

**OFFICE OF SPONSORED PROGRAMS –
PROCEDURES FOR CONFLICT OF INTEREST MANAGEMENT AND REPORTING**

I. Purpose

Spectrum Health is committed to conducting all research activities and sponsored programs in accordance with the highest standards of integrity and ethics. The [*System Policy: Conflicts of Interest – Research and Sponsored Programs*] sets forth principles, policies, and procedures designed to identify financial conflicts of interest and to eliminate or mitigate the potential adverse effects of such conflicts on the rights and welfare of participants and the objectivity with which a research study or sponsored program is designed, conducted and/or reported. Capitalized terms used in this procedures document have the same meaning as set forth in the [*System Policy: Conflicts of Interest – Research and Sponsored Programs*].

As required by the PHS Regulations, the Research Conflict of Interest Committee (“Committee”) functions as Spectrum Health’s “Institutional Official(s),” and, as such, is primarily responsible for review and oversight of all Financial Interest disclosures made pursuant to the [*System Policy*].

The Office of Sponsored Programs is responsible for supporting the functions of the Committee and ensuring compliance with all reporting and public accessibility requirements for Financial Conflicts of Interest related to PHS-funded research. The Office of Sponsored Programs is also responsible for oversight of subrecipients of PHS funding.

II. Procedures

A. Investigator Disclosures

Each Investigator will be prompted annually to disclose Financial Interests, in accordance with Spectrum Health’s annual conflict of interest disclosure process. The Investigator will also be prompted to disclose Financial Interests when the Investigator submits a grant proposal or application to the Office of Sponsored Programs. This disclosure will be done through the Office of Sponsored Programs Proposal Routing Form.

In addition, the Investigator must provide a disclosure within thirty (30) days after the Investigator (or his/her spouse or dependent child) receives a NEW financial interest related to his/her Institutional responsibilities OR after the Investigator identifies a Financial Interest that was not previously disclosed at one of the time(s) listed above. This disclosure requirement applies after a research project or sponsored program has begun AND continues until one year (i.e., twelve months) after the end of the project/program.

All disclosures will be made electronically (to the extent possible), through current software program(s), in accordance with Spectrum Health’s policies and procedures on conflicts of interest disclosure.

B. Committee Review of Financial Interest Disclosures

As the designated Institutional Official(s), the Committee will be responsible for reviewing all Financial Interest disclosures, in accordance with the requirements set forth in the *[Committee Procedures]*.

C. Reporting Requirements [PHS-FUNDED RESEARCH ONLY]

If the Committee determines that an FCOI exists and it is related to PHS-funded research, Spectrum Health will report such FCOI to the PHS awarding component (e.g., National Institutes of Health) prior to the expenditure of any funds for the award (i.e., the “initial report”).

For all new FCOI and all FCOI that are identified subsequent to the initial report (e.g., upon participation of an Investigator who is new to the research project, or identification of an FCOI not previously disclosed), Spectrum Health will make the FCOI report to the PHS awarding component within sixty (60) days of identification or disclosure of the Financial Interest (See **Section C, Management Plan**).

Each FCOI report will include sufficient information to enable the PHS awarding component to understand the nature and extent of the FCOI and to assess the appropriateness of the Management Plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- a. Project number;
- b. Project title;
- c. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- d. Name of the Investigator with the FCOI;
- e. Name of the entity with which the Investigator has the FCOI;
- f. Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- g. Value of the Financial Interest;
- h. A description of how the Financial Interest relates to the PHS-funded research and the basis for the Committee’s determination that the Financial Interest conflicts with such research; and
- i. A description of the key elements of the Management Plan.

FCOI reports to PHS will be submitted by the Director of the Office of Sponsored Programs through the NIH Era Commons.

During the period of the PHS award, the Office of Sponsored Programs will also submit an annual FCOI update. The annual update will include any changes in information regarding the previously disclosed Financial Interest (e.g., updated value of a previously disclosed equity interest) and any changes to the Management Plan.

D. Reporting After Retrospective Review

Whenever there is noncompliance with the *[System Policy]* or a Management Plan, the Committee will conduct a retrospective review, to determine whether—*during the period of noncompliance*—the research project or sponsored program was biased in its design, conduct and/or reporting.

Noncompliance with the *[System Policy]* may include, but is not limited to, failure to timely identify or manage an FCOI; failure to disclose a Financial Interest that the Committee determines to be an FCOI; or failure to review or manage an FCOI.

Following a retrospective review related to PHS-funded research, the Office of Sponsored Programs will submit an update to any previously submitted FCOI report, if applicable/appropriate.

E. Public Accessibility of Information [PHS-FUNDED RESEARCH ONLY]

Information related to the FCOI of Senior/Key Personnel for a PHS-funded research project will be publicly accessible, so long as the Financial Interest is held by the Senior/Key Personnel. Spectrum Health will make this information available via a written response to any requestor within five (5) business days of the request. The written response will include, at a minimum, the following:

- (i) Project number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) Name of the Investigator with the FCOI;
- (iv) Name of the entity with which the Investigator has the FCOI;
- (v) Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vi) Value of the Financial Interest.

All written requests for information related to the FCOI of Senior/Key Personnel will be submitted to the Office of Sponsored Programs. Spectrum Health's publicly accessible website will include information about how and where the requests for information may be submitted.

F. Subrecipient Requirements [PHS-FUNDED RESEARCH]

For a PHS research subawards made by Spectrum Health to a Subrecipient, the written subaward agreement will include a Financial Conflict of Interest provision that requires the Subrecipient to provide to certify that it complies with the PHS Regulations through its own institutional policy. If a Subrecipient does not have its own FCOI policy that meets the requirements of the PHS Regulations, the Subrecipient will be required to follow Spectrum Health's policy (i.e., the Subrecipient's Investigator must disclose Financial Interests to the Committee, to determine whether an FCOI exists).

The Office of Sponsored Programs is responsible for monitoring the Subrecipient's compliance with the PHS Regulations, Spectrum Health's policy (if the Subrecipient does not have its own), and any Management Plan(s). The Office of Sponsored Programs will also be responsible for reporting all identified FCOI to the PHS awarding component (See **Section C, Reporting Requirements** above).