

## Financial Conflict of Interest (FCOI)

### Frequently Asked Questions (FAQs) at Children's

#### **What is a "financial interest"?**

Briefly, a financial interest is anything of economic or monetary value, including but not limited to, compensation in exchange for personal services (e.g., consulting fees, honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

#### **What is a Financial Conflict of Interest (FCOI)?**

A divergence between an individual's financial interests and that individual's Hospital obligations, such that an independent observer might reasonably question whether the performance of the Hospital obligations are adversely affected (or have the potential to be) by considerations of personal gain, and in the case of research, includes the existence of a significant financial interest of an investigator that could directly and significantly affect the design, conduct or reporting of the research.

#### **What is the purpose of the FCOI regulation?**

The PHS regulation promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting of research funded under NIH grants, cooperative agreements or contracts will be biased by any conflicting financial interest of an Investigator.

#### **Is Children's covered by the FCOI regulation?**

Yes. The regulation is applicable to each Institution that applies for NIH grants for research or submits a proposal for a research contract and to any Investigator participating in that research.

#### **Is Children's policy on FCOI the same as the minimum requirements in the PHS regulations?**

No. In an effort to ensure that all research at Children's complies with the regulations, Children's policy is more stringent than the federal regulations.

#### **What is considered "significant financial interest (SFI)" at Seattle Children's?**

- For all human subject research, **any** financial interest is considered significant
- For all research other than Human Subjects Research and all Technology Transfer Transactions, (i) any Financial Interest (including Compensation, Equity and Intellectual Property) where the total aggregate value exceeds \$10,000, or (ii) any Equity Interest representing more than a 5% ownership in any single entity.

#### **Who is required to report financial interests?**

All Investigators and Inventors are required to report his or her significant financial interests. This includes the financial interests of his/her spouse (or domestic partner) and dependent children.

#### **Who is considered an "Investigator" for this purpose?**

**Any** person (including his/her spouse or domestic partner and dependent children) who is responsible for the design, the conduct or the reporting of the results of research activities is considered an Investigator for the purposes of FCOI regulations. This includes but is not limited to research staff such as clinical research associates, research nurses and technicians, post-doctoral fellows, graduate students, staff scientists, and data specialists.

#### **When should I report my significant financial interests?**

Inventors should report their significant financial interest upon direction from the IP Core. Investigators should report their significant financial interest

- when a proposal for a research project is submitted to the Office of Sponsored Research (OSR),

- when a human subjects application is submitted to the Institutional Review Board (IRB),
- prior to engaging in any non-sponsored, unfunded, or similar research,
- when a Significant Financial Interest arises during the course of research.

**How should I report my significant financial interests?**

All Investigators need to indicate whether or not they have SFI on applications that are submitted to the IRB, and on research project proposals that are submitted to OSR (via OSR-10 forms). If you are an Investigator or Inventor with SFI, you must send a completed SFI report form to Nicole Jacobs, Research Integrity Officer, in the Office of Research Compliance.

**Does attending an investigator meeting need to be reported?**

Yes. For all human subject research, any financial interest is considered significant and must be reported, therefore all travel, hotel, conference or investigator meeting fees (whether reimbursed or paid for in advance) are compensation arrangements that meet the definition of a financial interest.

**I am an investigator in clinical trial network which requires me to report my significant financial interests to the network steering committee/operations office on an annual basis. Am I still required to report my significant financial interests to Children's as well?**

Yes. Reporting your interests to another entity on any research project does not fulfill your obligations under Children's Financial Conflicts of Interest Policy.