Policy

Geisinger

Title: **Financial Conflicts of Interest in Research**	
Joint Commission Chapter Section: 14.0 Research	*Date ORIGINAL policy was created:* August 20, 2012
This policy belongs to: Office of Research Compliance	
Committee/Council Approval(s): Associate Vice President, Research	*Date of COMMITTEE Approval(s):* August 3, 2021

☒ **This Policy contains one or more PROCEDURES outlining the methods and applicability of this Policy.**

This policy applies to the following Geisinger Entities:

CLINICAL ENTITIES *(includes Geisinger entities providing health care services, i.e., hospitals, group practices, clinics)*	
☒ Community Medical Center (CMC or GCMC)	☒ Geisinger Lewistown Hospital (GLH)
☒ Endoscopy Center of Geisinger Lewistown Hospital	☒ Geisinger Medical Center (GMC)
☒ Geisinger Bloomsburg Hospital (GBH)	☒ Geisinger Medical Center Muncy (GMCM)
☒ Geisinger Clinic (GC)	☒ Geisinger Pharmacy, LLC
☒ Geisinger Community Health Services (GCHS)	☒ Geisinger Wyoming Valley Medical Center (GWV)
☒ Geisinger Encompass Health, LLC	☒ GMC Outpatient Surgery - Woodbine
☒ Geisinger Endoscopy-Montoursville (a facility of G-HM)	☒ GWV Outpatient Surgery - CenterPoint
☒ Geisinger-HM Joint Venture (G-HM)	☒ Marworth
☒ Geisinger Healthplex State College Outpatient Surgery and Endoscopy Center, a department of Geisinger-Lewistown Hospital	☒ West Shore Advanced Life Support Services, Inc. (WSALS or Geisinger EMS)
☒ Geisinger Jersey Shore Hospital (GJSH)	

NON-CLINICAL ENTITIES *(includes Geisinger business/corporate entities not providing health care services)*	
☒ Geisinger Commonwealth School of Medicine (GCSOM)	☒ Geisinger System Services (GSS)
☒ Geisinger Health (GH or GHF)	☒ GNJ Physicians Group (GNJ)
☒ Geisinger Health Plan (GHP)	☒ ISS Solutions, Inc. (ISS)
☒ Geisinger Quality Options, Inc. (GQO)	☒ Keystone Health Information Exchange, Inc. (KeyHIE)

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, either real or perceived, 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, Research Regulatory Committee members, those who hold research administrative positions, and other research staff as outlined below. This Policy does not cover conflicts of commitment.

POLICY

Geisinger is committed to the following guiding principles for dealing with FCOIs related to research:

1. Geisinger is committed to conducting the highest quality research and utilizing knowledge into practical applications for public good, especially in areas with the potential to improve medical care and the health of patients, while ensuring the well-being of all its patients, and those who volunteer as human research subjects.

2. Geisinger strives to create an environment that offers autonomy for investigators to pursue topics of their own choosing and the ability/aptitude to publish results that are free of bias. Geisinger recognizes that participation in outside professional and commercial activities makes important direct and indirect contributions to the vitality and strength of the institution.

3. Geisinger recognizes that these imperatives generate the potential for serious FCOIs and wishes to safeguard the reputation of both Geisinger and its investigators by setting out requirements for disclosing potential FCOIs in research. The procedures for reviewing such disclosures, and determining what corrective measures, if any, should be instituted.

4. Reviews of potential FCOI should be undertaken in light of the following propositions:

a. FCOIs per se are inevitable and do not necessarily represent any impropriety when disclosed in advance, but failure to disclose a potential conflict for administrative review and response is a violation of Geisinger policy.
b. There is a rebuttable presumption against participation in research that involves a conflicted investigator and in situations when Geisinger has a FI (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, which includes:
    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, the safety of Geisinger patients, and protects the reputation of Geisinger and its staff.
        a. Examples of such compelling circumstances include:
            i. Research that can only be done with insights, knowledge, resources, or special patient populations of the investigator or the institution.
            ii. Research in which the risk to human subjects is sufficiently low.
    4. FCOIs may be so profound that under limited circumstances, it would be best for all concerned if the staff member and organization did not participate in a particular transaction.

5. In cases where a decision is made to allow research at Geisinger in which a personal or ICOI exists, the conflict must be managed.

Reviews of ICOIs are conducted with adherence to Geisinger Conflicts of Interest Policy for Employees and Institutional Conflicts.

5. Geisinger investigators and institutional decision makers have an obligation:
   a. To recognize that their primary professional responsibility is to Geisinger.
   b. To be alert to the possibility that outside obligations, FIs, or employment relationships run the risk of compromising their objectivity as clinicians, researchers, and administrators.
   c. To be cognizant of ICOI policies.
   d. To consider in advance whether actions they contemplate might create a COI and take appropriate action prior to engaging in activities in which a conflict exists and to report relevant facts promptly to appropriate Geisinger officials.

6. 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. Additionally, faculty members may not transfer or commit to transfer intellectual property outside of Geisinger without going through approved procedures.

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 (COI)**: 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. COIs 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 individual, includes:
   a. The individual’s spouse or domestic partner.
   b. The individual’s parents or siblings.
   c. The individual’s child, grandchild, or great grandchild.

5. **Financial Conflict of Interest (FCOI)**: Financial conflict of interest exists when Geisinger, through the Research Conflict of Interest (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 (FI)**: A financial interest includes anything of monetary value, whether or not the value is readily ascertainable. The term, FI, does not include the following:

a. Salary, royalties, or other remuneration paid by Geisinger to investigators employed or appointed by Geisinger, including:
   i. Intellectual property rights assigned to Geisinger and agreements to share in royalties related to such rights.
   ii. 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.
   iii. 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
   iv. 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 (ICOI)**: 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:

a. Licensing, technology transfer, and patents.
b. Investments of Geisinger.
c. Gifts when the donor has an interest in the research.
d. FIs of senior administrators; or
e. Other FIs.

8. **Interested Business**: With respect to any research conducted by an individual, any business that:

a. Funds such research in whole or in part, whether through a research agreement, gift, or other arrangement.
b. 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.
c. Holds an Investigational New Drug application or Investigational Device Exemption for a technology being investigated in such research.
d. Owns, licenses, or has any other contractual interest in a technology being investigated in such research; or
e. 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 FCOI, which can include reducing, eliminating, or managing the FCOI, 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. A different type of FI (e.g., royalty payment versus consulting fees), or increased value than what was previously disclosed from the same entity that meets or exceeds the threshold.
b. 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 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 FI 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.

16. **Remuneration** includes:

a. 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.
b. 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 (RCC)**: Committee members for the following regulatory committees: Institutional Review Board (IRB), Institutional Biosafety Committee (IBC), Radiation Safety Committee – Human Research Subcommittee (RSC), Research Compliance Committee (RCC), Research Conflict of Interest (RCOI) Committee, Scientific Review Committee (SRC).

19. **Senior/Key Personnel**: The principal investigator/program director and any other person identified as senior/key personnel by Geisinger in a grant application, IRB application, or any report related to the research. This includes individuals responsible for the design, conduct, or reporting of research, regardless of title, position, or research funding source (which may include, for example, collaborators and consultants).

20. **Significant Financial Interest (SFI)**: Any FI 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:

a. 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.
b. 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
c. 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.

RESPONSIBILITIES

N/A

EQUIPMENT/SUPPLIES

N/A

PROCEDURE

General Responsibilities of Investigators Related to this Policy.

a. Read, understand, and abide by this policy.
b. Complete training regarding FCOIs:
    a. Prior to engaging in any research activities.
    b. At least every four (4) years; and immediately when any of the following circumstances apply:
        i. Geisinger revises its FCOI policy or procedures in any manner that affects the requirements of investigators.
        ii. An investigator is new to Geisinger.
        iii. Geisinger finds that an investigator is not in compliance with this policy or prescribed FCOI management plan.

c. To not begin any research until any real or perceived COIs related to such research are reduced, managed, or eliminated.
d. To work with institutional committees and officials to avoid, eliminate, reduce and/or manage COIs, and abide by final decisions rendered in regard thereto by said committees and officials.
e. Report contemplative actions that could create real or apparent COIs before such actions are finalized to their supervisor and to the Office of Research Compliance.
    i. When an investigator reports a real or potential FCOI only after they have taken an action to create it, there shall be a rebuttable presumption that the investigator failed to report the matter in a timely fashion.
f. Make reasonable efforts to provide institutional authorities with sufficient time to assist in managing potential FCOIs.

2. Investigator Disclosure of Financial Interests to Geisinger

a. Each investigator must report to Geisinger all of their FIs at least annually, and within thirty (30) days of discovering or acquiring a new FI or any information to reflect any changed circumstances using Geisinger's Annual Conflict of Interest Questionnaire. Geisinger reserves the right to request additional information and supporting documentation as needed.
b. 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. The following information must be disclosed within thirty (30) days of the reimbursed travel:
    i. the purpose of the trip, the identity of the sponsor/organizer.
    ii. the destination, and.
    iii. the duration of the trip.

    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.
c. 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. In addition, each investigator listed on a sponsored project application must attest that there is no COI related to such research or must disclose all of their FIs related to such research, as applicable.
d. Prior to conducting research that involves human subjects, each investigator on the IRB application must have a current Annual Conflict of Interest Questionnaire on file at the time of IRB submission. In addition, the principal investigator must attest to completing the Annual Conflict of Interest Questionnaire and required training, attest that they believe all co-investigators have completed the Annual Conflict of Interest Questionnaire, and indicate if they have a relationship with the study sponsor. A current questionnaire must be on file for each investigator at the time of any submission for a study that involves human subject's research. The questionnaire is not required for the submission of Research Determination Worksheets (RDWs).

3. Other Research Staff Disclosure of Financial Interest to Geisinger - Pursuant to Geisinger Policy Conflicts of Interest Policy for Employees and Institutional Conflicts, if any employee involved in research has any financial or outside

interests or outside activities that create an actual or potentially perceived COI, they must disclose such interest or activity to their supervisor.

4. **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 with respect to FCOIs. These include but are not limited to 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94.

5. 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.

a. Related to Research: An 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 FI could be affected by the research. The ORC may seek the input of the investigator and their department/unit head in the determination of whether the SFI is related to research.
b. FCOI Determination: The RCOI Committee or the ORC, under authority granted by the RCOI Committee, will determine if the SFI could directly and significantly affect the design, conduct or reporting of related research. If the Committee or ORC finds that an FCOI exists, then it will also determine whether the FCOI should be managed or eliminated prior to the expenditure of funds for the related research.

If, in the course of ongoing research, an investigator who is new to participating in research, or an existing investigator discloses an SFI, the ORC or RCOI Committee shall review the SFI, and, if 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 determined, then disclosure to potential participants or the public cannot be used as the sole method of FCOI management.

6. 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. The following may be imposed to manage an FCOI on either an interim or permanent basis include, but are not limited to:

a. Public disclosure of the FCOI (e.g., in presentations or publications of the related research).
b. Disclosure of the FCOI to human participants, if applicable.
c. 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.
d. 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).
e. Modification of the research plan.
f. 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.
g. Reduction or elimination of the SFI (e.g., sale of an equity interest); or
h. Severance of the relationship giving rise to the FCOI

The submission of a protocol to the IRB includes a question regarding whether the principal investigator has a relationship with the study sponsor. If so, the IRB staff reviews the submission for a management plan or contacts the ORC staff to determine if there is a management plan in place. An IRB Chair or Director 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 a necessary FCOI management plan 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 determined necessary for the protection of human participants.

The investigator shall document their agreement to abide by the FCOI management plan in order to finalize the FCOI management plan. ORC staff keeps this documentation of agreement. 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 within five (5) days of the FCOI management plan being sent to the investigator. The RCOI Committee shall determine whether to accept any requested changes.

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.

7. **Research Conflict of Interest Committee -** Geisinger has established a system-wide RCOI Committee which is responsible for establishing and communicating standards with respect to research related COIs and conducting the review and disposition of such potential COIs. The RCOI Committee is responsible for control and management of all research related COIs, including development and oversight of a management plan to eliminate, reduce, or manage actual or apparent COIs. 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. 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).

8. **Non-Compliance** – Failure of an investigator to report any potential COI could result in notification of principal investigator and/or supervisor removal of investigator from research studies, and recommendation to the IRB to suspend studies.

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

ATTACHMENTS

https://grants.nih.gov/faqs#/financial-conflict-of-interests.htm

REFERENCES

Geisinger Annual FCOI Questionnaire

U.S. Public Health Service regulations - 42 CFR Part 50 Subpart F 'Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought https://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm

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 https://orip.nih.gov/sites/default/files/CFR-2007-title45-vol1-part74_SECUREDDOCUMENT.pdf

Food and Drug Administration regulations - 21 CFR Part 54
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=54&showFR=1

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