

**Financial Conflict of Interest (FCOI) Policy**  
**For Children's Cancer Therapy Development Institute Investigators on Federal Grants**

**Updated February 2021**

## **Introduction**

This policy describes required reporting for investigators of any financial conflicts of interest (FCOI) and ensures compliance with the requirements of 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought."

## **Definitions**

**The Institution** is defined as Children's Cancer Therapy Development Institute.

An **Investigator** is defined as any individual, regardless of title or position, who is responsible for the design, conduct, or reporting of research involving the institution.

A **Financial Conflict of Interest** (FCOI) is defined as a circumstance in which an investigator's outside financial interest or obligation may have the potential to impact objectivity in research.

A **Significant Financial Interest** (SFI) is defined as any financial interest, both foreign and domestic, that reasonably appears to be related to an investigator's institutional responsibilities. A SFI includes financial interests of an investigator's spouse and dependent children. A SFI is not always a FCOI.

## **Policy**

The institutional policy consists of the following:

- Each investigator must complete Conflict of Interest training at [citiprogram.org](http://citiprogram.org) prior to participating in research related to any federally-funded grant, and at least every four years afterwards. Retraining can also be triggered when there is a revision to policy, or if an investigator has not complied with the policy.
- Each investigator must complete and sign a Conflict of Interest form to disclose any FCOI or SFI prior to participating in research related to any federally-funded grant or if they are new to the institution, and at least once per year afterwards. This also serves as a means to inform the investigator of

the institution's FCOI policy, the investigator's disclosure responsibilities, and federal regulation.

- Each investigator must complete a Conflict of Interest form within 30 days of the acquisition or discovery of a new SFI.
- The institutional official is responsible for reviewing all Conflict of Interest disclosures and determining whether a SFI is related to PHS-funded research and, if so, whether it is a FCOI. Guidance will be provided by 42 CFR 50, Subpart F.
- If a FCOI exists, then a management plan will be implemented and initial and annual FCOI reports will be provided to the NIH through eRA Commons in accordance with 42 CFR 50, Subpart F.
- The institution keeps FCOI-related records on file for a minimum of three years after the date the final expenditure report is submitted to the PHS or from other dates specified in 45 CFR 74.53(b) and 92.42(b), where applicable. These records can be made available within 5 days of a written request.
- This policy document will be available on the institution's website and will be updated at least annually.

## **Non-compliance**

In the event that investigators do not comply with the requirements of this policy and process, including failing to disclose a SFI or failing to comply with a FCOI management plan, the institution may implement sanctions or other administrative actions, such as retraining the investigator, suspending the investigator's participation in a research project, terminating the investigator's employment with the institution, disclosing the FCOI on any public presentation of the results of the research, or reporting the incident to the NIH or other federal agency.

**Questions about this policy can be directed to the institutional official at [admin@cc-tdi.org](mailto:admin@cc-tdi.org).**