, above.

4.5.2 Retrospective Review. Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI that is determined by the Institution to constitute an FCOI, failure by the Hospital to review or manage such an FCOI, or failure by the Investigator to comply with an FCOI management plan, the Designated Official will, within 120 days of the Hospital's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-Funded Research to determine whether any PHS- Funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in design, conduct, or reporting of such Research.

The Research Integrity Office will document the retrospective review in accordance with federal requirements set in 42 CFR, Part 50, Subpart F, §50.605(a)(3)(ii)(B)(1)-(9), for PHS-funded research grants or cooperative agreements, or 45 CFR Part 94, §94.5(a)(3)(ii)(B)(1)-(9), for PHS-funded research contracts, and if appropriate, will update the previously submitted FCOI report, describing the new management plan.

4.5.3 Notification and Mitigation Report. If the Designated Official finds bias in the design, conduct, or reporting of PHS-Funded Research, the Research Integrity Office will notify the PHS awarding component promptly and submit a mitigation report, as required by and including all key elements specified in 42 CFR, Part 50, Subpart F, § 50.605(a) (3) (iii) and 45 CFR, Part 94, § 94.5(a) (3) (iii), described further in section H (3), below.

4.5.4 Interim Measures. At any time, the Designated Official may determine that interim measures are necessary with regard to the Investigator's participation in the PHS-Funded Research.

4.6 Training

Every Investigator will complete training on Investigator policy responsibilities at the following times:

1. Prior to engaging in PHS-Funded Research and at least once every four years thereafter;
2. When this appendix is revised in any manner that affects the requirements of Investigators;
3. When an Investigator is new to the Hospital, even if the PHS-Funded Research has already begun;
4. When an Investigator is not in compliance with this appendix or a management plan, as determined by the

Designated Official.

4.7 Sub-recipients

If the Hospital is the grantee and conducts PHS-Funded Research through a sub-recipient (e.g. subcontractors or consortium members), the Designated Official will take reasonable steps to ensure that sub-recipient Investigators comply with this policy, as follows:

4.7.1 The Hospital's written agreement with the sub-recipient will establish whether this policy or the sub-recipient's FCOI policy will apply to the sub-recipient's Investigators. The written agreement will state either that:
a. The sub-recipient certifies that its FCOI policy complies with the applicable federal regulations, and that the sub-recipient's Investigators will comply with the sub-recipient's policy or,
b. If the sub-recipient cannot provide such certification, that sub-recipient Investigators are subject to this policy.

4.7.2 If the sub-recipient's policy applies, the written agreement will specify the time period(s) for the sub-recipient to report all identified FCOIs initially and annually thereafter to the Hospital. The time period(s) will be sufficient to enable the Hospital to provide FCOI reports to the PHS prior to the expenditure of funds and within 60 days of finding any additional FCOI.

4.7.3 If the Hospital' policy, as awardee, applies; the sub-recipient Investigators will disclose all SFIs that are directly related to the sub-recipient's work for the Hospital. The written agreement with the sub-recipient will specify the time period in which to comply, sufficiently allowing the Hospital enough time to comply timely with its review, management and reporting obligations, e.g., to provide FCOI reports to the PHS prior to the expenditure of funds, within 60 days of finding any additional FCOI and annually thereafter.

4.8 Reporting of Financial Conflict of Interest

4.8.1 Prior to the Institution's expenditure of any funds under PHS-Funded Research, the Designated Official shall provide to the PHS, as required, an FCOI report regarding any Investigator's FCOI (unless eliminated) and ensure that a management plan has been implemented. The report to PHS will contain all the information required under federal regulations at 42 CFR, Part 50, Subpart F, § 50.605(b) (3) and 45 CFR, Part 94, §94.5(b) (3), as applicable.

4.8.2 For newly acquired FCOIs during ongoing PHS-Funded Research, described in Section 4.4 above, the Designated Official shall provide to the PHS awarding component, within sixty (60) days, a report ensuring that the Hospital has implemented a management plan.

4.8.3 For FCOIs not previously disclosed, reviewed or managed during ongoing PHS-Funded Research, described in Section 4.5 above, the Designated Official shall, if the retrospective review results in a finding of bias in the design, conduct or reporting of the PHS-Funded Research, promptly submit its mitigation report to the PHS awarding component. In accordance with 42 CFR, Part 50, Subpart F, § 50.605(a) (3) (iii) and 45 CFR, Part 94, §94.5a) (3) (iii), the mitigation report shall include the key elements documented in the retrospective review and a description of the impact of the bias on the PHS-Funded Research and the Hospital's plan of action or actions taken to eliminate or mitigate the effects of the bias.

4.8.4 After the submission of any initial report with regard to ongoing PHS-Funded Research, the Designated Official shall provide the PHS awarding component with annual FCOI reports that address

the status of the FCOI and any changes to the management plan for the duration of the PHS-Funded Research (including extensions with or without funds) in the time and manner specified by the PHS awarding component.
The annual FCOI reports for NIH awards are due at the same time as when the grantee is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension.

4.8.5 The Research Integrity Office on behalf of the Hospital shall, upon request of the PHS, make information available to the PHS relating to any Investigator disclosure of financial interests and the Hospital's review of, and response to, such disclosure, whether or not the disclosure resulted in the Hospital's determination of a FCOI.

4.9 Maintenance of Records

The Research Integrity Office will maintain records relating to all Investigator SFI disclosures, including the review of and response to such disclosures (whether or not resulting in a FCOI finding), and any other action under this appendix, for seven years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b), relating to records retention.

4.10 Public Accessibility

4.10.1 This policy and all related forms shall be made publicly available on the Hospital' website (currently at http://www.sickkids.ca/research).

4.10.2 Upon written request to the Hospital's Research Integrity Office, information will be provided including, at a minimum, that specified in 42 CFR, Part 50, Subpart F, §50.605(a)(5)(ii) and 45 CFR, Part 94, § 94.5(a)(5)(ii), concerning a specific SFI disclosed to and meeting the following criteria:
a. The SFI was disclosed and is still held by the Investigator;
b. The Institution has determined that the SFI is related to the PHS-Funded Research; and
c. The Institution has determined that the SFI is an FCOI.
Information concerning the SFIs of Investigator shall remain available for responses to written requests for at least three years from the date that the information was most recently updated. When the PHS-Funded Research is conducted by a sub-recipient Investigator, and under their written agreement the sub-recipient is required to comply with the sub-recipient's FCOI policy, the sub-recipient will have the responsibility of making such information publicly accessible.
Responses will be returned within five (5) business days from when the Hospital Research Integrity Office receives the request.

5.0 Responsible Parties

The Hospital's Research Integrity Office is responsible for overseeing implementation of and ensuring compliance with this appendix, in close collaboration with the Grants Management Office which will identify those researchers applying to PHS-funded programs at the outset. The Review Committee is responsible for supporting implementation and compliance.

6.0. Related Policies and References

6.1 Related SickKids Policies

1. Principal Investigator Eligibility and Responsibility for Research Awards and Contracts

2. Intellectual Property

6.2 References

1. Promoting Objectivity in Research. 42 CFR, Part 50, Subpart F.
2. Responsible Prospective Contractors. 45 CFR, Part 94.
3. National Institutes of Health Final Rule on Conflict of Interest Summary. Policy and Medicine. August 25, 2011.
4. Financial Conflict of Interest. 2011 Revised Regulation FCOI Webinar for Grantees Provided by the National Institutes of Health, November 30, 2011.