

**Genesis Health System
GHS Administrative Policy**

Subject: **CONFLICT OF INTEREST-
RESEARCH**

Effective Date: 2/5/10

Section: Health System Administrative
Policy

Reviewed/Revised: 3/20/17

Responsibility: Chief Medical Officer

Review Cycle: Biennial

Approved by:



I. POLICY:

It is Genesis Health System's (hereinafter "GHS") policy to appropriately identify and evaluate potential Conflicts of Interest to protect the safety and well-being of Subjects and the integrity and objectivity of Research conducted at GHS. No Research will be conducted at Genesis without prior review and clearance for potential Conflicts of Interest.

II. APPLICABLE HEALTH SYSTEM ENTITIES:

All Genesis Health System entities:

- Genesis Medical Center Davenport
- Genesis Medical Center Illini Campus
- Genesis Medical Center DeWitt
- Genesis Medical Center DeWitt West Wing
- DeWitt Hospital Foundation
- Genesis Health Group
- Family Medical Center
- Genesis Behavioral Resources
- Genesis Occupational Health

- Genesis VNA
 - Genesis Hospice
 - Genesis VNA Clarissa C. Cook
Hospice House
 - Genesis Home Medical Equipment
 - Crescent Laundry
 - Genesis FirstMed Pharmacy
 - Illini Restorative Care
 - Genesis Health Services Foundation
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- Illini Hospital Foundation Illini Healthcare, Inc.
 Genesis Workers Compensation Insurance Trust
 Genesis Illinois Properties

III. APPLICABLE ORGANIZATIONAL ROLES:

Genesis Health System Institutional Review Board
Research & Grants Administration Staff
Principal Investigators
Clinical Research Coordinators

IV. PURPOSE:

The purpose of this Conflicts of Interest-Research Policy ("Policy") is to set forth the responsibilities of research team members, GHS Chief Risk & Compliance Officer and GHS management with respect to disclosing, identifying and documenting interests in and with other organizations or individuals that fund or sponsor research or are otherwise interested in and affected by the outcome of research at GHS. Research team members include all principal investigators, sub-investigators, clinical research nurses, administrative staff and coordinators, and any GHS members involved in the performance of a research study at GHS.

V. DEFINITIONS:

Conflict of Interest: a potential for a Conflict of Interest arises when GHS or an individual holds a financial or associational interest that may render, or create the appearance of rendering, GHS or the individual, incapable of making a decision that is in the best interests of GHS, sponsors with whom GHS has contracted with to perform certain clinical activities and of the individuals GHS serves in its clinical and research activities. The mere existence of such an interest does not necessarily result in a Conflict of Interest. However, it is important that any such interest is identified and evaluated before GHS or other holder of the interest becomes involved in a decision or activity that could be biased by the interest.

Individual Conflicts of Interest: Financial or associational interests held personally by an individual in or with an outside entity or individual.

Institutional Conflicts of Interest: Financial or associational interests held by GHS itself, directly or indirectly, in or with an outside entity.

Imputed Conflicts of Interest: direct or indirect individual financial or associational interests held by an "Institutional Official" of GHS (e.g., Board Member, executive officer, department director) that are imputed to GHS because

of the job responsibilities or decision-making authority the individual holds within GHS.

Significant Financial Interest: A significant 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 \$5,000. 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 \$5,000, 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.

Associational Interest: An interest that stems from an individual's or entity's formal or informal participation in or involvement with (directly or indirectly such as through a family member) an organization or entity that, in turn, has a financial or economic stake in an industry entity engaged in research activities.

Covered Person: Any investigator performing or proposing a research study at Genesis Health System, and any research team members responsible for the design, conduct or reporting of a research study at Genesis Health System.

VI. GENERAL CONSIDERATIONS:

All research team members have a duty at all times to conduct research in an impartial and unbiased manner, in the best interests of GHS and the human subjects, and in strict compliance GHS policies and applicable law. All research team members also have a duty to cooperate with the Research and Grants Administration (hereinafter "RGA"), the Senior Research Support Liaison (hereinafter "RSL") and the Conflicts of Interest in Research Representatives of the Institutional Review Board (hereinafter "COIRR") and its delegates in the administration and enforcement of this policy.

This policy is intended to supplement (not replace) any applicable laws, ethical rules and/or principles governing conflicts of interest. To the extent that other federal or state laws may impose more restrictive conflicts of interest standards, including more extensive reports of actual or potential conflicts of interest, this policy shall be deemed to be modified to assure compliance with these more restrictive standards.

VII. PRACTICE/PROCEDURE:

REPORTING OF INDIVIDUAL INTERESTS BY COVERED PERSON

General.

1. All information reported by Covered Persons during the conflicts of interest reporting and review process described herein shall be confidential, except as necessary to implement this policy or as otherwise required by applicable law.
2. All Covered Persons are required to cooperate with the RGA, the RSL and the COIRR in the administration of the process for reporting of interests that could give rise to a conflict of interest.

Conflicts of Interest Reporting.

Covered Persons must meet the following reporting obligations. Meeting these requirements does not relieve a Covered Person from meeting the general continuing reporting requirements described in this policy.

1. Annual Conflicts of Interest Reporting. All research team members responsible for the design, conduct or reporting of a research study at any time will report annually any financial or associational interests held in organizations who may be funding or sponsoring research.
2. Covered Persons who are newly hired or retained after submission of the research study application must submit electronically a conflicts of interest questionnaire promptly after being so hired or retained.
3. Responsibility of Principal Investigator. The principal investigator on a study shall be responsible for all Covered Persons on the study completing and submitting electronically a conflicts of interest questionnaire.

Continuing Conflicts of Interest Reporting.

If, at any time after submitting a conflicts of interest questionnaire required by this policy, a Covered Person becomes aware of a new interest, or a change in any interest previously reported, the Covered Person shall promptly make a report of the interest by submitting a new conflicts of interest questionnaire.

Conflicts of Interest Database.

1. The Corporate Compliance department implemented a Conflicts of Interest Database ("Database") to assist with identification and management of potential conflicts of interest. The Database contains information relating to all of the reported interests of Covered Persons, Institutional Officials and GHS.
2. The Database shall record all interests reported, including but not limited to the contents of all individual, Institutional Official, and Chief Financial Officer's conflicts of interest questionnaires.
3. Covered Persons are responsible for submitting information to the system-wide Database regardless of whether they have any interests or not. This questionnaire will be required annually and will be updated if any information changes throughout the year.
4. The conflict of interest questionnaire can be accessed by cutting and pasting the following link in the address bar: <https://genesis.coi-smart.com>. The user ID is most often last name, first initial and the password can be reset upon opening the link. If problems are encountered when accessing the website they should be referred to the GHS Compliance Office at 563-421-6486.
5. Each Covered Person shall acknowledge at the end of the conflict of interest questionnaire that the information submitted is true, accurate and complete, and that such Covered Person:
 - a) Has read the conflict of interest policies and related materials;
 - b) Has read and understands the conflict of interest policies and related materials;
 - c) Agrees to comply with the conflict of interest policies and related materials;
 - d) Has reported electronically any interests required to be reported under this policy; and
 - e) Agrees to promptly report, in accordance with this policy, any change in the information he/she provided on the current conflicts of interest questionnaire.

REPORTING INSTITUTIONAL INTERESTS

- A. The RGA and/or RSL shall establish and keep updated a list of persons that constitute the Covered Persons as it relates to research. These individuals will include any investigator performing or proposing a research study at Genesis
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Health System, and any research team members responsible for the design, conduct or reporting of research at Genesis Health System. The Corporate Compliance Department will establish and keep updated a list of the GHS Executive Team, Genesis Board and those persons who have the authority to affect decisions made by GHS.

- B. Annually, Genesis Health System will disclose all institutional interests held including all financial and associational interests.

PRODUCTION OF CONFLICT OF INTEREST INFORMATION

After receiving a research application, the RSL or designee, shall submit to the COIRR: (1) a report generated from the Database of interests reported by the principal investigator and any other key members of the research team, 2) any written reports related to the proposed research study and 3) a list of all institutional interests held by GHS.

IDENTIFICATION OF POTENTIAL CONFLICTS OF INTEREST

- A. Conflict Match.

The RGA shall run a search for conflicts on the Database. A report of all conflict matches that relate to the study in question will be generated and submitted for review by the COIRR.

ASSESSMENT AND MANAGEMENT OF CONFLICTS OF INTEREST

- A. Proposed Studies: Assessing an Interest.

1. The COIRR shall review the report generated by the Database to determine whether any reported interest presents a potential conflict of interest.
 2. The COIRR may request additional information from the person who made the reports.
 3. The COIRR may use the Conflicts of Interest in Research Review Checklist to ensure that the COIRR address and respond to potential conflicts of interest in an appropriate and uniform manner. The Conflict of Interest in Research Review Checklist shall contain management strategies that address the most common potential conflicts of interest.
 4. If the COIRR determine that the interest at issue constitutes a conflict of interest, the COIRR need to evaluate whether it is manageable in accordance with Section VII.B of this policy.
 5. If the COIRR determine that an interest does not constitute a conflict of interest, the COIRR may grant clearance for the research, however,
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clearance by the COIRR does not constitute overall approval of the research.

B. Managing Conflicts of Interest

1. Manageable

- a. If the disclosed interest is a conflict of interest that the COIRR determine is manageable, the COIRR shall prepare a conflict of interest management plan that incorporates management strategies designed to reduce the risk of subject harm and threats to research integrity. The plan will be shared at the IRB meeting when the study is reviewed.
- b. The RGA, RSL and/or COIRR shall inform the principal investigator that, as a condition of the approval of the research application, the principal investigator and other members of the research team must comply with the management strategies articulated in the conflict of interest management plan.

2. Non-Manageable

If the COIRR determine that the conflict of interest is not manageable, it shall recommend that the research be rejected unless the Covered Person divests the interest.

C. Findings & Recommendations.

1. The RGA will send a copy of the management plan to the principal investigator or research team member who requires a management plan.
2. The RGA will send a copy of the COIRR findings and any additional documentation needed to the IRB.
3. The RGA will document any disclosed interests and the COIRR/IRB findings in the conflicts of interest database.

D. Reporting and Access to this Policy and Related Forms.

1. GHS shall disclose this policy (and all corresponding procedures, guidelines, forms and tools), to all Covered Persons on a biennial basis and shall promptly advise all Covered Persons in writing of any substantive changes to this policy and such related materials. This policy and all such related materials shall be available to Covered Persons at all times through the GHS intranet (Policy Manager) and from the RGA.
 2. Covered Persons are responsible for consulting the GHS intranet (Policy Manager), the research website at www.genesishealth.com/research or the
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RGA for the most current version of this policy and related forms as follows:

- a. In all cases when this policy would require consideration of the potential for conflicts of interests in research decisions or activities in which they are involved at GHS, and
 - b. As otherwise necessary to meet their reporting and other obligations under this policy.
3. Covered Persons are encouraged to contact the RGA, the RSL, the COIRR or the Corporate Compliance Officer regarding any questions or potential reporting situations that may be unclear to them.

E. Failure to Comply with this Policy.

Failure to report an interest, or otherwise to comply with this policy and any decision made or conflict management plan developed pursuant to this policy is grounds for a study to be terminated.

PUBLIC ACCESSIBILITY

The Genesis Health System Conflicts of Interest-Research policy will be made available on the Genesis website at www.genesishealth.com/research. In addition, Genesis will respond within 5 business days to any request for information about significant financial interests held by Covered Persons related to a Public Health Service (PHS) funded research study.

TRAVEL

Investigators will disclose all sponsored or reimbursed travel related to their institutional responsibilities, including:

- Purpose
- Sponsor
- Destination
- Duration

TRAINING

In accordance with 42 CFR Part 50, Subpart F, all Covered Persons participating in research sponsored by PHS or PHS-like agencies (i.e., agencies that have adopted PHS-like financial conflicts of interest regulations) must complete a Conflicts of Interest in Research training prior to engaging in research related to any PHS-funded grant and at least every four years after

that. Covered Persons must complete Conflicts of Interest in Research training immediately when any of the following circumstances apply:

1. Genesis revises its Conflicts of Interest - Research policy or procedures in any manner that affects the requirements of Covered Persons;
2. A Covered Person is new to Genesis; or
3. The Genesis IRB finds that a Covered Person is not in compliance with Genesis' Conflict of Interest - Research policy or management plan.

VIII. REFERENCES:

42 C.F.R. Chapter 1, subchapter D, Part 50, Subpart F
45 C.F.R., subtitle A, subchapter A, Part 94

IX. SUPERCEDES:

N/A

X. CROSS REFERENCE:

N/A

XI. ENDORSEMENTS:

Genesis Health System IRB
Quality and Safety Committee of the GHS Board
Genesis Health System Board of Directors
