



**Annual Conflict of Interest Disclosure Form
for Specified Employees**

Name (please print)	Department
Title	Date

The Conflict of Interest Policy (GF-RA-330-001) addresses how issues of actual, potential and perceived conflicts of interest should be identified, disclosed, and managed. This form is designed to identify and disclose known conflicts in an effort to properly disclose and manage them.

I have read The Guthrie Clinic's Conflict of Interest in Clinical Research Policy GF-RA-330-001 and understand that as an employee of Guthrie it is my obligation to act in a manner which promotes the best interests of The Guthrie Clinic at all times and to communicate conflicts of interest prior to making any decisions or taking actions on behalf of The Guthrie Clinic.

My answers to this disclosure form are correctly stated to the best of my knowledge and belief. Should a possible conflict of interest arise in my responsibilities to The Guthrie Clinic, I recognize that I have the obligation to notify the Internal Audit and Compliance Department and to abstain from any participation in the matter until the Internal Audit and Compliance Department can determine how that matter shall be resolved. If any relevant changes occur in my affiliations, duties, or financial circumstances, I recognize that I have a continuing obligation to file an amended "Conflict of Disclosure Form" with the Internal Audit and Compliance Department.

Signature

Date

Please complete the following questions, and submit this form to the appropriate designated individual as notes on the last page of this form.

1. Are you or a family member an officer, director, trustee, partner (general or limited) , employee or regularly retained consultant of any company, firm or organization that presently has business dealings (including sponsored research) with The Guthrie Clinic or which might reasonable be expected to have business dealings (including sponsored research) with The Guthrie Clinic in the coming year ?

Yes No

If yes, please list the name of the company, firm, or organization, the position held, and the nature of the business which is currently being conducted with Guthrie Health or which may reasonably be expected to be conducted with The Guthrie Clinic in the coming year.

2. Do you or a family member have a financial interest (direct or indirect) in a company, firm, or organization which currently has business dealings (including sponsored research) with The Guthrie Clinic or which may be reasonably expected to have such business dealings with The Guthrie Clinic in the coming year ?

Yes No

If yes, please list the name of the company, firm, or organization, the nature of the interest and the name of the person holding the interest, and the nature of the business which is currently being conducted with The Guthrie Clinic or which may reasonably be expected to be conducted with The Guthrie Clinic in the coming year.

3. Do you or a family member have a financial or personal interest in an entity which The Guthrie Clinic has a financial or other vested interest?

Yes No

If yes, please provide the details below:

4. Have you or a family member accepted gifts, gratuities, lodging, dining, or entertainment that might reasonably appear to influence your judgment or actions concerning the business of The Guthrie Clinic?

Yes No

If yes, please provide the details below:

5. Do you have any other interest or role in a firm or organization, where that interest or relationship might reasonably be expected to create an impression or suspicion among the public having knowledge of your acts that you engaged in conduct in violation of your trust as a The Guthrie Clinic employee?

Yes No

If yes, please provide the details below:

6. Do you have a family member employed by an entity of The Guthrie Clinic? If yes, please specify the name(s) of the individual(s), the entity they work for, and their role in the organization.

Yes No

Question 7 is specifically for those employees involved in Guthrie research activities. If this description does not apply to you, please select "N/A" as your answer to question 7.

7. Do you have any pending, threatened, or actual lawsuits in connection with a financial interest in research?

Yes No N/A

If yes, please provide the details below:

If any material changes to the responses provided on the annual disclosure form occur before the next form is due, the trustee, officer, or employee is required to update the information on this form in writing, and submit the update to the Internal Audit and Compliance Department.

Form Reviewed by: _____

Remedial Actions to be taken:

The Guthrie Clinic Internal Audit and Compliance Department will follow-up on all recommended actions to ensure compliance.

Definitions

Family member or family relationship is defined as spouse, significant other or dependent children,

Significant Other - a person (not necessarily a spouse) with whom you cohabitate or have an intimate relationship.

Guthrie Foundation
POLICY & PROCEDURE

SECTION: Administrative	SUBJECT: Managing Individual Financial Conflicts of Interest in Clinical Research	DEPT. Research Administration
EFFECTIVE: 11-AUG-2014		POLICY #GF-RA-330-001
SUPERCEDES: 20-May-2013		PAGE # 1 of 6
DISTRIBUTION: All Departments		

Policy 1

Purpose..... 1

Scope..... 1

Definitions..... 2

Procedures..... 4

 A. Evaluation of Disclosures 4

 B. Management of Conflicts of Interest..... 4

 C. Noncompliance with Management Plans..... 5

 D. Annual Review of Policy and Procedures..... 6

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 GH.COM-928-3023. 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

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pharmaceutical studies will not be biased by the significant financial interests or obligations of any individual participating in research. Investigators required to file a disclosure form include those in the roles of Principal Investigator (PI), Co-Principal Investigator, Sub-Investigators and any individual who is in a significant decision-making role or who has (or, if funded, will have) signature authority for a Guthrie Foundation Account. To comply with this policy, each investigator must annually complete the online “Specified Employee Conflict of Interest Form” distributed by the Guthrie’s Compliance Office. 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.; President & COO , TGC; CFO , TGC; Medical Director, TGC; Vice President of Internal Audit/Compliance, TGC; Compliance Officer, Guthrie Medical Group P.C.; Compliance Officer, TGC Acute/Post Acute Facilities; and General Counsel, TGC

Investigator Investigator means the Project Director (PD), Principal Investigator, Co-Principal Investigator, 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 is 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. 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 is received from the entity in the twelve months preceding the disclosure, 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 rose 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 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 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;

PD/PI or contact PD/PI if a multiple PD/PI model is used;

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.

Policy #: GF-RA-330-001
Title: Managing Individual Financial Conflicts of Interest in Clinical Research
Date: 11-Aug-2014
Page 6 of 6

(Policy GF-IRB-322-053 *Responding to Allegations of Non-Compliance.*)

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

Key contact: Director Guthrie Foundation

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