GUNDERSEN HEALTH SYSTEM®

Policy

Subject	Reporting and management of significant financial interests to promote objectivity in research
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Section	Compliance and Ethics
Subsection	General
Category	Corporate
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References

Department of Health and Human Services, 42 CFR Part 50, 45 CFR part 94 [Docket Number NIH-2010-0001], Federal Register, Final Rule, effective August 25, 2011 (http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf). National Institutes of Health, Office of Extramural Research, Notice NOT-OD-11-109, Publication of the Revised NIH Grants Policy Statement: Policy Changes, Clarifications, and Document Enhancements, effective August 22, 2011, revised October 20, 2011.

Conflict of Interest Policy: GL-3017

Applicable To

All employees and programs of Gundersen Clinic, Ltd. and Gundersen Lutheran Medical Center, Inc. collectively referred to hereafter as "Gundersen Health System."

Detail

On May 8, 2009, the NIH released an Advance Notice of Proposed Rulemaking and based on the comments received, published a Notice of Proposed Rulemaking (NPRM) in the Federal Register on May 21, 2010. The NIH received 136 comments to its NPRM, and addressed each in the Final Rule. The Final Rule was published in the Federal Register on August 25, 2011. This document lists the policy and procedures for the reporting and management of any and all significant financial interests to be followed by all employees who are Investigators in new protocols awaiting IRB approval or open protocols at Gundersen Health System to, 1) comply with the Final Rule, and 2) work toward promoting objectivity in research.

Failure to follow this set of procedures, especially in cases in which it is determined that a significant financial interest (SFI) results in a financial conflict of interest (FCOI), could lead to sanctions including, but not necessarily limited to: the stoppage and revocation of IRB approval for a research protocol; the removal of an individual investigator from a protocol; the barring of an investigator from conducting future research at Gundersen Health System; the review and reporting of noted FCOI to the awarding component of Public Health Service (PHS) funded research protocols; the termination of Public Health Service funds to a research protocol by the awarding component; and the termination of employment with Gundersen Health System.

Implementation

1. Gundersen Health System employees engaged in Institutional Review Board (IRB) approved research at Gundersen Health System as an investigator (please see "Investigator" in the

"DEFINITIONS" section) must undergo financial conflict of interest training every four years or sooner if: the investigator is a new researcher (i.e., has never participated in, or previously been named on, a research protocol), the investigator is a new employee of Gundersen Health System; there is a change to Gundersen Health System's policy on the "Reporting and management of significant financial interest to promote objectivity in research;" or the investigator has been found noncompliant with the policy listed here in the "Reporting and management of significant financial interest to promote objectivity in research."

a. Traditional students with temporary employment (for example, Summer Research Fellows), as well as employees who are engaged in non-scientific projects only (for example, quality improvement projects), are not required to undergo financial conflict of interest training.

b. A new employee or new researcher named as an investigator on a new or current, on-going research protocol at Gundersen Health System must undergo financial conflict of interest training within 45 days of being added to the protocol. Gundersen Health System's IRB will not approve a new employee or new researcher as an investigator on a protocol until the individual has completed financial conflict of interest training at Gundersen Health System.

c. An investigator who has been found noncompliant with the policy on the "Reporting and management of significant financial interest to promote objectivity in research," must undergo financial conflict of interest training within 45 days of receiving notice of noncompliance. Gundersen Health System's IRB will disallow any investigator deemed noncompliant from participating in or with any research protocol at Gundersen Health System until he or she has completed the financial conflict of interest training.

d. Gundersen Health System has elected to use the Financial Conflict of Interest training tutorial offered by the NIH's Office of Extramural Research. The tutorial can be accessed either by going to the NIH Office of Extramural Research, or by clicking the following link. To successfully complete the financial conflict of interest training, individuals must submit a certificate of completion to the Gundersen Health System IRB Coordinator: Gundersen Health System, 1900 South Ave., C03-006B, La Crosse, WI, 54601, current email: mahadley@gundersenhealth.org.
http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

2. In addition to Gundersen Health System's "Conflict of Interest Disclosure" requirement, an employee must have completed a "Conflict of Interest Disclosure Statement" with the GHS Compliance department within the 12 months prior to working on research at GHS as an investigator. GHS employees who are investigators on research protocols must also complete a "Conflict of Interest Disclosure Statement" with the GHS Compliance department when the investigator has a new SFI.

   a. A new employee who is seeking approval from the Gundersen Health System IRB to continue with, or transfer, a research protocol from another institution must indicate on

the "Conflict of Interest Disclosure" any SFI or FCOI for that protocol. Gundersen Health System's IRB will not approve the transfer of a protocol from another institution to Gundersen Health System until the all investigators on the protocol who are new employees to Gundersen Health System have submitted a "Conflict of Interest Disclosure Statement."

b. Any and all investigators must complete a "Conflict of Interest Disclosure Statement" within 30 days of discovering, acquiring, or receiving a new SFI.

3. For travel by an investigator that is related to a current IRB approved research protocol at Gundersen Health System, and that is paid for by an outside entity or entities, the investigator must include in his or her "Conflict of Interest Disclosure Statement": the purpose of the trip, the identity of the sponsor or organizer paying for the trip, and the destination and duration of the trip.

    a. Travel by an investigator that is related to a current IRB approved research protocol at Gundersen Health System that is paid by government institutions or organizations, institutions of higher education, academic teaching hospitals, medical centers, and research institutes affiliated with an institution of higher education are exempt from this requirement.

4. An SFI reported on a "Conflict of Interest Disclosure Statement" by an investigator on a research protocol at Gundersen Health System will automatically be assessed by Gundersen Health System's Conflict of Interest (COI) Review Panel to determine if the SFI constitutes an FCOI. Any SFI determined by the COI Review Panel to be an FCOI will mandatorily have a management plan established by the COI Review Panel. Any SFI greater than $25,000.00 will automatically have a management plan established by the COI Review Panel. Management plans will be established on a case-by-case basis, and will attempt to account for the degree of potential influence the SFI may have on an Investigator as determined by the COI Review Panel. A management plan does not necessarily disqualify an investigator from participating in or with a research protocol at Gundersen Health System.

    a. An investigator on a protocol at Gundersen Health System who reports an SFI on his or her "Conflict of Interest Disclosure Statement" will be permitted to continue participating in or with that research protocol while the COI Review Panel deliberates. This includes investigators who report a SFI greater than $25,000.00

    b. When the COI Review Panel determines that an SFI constitutes an FCOI, a management plan will be established by the COI Review Panel which could include, but not necessarily limited to: a payment disbursement plan for royalties, disallowing the investigator from involvement with subject recruitment efforts, or disallowing the investigator from being the "Principal Investigator" on the protocol.

i. For research protocols at Gundersen Health System in which there is PHS funding, a management plan must be established for investigators with a FCOI prior to the expenditure of the PHS funds.

c. When the COI Review Panel establishes management plan for an investigator on a research protocol at Gundersen Health System, the investigator will have 4 weeks from the time of notification to appeal or seek revision of the management plan with the Gundersen Health System IRB. Gundersen Health System's IRB will have the authority of expedited review to accept, reject, or require the COI Review Panel to revise the management plan.

i. If no appeal or revision of a management plan is sought by an investigator on a research protocol at Gundersen Health System, the investigator will have 45 days from the original notification to comply with the management plan.

ii. If an appeal or revision of a management plan is sought by an investigator on a research protocol at Gundersen Health System, and the Gundersen Health System IRB does not reject the management plan, the investigator will have 45 days from notification by the IRB to comply with the management plan.

d. An investigator on a research protocol at Gundersen Health System who does not comply with a management plan regarding an FCOI within 45 days will be deemed noncompliant, and will be immediately disallowed from participating in or with any research protocol at Gundersen Health System until the investigator complies with the management plan and undergoes financial conflict of interest training.

i. For research protocols at Gundersen Health System in which there is PHS funding, and either an investigator on such a protocol is deemed noncompliant or the management plan appears to have biased the design, conduct, or reports from the research protocol, a mitigation report will be created by the COI Review Panel and submitted to both the awarding component of the PHS funding and the NIH within 120 days, and on an annual basis for the duration of the PHS funding period. A mitigation report will include at least the follow items: the key elements of the management plan, the name of the entity that is the source of the SFI, the nature of the financial interest, the value of the financial interest, a description of how the financial interest relates to the research, and the basis for considering the SFI an FCOI.

e. A FCOI transferred from another institution to Gundersen Health System by a new employee will require a new management plan to be established by Gundersen Health System's COI Review Panel prior to Gundersen Health System's IRB approving the new employee as an investigator on a research protocol.

5. A research protocol at Gundersen Health System for which any investigator has an SFI must include in the protocol a plan to disclose the SFI to any potential person consenting to

participation in the research as part of the informed consent process. Gundersen Health System's IRB will not approve a research protocol that involves human research subjects for which an investigator has a SFI until the protocol includes a plan to disclose the SFI to persons consenting to participation in the research.

OVERSIGHT AND RESPONSIBILITY:
Gundersen Health System's Conflict of Interest Review Panel and Human Subjects Committee are responsible for the implementation of this policy.
Gundersen Health System's Human Subjects Committee is responsible for the oversight and education of this policy.

DEFINITIONS:
Conflict of Interest Review Panel (COI Review Panel): a group of individuals at Gundersen Health System responsible for assessing SFIs noted on a "Conflict of Interest Disclosure Statement." It includes representatives from the Human Subjects Committee, the Research Committee, Corporate Compliance, and the Legal department.

Financial conflict of interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, and reporting of research.

Investigator: an individual who is named on a research protocol as a Principal Investigator (or equivalent), and any other person, regardless of title or position, who is responsible for [overseeing] the design, conduct, or reporting of research.

Institutional Review Board (IRB): A group of individuals responsible for reviewing and approval research protocols involving human subjects, and at Gundersen Health System, is also referred to as the Human Subjects Committee.

National Institutes of Health (NIH): an agency under the United States Department of Health and Human Services, and the group responsible for issuance of the Final Rule.

Public Health Service (PHS): the term used to describe the eight agencies that make up the Department of Health and Human Services. "PHS funding" refers to research funding that is provided through one of these eight agencies.

Significant Financial Interest (SFI): A financial interest consisting of one or more of the following interests of an Investigator (including those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. A publicly traded entity in which the value of any remuneration (e.g., consulting fees, honoraria, paid authorship) received from the entity in the twelve months preceding the disclosure and the value of any equity interest (e.g., stock, stock options, other ownership interest) in the entity as of the date of disclosure, when aggregated, exceeds $5,000.00 (as determined through reference to public prices or other reasonable measures of fair market value).

2. A non-publicly traded entity, in which the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000.00, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest.

3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

ISSUING OFFICES:
Conflict of Interest Review Panel
Human Subjects Committee