

**Children's Healthcare of Atlanta  
Conflict of Interest Training**

Name: \_\_\_\_\_

Date Completed: \_\_\_\_\_

**Overview:** In the summer of 2012, the Department of Health and Human Service (DHHS) required Institutions to inform each Investigator of their Institution's policy on Financial Conflicts of Interest, the Investigator's responsibilities regarding disclosure of Significant Financial Interests, and require each Investigator to complete training regarding the same prior to engaging in research related to any Public Health Service (PHS) funded projects and every four years.

**Instructions:** You are instructed to carefully read each regulation, policy, and procedure. You will then be asked to initial that you have read, understood, and will comply with both Federal regulations and Children's Healthcare of Atlanta policies and procedures regarding Investigator's responsibilities for disclosing significant financial interests.

Please contact the Research Compliance Manager or the Chief Compliance Officer should you have any questions regarding the below regulations and/or policies.

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**Department of Health & Human Service Final Rule on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94)**

<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

**Children's Policy 1.58 for Individual Conflicts of Interest in Research**

<http://careforceconnection/PoliciesandProcedures/Administrative%20and%20Operational/1-58.pdf>

**Investigator's Responsibilities**

**Who Must Complete the Investigator Disclosure/Conflict of Interest Statement?**

At a minimum, the term Investigator includes the following:

- Project Directors, Principal Investigators, and/or members of the research team identified as senior/key personnel on the grant or contract application, progress report, or any other report;
- Individuals identified by the Principal Investigator or Project Director who are responsible for and have substantial independent decision making in respect to the

design, conduct or reporting of the research, such as Collaborators or Consultants named on the grant; and

- The Investigator must report Significant Financial Interests for himself /herself and for his/her spouse, and dependent children that are related to the **Investigator's institutional responsibilities**.

### **What Must Be Reported?**

Children's has eliminated the de minimis threshold of \$5000 for reporting financial interests. **ANY** financial interest must be reported. The following Financial Interests in entities related to an Investigator's teaching, research, administrative, or clinical duties at Children's must be reported:

- Payments for services including salary, consulting fees or honoraria;
- Equity or ownership interest in a corporation, partnership, limited partnership, limited liability company, sole proprietorship or other form of entity; stock options or other financial interests;
- Proprietary or other intellectual property rights, including but not limited to inventions, patent rights (including patent applications), licensing fees, trademarks, service marks, domain names, trade secrets, trade dress rights, formulas, designs, software, programming code, intangible rights in machines, compositions of matter and devices, techniques, processes, procedures, systems or formulations, copyrights or royalties;
- Service as a director, officer, partner, trustee, employee or other position of any sponsor or agency;
- Any compensation whose value could be affected by the outcome of the research; or
- Sponsored travel

### **When Should This Be Reported?**

**Children's will not submit a proposal, and an award cannot be issued to Children's unless and until Children's has on file, all *Investigators* (Key senior personnel) Disclosure/Conflicts of Interest forms associated with a proposal.**

- Each Investigator must report any Significant Financial Interest **prior to** submitting a formal proposal to any proposed sponsor of the research; or
- Investigators are required to update their reports in real time to reflect changes in or additions of Significant Financial Interests Requiring Disclosure. In cases where Investigators are not aware of the existence of a Significant Financial Interest at the time of a proposal, or if the Significant Financial Interest develops after submission of a proposal, then Investigators shall report the interest to the Research Compliance Manager within 30 days of learning of the interest.

- Each year of a grant or contract, an Investigator must update his/her Investigator Conflict of Interest form. The form must be updated at the time of the annual progress report, twelve (12) months after the notice of award, or the initiation of research, whichever date is earliest.

### **Consequences of Non-Compliance**

- Failure to make the necessary disclosure or follow an agreed upon management plan is a violation of Children's policy.
- The Research Conflict of Interest Committee shall review and take appropriate action to as they deem appropriate in the circumstance.
- Sanctions for non-compliance may include reprimands or other appropriate measures, up to and including termination.

### **Required PHS Procedures for failure to comply with policy or management plan**

In addition the above review and sanctions, Children's and PHS Investigators are subject to the following procedures when a Financial Conflict of Interest (FCOI) is not identified or managed in a timely manner including failure by the Investigator to disclose a Significant Financial Interest that is determined by Children's to constitute a Financial Conflict of Interest; failure by Children's to review or manage such a Financial Conflict of Interest; or failure by the Investigator to comply with a Financial Conflict of Interest management plan.

- A. Children's must implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such Financial Conflict of Interest going forward.
- B. Within 120 days of Children's determination of noncompliance, Children's must complete a retrospective review of the Investigator's activities and the PHS funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
- C. Children's must document the retrospective review and include a detailed methodology used for the retrospective review (*e.g.*, methodology of the review process, composition of the review panel, documents reviewed).
- D. Based on the results of the retrospective review, if appropriate, Children's shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

If the retrospective review team members find bias, Children's is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the

retrospective review above and a description of the impact of the bias on the research project and Children's plan of action or actions taken to eliminate or mitigate the effect of the bias (*e.g.*, impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, Children's will submit to the PHS Awarding Component FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the Financial Conflict of Interest, Children's may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded research project between the date that the Financial Conflict of interest or the Investigator's noncompliance is determined and the completion of Children's retrospective review.

I have read the Final Rule and I understand that I am responsible for complying with the Federal Regulations set forth by DHHS for which PHS funding is sought.

I have read policy 1.58 and I understand that I am responsible for complying with the policies set forth by Children's Healthcare of Atlanta.

I have reviewed the Investigator's Responsibilities and I understand that I am responsible for complying with the policies and procedures of Children's Healthcare of Atlanta.

Initials

By submitting this form, I \_\_\_\_\_, certify that:

- I have read the policies and procedures outlined by DHHS and Children's Healthcare of Atlanta.
- I agree to comply with the policies and procedures outlined by DHHS and Children's Healthcare of Atlanta.
- I am the person named above submitting this report.