

## RESEARCH CONFLICT OF INTEREST COMMITTEE PROCEDURES

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### 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.

The Research Conflict of Interest Committee functions as Spectrum Health’s “Institutional Official(s),” as required by PHS Regulations, and is given responsibility, on behalf of the organization, to review Financial Interest disclosures, identify Financial Conflicts of Interest, and create Management Plans where appropriate. This Committee functions as a subcommittee of the Medical Professionals Conflicts Committee [*See Summary of COI Process document*]. The Committee’s charge, duties and membership are further described in the [*Research COI Committee Charter document*].

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.*]

### 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 protocol to the Spectrum Health IRB, or when he/she submits a grant proposal or application to the Office of Sponsored Programs.

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**

All Financial Interest disclosures will be made available to the Committee for review, in accordance with the requirements described below:

1. For each new project, the Committee will review all Financial Interest disclosures before the project begins. Specifically, for PHS-funded research, the Committee will review all Financial Interest disclosures before the expenditure of PHS funds.

2. For each Financial Interest, the Committee will determine:

**a. Is the Financial Interest *related to the research or sponsored program*?**

A Financial Interest is *related to* the research or sponsored program if the Committee determines that the Financial Interest could be affected by the research/sponsored program OR is in an entity whose financial interest could be affected by the research/sponsored program.

**b. If the Financial Interest is *related to the research or sponsored program*, does it constitute a Financial Conflict of Interest?**

A Financial Conflict of Interest exists if the Committee determines that the interest could *directly and significantly* affect the design, conduct or reporting of the research or sponsored program. In making this determination, the Committee will consider—and may ask the Investigator to provide—additional information related to the following factors:

- Nature of the interest (e.g., consulting, equity interest, speaking fee, travel, etc.)
- Value or amount of the Financial Interest
- The Investigator’s role in the project, e.g., consenting/enrolling patients, data analysis, publication & reporting, etc.
- Risk profile of the project (i.e., to project participants, to the organization, etc.)
- Additional information regarding the relationship of the Financial Interest to the particular research project or program

The Committee will contact the Investigator to provide additional information, if necessary, to assist with the Committee’s review and determination.

The Committee may also seek additional information from Spectrum Health Innovations, to determine whether the research or sponsored program could impact any existing—or create any new—intellectual property rights.

3. If the Committee determines that an FCOI exists, the Committee will develop a Management Plan (See **Section C, Management Plans** below).

4. In addition, if the Committee determines that an FCOI exists with respect to a PHS-funded research project, Spectrum Health will report certain information to PHS, as required by Federal regulations and as further described in the [*System Policy*] and the [*Office of Sponsored Programs Procedures for Conflict of Interest Management and Reporting*].

### C. Management Plans

A Management Plan related to an FCOI in research or a sponsored program will be developed by the Committee and implemented before the research project or sponsored program begins.<sup>11</sup>

A possible Management Plan may include, is not necessarily limited to, the following:

- I. Public disclosure of the FCOI (e.g., when presenting or publishing);
- II. Disclosure of the conflict to institutional committees, research or program participants (e.g., through consent documents), and data safety monitoring boards;
- III. Modification of the research protocol or sponsored program plan;
- IV. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research or sponsored program (e.g., cannot conduct data analysis, restricted from recruiting human subjects and/or conducting the informed consent process—*see below*);
- V. Reduction or elimination of the Financial Interest (e.g., divestiture or sale of an equity interest);
- VI. Severance of relationship(s) that create the Financial Interest;
- VII. Appointment of an independent monitor capable of taking measures (e.g., review of data) to protect the design, conduct and reporting of the research or sponsored program against bias resulting from the FCOI; and/or
- VIII. Appointment of an independent monitor to review the consent process or the appropriateness of clinical care provided to research/program participants, if applicable.

In determining the Management Plan for an FCOI related to human subject research, the Committee will consider, among other things, whether the Investigator will be allowed to participate in the following activities:

- Subject recruitment;
- Screening for inclusion/exclusion criteria;
- The consent process;
- Clinical evaluation of subjects during the research;
- Reporting of data; and/or
- Conducting data analysis.

In general, the Committee will permit the Investigator to participate in the foregoing activities only if compelling circumstances justify such participation. Compelling circumstances may exist when, for example, the Investigator is the only individual at Spectrum Health with the expertise necessary to conduct certain study-related activities.

The Management Plan for an FCOI related to human subject research will be reviewed by the Spectrum Health IRB before the research project begins. (See the *[IRB/HRPP Procedures for Conflict of Interest Review and Management]*). The Spectrum Health IRB may (1) approve with the Management Plan; (2)

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<sup>11</sup> For a PHS-funded research project, this means that the management plan must be developed and implemented before the expenditure of any funds.

make additional recommendations to the Committee with respect to the Management Plan; or (3) determine that the FCOI cannot be managed sufficiently to protect the rights, safety and welfare of human subjects, in which case the IRB and the Committee will determine appropriate steps to be taken, e.g., the research may not be conducted at Spectrum Health, the Investigator may not be involved in the research study, or the Investigator must eliminate his/her FCOI before the research can take place at Spectrum Health.

The Management Plan may specify the steps to be taken to monitor and verify the Investigator's compliance with the Plan (See **Section E.1, Monitoring of Compliance** below).

The Management Plan will be documented (electronically, to the extent possible, e.g., in COISmart) and must be reviewed and acknowledged by the Investigator.

#### **D. New Disclosures and Interim Management Plans**

If an Investigator who is new to a research project or sponsored program discloses a Financial Interest OR if an existing Investigator discloses a new Financial Interest, the Committee will, within sixty (60) days of the disclosure, review the Financial Interest and determine whether an FCOI exists; if so, the Committee will develop and implement, on at least an interim basis, a Management Plan.

In the case of PHS-funded research, the Committee will also determine whether reporting to PHS is required (See the *[System Policy]* and the *[Office of Sponsored Programs Procedures for Conflict of Interest Management and Reporting]*). Depending on the nature of the Financial Interest, the Committee may determine that additional interim measures are necessary between the date of disclosure and completion of the Committee's review.

If a Financial Interest was not disclosed by an Investigator or, for whatever reason, was not previously reviewed by the Committee, the Committee will, within sixty (60) days of the Committee's receipt of the disclosure, review the Financial Interest and related information and determine whether an FCOI exists; if so, the Committee will develop and implement, on at least an interim basis, a Management Plan. In the case of PHS-funded research, the Committee will also determine whether reporting to PHS is required (See the *[System Policy]* and the *[Office of Sponsored Programs Procedures for Conflict of Interest Management and Reporting]*).

#### **E. Compliance**

##### **1. Monitoring of Compliance**

If the Committee issues a Management Plan, the Committee will monitor compliance with the Plan until its completion, or until the completion of the research project or sponsored program to which the Investigator's FCOI relates.

The Committee's monitoring activities may include annual or periodic Investigator self-certification of compliance; review of Investigator publications and presentations prior to issuance; or in-person meetings with the Investigator to review steps taken to implement the Plan.

## **2. 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.

The retrospective review will be completed within one hundred twenty (120) days of the Committee’s determination of noncompliance.

The Committee will determine the methodology for the review process, as well as the composition of the review panel and the documents to be reviewed. The Committee will document the results of the review, including, but not limited to, the following:

- (i) Project number;
- (ii) Project title;
- (iii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iv) Name of the Investigator with the FCOI;
- (v) Name of the entity with which the Investigator has the FCOI;
- (vi) Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vii) Reason(s) for the retrospective review;
- (viii) Detailed methodology used for the review (e.g., methodology for review process, composition of review panel, documents reviewed);
- (ix) Findings of the review; and
- (x) Conclusions of the review.

## **3. Corrective Action**

Depending on the nature of the FCOI, the Committee may determine that additional interim measures are necessary with regard to the Investigator’s participation in the project between the date that the FCOI or the Investigator’s noncompliance is determined and the completion of the Committee’s retrospective review.

Based on the results of the retrospective review, the Committee will determine what action(s) will be taken to manage the FCOI going forward.

If the Investigator failed to comply with the *[System Policy]* or the requirements of a Management Plan, the Committee may also recommend further corrective action based on applicable Spectrum Health policies and procedures (e.g., IRB/Human Research Protection Program, Human Resources, Medical Staff, Leadership, etc.).

**F. Committee Documents and Record Retention**

All Committee meetings and communications will be recorded in writing. All decisions regarding review of Financial Disclosures and determinations of FCOI and Management Plans will also be recorded in writing. All such Committee documents will be retained by Spectrum Health, in accordance with the *[Spectrum Health Records Retention Policy]*.