

Conflicts of Interest - Research and Sponsored Programs

This Policy is Applicable to the following sites:

Continuing Care, Corporate, Gerber (Newaygo County General Hospital Association), NFAM, Outpatient/Physician Practices, Priority Health, Reed City (Reed City Hospital Corporation), SH GR Hospitals (Spectrum Health Hospitals), SHMG, United/Kelsey (Spectrum Health United; Spectrum Health Kelsey Hospital), Zeeland (Zeeland Community Hospital)

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Department Area:	Research

1. PURPOSE

Spectrum Health is committed to conducting all research activities and sponsored programs in accordance with the highest standards of integrity and ethics. This policy 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.

This policy applies to individuals involved in research and other sponsored programs, including grants, contracts, cooperative agreements and subawards, that: (1) are managed by the Spectrum Health Office of Sponsored Programs; (2) are submitted to and overseen by the Spectrum Health Institutional Review Board (IRB); and/or (3) make use of the space, facilities, materials, personnel or other resources of Spectrum Health.

Individuals involved in the design, conduct and/or reporting of research or a sponsored program at Spectrum Health are required to disclose Financial Interests related to their Institutional Responsibilities. A multi-disciplinary Committee will review all Financial Interest disclosures related to a particular research project or sponsored program and, where appropriate, will develop a Management Plan to eliminate or modify (and monitor) any Financial Conflicts of Interest.

This policy details the following:

- Investigators' responsibility to disclose any Financial Interests related to their Institutional Responsibilities;
- Spectrum Health's responsibility to review all Financial Interest disclosures and determine whether such interests rise to the level of Financial Conflicts of Interest (FCOIs);
- Spectrum Health's policy regarding Management Plans for FCOIs and review of such plans by the Spectrum Health IRB;
- Spectrum Health's policy for reporting FCOIs to the Public Health Service and making publicly available certain information related to the FCOI of Senior/Key Personnel;

- Requirements for subrecipients of Public Health Service (PHS) funding; and
- Education and training requirements related to FCOI.

This policy meets the requirements of and responsibilities for compliance with (1) regulations pertaining to federally-funded research (i.e., the “PHS Regulations,” defined below); (2) accreditation standards of the Association for the Accreditation of Human Research Protection Programs (AAHRPP); and (3) FDA Requirements for Financial Disclosure by Clinical Investigators (Title 21 CFR Part 54).

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 oversight of this policy and all Financial Interest disclosures made pursuant to this policy. The Committee’s structure and processes for review of Financial Interests and development of Management Plans are described in a separate document entitled, *Spectrum Health Research Conflict of Interest Committee Procedures*.

Appendix A defines capitalized terms used throughout this policy.

Appendix B diagrams the Investigator’s responsibility to disclose Financial Interests and Spectrum Health’s responsibility to identify and manage Financial Conflicts of Interest related to research and other sponsored programs. This policy (including the **Appendices**) will be maintained on Spectrum Health’s publicly accessible website.

NOTE: This policy addresses only *individual financial* conflicts of interest. It does not address *non-financial* conflicts of interest nor does it address *organizational* or *institutional* conflicts of interest. Non-financial and institutional conflicts of interest are addressed in other Spectrum Health policies.

2. POLICY

2.1 Investigator Disclosure Requirements

An Investigator who is planning to participate in, or is participating in, research or a sponsored program is required to disclose to Spectrum Health all Financial Interests (AND those of his/her spouse and dependent children) that are related to the Investigator’s Institutional Responsibilities.

2.1.1 WHO must disclose Financial Interests?

A Principal Investigator (PI), Program Director (PD) or anyone else, *regardless of title or position*, who is responsible for the design, conduct, and/or reporting of research or a sponsored program must disclose his/her Financial Interests, in accordance with this policy. Individuals who must comply with this policy include, but are not limited to, site investigators, research nurses, coordinators, and other individuals who make a direct and significant contribution to the research or program data, or who consent and enroll participants. This may also include consultants and collaborators at outside organizations who are involved in research or another sponsored program that is conducted at, or awarded to, Spectrum Health.

2.1.2 WHAT must be disclosed?

An Investigator must disclose Financial Interests of the Investigator (AND those of his/her spouse and dependent children) that are related to the Investigator’s Institutional Responsibilities:

- I. Financial Interests are defined as anything of monetary value, including but not limited to:
 - salary or other payments for services (e.g., consulting fees, speaking fees, gifts, or honoraria);
 - equity interests (e.g., stocks, stock options, loans, notes or other ownership interests);

- intellectual property rights (e.g., patents, copyrights, rights to royalties or licensing fees and any income resulting from such rights).
- II. The Investigator must also disclose the occurrence of any reimbursed or sponsored travel related to his/her Institutional Responsibilities (including the purpose of trip, sponsor/organizer, destination, and duration). Investigators are NOT required to disclose travel that is arranged and paid for directly by Spectrum Health, or that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.

2.1.3 WHEN must disclosures be made?

An Investigator will be required to disclose Financial Interests on an annual basis through Spectrum Health's annual conflict of interest disclosure process.

In addition to an annual disclosure, an Investigator must disclose any new and/or updated Financial Interests at the following point(s) in time:

- I. If the research or sponsored program is submitted to the Public Health Service (PHS) for funding, at the time the application is submitted to the PHS agency (i.e., National Institutes of Health) or to the institution or organization that is responsible for submitting the application.
- II. At the time of submission of a new research protocol to the Spectrum Health IRB—*regardless of funding source for the project*—AND again at the time of continuing review.
- III. 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.

If the Investigator is added to a research project or other sponsored program after it has begun, the Investigator must disclose his/her Financial Interests at that point in time and thereafter in accordance with the above timeline.

At the time of a required disclosure, the Investigator must provide information on all Financial Interests that the Investigator (AND his/her spouse and dependent children) have received in the preceding twelve (12) months.

2.1.4 HOW will disclosures be made?

The 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.

2.2 Research Conflict of Interest Committee

The Research Conflict of Interest Committee is responsible for the review of Financial Interest disclosures, creation of Management Plans and identifying FCOI to be reported to PHS. The Committee is comprised of physicians, researchers, and Spectrum Health compliance, legal and administrative staff.

The Committee is a subcommittee of the Medical Professional Conflicts Committee and, as such, functions within Spectrum Health System's framework for conflicts of interest.

All Financial Interest disclosures will be made available to the Committee for review, in accordance with the requirements described below and the process outlined in the *Spectrum Health Research Conflict of Interest Committee Procedures* document.

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.

For each Financial Interest, the Committee will determine:

2.2.1 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.

2.2.2 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.

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 below in **Section 2.4, Reporting Requirements**.

2.3 Management Plans¹

The Committee will develop a Management Plan for each FCOI. The Plan must be implemented before the research project or sponsored program begins.²

Each Management Plan will be documented and must be reviewed and acknowledged by the Investigator. In addition, each Management Plan for FCOI related to human subject research will be reviewed and approved by the Spectrum Health IRB.

2.4 Reporting Requirements [PHS-FUNDED RESEARCH ONLY]³

¹ The Committee's processes for review of disclosures and development of Management Plans are described in the document, *Spectrum Health Research Conflict of Interest Committee Procedures*.

² For a PHS-funded research project, this means that the management plan must be developed and implemented before the expenditure of any funds.

³ Procedures for reporting FCOIs related to PHS-funded research are described in the document, *Spectrum Health Office of Sponsored Programs Procedures for Managing and Reporting Conflicts of Interest*.

If an FCOI 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 2.3, 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. FCOI reports to PHS will be submitted by the Director of the Office of Sponsored Programs.

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.

Following a retrospective review (See **Section 2.8, Compliance**), the Office of Sponsored Programs will submit an update to any previously submitted FCOI report, if applicable/appropriate.

2.5 Subrecipient Requirements [PHS-FUNDED RESEARCH ONLY]

For a PHS subaward 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 2.4, Reporting Requirements**).

2.6 Public Accessibility of Information [PHS-FUNDED RESEARCH ONLY]⁴

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.

All 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.

2.7 Education and Training

All Investigators and Subrecipients required to adhere to this policy must complete FCOI training. Training records will be made available to the Committee. Training will include the following topics (1)

⁴ Procedures for ensuring public accessibility of information regarding FCOIs related to PHS-funded research are described in the document, *Spectrum Health Office of Sponsored Programs Procedures for Managing and Reporting Conflicts of Interest*.

Spectrum Health’s policy on financial conflicts of interest in research and other sponsored programs; (2) the Investigator’s disclosure responsibilities; and (3) the PHS Regulations.

Training will be required at least every four (4) years, and immediately in the event of any of the following: (1) Spectrum Health’s FCOI policies change in manner that affects Investigator disclosure/compliance requirements, (2) an Investigator is new to Spectrum Health, or (3) an Investigator is found to be noncompliant with this policy or a specific Management Plan.

If the Investigator is participating in PHS-funded research, he/she must—at a minimum—complete FCOI training prior to engaging in such research.

2.8 Compliance

An Investigator must adhere to this policy and any Management Plan issued by the Committee. Failure to comply with this policy or a Management Plan will trigger a requirement to complete the FCOI training module (See **Section 2.7, Education and Training**).

2.8.1 Monitoring of Compliance

Investigator disclosures and compliance with this policy will be monitored by the Office of Sponsored Programs and the Spectrum Health IRB, in concert with the Spectrum Health Office of Organizational Integrity/Compliance.

If the Committee issues a Management Plan, the Committee and Spectrum Health 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.

In addition, the education and training requirements (See **Section 2.7** above) will be jointly monitored by the Office of Sponsored Programs and the Spectrum Health IRB.

2.8.2 Retrospective Review

Whenever there is noncompliance with this policy, 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 this 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; failure to review or manage an FCOI; or failure to comply with a Management Plan.

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

2.8.3 Corrective Action

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 this 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.).

2.8.4 Reporting Results of Retrospective Review [PHS-FUNDED RESEARCH ONLY]

If the failure of an Investigator to comply with this policy or a Management Plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Office of Sponsored Programs shall promptly notify the PHS awarding component of the corrective action to be taken. The report to PHS will include a mitigation report that describes the impact of the bias on the research project and the plan of action to eliminate or mitigate any such bias. Thereafter, the Office of Sponsored Programs will submit an FCOI update annually, as specified in this policy.

2.8.5 PHS Review, Access to Records, and Required Publication Disclosure [PHS-FUNDED RESEARCH ONLY]

In accordance with the PHS Regulations, the PHS awarding component (and/or HHS) may, at any time before, during, or after PHS-funded research award, inquire into any Investigator disclosure of Financial Interest(s) and Spectrum Health's review of, and response to, such disclosure(s), regardless of whether the disclosure(s) resulted in the Committee's determination of any FCOI.

In the event of such an inquiry or request for information by the PHS awarding component and/or HHS, Spectrum Health will submit to PHS/HHS, or permit onsite review of, all information and records pertinent to the requirements of the PHS Regulations and this policy.

PHS/HHS may decide that a particular FCOI will bias the objectivity of PHS-funded research to such an extent that further corrective action is needed, or that the FCOI has not been appropriately managed in accordance with the PHS Regulations. For instance, PHS/HHS may impose special award conditions, in accordance with Federal regulations (i.e., 45 CFR 74.14 and 92.12).

If PHS/HHS determines that the PHS-funded research project is a clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, and that project has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported as required by the PHS Regulations, Spectrum Health shall require the Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations (for the purpose of making such disclosure).

2.9 Retention of Records

Spectrum Health will maintain records of all Investigator disclosures, all actions taken with respect to each FCOI (as determined by the Committee), and all information concerning FCOI held by Senior/Key Personnel participating in PHS-funded research for a minimum of three years following close-out of the research project or sponsored program. (See **System Policy: Records Management, Retention and Destruction, SH-ADMIN-OOI-005**).

3. Revisions

Spectrum Health reserves the right to alter, amend, modify or eliminate this policy at any time without prior written notice.

4. References

21 CFR Part 54

42 CFR Part 50

45 CFR Part 50, Subpart F

45 CFR Part 94

[Research Conflict of Interest Committee Procedures](#)

[Office of Sponsored Programs - Conflict of Interest Reporting Management Procedures](#)

5. Policy Development and Approval

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Not Assigned

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6. Keywords

research, conflict of interest, coi, individual coi, sh-admin-res-020

APPENDIX A
Definitions

Committee: refers to the Research Conflict of Interest Committee. The Committee's responsibilities include the review of disclosures, creation of management plans and identification of FCOIs to be reported to PHS. The Committee's structure and governance are described in separate charter document(s) and/or Spectrum Health policies and procedures.

Disclosure: an Investigator's disclosure of Financial Interests to the Committee.

Financial Conflict of Interest (FCOI): as determined by the Committee, a Financial Interest that could directly and significantly affect the design, conduct, or reporting of research or a sponsored program.

Financial Interest: anything of monetary value, **including but not limited to:**

- salary or other payments for services (e.g., consulting fees, speaking fees, gifts, or honoraria);
- equity interests (e.g., stocks, stock options, loans, notes or other ownership interests);
- intellectual property rights (e.g., patents, copyrights, rights to royalties or licensing fees and any income resulting from such rights).

Financial Interest **does not include:**

- salary, royalties, or other remuneration from Spectrum Health, if the Investigator is employed by Spectrum Health;
- income from investment vehicles such as mutual funds and retirement accounts;
- income from seminars, lectures, or teaching engagements sponsored by Federal, state, or local government agencies, institutions of higher education, academic teaching hospitals, or medical centers or research institutes affiliated with institutions of higher education; and
- income from service on advisory committees or review panels for Federal, state, or local government agencies, institutions of higher education, academic teaching hospitals, or medical centers or research institutes affiliated with institutions of higher education.

HHS: means the United States Department of Health and Human Services. The Public Health Service (PHS) encompasses a number of HHS' operating divisions, including the National Institutes of Health (NIH).

Institutional Responsibilities: professional responsibilities at or on behalf of Spectrum Health. This includes professional/medical practice, research, teaching, and committee memberships (e.g., service on Medical Staff committees, the Institutional Review Board, and quality/peer review committees). This may also include membership and/or participation in research or a sponsored program for which funding is held and managed by Spectrum Health (e.g., the Grand Rapids Clinical Oncology Program (GRCOP) and the Health Resources and Services Administration (HRSA) award for primary care residency expansion through Grand Rapids Medical Education Partners (GRMEP)).

Investigator: the Principal Investigator (PI), Program Director (PD) and anyone else, *regardless of title or position*, who is responsible for the design, conduct, and/or reporting of the research or sponsored program. This includes site investigators, research nurses, coordinators, and other individuals who make a direct and significant contribution to the research or program data, or who consent and enroll participants, for example. This may also include consultants and collaborators at other organizations.

Management Plan: a plan developed by the Committee to manage, reduce or eliminate an identified FCOI to ensure, to the extent possible, that the design, conduct and reporting of research or sponsored program will be free from bias.

PHS Regulations: Federal regulations regarding the *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought* (Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F for grants or cooperative agreements and Title 45 CFR Part 94 for research contracts).

Research: a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Report: Spectrum Health's submission of information to PHS regarding FCOI related to PHS-funded research.

Senior/Key Personnel: the Program Director/Principal Investigator (PD/PI) and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation, and who are identified as "Key Personnel" in a proposal or report submitted to PHS.

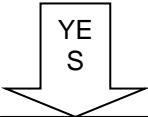
Sponsored Program: any externally funded grant, contract or cooperative agreement awarded to Spectrum Health in which the sponsor requires reporting, invoicing or auditing. All Federal and state awards, as well as industry and private research awards, are considered Sponsored Programs.

Subrecipient: a subcontractor or consortium member that performs a portion of PHS-funded research or a sponsored program which is awarded to Spectrum Health.

APPENDIX B

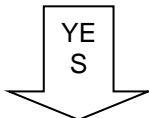
Are you involved in the conduct of “research” or a “sponsored program”?

1. “*Research*” – a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
2. “*Sponsored program*” – project or activity funded or supported by a Federal or state agency through a grant, cooperative agreement, contract or subaward from another organization (i.e. as the “prime” recipient/awardee).



Are you an “Investigator”?

“*Investigator*” means the Principal Investigator (PI), Program Director (PD) and anyone else, regardless of title or position, who is responsible for the design, conduct, or reporting of the research or sponsored program. This includes research nurses, coordinators, and other individuals who make a direct and significant contribution to the study data, or who consent and enroll patients, for example. This may also include consultants and collaborators at other organizations. For GRCOP, this may include site investigators and other personnel at member organizations.



In the past twelve months, have you or your spouse or dependent children received any “financial interest” related to your “institutional responsibilities”?

1. “*Institutional responsibilities*” means your professional responsibilities at or on behalf of Spectrum Health. This includes professional/medical practice, research, teaching, and institutional committee memberships (e.g., service on Medical Staff committees, the Institutional Review Board, and quality/peer review committees). This also includes membership and participation in GRCOP studies.
2. “*Financial interest*” means
 - (a) anything of monetary value (e.g., salary, consulting fees or honoraria) received from a publicly traded or a non-publicly traded entity;
 - (b) equity interest (e.g., stock, stock options, or other ownership interests) in a publicly traded or non-publicly traded entity; or
 - (c) intellectual property rights (e.g., patents or copyrights), upon receipt of income related to such rights (e.g., royalty or license payments).

“Financial interest” also includes any travel that is reimbursed or sponsored by an entity other than a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an Institution of higher education.

“Financial interest” **does not include:**

- salary, royalties, or other remuneration from Spectrum Health, if you are employed by a Spectrum Health entity;
- income from investment vehicles such as mutual funds and retirement accounts;
- income from seminars, lectures, or teaching engagements or income from service on advisory committees or review panels sponsored by Federal, state, or local government agencies, institutions of higher education, academic teaching hospitals, medical centers or research institutes affiliated with institutions of higher education.

YES



You must disclose financial interests related to your institutional responsibilities at the following time(s):

- At the time of submission of any new research protocol to the Spectrum Health Institutional Review Board, regardless of funding source (and again at the time of continuing review). If you are not listed on the initial IRB application but are later added as an “Investigator,” you must disclose your financial interests at that time.
- If you are involved in a research or other program submitted to the Public Health Service (e.g., NIH, HRSA or CDC) for funding, at the time the application is submitted. If you are not listed on the initial application but are later added as an “Investigator,” you must disclose your financial interests at that time.
- After a research project or sponsored program has begun, within thirty days after you receive a new financial interest related to your institutional responsibilities, or after you identify a financial interest that was not previously disclosed at one of the time(s) listed above.

You will also be required to disclose financial interests related to your institutional responsibilities on an annual basis, through Spectrum Health’s annual conflict of interest disclosure process.

DISCLOSURE(S)
) MADE

INVESTIGATOR
RESPONSIBILITIES

SPECTRUM HEALTH
RESPONSIBILITIES

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/COI Coordinator] determines that the financial interest could be affected by the research or sponsored program, or is in an entity whose financial interest could be affected by the research or sponsored program.

YES

Does the financial interest 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