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**POLICY NAME:** Conflicts of Interest

**POLICY ID:** C-14

**DEPARTMENT:** Corporate Compliance

**POLICY EFFECTIVE DATE:** 09/26/1990

**POLICY LAST UPDATED DATE:**  
09/09/2020

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## I. POLICY STATEMENT

All Children's National employees, and in particular those who are authorized to:

- spend Children's National funds;
- enter into contracts;
- hire independent contractors or;
- purchase supplies or materials or services for Children's National

agree to use their authority solely in Children's National's best interests. Employees must avoid even the appearance that their personal interest might influence their actions on behalf of Children's National. The Children's National Code of Conduct describes the way in which employees must conduct business. Children's National employees are expected to conduct themselves on and off duty in a manner consistent with the mission, values and interests of the organization. All employees must avoid activities that would compromise the objectivity and integrity of their actions on behalf of Children's National or would give the appearance of having compromised their actions.

Employees should not solicit or accept any personal gift, gratuity, favor, entertainment, loan, reward or anything of monetary value that might influence their judgment concerning the provision of patient care, or the performance of their duties.

Employees should not use their position or status at Children's National, or information acquired as a result of their position or status for personal gain or for the personal gain of others with whom they may have a familial, romantic or personal relationship.

Employees may not work or consult for, advise or manage any business or entity that does significant business with Children's National or is a competitor of Children's National without first making a full disclosure and agreeing with the management plan designed by the Compliance Department.

Employees may not hire or conduct business on behalf of Children's National with a relative or a person with whom they have a familial (spouse, spousal equivalent and/or dependent children), romantic or personal relationship unless they have fully disclosed the relationship and have agreed with the management plan designed by the Compliance

Department.

Employees may not conduct business on behalf of Children's National with a business or entity in which the employee has a financial, familial or other personal interest, unless they first disclose both the nature of interest and proposed business dealings and agreeing with the management plan designed by the Compliance Department.

## II. PROCEDURE

### A. Definitions

Conflict of Interest	<p>A Conflict of interest (COI) exists if an individual's position or authority may be used to influence or make decisions that lead to any form of financial or personal gain for that individual or his or her family, or there is a divergence between the individual's private interests and professional obligations such that an independent observer might reasonably question actions taken by the individual. A conflict of interest is material if an ordinary person would take it into account in making a decision. Material conflicts of interest, particularly those where significant financial interests exist, are within the scope of this Procedure. The term conflict of interest refers especially to situations in which financial or other personal considerations may compromise, or may have the appearance of compromising, an employee's professional judgment in conduct or report of research, collection, analysis and interpretation of data, hiring of staff, procurement of materials, sharing of results, choice of protocol and the use of statistical methods. The mere appearance of a conflict may be as serious and potentially damaging as an actual distortion of research, teaching or administrative goals, processes, or outcomes, and therefore is treated as a conflict of interest under this Procedure. Conflict of interest depends on the situation, and not on the character or actions of an individual.</p>
Covered Person	<p>Covered Persons are all employees of Children's National, including Senior Leadership, investigators, including principal investigators, project directors, and any other person responsible for the design, conduct, or reporting research conduct at Children's National, faculty, physicians, dentists, licensed independent practitioners and other advanced practice providers, individuals involved in the selection, purchase, or prescription of medications, devices, or services for patient care, individuals involved in making or advising purchasing decisions, and anyone advised to disclose</p>

	by the Compliance Department.
Significant Financial Interest	<p>Significant Financial Interests are defined as interests in any one enterprise or entity valued at greater than \$5,000; interests representing more than 5 percent ownership; or an equity interest valued at \$5,000. Significant financial interests are aggregated for the investigator and family members.</p> <p>Significant financial interests include:</p>

	<p>a. Any financial interest of the investigator or other key personnel that could possibly affect or be perceived to affect the results of the research, educational or services activities funded or proposed for funding;</p> <p>b. Salary or other payment for services (e.g., consulting fees, sponsored/reimbursed travel expenses, living expenses or honoraria);</p> <p>c. Equity interests (e.g., stocks, stock options or other ownership interests); or</p> <p>d. Intellectual property rights (e.g., patents, copyrights and royalties from such rights including licensing arrangements through CRI or Children's National).</p> <p>The term does not include:</p> <p>a. Salary or other non-royalty remuneration from CRI or Children's National;</p> <p>b. Income from seminars, lectures or teaching engagements sponsored by nonprofit entities;</p> <p>c. Income from service on advisory committees or review panels for nonprofit entities; or</p> <p>Financial interests in business enterprises or entities if the value of such interests does not exceed \$5,000 (or \$5,000 per annum if such interests represent salary, fees or other continuing payments) or does not represent more than 5 percent ownership or an equity interest valued at \$5,000 or greater for any one enterprise or entity when aggregated for the investigator and the investigator's family members.</p>
<p>Uncompensated Interests</p> <p>Talent Program</p>	<p>Uncompensated includes honorary appointments or titles or career advancement opportunities, that have not directly provided monies, but have provided official recognition, office space, laboratory space, materials, staff, etc.</p> <p>Note: NIH requires applicants to list all positions and scientific appointments both domestic and foreign held by senior/key personnel that are relevant to an application including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct,</p>

<p>Business Relationship p</p>	<p>visiting, or honorary).</p> <p>The talent program refers to organizations seeking to learn about US scientific research through recruitment programs that target scientists, researchers, engineers, and entrepreneurs of all nationalities working or educated in the United States.</p>
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	Business Relationship is one in which an investigator, or a family member, serves as an officer, director, employee, partner, trustee or controlling stockholder of an organization, for-profit or not-for-profit, that does business with CRI or Children's National or their affiliates.
Vendor	A Vendor is any person or entity or representative thereof that has or is seeking to enter into a business relationship with Children's National to provide any equipment, supply, facility, item or service for payment, including but not limited to medical or office supplies, furniture, medical devices, pharmaceutical products, clinical services, consulting, and maintenance services.
Senior Leadership	Senior Leadership is any individual required to be listed on the IRS Form 990 including Officers, Directors, Trustees, Key Employees, and Highest Compensated Employees as defined by the IRS.
Investigator or Key Personnel	Investigator or Key Personnel is defined as any person responsible for (the design, conduct or reporting of research. The definition is not limited by professional discipline or academic position, and in some cases may include support staff, pre- doctoral graduate students, postdoctoral fellows and volunteers. For the purposes of disclosure, the term "investigator" includes the investigator's family members.

## B. General Principles

**1. Disclosure Procedure.** Employees must disclose a real or potential conflict of interest annually by submitting the annual disclosure form. The disclosure shall include the name and nature of the business or entity, the service the employee will provide, the length of service expected and all compensation and benefits the employee expects to derive from the service. Employees must respond to all questions on the disclosure form prior to the end of the disclosure period. Any changes must be updated within 30 days. In addition to the management plan, the employee may be required to obtain written approval from a Corporate Vice President or above before the employee may engage in such an outside interest.

**2. Individuals Required to Disclose Conflicts of Interest.** Children's National and its subsidiaries require Covered Persons to disclose actual, potential, and perceived conflicts of interests and commitments so that we can protect the integrity of professional judgment and preserve public trust in our work.



All Faculty at Children's National are employees and must conform to the reporting requirements. Faculty with full-time appointments at George Washington University will submit annual conflict of interest disclosure forms to Children's National only, and the Compliance Department will send reports to George Washington University. Outside income statements will be updated annually and filed in the Medical Staff Office.

Faculty and Staff involved in Research activities must comply with disclosure Requirements of Children's Research Institute as described below (See Section D, Conflicts of Interest in Research). Faculty and Staff involved in Public Health Service (PHS)-funded research must comply with the regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F) and Responsible Prospective Contractors (45 CFR Part 94).

Faculty members are expected to conduct interactions with the pharmaceutical, biotechnology and device industries with the highest degree of personal integrity and professionalism (See Section E, Interaction with Industry).

**3. Gifts from patients.** If a patient's family wishes to make a donation, they should be encouraged to contact the Children's National Foundation office. They may designate their gift for a special, specific purpose.

**4. Gifts from persons or entities (vendors).** In general, employees should not accept any gift or gratuities directly from vendors, consultants or independent contractors. Soliciting gifts from vendors and gratuities is strictly prohibited.

Children's National employees, faculty, researchers, residents, and clinical volunteers shall not directly accept gifts or entertainment (including food and meals), regardless of value, from pharmaceutical companies or medical device manufacturers or suppliers with respect to any activity at any Children's National site. Such gifts, regardless of value, may create an express or implied expectation of quid pro quo.

In limited circumstances, vendors may provide education and training materials, or support celebrations or other events with small items, food, or direct training. Such donations should be approved in advance by the Division Chief or above, and the Children's Hospital Foundation must be notified of such donations (See Employee Gifts and Gift Card Procedure, CH:FI:19P). Vendor-sponsored education, training and conferences should

be approved by the Compliance Department. Token "consulting" or "advisory" arrangements should not be used to justify compensation.

It is also permissible to accept medical or scientific books if neither the book nor its packaging carries the name or logo of a biomedical, pharmaceutical, or medical device company and if the books are distributed through Children's National. Anatomical models and illustrations (i.e., posters) may be accepted provided they do not carry the name or logo of a biomedical, pharmaceutical, or medical device company and if they are distributed through the Hospital. Division Chiefs should maintain a record of the source, amount, and utilization of these educational gifts.

On occasion, physicians, staff, managers or employees may accept gifts of nominal value (\$100) if the following requirements are met:

The donor makes similar gifts to others  
The gift is not linked to referrals, and

The acceptance of the gift will not influence or appear to influence the performance of the employee's duties

All vendor donations or gifts of funds must be coordinated through the Children's National Hospital Foundation as outlined in the Vendor Management and Solicitation Policy and Procedure (See CH:FI:18 and CH:FI:18P). Gifts from industry must also be managed in accordance with Interaction with Industry guidelines (See Section E, Interaction with Industry).

Industry promotional items may not be displayed at any Children's National site without permission from Public Relations relative to the Children's National logo and the appropriateness of the content.

When invited to an individual or small group meal by an industry representative, Children's National employees must pay for their own food and drink.

Compliance with these guidelines is critical to avoid violating anti-kickback statutes, STARK and other laws governing Children's National reporting.

**5. Use of position for personal gain or influence.** No employee may request or accept services of a personal nature from any other Children's National employee, including but not limited to, services involving the employee's non-work time and matters unrelated to Children's National business, unless approved by a Corporate Vice President or above.

No employee may use his or her position with Children's National, or that of any other hospital employee, to obtain an advantage in negotiations with a business, entity or person for any purpose unrelated to Children's National. This includes, but is not limited to, negotiations for the purchase of goods or services for the employee's personal use.

**6. Organizational Information.** Misuse of organizational information, including protected patient information, non-public, proprietary organizational information obtained as a result of employment or position

may not be used for personal gain or for the gain of others. Employees who have concerns may report to (TEL-A-BEAR) at 1- 844-835-2232. Employees may also report directly to Legal, Compliance or Human Resources Departments. (See Section G, Oversight/Authority)

### **C. Institutional Conflicts of Interest**

An organizational conflict of interest is a situation in which the mission of the organization appears to be in conflict with an outside interest or relationship, including interests and relationships of the organization's Senior Leaders. If research is involved, it is defined as a situation in which the financial investments or holdings of organizational

leaders might affect or reasonably appear to affect organizational processes for the design, conduct, reporting, review, or oversight of research.

Children's National is committed to ensuring that such relationships and outside interests do not result in inappropriate influence, or the perception of such influence. Further, no outside relationship or financial interest of Children's National or its leadership should interfere or compromise with the mission.

## **1. Organizational Oversight**

a. Organizational conflicts of interest are of significant concern when financial interests create the potential for inappropriate influence over Children's National's activities, personnel, or resources. Significant organizational conflicts of interest may include, but are not limited to the following:

1. Any significant financial interest, any significant management influence, or any influence of the Board of Directors in a non-publicly traded company
2. Current or pending ownership interest (including shares, partnership stakes, or derivative interests such as stock options) in a publically-traded company of \$50,000.00 or more
3. A gift of \$50,000.00 or more by an individual or third-party company that may reasonably be seen as directly benefitting from a specific research project
4. Personal Significant Financial Interests or holdings of a Senior Leader in any one enterprise or entity valued at greater than \$5,000; interests representing more than 5 percent ownership; or an equity interest valued at greater than \$5,000. Significant financial interests are aggregated for the Senior Leader and family members
5. Significant financial interest in and/or collaboration with an international entity
6. Financial interest in and/or collaboration with an entity that could be perceived as a competitor of Children's National
7. Financial equity in start-up companies of Children's National employees

b. Any significant actual or potential organizational conflict of interest will be reviewed by the Chief Compliance Officer, the Children's National ICOI Committee, and the Legal Affairs/Audit Committee, in consultation with the appropriate Division Chief, the Chief Academic Officer, outside counsel, or any other independent advisor or expert as needed, to determine the appropriate management strategy.

c. In reviewing potential organizational conflicts of interest, the Chief Compliance Officer, the Children's National Conflict of Interest Oversight Committee, and the Legal Affairs/Audit Committee will evaluate all relevant factors including the following:

1. Level and type of financial interests or relationships held by Children's National and/or Senior Leader(s)
2. Level of risk to research participants (in consultation with the Chief Academic Officer)
3. Effect on the integrity and objectivity of the proposed research or investment decision
4. How direct and immediate a Senior Leader's authority is over the research

investigator, or business decision at issue

5. Perceived reputational risk to Children's National

d. Management Strategies may include, but are not limited to, the following:

1. Recusing oneself from relevant decision making
  2. Reducing, modifying, or eliminating the financial interest
  3. For conflicts related to the organizational ownership of equity, the decision that the organization will not conduct clinical trials on the technology of the company (in consultation with the Chief Academic Officer)
  4. For conflicts related to a major donation, a separation from those involved in soliciting/managing the gift and those involved in any related research, clinical care, or investment decisions
  5. For conflicts related to research, disclosure of the financial interest in informed consent documents, publications, presentations, future grant applications and other communications
  6. For conflicts related to research, establishing a monitoring process to protect the integrity of the research and the well-being of research participants
- Not proceeding with the activity related to the financial interest

## **2. Investments and Not-for-Profit Status**

a. In order to ensure that investment decisions do not influence or compromise the integrity of Children's National's mission, investment decisions are separate from the oversight of its charitable mission. This separation reflects Children's National's commitment to its patients, human subjects in research, and the integrity of our clinical and research endeavors.

b. All Children's National investment decisions must comply with the IRS current rules and regulations for not-for-profit 501(c)(3) hospitals.

## **3. Outside Interests of Senior Leadership**

a. A Senior Leader's investment in an entity in which Children's National does business may give rise to an organizational conflict of interest.

b. Senior Leaders should avoid investing in or otherwise engaging in personal financial or fiduciary relationships with for-profit entities that sponsor research or have significant business relationships with Children's National where the Leader is likely to have involvement in or direct supervisory authority over decisions related to such entities.

- c. Senior Leaders may not participate in decisions at Children's National relating to entities in which they have an interest.
- d. All financial interests of Senior Leaders must be reported and reviewed in accordance with this Procedure.

#### **4. Outside Interests of Board Members**



- a. Each Director, within 30 days after his/her initial election and annually thereafter, must submit to the Director of Board Relations a Conflicts of Interest Questionnaire and Acknowledgement form. If, subsequent to completion of the questionnaire, a Director becomes aware of a potential conflict of interest, the Director should promptly disclose such interest to the Board or the Enterprise Risk and Compliance Committee and the Chief Compliance Officer.
- b. The Board or the Enterprise Risk and Compliance Committee, with the advice and support of the Chief Compliance Officer, will determine whether a Board member's disclosure is a potential conflict of interest by meeting, discussing, and voting on the matter.
- c. In addition to the Chief Compliance Officer, the Board or Committee may retain any independent advisors or experts as the Committee deems necessary to assist in such determination.
- d. The Board will manage any identified conflicts of interest in accordance with its Conflicts of Interest Disclosure Requirements (CNMC Bylaws, Art. 2, and Sec. 11).

## **5. Gifts**

- a. The Foundation should report significant corporate gifts (over \$50,000.00) and prospects regularly to the Board of Directors and the Chief Compliance Officer. The Chief Legal Officer may also inquire about gifts to the organization for the purposes of identifying and managing conflicts of interest.
- b. If any potential conflict is identified, the Chief Compliance Officer will work with Senior Leaders, including as appropriate, the Chief Legal Officer, the Office for the Protection of Humans Subjects, and/or the chair of the Institutional Review Board to ensure a plan is implemented to eliminate or manage the conflict.
- c. For gifts related to research: Consideration will be given to various factors related to the gift, including whether or not the gift is held for the benefit of the unit where the research is conducted, and whether any Senior Leader involved in soliciting the gift has any an authority to affect the conduct, review, or oversight of proposed research.

## **D. Conflicts of Interest in Research**

Children's Research Institute (CRI) acknowledges that conflicts of interest are neither inherently wrong nor avoidable in all cases. CRI's goal is to develop the means to manage material conflicts of interest and ensure that the integrity of the investigator, CRI, the academic research, data collection and analysis, training or clinical activities of Children's National community are not compromised or perceived to be compromised by considerations of personal gain or financial benefit.

Therefore, it is the policy of Children's National's subsidiary, Children's Research Institute, that all research personnel must refrain from any conflicts of interest, ensuring their activities and interests do not conflict with their obligations to CRI or its welfare.

The appearance of a conflict of interest may be serious and potentially damaging as a lack of objectivity. Apparent conflicts of interest should be evaluated and managed with the same degree of consideration as known conflicts of interest.

## **1. Applicability**

This Section is applicable to all personnel and members of the CRI community, including investigators and subcontracted entities, who are engaged in basic, clinical or translational research, research training, drug or medical/scientific device testing or any organized pursuit of new knowledge within the context of their employment or affiliation with CRI, Children's National or their affiliates.

## **2. Governing Law**

Covered persons should be aware that as a result of their financial interest or fiduciary role in a company they might have additional reporting obligations under various federal or state laws. For example, there are regulations under the National Science Foundation (NSF), the Food and Drug Administration (FDA) and the Securities and Exchange Commission (SEC).

For PHS-funded research only: Pursuant to the Public Health Service (PHS) revised regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F) and Responsible Prospective Contractors (45 CFR Part 94), investigators planning to participate in, or participating in, PHS-funded research are required to disclose their significant financial interests (and those of their spouses and dependent children) that reasonably appear related to their institutional responsibilities in addition to any reimbursed or sponsored travel related to the institutional responsibilities.

Significant Financial Interest is defined by regulation as:

- a. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
  1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity

interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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;

2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

b. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., 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 their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an accredited U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an accredited U.S. institution of higher education. The disclosure must include the following: (1) the purpose of the trip; (2) the identity of the sponsor/organizer; (3) the destination; and (4) the duration.

c. Significant Financial Interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an accredited U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an accredited U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

### **3. Human Subjects and Other Research**

a. Children's National has an obligation to protect the rights and welfare of research participants and to ensure the integrity of the research.

b. The risks of organizational conflicts of interest may include the possibility that the integrity and objectivity of the institution's research may be threatened or may be perceived to be threatened; such risks are particularly

acute in human subjects research, when the protection of human subjects may be adversely affected. This could occur, for example, if Children's National or one of its Senior Leaders may have a financial interest in a company sponsoring human subjects research being conducted by Children's National or own proprietary technology that is being utilized in the research.

c. Compliance will review the individual disclosures of researchers as outlined in the Conflict of Interest Policy and Procedure (C-14 and C-14P) and in accordance with relevant Federal regulations including Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F).

d. Conflicts of interest that may be related to the organization's research endeavors will be reviewed by Compliance, Children's National Institutional Conflict of Interest Committee, and the Chief Academic Officer as needed. When necessary, the Committee will develop management plans and provide copies of the management plans to the Institutional Review Board (IRB) for final approval.

e. The IRB will typically require disclosure to potential human subjects in the informed consent document if a key investigator, study team personnel, or Children's National has a financial interest in the research.

#### **4. Conflict of Interest Procedure Administration**

The Compliance Department in conjunction with the Conflict of Interest Committee will administer this COI Procedure by:

- Evaluating guidelines that identify the types of potential conflicts of interest in industry-partner relationships that will be considered material;
- Establishing the procedures to ensure the prompt review of grant and protocol specific conflicts of interest by Compliance, Grants and Contracts and human and animal regulatory committee
- Reviewing any request by an investigator with significant financial interests to determine whether he or she may not conduct research and provide recommendation to the regulatory committees.
- Developing and overseeing procedures to manage or eliminate material conflict of interest when an investigator with significant financial interests is permitted to conduct research.
- Documenting and maintaining records necessary for reporting to the federal government on management of conflict of interest.
- Communicating with applicable IRBs and federal agencies summary information about the nature and amount of any significant financial interest in regulated research, and responding to public requests for such information, as required by law.
- Assuring confidentiality of the disclosure, review and management of conflicts of interest, to the extent possible.
- Developing and overseeing training on financial conflicts of interest for PHS- supported Investigators, and monitoring compliance with such training, as required by law.

#### **5. Reporting Responsibilities of Investigators**

All investigators are required to report any potential Conflict of interest upon submission of study proposals to the IRB. All significant financial interests that would reasonably appear to be affected by the individual's current or anticipated research, particularly with regard to research involving human subjects must be reported. In making such reports, each investigator must declare explicitly whether he or she does or does not have such financial interests. Failure to report is non-compliant with this Procedure and does not signify a report of no significant financial interests. Newly hired investigators are



required to submit a completed Conflict of Interest Disclosure Form within thirty (30) days after hire or assumption of investigator responsibilities. All investigators must complete updated Conflict of Interest Disclosure forms annually. An investigator must also file an updated disclosure form within thirty (30) days after there is a material change in that investigator's significant financial interests. If an investigator fails to provide any required disclosures, research may not proceed until the investigator discloses the required information. Management Plans issued to Investigators are shared with the investigator's manager, and may be shared with Chief Academic Officer.

## **6. Remedies for Significant Financial Interests in Research**

**a. Prohibition of Research Participation Where Significant Financial Interest Exists.** If, upon reviewing specific evidence provided by the investigator with a significant financial interest, the Compliance Department believes that a conflict of interest is incompatible with research, she or he will recommend to the appropriate IRB that the investigator be required to eliminate the relevant financial interest before beginning the project or be barred from participation in the research.

**b. Rebuttal Presumption against Significant Financial Interests in Research.** CRI will presume, in order to assure that all potentially problematic circumstances are reviewed, that an investigator with significant financial interests may not conduct the research in question. This rule is not intended to be absolute. An investigator may rebut the presumption by demonstrating facts that, in the opinion of the Chief Compliance Officer, constitute compelling circumstances. The investigator would then be allowed to conduct the research under conditions specified by the Chief Compliance Office and approved by the responsible IRB.

**c. Management of Significant Financial Interest in Research.** Where the Chief Compliance Officer determines that compelling circumstances justify significant financial interests in research, those interests and the research in question will be managed through rigorous, effective and disinterested monitoring undertaken by individuals with no financial or professional ties to the research or direct reporting relationships to the researchers. Monitoring programs include, but are not limited to, the following: regular audits of the informed consent and enrollment process, a requirement to escrow the financial interest until the investigational product has been approved and on the market for a specified time period, the use of data safety monitoring boards, requiring that the role of the investigator with the financial interest be

limited or divestiture of the financial interest.

## **7. Appeals**

If an investigator believes that a determination made and adopted by the Chief Compliance Officer is not appropriate or is based on erroneous information, the investigator may submit a written request for review to the Children's National Institutional Conflict of Interest Committee.

## **8. Accessibility of Information**

CRI may seek from investigators subject to this Procedure any information relevant to insuring compliance with this Procedure. It is expected that investigators will provide any relevant information requested. The information received shall be handled confidentially unless public disclosure is part of the Conflict of Interest Procedure, or unless such disclosure is required by law.

## **E. Interaction with Industry**

Children's National is committed to the development of drugs, biologics and devices for the benefit of children's health and well-being (See the Vendor Management Policy and Procedure and the Employee Gift Policy and Procedure, CH:FI:18 and CH:FI:18P; CH:FI:19 and CH:FI:19P). Discovery, safety/efficacy evaluation, and appropriate use of products require collaboration among academic pediatric institutions, government, and industry. Children's National acknowledges the ideological differences between academia and industry and is committed to conducting interactions in a transparent manner and one that minimizes individual and institutional conflicts of interest.

Children's National endorses the principles published by the Association of American Medical Colleges (AAMC) regarding the interactions between academic medical institutions and industry as described below:

- The interactions should serve to enhance the public health.
- The interactions should be transparent.
- All the interactions between academic medical centers and industry must reflect high standards of medical professionalism that reach beyond applicable laws and regulations.
- The interactions should be reciprocal, with knowledgeable parties on both sides of the interactions.
- The interactions should support and enable the free exchange of information in appropriate settings in a manner adherent to applicable law and consistent with the standards of medical professionalism. Interactions should also be consistent with additional standards that may be established to assure that exchanges of information are evidence-based and free of bias to the maximum possible extent.

- The interactions must serve both academic medicine and the legitimate missions of industry.
- Compensation structures and arrangements should be consistent with the foregoing principles.

Further, it is the policy of Children's National that employees notify the Compliance Department of any possible Conflicts of Interest. Faculty and Staff involved in Research activities must comply with disclosure requirements of Children's Research Institute and

federal regulations. These disclosures include, but are not limited to, relationships with industry.

## **1. Compliance with Law**

a. **The Physician Payment Sunshine Act of the Patient Protection and Affordable Care Act of 2012 ("Sunshine Act"):** The Federal Sunshine Act was created to ensure transparency in the financial relationships between the life sciences industry and physicians and teaching hospitals. The Sunshine Act requires companies that manufacture drugs, medical devices, and biologics to provide to Centers for Medicare & Medicaid Services ("CMS") detailed information about payments and other transfers of value worth over \$10 from manufacturers to physicians and teaching hospitals. Physician types include doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors. Such information will be made available to the public beginning in 2014.

b. **Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F):** Investigators planning to participate in, or participating in, Public Health Service (PHS)-funded research are required to disclose their significant financial interests (and those of their spouses and dependent children) that reasonably appear related to their institutional responsibilities. Investigators are also required to disclose to any reimbursed or sponsored related to the institutional responsibilities. Investigators' regulatory and institutional disclosure obligations are described in greater detail in Children's National's Conflicts of Interest Procedure.

## **2. Transparency**

a. Children's National endorses the principles published by the Association of American Medical Colleges (AAMC) regarding the interactions between academic medical institutions and industry.

b. Faculty and researchers (and their staff) who interact or have relationships with industry may be subject to the reporting requirements of the Sunshine Act and the PHS revised regulations outlined above.

c. The Chief Compliance Officer will keep a log of all reported relationships. Physicians and applicable researchers should keep track of all payments from industry and report to the Chief Compliance Officer any discrepancies between his/her record of such payments and those reported by industry sponsors to CMS.

d. This Procedure and its related Policy applies to interactions with all subsidiaries and affiliates that are under the control of any Company and to any Person that is a member of Pharmaceutical, Biotechnology, and Device Industry and their representatives and agents.

### **3. Industry Access to Children's National Sites**

a. Vendors and sales representatives may not have access to the patient care areas except by special arrangement in advance. This requirement is intended to protect the representative

from illness, and to protect the Children's National patients.

b. Access will be permitted only on invitation from an authorized Children's National employee. Authorization for appointments resides with designated staff in Purchasing, Pharmacy, and Perioperative Services. Vendor and sales representative appointments should be appropriately reflected in administrative records such as calendars. Such representatives when in the facility must be accompanied by a Children's National employee at all times.

c. Industry representatives who are qualified healthcare professionals or scientists who wish to provide information on their products may do so only if they are (1) invited by the Division Chief and (2) in faculty-supervised, structured group settings that provide the opportunity for interaction and critical evaluation. Involvement of students and trainees in such meetings should occur only with direct and continuous supervision by the faculty member who issued the invitation. No individual whose primary purpose for being at Children's National is marketing may participate in such meetings. The primary purpose for these meetings should be related to education and instruction as opposed to marketing and sales.

d. Drug manufacturer representatives at Children's National sites within the District of Columbia hold a valid license to practice pharmaceutical detailing from the District of Columbia Board of Pharmacy and must be prepared at all times to show proof of licensure.

#### **4. Pharmaceutical Samples**

a. Children's National physicians are expected to make treatment decisions, prescribe drugs, and select medical devices on the basis of sound scientific and medical evidence. Samples may be accepted and used pursuant to the procedure outlined in the Medication Samples Policy (CHPC:M:65).

b. Sample packages must be clearly designated or imprinted with the following statement, "Sample Use Only – Not For Sale, Trade or Purchase."

#### **5. Industry-Sponsored Gifts and Funds**

a. All vendor solicitations of donations or gifts of funds must be coordinated through the Children's National Hospital Foundation as outlined in the Vendor Management and Solicitation Policy and Procedure (See CH:FI:18 and CH:FI:18P). Solicitations of funds or donations include, but are not limited to, requests for program underwriting; requests for operational support or

funding for care providers; requests for funds for or in-kind support for equipment or materials; requests for contributions to support research.

b. Scholarships and other educational funds substantially supported by industry must be approved by the appropriate Chief Medical Officer.

c. There may be no express or implied quid pro quo (i.e., promises of purchases) in connection with such donations or support.



Children's National faculty should be familiar with and adhere to Children's National's purchasing and procurement policies (See CH:FI:08 Authority to Purchase Policy and CH:FI:08P Authority to d. Purchase Procedure).

## **6. Continuing Medical Education Programs**

- a. The Chief Compliance Officer should be aware of all requests for industry support and receipt of funds for continuing medical education activity or other professional education.
- b. Children's National staff may participate in industry- sponsored Continuing Medical Education (CME) or other similar educational activities when the activity is ACCME- accredited (Accreditation Council for Continuing Medical Education) or meets ACCME standards for commercial support. Professional education for non- physicians must comply with comparable standards.
- c. Children's National faculty, staff, students, and trainees should not accept more than modest meals or social activities in connection with non-ACCME- accredited continuing medical education programs. Funding cannot be accepted to support social activities that do not have an educational component. Industry funding may not be accepted to support the costs of internal department meetings, retreats, or social events.
- d. Exceptional circumstances related to participation in industry- sponsored educational events require written approval from the Division Chief.

## **7. Participation in Industry-Sponsored Programs**

- a. **Speaking for Industry:** Faculty members are discouraged from joining speaker's bureaus. If one chooses to speak at an industry sponsored program, the faculty member should retain full control and authority over professional material the faculty member presents and does not allow such communications or presentations to be subject to prior approval by any commercial interest other than approval for the use of proprietary information. If a faculty member's participation in any way endorses a product, then they must be licensed with the District of Columbia as a pharmaceutical detailer.
- b. **Consulting/proctoring for industry:** Children's National employees may be involved in advisory/consulting/proctoring roles with Industry in accordance with the criteria outlined below.

1. A written non-disclosure agreement must be in place prior to discussion of confidential non-public information or proprietary information with outside entities.
2. A written consulting agreement (contract) must be in place before engaging in formal advisory/consulting/proctoring roles.
3. The consulting or proctoring contract must be approved by the employee's supervisor.
4. The supervisor must review the consulting or proctoring contract for any conflict related to time and effort (i.e., assess whether it is reasonably possible to perform both the proctoring and consulting responsibilities and the responsibilities of employment at Children's National) and any conflict related to subject matter, i.e., assess whether the

consulting or proctoring responsibilities would allow the employee to continue to make decisions in the best interest of Children's National.

5. If the supervisor determines there is a conflict of interest, the supervisor must either devise a management plan for the employee in consultation with the Compliance Department or prohibit the employee from engaging in the consulting or proctoring role. If the supervisor needs advice regarding the proper assessment of the conflict, he or she must contact the Compliance Department. All management plans must be submitted to the Compliance Department.

6. If the supervisor discovers that an employee is already engaged in a consulting or proctoring role, the employee must immediately submit his or her consulting or proctoring contract in order for the relevant supervisor to conduct the assessment outlined above, and the employee must notify the Compliance Department.

7. The consulting and proctoring responsibilities must be approved in writing by the Chief Academic Officer or the Chief Medical Officer. Individual/personal compensation without associated tangible service or work product is considered a gift and is not allowed.

8. Consulting or proctoring done as part of professional activities as employees of Children's National (i.e., consulting or proctoring in which the contract is with the institution and compensation is received by the institution) must be approved by the relevant Division Chief, including an agreeable time commitment

9. Payment for consulting or proctoring services should be based on fee-for-service and reimbursement should be at fair market value.

10. Management Plans are developed based on self-reported information. If additional information becomes available or if the situation should change in any way, the employee and/or supervisor must notify the Compliance Department.

## **8. Medical Ghost-Writing and Ghost-Authoring**

Children's National employees are responsible for publications listing them as authors. Employees may not permit their professional publications or presentations of any kind, oral or written, regardless of medium, to be ghost-written by any party (i.e., pharmaceutical companies, medical devices manufacturers, and medical societies). Employees may not participate in ghost-writing or ghost-authoring of professional presentations of any kind, oral or written, regardless of medium.

## **F. Conflicts of Interest in Intellectual Property and Commercialization**

Children's National strives 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.

Inherent in the relationships and interactions that develop during research and commercialization of cutting-edge treatment is the risk of potential or actual conflicts of interest . Conflicts of interest may be financial or conflicts of commitment, and may

result in competing and/or conflicting interests and obligations. Conflicts of interest can be anticipated to result from the research and commercialization efforts at leading academic medical centers. When inventors, company founders, stockholders or others who stand to benefit from the technology's commercial success are also involved in continuing academic research on the technology, a conflict of interest exists.

### **1. Intellectual Property**

- a. See Children's National Intellectual Property (CNMC:A:08B).
- b. New employees are required to disclose any and all intellectual property in which they have a material interest that (1) pre-dates their employment with Children's National, (2) was developed outside of Children's National time and resources during their employment, or (3) for which rights, title and interests were returned to the them by Children's National. Disclosure must be made at the time of on boarding, employment on the Employee Intellectual Property (IP) Agreement, and annually on the Conflict of Interest Disclosure Form or when a change occurs.
- c. The Employee Intellectual Property (IP) Agreement form will be distributed via electronic submission in the new hire on-boarding portal process. The completed form will be stored in the employee's file and a copy will be provided to the Compliance Department should any need for follow-up by the Compliance Department and/or the Innovation Ventures Department arise with regard to IP or conflict of interest. The employee's file will be updated in accordance with the Children's National process for management of Intellectual Property and Conflicts of Interest.

### **2. Commercialization**

- a. **See C-31 Conflicts of Interest in Commercialization.**

### **3. Licensing, Technology Transfer, and Patents**

- a. When Children's National (or its subsidiary) licenses technology or other intellectual property, it may receive equity in a company as a result of that license and/or a royalty or other fee as compensation for the use of that intellectual property. Children's National may also receive equity or other financial interests as part of a co-investment in the company.
- b. An Organizational Conflict of Interest is created if an investigator at Children's National undertakes to do research on a drug, device, biologic or

other item on which Children's National has a patent, has licensed the intellectual property, or receives royalties or other fees. Such conflicts of interest have the potential to impact a faculty member's research adversely if it is not properly managed or eliminated.

c. The Intellectual Property Policy and Procedure (CNMC:A:08B and CNMC:A:08BP) govern the treatment of intellectual property that is invented or developed by employees of Children's National and the Children's National Conflicts of Interest Policy and Procedure.

d. The Intellectual Property Committee considers all issues concerning intellectual property organization-wide including the way Children's National makes decisions about the investment and commercialization potential of the intellectual property it holds and conflicts of interest.

## **G. Oversight/Authority**

### **1. Oversight**

The Institutional Conflict of Interest Committee (ICOI) shall facilitate the adoption, implementation, interpretation, and monitoring of the COI policies and procedures with the primary purpose of preserving the integrity of Children's National. The ICOI reports to the Compliance Management Committee and to the Enterprise Risk Compliance Committee (ERCC).

The Chief Compliance Officer shall provide information relating to Board of Directors (BOD) member COIs to the Chair of the Children's National Board of Directors and to ERCC, as well as to the Chair of the relevant Board on which the relevant BOD member serves.

### **2. Authority**

The ICOI Committee will advise on COI issues. In all instances, the Committee is empowered to:

- Develop or amend COI policies and procedures;
- Oversee the annual, updated, and new hire/appointment COI disclosure process for BOD Members and employees;
- Review annual, transactional and research COI disclosures to determine whether the COI is related to the BOD member's fiduciary duties to CNMC or an employee's field of clinical, research, institutional, or professional responsibilities, and, if so, develop a plan to manage, reduce, or eliminate the actual, potential, or perceived COI;
- Consult with appropriate members of Children's National's administration and with the relevant BOD member or employee in the development of plans for managing, reducing, or eliminating actual, potential, or perceived COI;
- Coordinate with organizational entities or offices with an interest in the outcome of the review and management of the COI. For example, management plans developed for employees who are engaged in human subjects research will be disclosed to the Office

for the Protection of Human Subjects (OPHS);

- Oversee assigned monitors of COI management plans to ensure monitoring is occurring;
- Recommend, when necessary, BOD member or employee sanctions or other administrative actions when management plans are not followed;
- Provide initial, annual, and revised COI reports to external agencies, as applicable; and
- Maintain ICOI Committee records in accordance with the policy and regulatory requirements



### **3. Support**

Management and support services for ICOI Committee operations and activities shall be provided by the Compliance Department at the direction of the Chief Compliance Officer.

### **4. Frequency of Meetings**

The ICOI Committee will meet regularly but no less than six times a year to evaluate COI disclosures and COI program matters unless a meeting is cancelled by the Chairperson.

The Chairperson may schedule a special meeting if the Committee needs to address an urgent COI issue before the next regularly scheduled meeting.

Notice of time and place of the meeting will be given at least one week in advance. The Chairperson may call a special meeting upon a three day notice.

A quorum of the membership is required for the Committee to meet to conduct full committee business and vote on actions. A quorum shall consist of a simple majority, which must include the ICOI Committee Chairperson.

### **5. Membership**

The ICOI Committee shall have representation from the main administrative areas of Children's National to ensure multidisciplinary participation. It shall consist of voting members and alternates appointed by each area leader, including a Chair, who shall be appointed by the Chief Compliance Officer, after consultation with the Compliance Management Committee. George Washington University (GW) will appoint a voting member who will participate in meetings in which the committee will assess COIs for individuals with dual employee appointments at CN and GW.

Members include: the Chairperson; one community representative; one hospital based pediatric specialist; one ambulatory care pediatric specialist; one representative from pharmacy; one clinical nurse; one researcher, (if possible representing bench, animal, and human subjects research); one grants and contracts representative; one representative from the innovation office; one human subjects protections representative; one representative from the Institutional Review Board, one development office

representative; one representative from the procurement office; one compliance department representative; one legal department representative, and George Washington University Ad Hoc representative.

ICOI Committee employee members shall receive no compensation for their service, but will receive hours of protected time for such service in consultation with the corresponding area chief.

All ICOI Committee members shall be subject to appointment and removal by the Chief Compliance Officer, in his or her sole discretion, provided notice is given to the Compliance Management Committee.

## **6. Non-Member Participation**

The ICOL Committee, the Compliance Department or Chief Compliance Officer may invite non-committee individuals to attend a meeting in order to provide the Committee with information that is relevant and necessary to its review and analysis.

## **7. Subcommittees/Working Groups**

In carrying out its function, the ICOL Committee may establish ad-hoc subcommittees as needed, composed of at least two members of the ICOL Committee and non-member consultants, to execute various duties related to the objectives and policies of the ICOL Committee. The advice of a subcommittee shall be reported to the ICOL Committee. The Committee will discuss subcommittee findings, at which time the full committee will determine the appropriate action to be taken.

## **8. Conflicts of Interest for ICOL Committee Members**

No ICOL Committee member shall participate in the discussion, management, or resolution of any individual's actual, perceived, or potential COI if that COI Committee member has an actual, perceived, or potential conflict with the matter under review (i.e., a circumstance that could reasonably appear to compromise the impartiality of the member's decision making regarding the individual/matter).

## **9. Resolution Process**

If the ICOL determines that the COI exists, the committee shall recommend how the COI should be eliminated, reduced or managed. The Compliance department will prepare a Conflict Management Plan containing the recommendations of the ICOL committee. Each plan will be communicated in writing to the interested party and to the area chief who will be responsible for the plan's implementation and monitoring.

Any BOD member or employee who is impacted by a decision by the COI Committee and disagrees with the recommendations of the Committee should initiate a meeting with the Chief Compliance Officer, the Chief Legal Officer and the BOD member's or employee's leader (i.e., the Board Chair or department leader, respectively) to explore alternative management strategies.

Modifications to the recommended management plan should be

forwarded for discussion at the next regularly scheduled meeting of the ICOI Committee or, if time sensitive, during an ad hoc meeting consisting of a quorum of Committee members.

A BOD member or employee's failure to comply with the Conflict of Interest Management Plan will be subject to review by the Board Chair or department leader respectively and the Chief Legal Officer.

## **10. Records**

All ICOI documents and associated records will be kept by the Compliance Department. At a minimum, the following COI documents will be retained:

- ICOI Committee meeting minutes;
- copies of notification of ICOI Committee actions and other relevant information;
- annual, updated, and new hire/appointment disclosures;
- Management plans; and
- ICOI Committee correspondence.

Such documents shall not be disclosed except as needed to resolve or manage a real, apparent, or potential COIC, or as otherwise required by law or policy. All such documents shall be kept in a secured location (e.g., locked cabinet).

All COI documents and associated records will be retained in accordance with corporate governance laws and Public Health Service Regulations.

## **11. Annual Reports**

### **a. Aggregate Data**

The COI Committee shall submit an annual report to the Compliance Management Committee (CMC). The report shall contain data as to the number of conflicts reviewed and the nature of resolutions and data as to any trends. Starting with the report for the second year of this program, the annual report shall also include data from the previous year.

### **b. Management Plans**

The Chief Compliance Officer, or his or her designee, shall annually provide copies of BOD member management plans to the affected BOD members' Board Chairs and copies of employee management plans to the affected employees' department leaders. All management plans shall bear a "CONFIDENTIAL" legend with instructions that the plans shall not be disseminated beyond managers and leaders with a need to know.

## **H. Record Retention**

Records under this Procedure will be retained for at least three years from the date of final expenditures report submission in connection with research, or other dates as specified in 42 CFR 50.604(i) and 45 CFR 74.53(b).

## **I. Interpretation**

Questions concerning interpretation or applicability of this Procedure should be directed to the Compliance Department who will resolve questions in coordination with the Compliance Management Committee (CMC).

## **J. Sanctions for Failure to Comply**

Failure to comply with this Conflict of Interest Procedure may result in the consequences noted herein consistent with Corrective Action Policy Procedure (available on the Intranet).

#### **K. Requests for Information**

Requests for information on financial conflicts of interest related to PHS-funded research shall be directed to the Compliance Office. The Chief Compliance Office shall respond to the request within five business days of the date in which he or she receives the request.

### **III. ACCOUNTABLE EXECUTIVE(S) AND REVIEWER(S)**

A. Accountable Executive(s): Percy, Catherine

B. Committee(s) Responsible for Review: Compliance Management Committee