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Research Policy Manual

GEISINGER	<i>Policy</i>	<i>Section</i>	<i>Title</i>
	14.702	14.0 Research	Geisinger Policy on Financial Conflicts of Interest in Research

<i>This policy applies to:</i>		
<input checked="" type="checkbox"/>	Geisinger Medical Center campus	Geisinger Health
<input checked="" type="checkbox"/>	Geisinger Wyoming Valley Medical Center campus	<input checked="" type="checkbox"/> Geisinger Lewistown Hospital
<input type="checkbox"/>		Geisinger Holy Spirit
<input checked="" type="checkbox"/>	GMC Outpatient Surgery-Woodbine	<input checked="" type="checkbox"/> Geisinger Holy Spirit Medical Group
<input type="checkbox"/>		<input checked="" type="checkbox"/> Holy Spirit Corporation
<input checked="" type="checkbox"/>	Community Practice Service Line	<input checked="" type="checkbox"/> Holy Spirit Ventures, Inc.
<input checked="" type="checkbox"/>	Geisinger Community Health Services	
<input checked="" type="checkbox"/>	Marworth	<input checked="" type="checkbox"/> Holy Spirit Health System
<input checked="" type="checkbox"/>	Geisinger Medical Laboratories	
<input checked="" type="checkbox"/>	Geisinger Clinic	
<input checked="" type="checkbox"/>	Geisinger System Services	GNJ Physicians Group
<input checked="" type="checkbox"/>	Geisinger Gray's Woods Outpatient Surgery & Endoscopy Center	<input checked="" type="checkbox"/> Geisinger Commonwealth School of Medicine
<input checked="" type="checkbox"/>	Geisinger Health Plan	<input checked="" type="checkbox"/> Geisinger Endoscopy – Montoursville
<input checked="" type="checkbox"/>	Family Health Associates of Geisinger Lewistown Hospital	Geisinger Jersey Shore Hospital
<input checked="" type="checkbox"/>	ISS Solutions, Inc.	Geisinger Jersey Shore Hospital Foundation
<input checked="" type="checkbox"/>	Geisinger Gastroenterology and Endoscopy Center - Lewistown	
<input checked="" type="checkbox"/>	Geisinger Community Medical Center	
<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Geisinger Bloomsburg Hospital	
<input type="checkbox"/>		

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PURPOSE:

Geisinger is committed to overseeing the conduct of Research in a manner that ensures the integrity of the Research process and maintains the trust of the public, Research volunteers and sponsors in the integrity and credibility of its Researchers, staff and Research programs. This policy is designed to maintain that trust and to help ensure institutional compliance with applicable government regulations concerning outside financial relationships and Research.

Geisinger recognizes the importance of relationships between Researchers and outside organizations and seeks to encourage such relationships. These relationships can give rise to significant discoveries and to the translation of those discoveries into useful products. Productive relationships with outside organizations also inspire new avenues of inquiry and provide opportunities to test Research. However, the financial incentives that accompany such relationships may lead to Financial Conflicts of Interest. Such Conflicts of Interest have the potential to create real or apparent bias in Research. Conflicts of Interest may affect Research integrity and may place human Research subjects at additional risk. Conflicts of Interest, and even the appearance of Conflict of Interest, may reduce public confidence in the Research enterprise.

PERSONS AFFECTED:

This is a system-wide Policy that applies to all Investigators who conduct Research at Geisinger, whether or not federally funded, and Research Regulatory Committee members. This Policy does not cover conflicts of commitment.

POLICY:

Geisinger is committed to the following guiding principles for dealing with Financial Conflicts of Interest related to Research:

1. Geisinger is committed to conducting the highest quality Research and to creating an environment that supports creativity and innovation.
2. Geisinger is committed to the translation of new knowledge into practical applications for public good, especially in areas with the potential to improve medical care and the health of patients.
3. Geisinger strives to create an environment that nurtures the freedom of Investigators to pursue topics and methodologies of their own choosing, and the right to publish results that are free of bias, challenge the status quo and might differ from expected outcomes.
4. Geisinger has a legal and moral responsibility to protect the integrity of Research carried out by its staff.
5. Geisinger has a legal and moral responsibility to ensure the well-being of all its patients, but especially those who volunteer as human Research subjects.
6. Geisinger recognizes that Investigator participation in outside professional and commercial activities makes important direct and indirect contributions to the vitality and strength of the institution.
7. Geisinger recognizes that these imperatives generate tension and the potential for serious Financial Conflicts of Interest (FCOI). Geisinger wishes to safeguard the reputation for academic integrity of both Geisinger and its Investigators by setting out requirements for disclosing potential Financial Conflicts of Interest in Research and the procedures for reviewing such disclosures and determining what corrective measures, if any, should be instituted. To do otherwise could impair the credibility of the academic Research enterprise.
8. Reviews of potential FCOI should be undertaken in light of the following propositions:
 1. Financial Conflicts of Interest per se are inevitable
 2. Financial Conflicts of Interest do not necessarily represent any impropriety when disclosed in advance.
 3. Any failure to disclose a potential conflict for administrative review and response would be a violation of Geisinger policy.
 4. There is a rebuttable presumption against participation in Research that involves a conflicted Investigator and in situations when Geisinger has a Financial Interest (beyond normal sponsorship) in a Research project or sponsor. In such cases the burden is on the conflicted Investigators to present evidence of compelling circumstances that would allow this restriction to be overturned.
 - Other criteria to be considered in overturning the rebuttable presumption include:
 1. Whether the Research is consistent with the core mission of Geisinger
 2. Whether the potential benefit of the Research outweighs the inherent risks of attempting to Manage the FCOI
 3. Whether the FCOI can be Managed in a way that ensures the integrity of the Research and safety of Geisinger patients, and protects the reputation of Geisinger and its staff
 - Examples of such compelling circumstances could include the following:
 1. Research that can only be done with insights, knowledge, resources or special patient populations of the Investigator or the institution.
 2. Research in which the risk to human subjects is sufficiently low.
 5. Financial Conflicts of Interest may be so profound that under some (limited) circumstances that it would be best for all concerned if the staff member and organization did not participate in a particular transaction.
 6. The Research and/or Institutional Conflict of Interest Committees will draw up a management plan describing a set of required actions to eliminate, reduce, and Manage the impact of Financial Conflicts of Interest.
9. In cases where a decision is made to allow Research at Geisinger in which personal or institutional Conflicts of Interest exist, the conflict must be managed. Management of personal or institutional Financial Conflicts of Interest requires a minimum of three components:
 1. Transparency - the conflict must be disclosed to all parties involved in the Research process
 2. Separation of financial activities and decision making from Research activities and decision making
 3. Independent validation of the Research findings - this would normally involve the use of an external monitor
10. Geisinger Investigators and institutional decision makers have an obligation:
 1. To recognize that their primary professional responsibility is to Geisinger
 2. To be alert to the possibility that outside obligations, financial interests or employment relationships run the risk of compromising their objectivity as clinicians, Researchers, and administrators
 3. To be cognizant of institutional Conflict of Interest policies
 4. To consider in advance whether actions they contemplate might create a Conflict of Interest and take appropriate action prior to engaging in activities in which a conflict exists and to report relevant facts promptly to appropriate Geisinger officials.
11. Relationships between Investigators and outside institutions must not impede the open communication of Research results. This includes sharing, in accordance with applicable legal and ethical principles, of data, samples, physical collections, and other supporting materials, unless their dissemination is governed by written proprietary agreements between Geisinger and a second party. If intellectual property is subject to the Geisinger's guidelines (such as those governing technology transfer), a faculty member may not transfer or commit to transfer that property outside Geisinger without going through approved procedures.

PERSONS AFFECTED:

This is a system-wide Policy that applies to all Investigators who conduct Research at Geisinger, whether or not federally funded, and Research Regulatory Committee members. This Policy does not cover conflicts of commitment or institutional Conflicts of Interest.

DEFINITIONS:

1. **Business:** (a) any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, limited liability company, trust or other for-profit commercial Entity; and (b) any not-for-profit Entity acting, directly or indirectly, as an agent for, or on behalf of, a commercial Entity, or controlled by a commercial Entity, i.e., where a commercial Entity owns or funds 50% or more of the not-for-profit Entity or otherwise controls the not-for-profit Entity's activities.
2. **Conflict of Interest:** Any Circumstance in which professional judgment regarding a primary interest (e.g., patient care or welfare; research integrity) threatens to be compromised by a secondary interest (e.g., financial gain; personal or professional reputation) resulting in real or perceived bias. Conflicts of Interest include Financial Interests and Leadership Roles, as defined herein, which could directly and significantly affect an Investigator's design, conduct or reporting of a research study.
3. **Entity:** any domestic or foreign, public or private, organization (excluding a Federal agency), association, business, partnership, sole proprietorship, firm, franchise, holding company, trust from which an Investigator (and Family) receives Remuneration or in which any person has an ownership or equity interest.
4. **Family:** with respect to any Investigator, includes:
 - The Investigator's spouse or domestic partner;
 - The Investigator's parents or siblings;
 - The Investigator's child, grandchild or great grandchild
5. **Financial Conflict of Interest:** a Financial Conflict of Interest exists when Geisinger, through the RCOI committee reasonably determines that an Investigator's Financial Interest is related to a Research project and could directly or significantly affect the design, conduct or reporting of the Research.
6. **Financial Interest:** A Financial Interest includes anything of monetary value, whether or not the value is readily ascertainable. The term, Financial Interest, **does not** include the following:
 - Salary, royalties, or other Remuneration paid by Geisinger to Investigators employed or appointed by Geisinger, including:
 - Intellectual property rights assigned to Geisinger and agreements to share in royalties related to such rights;
 - Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
 - Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a not-for-profit Research institute; or
 - Income from service on advisory committees or review panels for an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a not-for-profit Research institute.
7. **Institutional Conflict of Interest:** a situation in which the financial or business interests of Geisinger, or a Geisinger Official acting within his or her authority on behalf of Geisinger, can inappropriately affect or reasonably appear to inappropriately affect the Research, including:
 - Licensing, technology transfer, and patents;
 - Investments of the Health System;
 - Gifts, when the donor has an interest in the research;
 - Financial interests of senior administrators
 - Other financial interests
8. **Interested Business:** with respect to any Research conducted by an Individual, any Business that:
 - Funds such Research in whole or in part, whether through a Research agreement, gift, or other arrangement;
 - Supplies drugs, devices, software, services, or other goods that are the subject of or used in connection to such Research, or other deliverables in connection with the Research, pursuant to a material transfer agreement, a Research agreement or otherwise;
 - Holds an Investigational New Drug application or Investigational Device Exemption for a Technology being investigated in such Research;
 - Owns, licenses or has any other contractual interest in a Technology being investigated in such Research; or
 - Acts for or on behalf of another Interested Business, directly or indirectly. Depending on the relationship, this could include some medical education companies and other similar entities.
9. **Investigator:** the principal Investigator or program director and any other **Senior/Key Personnel**, regardless of title or position, who is responsible for the design, conduct, or reporting of Research (which may include, for example, collaborators and consultants), regardless of Research funding source.
10. **Investigator's Institutional Responsibilities:** an Investigator's professional responsibilities on behalf of Geisinger, which may include, for example: activities such as Research, Research consultation, teaching, professional practice, Institutional committee memberships and service on panels such as Institutional Review Board (IRB) or Data and Safety Monitoring Boards.

11. **Leadership Role:** Employment, consulting in any administrative or executive capacity, or serving as (i) a member of a board of trustees or board of directors, (ii) an officer, or (iii) a member of an advisory committee, advisory board or subcommittee of a board of trustees or a board of directors, whether remunerated or non-remunerated, in a research Sponsor or research-related organization.
12. **Manage:** taking action to address a real or perceived Financial Conflict of Interest, which can include reducing, eliminating or managing the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct and reporting of Research will be free of bias.
13. **New Significant Financial Interest (SFI)** can be either:
 - A different type or nature of SFI (e.g., royalty payment versus consulting fees) than what was previously disclosed from the same Entity that meets or exceeds the threshold.
 - The same type or nature of SFI (e.g., royalty payment) from a different Entity (e.g., company A versus company B).
14. **PHS:** Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (e.g., NIH, AHRQ, CDC).
15. **PHS Threshold:** the threshold established from time to time by Conflict of Interest regulations of the U.S. Public Health Service (42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94), above which a Financial Interest is considered "significant." Currently the PHS Threshold is: (i) income of \$5,000; or (ii) an equity interest that either: (a) has a value of \$5,000; or (b) represents 5% ownership (see also paragraph (c) under definition of Significant Financial Interest below).
16. **Remuneration includes:**
 - Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship) from any person or entity other than Geisinger;
 - Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value. This does not include income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
17. **Research:** any systematic investigation designed to develop or contribute to generalizable knowledge, including all basic, applied and demonstration Research in all fields of knowledge: (a) conducted pursuant to an agreement between Geisinger and a third party; (b) supported by funding that is administered through Geisinger (e.g., through the Office of Sponsored Programs, Research Executive Committee, center, institute or department); or (c) requiring review by a Geisinger regulatory body (e.g., the Institutional Review Board).
18. **Research Regulatory Committee:** Committee members for the following regulatory committees: Institutional Review Board (IRB), Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), Radiation Safety Committee (RSC)
19. **Senior/Key Personnel:** the principal Investigator/program director and any other person identified as Senior/Key Personnel by Geisinger in a grant application, progress report or any other report related to the Research. This includes individuals responsible for the design, conduct, or reporting of Research, regardless of title or position or Research funding source (which may include, for example, collaborators and consultants)
20. **Significant Financial Interest (SFI):** any Financial Interest that consists of one or more of the following interests of the Investigator (and Family) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
 - For a **publicly traded Entity:** SFI exists if the value of any Remuneration received from the Entity in the twelve months preceding the disclosure and the value of any equity interest in the Entity as of the date of the disclosure, when aggregated, exceeds \$5,000;
 - For a **non-publicly traded Entity:** SFI exists if the value of any Remuneration received from the Entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000 or when the Investigator (or Family) holds any equity interest (e.g., stock, stock option or ownership interest) in such Entity, regardless of the amount; or
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests received from an Interested Business, including non-Geisinger not for profit entities.
21. **Technology:** any methodology, information, software, compound, drug, device, diagnostic, medical or surgical procedure, or composition of matter intended for public use or Research.

PROCEDURE:

A. General Responsibilities of Investigators Related to this Policy

Investigators have an obligation (1) to be fully cognizant of this and related institutional policies concerning Conflicts of Interest, (2) to consider in advance whether any actions they contemplate might create a Conflict of Interest or the appearance of a Conflict of Interest, (3) to report relevant facts promptly to the appropriate body or officials, (4) to work with institutional committees and officials to avoid, eliminate, reduce and/or Manage conflicts of interest, and (5) to abide by final decisions rendered in regard thereto by said committees and officials. Investigators may not begin any Research until any real or perceived Conflicts of Interest related to such Research are reduced, managed, or eliminated.

Investigators are required to report actions that they are contemplating that could create real or apparent Conflicts of Interest before such actions are finalized to their supervisor and to the Chair of the RCOI Committee. They should make reasonable efforts to provide institutional authorities with sufficient time to assist them prospectively in Managing potential Financial Conflicts of Interest. When an Investigator reports a real or potential FCOI only after he or she has taken an

action to create it, there shall be a rebuttable presumption that the Investigator failed to report the matter in a timely fashion.

Failure of an Investigator to report any potential Conflict of Interest could result in notification of Principal Investigator and/or supervisor removal of Investigator from research studies, and recommendation to the IRB to SUSPEND studies.

Each Investigator shall:

1. Read, understand and abide by this policy,
2. Prior to entering into a relationship with a Interested Business, disclose Financial Interests as outlined in this policy, and
3. Complete training regarding Financial Conflicts of Interest:
 - Prior to engaging in any Research activities;
 - At least every four (4) years; and
 - Immediately when any of the following circumstances apply:
 - i. Geisinger revises its Financial Conflict of Interest policy or procedures in any manner that affects the requirements of Investigators;
 - ii. An Investigator is new to Geisinger; or
 - iii. Geisinger finds that an Investigator is not in compliance with this policy or prescribed FCOI management plan

B. Investigator Disclosure of Financial Interests to Geisinger

1. Each Investigator must report to Geisinger all of his/her Financial Interests at least annually using Geisinger's Annual Conflict of Interest Questionnaire. Geisinger reserves the right to request additional information and supporting documentation as needed.
2. Investigators must also disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to the Investigator's Institutional Responsibilities. This disclosure requirement does not apply to travel that is reimbursed or sponsored by Geisinger, a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a Research institute that is affiliated with an Institution of higher education. The following information must be disclosed within 30 days of the reimbursed travel: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip. In accordance with this policy, the RCOIC will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the Research.
3. No externally sponsored project application will be approved for submission to a sponsor by the Office of Sponsored Projects (OSP) unless each Investigator listed on the proposal has a current Annual Conflict of Interest Questionnaire on file and has completed the requisite training. New awards require all named investigators to have a current Annual Conflict of Interest Questionnaire on file. Each Investigator added to an ongoing Research project must have an Annual Conflict of Interest Questionnaire on file. In addition, each Investigator listed on a sponsored project application must attest that there is no conflict of interest related to such Research or must disclose all of his/her Financial Interests related to such Research.
4. Prior to conducting Research that involves human subjects, each Investigator on the proposal must have a current Annual Conflict of Interest Questionnaire on file at the time of IRB submission. In addition, each Investigator proposing to conduct such Research must disclose all of his/her Financial Interests related to such Research on the applicable IRB form. Such disclosures shall be submitted not later than the time a new application, an application for exemption, a Research Determination Worksheet, a protocol modification/amendment or a continuing review relating to such Research is submitted for review by the IRB.
5. Each Investigator must update their Annual Conflict of Interest Questionnaire within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Financial Interest or any information reported pursuant to Sections B.1. above, to reflect any changed circumstances.

C. General Responsibilities of the Institution Related to Financial Conflict of Interest in Research

Geisinger will comply with all applicable federal and state laws, regulations and policies regarding promoting objectivity in Research. These include, but are not limited to:

1. Maintaining an up-to-date, written, enforced FCOI policy of that complies with 42 CFR Part 50.601 et seq., and make such policy available via a publicly accessible web site, <http://www.Geisinger.org>;
2. Informing each Investigator of this policy on FCOI, the Investigator's responsibilities regarding disclosure of SFIs, and of the regulations at 42 CFR Part 50.601 et seq.;
3. Requiring each Investigator to complete training regarding the same and in accordance with the circumstances noted in Section A. of this policy, above;
4. Taking reasonable steps to ensure that any subrecipient Investigator of PHS-funded Research complies with subrecipient's institutional FCOI policy or this policy if subrecipient Investigator's institution does not have a FCOI policy consistent with 42 CFR Part 50.601 et seq.;
5. Providing guidelines consistent with 42 CFR Part 50.601 et seq. for the RCOI Committee to determine whether an Investigator's SFI is related to PHS-funded Research, and if so related, whether the SFI is a FCOI;
6. Taking such actions as necessary to Manage any FCOI, including any FCOI of a subrecipient Investigator of PHS-funded Research, pursuant to 42 CFR Part 50.601 et seq.;

7. Providing the PHS Awarding Component with FCOI reports, as required under the regulations found at 42 CFR Part 50.601 et seq.;
8. Maintaining records relating to all Investigator disclosures of Financial Interests, in accordance with section M. of this policy;
9. Establishing adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate; and
10. Ensuring public accessibility via written response within five business days of receipt of a request in the Office of Research Compliance, information (including Investigator name, title and role in respect to Research project, name of Entity in which SFI is held, and nature and value ranges of SFI) concerning any SFI disclosed to Geisinger that meets the following three criteria:
 - SFI was disclosed and is still held by Investigator/Senior/Key Personnel for PHS-funded Research projects;
 - Geisinger determines the SFI is related to the PHS-funded Research; and
 - Geisinger determines the SFI is a FCOI
11. Institutional Conflict of Interest is assessed with each externally sponsored project application prior to submission to the sponsor by the Office of Sponsored Projects and upon award of any funding.
12. Geisinger shall provide all FCOI reports to Research sponsors as required by federal FCOI regulations (42 C.F.R. §§ 50.604(h) and 50.605(b)) and rules (NSF 510), sponsor terms and conditions, and/or as may be required by an FCOI Management Plan.
13. Geisinger shall maintain records relating to Investigator SFI disclosures and the review and determination related to each disclosure (whether or not an FCOI was found and any FCOI Management Plan required) for at least three years from completion of the research as is required by federal FCOI regulations (42 C.F.R. § 50.604(i)).

D. Office of Research Compliance (ORC) Review and Determination

The ORC shall be responsible for (i) the review of all SFI disclosed in order to determine whether the SFI is related to Research and (ii) if so related, referral to the RCOI Committee in order to determine whether the SFI is a FCOI, unless the RCOI Committee has delegated its authority to the ORC to make this determination.

(1) Related to Research:

A SFI will be deemed to be related to Research if the SFI could be affected by the Research or is in an Entity or individual whose financial interest could be affected by the Research. The ORC may seek the input of the Investigator and/or his/her department/unit head in the determination of whether the SFI is related to Research.

The ORC shall refer SFI disclosures related to RCOI Committee for review and determination of whether an FCOI is present; provided, however, that the RCOI Committee is authorized to delegate to the ORC its authority to determine whether an SFI constitutes an FCOI, and in the event the RCOI Committee has delegated that authority to ORC through specific guidelines, the ORC may determine whether the SFI constitutes an FCOI without referral to the RCOI Committee.

(2) FCOI Determination:

The RCOI Committee or the ORC, under authority granted by the RCOI Committee, shall determine whether the SFI could directly and significantly affect the design, conduct or reporting of related Research. If the Committee or ORC shall find that an FCOI exists, then it shall also determine whether the FCOI shall be managed or eliminated prior to the expenditure of funds for the related Research.

If, in the course of on-going Research, an Investigator who is new to the Research discloses an SFI or an existing Investigator discloses a new SFI, then the ORC or RCOI Committee shall review the SFI, make an FCOI determination, as provided in the previous paragraph and, if the SFI is determined to constitute an FCOI, implement an FCOI Management Plan within sixty (60) days of the date of the disclosure. If, in the course of on-going Research, an Investigator discloses an SFI that was not disclosed in a timely manner as required by this Policy, the ORC or RCOI Committee shall review the SFI, make an FCOI determination, as provided in the previous paragraph and, if the SFI is determined to constitute an FCOI, implement an FCOI Management Plan within sixty (60) days of the date of the disclosure.

If human participants are involved in the related research, the RCOI Committee also shall determine whether the SFI will adversely affect the protection of participants. If the RCOI Committee has determined that the SFI will adversely affect the protection of human participants, then disclosure to potential participants or the public cannot be used as the sole method of FCOI management.

E. FCOI Management Plans

The RCOI Committee shall document its FCOI Management Plan, which shall specify the actions that have been, and/or shall be, taken to manage the FCOI. The Investigator's input regarding what actions should be included in the FCOI Management Plan shall be considered by the RCOI Committee. Examples of conditions and restrictions that may be imposed to manage an FCOI, either as a single condition or restriction, or as a combination of conditions and restrictions, and on either an interim or permanent basis include, but are not limited to:

- Public disclosure of the FCOI (e.g., in public presentations or publications of the related Research);
- Disclosure of the FCOI to human participants, if applicable;
- Appointment of an independent monitor capable and willing to take appropriate measures to protect the design, conduct and reporting of the Research against potential bias resulting from the FCOI;

- In instances in which residents, trainees, or students are involved in the Research, taking steps, to the extent possible, to protect their progress, intellectual property interests, and welfare (e.g., appointment of an independent monitor);
- Modification of the Research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research, including interim disqualification of personnel from the Research between the date of disclosure and the completion of the review of the matter;
- Reduction or elimination of the SFI (e.g., sale of an equity interest); or
- Severance of the relationship giving rise to the FCOI.

The submission of a protocol to the IRB includes a question regarding whether the Investigator has a COI with the submitted protocol. If so, the IRB Analyst contacts the ORC staff to determine if there is a Management Plan in place. An IRB Chair is also a member of the RCOI Committee to allow appropriate communication to the IRB Committee; and as such, is informed about the nature and amount of any SFI related to human participants in research, along with the RCOI Committee's findings, FCOI determination and any FCOI Management Plan approved by the RCOI Committee.

Investigators conducting Research involving human participants should note that review of SFI and implementation of an FCOI Management Plan, if such a Plan is necessary, by the RCOI Committee does not constitute approval of the Research proposed. The IRB has final authority on whether the proposed Research should be approved and shall not render its decision until after the RCOI Committee has reviewed the SFI and implemented any necessary FCOI Management Plan. The IRB shall consider the FCOI Management Plan, if any, in its final determination and also may include additional protections to the FCOI Management Plan if it deems they are necessary for the protection of human participants.

The Investigator shall document his/her agreement to abide by the FCOI Management Plan before the FCOI Management Plan may be finalized. This documentation of agreement is kept by ORC staff. The Investigator's supervisor, Principal Investigator of studies, and the IRB director will receive a copy of any new FCOI Management Plans. The Investigator may request changes to the provisions set forth in the FCOI Management Plan, if such changes are requested within five (5) days of the FCOI Management Plan being sent to the Investigator. The RCOI Committee shall consider the changes requested and make a determination whether to accept any of them.

Funding for the related Research shall not be released unless and until the FCOI Management Plan has been implemented and agreed to by the Investigator. If funding has already begun, the RCOI Committee may request the funding to be held pending the FCOI determination and the Investigator's agreement to the FCOI Management Plan, if any.

F. Research Conflict of Interest Committee

Geisinger has established a system-wide Research Conflict of Interest Committee (RCOI Committee), which is responsible for establishing and communicating standards with respect to research related Conflicts of Interest and carrying out the review and disposition of such potential Conflicts of Interest. The RCOI Committee is responsible for control and management of all research related Conflicts of Interest, including development and oversight of a management plan to eliminate, reduce or manage actual or apparent Conflicts of Interest. The RCOI Committee will document its findings and the basis for its decision with respect to any research; such documentation will be made available to the appropriate research regulatory committee, e.g., IRB, IACUC.

To the extent possible and as allowed by law, all Conflict of Interest Questionnaires and related information shall be kept confidential and may only be shared with other individuals identified case-by-case on a need-to-know basis (e.g. Institutional COI Committee, IRB).

G. Non-Compliance

Failure to comply with this policy may result in disciplinary action up to and including termination.

REFERENCES:

Geisinger Annual FCOI Questionnaire

U.S. Public Health Service regulations - 42 CFR Part 50—*Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought*

U.S. Public Health Service regulations - 45 CFR Part 74—*Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations*

Food and Drug Administration regulations - 21 CFR Part 54

Frequently Asked Questions – Responsibility of Applicants for Promoting Objectivity in Research (2011 Revised Regulations) - http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3189

Document Information

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<i>Developed</i>	<i>Revised/Reviewed*</i>	<i>Policy Owner</i>	<i>Approved by</i>	<i>Date</i>
08/20/2012	04/30/2019	Office of Research Compliance	Associate Vice President, Research	
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