

Status **Active** PolicyStat ID **12780568**



Origination 12/15/2008
Last Approved 12/8/2022
Effective 12/8/2022
Last Revised 12/8/2022

Owner **Vicky Hickey:**
Mgr, Research & Education
Area **Guthrie Foundation Research**
Applicability **The Guthrie Clinic - All Entities**

GF-RA-330-001 Managing Individual Financial Conflicts of Interest in Clinical Research

Applies to

All Departments

Policy

Individual financial conflicts of interest that may arise in the course of conducting research at The Guthrie Clinic must be identified, evaluated and managed. The regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants, cooperative agreements or sponsored pharmaceutical studies will be free from bias resulting from Investigator financial conflicts of interest. This policy is available via the www.guthrie.org website. Additionally all requests regarding financial conflicts of interest will be provided through a written response within five business days of a request.

Regulatory citations: 42CFR50, Subpart F; 21CFR54

Purpose

This document is intended to supplement the policy and procedures set forth in the Guthrie Clinic Policy Conflict of Interest Disclosure for Specified Employees (COM-928-3023 available at <https://guthrie-system.policystat.com/policy/9087242/latest/>). A financial conflict of interest in research exists when the financial interest in research of a covered individual or member of the immediate family of a covered individual may compromise, or have the appearance of compromising, the covered individual's professional judgment in conducting or reporting research. Such a conflict can affect the oversight of

research, collection, analysis, and interpretation of data, as well as hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants, and use of statistical methods.

Scope

This policy applies to all persons who perform, regulate or oversee research conducted under the auspices of The Guthrie Clinic ("Guthrie"). This policy requires that individuals submit an annual disclosure form to ensure that the design, conduct and reporting of any sponsored program activity which includes NIH grants, cooperative agreements and sponsored pharmaceutical studies will not be biased by the significant financial interests or obligations of any individual participating in research.

Individuals required to file a disclosure form include investigators - those in the roles of Project Director, Principal Investigator (PI), Co-Investigators, Sub-Investigators and any individual who is in a significant decision-making role for a research study - or anyone who has signatory authority for a Guthrie Foundation account related to research. The Director of Donald Guthrie Foundation has signatory authority for the review and approval of research grants awarded to researchers from the Donald Guthrie Foundation account. All applications for grants will be reviewed by the Director of Donald Guthrie Foundation. Grant applications requested for research by the Director of Donald Guthrie Foundation as a research investigator will be reviewed by the Enterprise Wide Compliance Committee when the dollar amount exceeds \$12000 for expenses (not included statistical consulting fees or publication fees).

To comply with this policy, each individual must annually complete the Specified Employee Conflict of Interest Form. Further, any investigator should submit an updated form within 30 days of discovering or acquiring a new significant financial interest.

Definitions

The Guthrie Clinic Enterprise Wide Compliance Committee This committee consists of CEO, The Guthrie Clinic (TGC); President, Guthrie Medical Group P.C.; CFO, TGC; Medical Director, TGC; Sr. Director of Internal Audit/Compliance, TGC; Compliance Officer, Guthrie Medical Group P.C.; Compliance Officer, TGC Acute/Post Acute Facilities; TGC Cortland Campus Compliance Officer; General Counsel, TGC; and Sr. Vice President Human Resources TGC

Investigator Investigator means the Project Director, Principal Investigator, Co-Investigators, Sub-Investigators and any other person in a significant decision-making role, regardless of title or position (i.e. research team members), who is responsible for the design, conduct, or reporting of research funded by the NIH or sponsored pharmaceutical studies, or proposed for such funding, which may include, for example, collaborators or consultants

Institutional Responsibilities Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, 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 Boards or Data and Safety Monitoring Boards.

Significant Financial Interest

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - i. With regard to any publicly traded entity, a significant financial interest 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 disclosure, when aggregated, exceeds the threshold. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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;
 - ii. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds the threshold; or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators also must 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 their Institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or 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, or a research institute that is affiliated with an institution of higher education.
 - At a minimum travel disclosures will include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.
3. Salary royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
4. Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights;
5. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;

Exclusions of Significant Financial Interest

- 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 research institute that is affiliated with an Institution of higher education; or

- Income from service on advisory committees or review panels for a federal, state or local government agency, 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.

Financial Conflict of Interest (FCOI) A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research or sponsored pharmaceutical studies.

Procedures

A. Evaluation of Disclosures

All covered individuals will disclose their financial interests in research annually or more frequently as circumstances may warrant. Disclosures will be evaluated by the Vice President of Internal Audit and Compliance and the Director of Guthrie Foundation

On an annual basis, the clinical research database will be utilized to generate a list of all investigators and study team members participating in research. Emails will be sent to these individuals soliciting completion of the financial conflict of interest form and responses will be tracked to ensure that all investigators and study team members provided disclosure. The list of completed forms including disclosures will be shared with the Director of the Guthrie Foundation who will discuss potential conflicts with the Compliance Officer to determine whether a management plan is required.

On an ongoing basis it is the responsibility of the investigator and study team members to disclose new potential financial conflicts of interest in research as they arise. Additionally, prior to any contract being formalized, the contracts office will confirm that the institutional financial conflict of interest form has been completed. If any new conflicts are disclosed they are reported to the Director of the Guthrie Foundation who will collaborate with the Compliance Officer to determine a management plan.

If examination of a disclosure indicates that a potential conflict of interest exists, or is likely to develop within the next year, then the Vice President of Internal Audit and Compliance will present the matter to the The Guthrie Clinic Enterprise Wide Compliance Committee for further review.

In addition to annual disclosures, matters of potential financial conflict of interest may be referred to the Vice President of Internal Audit and Compliance by the Institutional Review Board (IRB) because of concerns arising during examination of an application to conduct research involving human subjects; or by any member of the Guthrie staff with a relevant concern.

B. Management of Conflicts of Interest

If the Guthrie Clinic Enterprise Wide Compliance Committee determines that a situation presents a financial conflict of interest, it may either specify measures to be taken to manage the conflict or ask the Vice President of Internal Audit and Compliance to develop a management plan in consultation with the Director of Donald Guthrie Foundation and the Chair of the IRB. Further, if the Guthrie Clinic Enterprise Wide Compliance Committee identifies a significant financial conflict of interest that was not disclosed or reviewed in a timely manner, the designated official(s) shall within sixty (60) days review the significant financial conflict of interest, determine if an FCOI exists and implement an interim

management plan, if needed. If and when the investigator submits a protocol to the IRB for review, or if the investigator has an active protocol approved by the IRB, then the management plan will be communicated to the IRB of record for review at a convened meeting. If the IRB determines that the plan is not adequate, then the plan and the Board's comments are referred back to the Office of Internal Audit and Compliance for revision. The IRB has final authority in deciding acceptability of management plans in all cases of financial conflict of interest involving human subjects research.

Procedures for managing individual financial conflicts of interest will be tailored to the specific situation. A management plan may be simple, such as requiring an investigator to agree to certain stipulations, or complex, such as organizing an ad hoc committee to oversee aspects of the research over an extended period. All management plans will have the role and principal duties of the conflicted Investigator in the research project; conditions of the management plan; how the management plan is designed to safeguard objectivity in the research project; confirmation of the Investigator's agreement to the management plan; and how the management plan will be monitored to ensure Investigator compliance. The Director of Guthrie Foundation will provide administrative support for management plans.

Records related to disclosures and management of financial conflicts of interest will be maintained for at least three years from completion of the research.

C. Noncompliance with Management Plans

Noncompliance with procedures for managing conflicts of interest will be referred to the Vice President of Internal Audit and Compliance who will present the matter to the Enterprise Wide Compliance Committee for evaluation and resolution. In cases involving research on human subjects, findings are also communicated to the chair of the IRB and the IRB may determine a course of remediation.

Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a significant financial interest, failure by the Institution to review or manage an FCOI, or failure to comply with the management plan, the institution shall within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research. The retrospective review will include:

Project number;

Project title;

Program Director, Principal Investigator or designated contact;

Name of the Investigator with the FCOI;

Name of the entity with which the Investigator has an FCOI;

Reason(s) for the retrospective review;

Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

Findings and conclusions of the review.

Notify to NIH promptly and submit a mitigation report when bias is found. If bias is found through retrospective review, notify the NIH Awarding Component promptly (through the eRA Commons) and submit a mitigation report.

(IRB Policy Responding to Allegations of Non-Compliance(GF-IRB-322-053 available at <https://guthrie-system.policystat.com/policy/9152193/latest/>.)

D. Annual Review of Policy and Procedures

The Enterprise Wide Compliance Committee will review this policy for disclosing and managing financial conflicts of interest in research annually, or more frequently if necessary.

History:

| Revision | Author | Date reviewed/ revised | Changes | Reason for Changes |
|----------|------------------|---------------------------|---|--------------------|
| N/A | N/A | Dec. 15, 2008 | N/A | N/A |
| Revision | N/A | June 1, 2012 | N/A | N/A |
| Revision | Laura Fitzgerald | May 20, 2013 | Added process to obtain disclosures of reimbursed or sponsored travel related to institutional responsibilities; process to ensure reporting requirements are met; storage of COI records for 3 years | AAHRPP revisions |
| Revision | Laura Fitzgerald | August 11, 2014 | Institutional Name Changes and update definition of Enterprise Wide Committee | Name changes |
| Revision | Vicky Hickey | February 9, 2021 | Add process for research grants requested by the Director of Donald Guthrie Foundation | Clarify process |

Key contact: Director Guthrie Foundation

POLICY #GF-RA-330-001

All Revision Dates

12/8/2022, 2/18/2021, 8/11/2014, 5/20/2013

Approval Signatures

| Step Description | Approver | Date |
|-------------------------|---|-----------|
| Executive Director, DGF | Burt Cagir: Physician | 12/8/2022 |
| | Vicky Hickey: Mgr, Research & Education | 12/6/2022 |