

GREENVILLE HEALTH SYSTEM POLICY AND PROCEDURES	
Manual of Policy Directives	
POLICY NAME: Conflict of Interest Disclosure Requirements	POLICY NUMBER: S-015-03
EFFECTIVE DATE: June 26, 2017	REVISION DATE: June 26, 2017

SCOPE: Mark "X" as applicable

	Adult Hospitals		Adult		Clinical Licensed
	Children's Hospital		Pediatric		Clinical Unlicensed
	MIPH		Inpatient		Non-Clinical
	UMG/PIH		Outpatient		Nursing Only
X	System-Wide				
	X	GHS Greenville Memorial Hospital			
	X	GHS Greer Memorial Hospital			
	X	GHS Hillcrest Memorial Hospital			
	X	GHS Laurens County Memorial Hospital			
	X	GHS North Greenville Long Term Acute Care Hospital			
	X	GHS Oconee Memorial Hospital			
	X	GHS Patewood Memorial Hospital			
	X	GHS Surgery Center - Spartanburg			
	X	Provider based facilities associated with GHS hospitals			

POLICY STATEMENT: It is the policy of Greenville Health System (GHS) to identify, manage, and resolve conflicts of interest that may affect the decisions, transactions, and operations of Greenville Health System. This policy applies to employees, investigators and employed medical staff members. For GHS Physicians – In addition to submitting the corporate disclosure statement to the Office of Corporate Integrity (OCI), Physicians will submit an individual Conflict of Interest acknowledgment form or disclosure statement pursuant to Medical Staff Policy.

All GHS Employees are to refer to Section IV., Responsibilities of GHS regarding Conflicts of Interest. This section is applicable to all employees, Investigators and medical staff.

DEFINITIONS:

- **IMPORTANT:** Please refer to Appendix S-15-3 attached to this policy.

PROCEDURE:

- I. Purpose. The purpose of this policy is to promote objectivity in GHS business, including research, by establishing standards that provide a reasonable expectation that GHS business, including the design, conduct, and reporting of research, is free from bias resulting from financial conflicts of interest.
- II. Responsibilities of GHS – In General
 - a. Maintain written policies and guidance to manage Conflicts of Interests (COI).
 - b. Post COI policy and additional relevant information on GHS website (ghs.org).

THIS POLICY HAS BEEN REISSUED SINCE JULY 2004.

- c. Educate and inform all employees of their responsibilities toward this policy.
- d. Require GHS personnel covered under this policy (Interested Person) to complete a COI Disclosure Form on an as needed basis, but no less than annually.
- e. The OCI will review all COI Statements and report the findings to the GHS President and/or the Audit Committee, as the GHS President may direct.
- f. Designate a COI Review Committee(s) to review and manage COI Disclosures.
- g. Resolve disclosed COI and report findings to the appropriate GHS Governing Committee.

III. Responsibilities of GHS – For Investigators

In *addition* to the General Responsibilities described above, *For Investigators*:

Investigators participating in Commercial or Public Health Service (PHS) - Funded Research, GHS Office of Sponsored Programs and Office of Research Compliance (ORCA) will:

- a. Maintain records of disclosures of any and all reported research related Conflicts of Interests.
- b. Review and respond to reported research related Conflicts of Interest's.
- c. Establish enforcement mechanisms to ensure COI reporting compliance.
- d. Require researchers and staff to assist and collaborate in any and all COI investigations and resolve potential COI issues that are discovered.
- e. Assure researchers comply with a written research agreement that meets with the requirements of federal and state laws and regulation.

IV. Duty to Disclose – In General

Annual Disclosure Statement

- a. All Interested Persons identified as covered by this policy shall submit their individual COI to the OCI in a complete and timely manner.
- b. By being identified as an Interested Person covered by this policy, the GHS employee (physician and management staff) attests to the following:
 - i. Has received a copy of the GHS COI Policy
 - ii. Has read and understands the COI Policy
 - iii. Has agreed to comply with this COI Policy
 - iv. Understands that GHS is a charitable entity and is required to engage in activities which primarily accomplish and support these purposes.

V. Duty to Disclose – For Investigators/IRB Members

In addition to the General Duties to Disclose as described above, For Investigators:

Investigators participating in Commercial or Public Health System (PHS)-Funded Research, GHS will:

- a. Disclose any Significant Financial Interest (SFI) to the appropriate Institutional Review Board (IRB) as well as to the OCI, by submitting a completed GHS Investigator and IRB Member Conflict of Interest statement as found on the GHS website www.university.ghs.org/eirb, on an annual basis or during Continuing Review via the eIRB Continuing Review module. In accordance with the Office of Human Research Protection Policy (HRPP)9.0 Conflicts of Interest in Research and 42 CFR §50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.
- b. Require Investigators to disclose known or potential Significant Organizational Interests (SOI) no later than at the time of application; within thirty (30) days of

- discovering the SOI; and at least annually.
- c. IRB Members shall follow Office of Human Research Protection policy – 501 HRPP
- VI. Management of Conflicts of Interest – In General
- a. If GHS determines that a GHS employee, covered by this policy did not comply with the terms of this Conflict of Interest – Annual Disclosure policy, or if GHS discovers that one of these individuals had a Significant Financial or Organizational Interest that was not disclosed in a timely manner pursuant to this Policy, GHS will conduct a retrospective review, and if, upon conclusion of the review, the GHS Conflict of Interest Committee finds that a conflict of interest existed that could have affected the decision-making and/or independent judgment of the individual, GHS will take appropriate steps in accordance with this Policy to manage or eliminate the conflict and report its finding to the appropriate GHS administrative body.
- b. Purchasing Evaluations, Committees and Workgroups: An employee, Investigator, or member of our Medical Staff who has a disclosable Financial Interest, must disclose this at the beginning of any meeting as appropriate to the context of that meeting (for example, being paid as a speaker or consultant for a medical equipment supplier or pharmaceutical company whose product is being evaluated by the committee). The individual disclosing the Financial Interest may continue to participate in the work of the group or committee evaluating products or services. When discussions are finalized the Chair of the Committee may, based on the significance of the Financial Interest, ask the individual to recuse themselves from the actual purchasing decision.
- VII. Management of Conflicts of Interest – For Investigators
- a. If GHS determines that an Investigator did not comply with the Conflict of Interest – Annual Disclosure policy, or if GHS discovers that the investigator had a Significant Financial or Organizational Interest that was not disclosed in a timely manner pursuant to this Policy, GHS will conduct a retrospective review, and if, upon conclusion of the review, the GHS Conflict of Interest Committee finds that a conflict of interest existed that could have affected the design, conduct or reporting of the research, GHS will take appropriate steps in accordance with this Policy to manage or eliminate the conflict and report its finding to the funding agency, if required by law. The GHS report will address the conflict’s impact on the research project, and the actions that GHS took or will take to eliminate or mitigate the harm.
- b. Retrospective Review: In the event of failure to meet the requirements of the PHS Financial Conflict Of Interest (FCOI) regulations, including failure by the Investigator to timely disclose a Conflict of Interest that is determined to constitute an FCOI, GHS’s failure to review or manage such an FCOI, or Investigator failure to comply with an FCOI management plan, GHS will, within 60 days of its determination of noncompliance, complete a retrospective review of the Investigator’s activities and the PHS-funded Research project to determine any bias in the design, conduct or reporting of Research during the time period of the noncompliance. GHS will document the retrospective review in accordance with its Conflict of Interest Policy and applicable PHS regulations.
- VIII. Posting of Financial Conflict of Interest Information – Research
- a. For each research related Financial Conflict of Interest that is found to exist by the GHS Conflict of Interest Committee, GHS will make the following information

available on the GHS Web Site of each individual identified with the aforementioned conflict:

- i. The individual's name
 - ii. The individual's title and role with respect to the research
 - iii. The name of the entity in which the SFI is held
 - iv. The nature of the SFI
 - v. The approximate value of the significant financial interest
- b. GHS Research Compliance Office will update the information required by this section annually. In addition, for any financial conflict of interest not previously available or identified, GHS will make the information required by this section available not later than the 60th day after the financial conflict of interest is identified.
- c. The information must note that it is current as of the date listed and is subject to updates.
- d. The information required by this section must remain available for three years after its most recent update.
- e. For PHS-funded research, in regard to project directors, principal investigators, and other senior or key personnel, this information must be available BEFORE expending PHS funds.
- IX. Final Determination Regarding Conflict of Interest (Review of Disclosures)
- a. Any disclosure of an interest of \$5,000 or greater will be reviewed by the GHS Conflict of Interest Committee.
 - b. The GHS Conflict of Interest Committee has the responsibility and authority to approve the acceptability of a management plan for conflicts of interest.
 - c. The GHS Conflict of Interest Committee will notify the Discloser in writing of its decision.
 - d. All payments to physicians will be reviewed and compared in light of the CMS Open Payments web site portal. When required the OCI will work with individual physicians to reconcile payment information between the disclosure and the Open Payment listing.

Should the GHS Conflict of Interest Committee determine an employee, Investigator, or member of our Medical Staff has an identified Conflict of Interest, the Committee will require the individual to disclose such conflict of interest at the beginning of any meeting as appropriate to the context of that meeting, and/or as called upon by the meeting Chair or representative designee.

X. Record Retention

- a. Records regarding Conflict of Interest, including those required by the PHS regulations, shall be maintained for a period of at least three (3) years from the date when the final expenditure report, final annual report, or disclosure occurred, whichever is later as required by 42 CFR §50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest. If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

XI. Sanctions

- a. Failure to comply with this Policy will be grounds for disciplinary action pursuant to

the relevant GHS Policy.

In addition, federal regulations may require reports to the federal sponsor of any information which may show a violation of GHS policy. GHS may require mandatory education, monitoring of research, suspension of research privileges, suspension or termination of research or enacting other sanctions as appropriate. In addition, sponsors may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and manage Significant Financial Interests related to federally sponsored projects.

XII. Administration of Conflict of Interest Policy

- a. The OCI will administer this Conflict of Interest Policy, including the administration and monitoring the Annual Individual Conflict of Interest Statements.

RELATED DOCUMENTS (optional):

The following GHS policies are pertinent to the provisions of this policy and have reference to specific conditions related thereto:

GHS Policy S-104-1, Business Ethics and Conduct

GHS Office of Human Research Protection policy HRPP

IRB Member Conflict of Interest Policy No.7.0

Conflicts of Interest in Research Policy No. 9.0

Office of Human Research Protection policy – 501 HRPP

42 CFR 50.601 et seq. and 45 CFR 94.1 et seq.

http://grants.nih.gov/grants/policy/coi/coi_faqs.htm

GREENVILLE HEALTH SYSTEM POLICY AND PROCEDURES	
Manual of Policy Directives	
POLICY NAME: Conflict of Interest Annual Disclosure – Appendix A: Definitions	POLICY NUMBER: S-015-03.A1
EFFECTIVE DATE: September 14, 2017	REVISION DATE: September 14, 2017

SCOPE: Mark “X” as applicable

	Adult Hospitals		Adult		Clinical Licensed
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	X	GHS North Greenville Long Term Acute Care Hospital			
	X	GHS Oconee Memorial Hospital			
	X	GHS Patewood Memorial Hospital			
	X	GHS Surgery Center - Spartanburg			
	X	Provider based facilities associated with GHS hospitals			

DEFINITIONS:

- Affiliate- Any organization that is directly or indirectly controlled by GHS.
- Conflict of Interest- Due to activities or relationships with other persons or organizations, an individual is unable or potentially unable, to remain impartial, that the individual’s objectivity is, or might be otherwise impaired, or that the individual has, or might acquire, an unfair competitive advantage. Information that is relevant to a conflict of interest determination includes stock holdings and investments of the individual, the individual’s spouse, and children or significant other; current positions held or under negotiation; any other sources of income; involvement in the design, conduct, or reporting of research and any other relevant information that may have a bearing on the individual’s proposed participation in such activity.

For members of the employed medical staff, this also includes any (1) contractual, employment, or Financial Interest with a non-affiliated hospital or other Health Care Organization that competes with GHS or any Affiliate or (2) service in a position of strategic or medical direction leadership in any such non-affiliated hospital or other Health Care Organization, provided, however, that membership on another health care provider’s medical staff or as a member of a group practice shall not be considered as a Conflict of Interest; or (3) a compensation arrangement, including the provision of travel accommodations and/or entertainment, from a third-party vendor in exchange for promotion or sponsorship of that vendor’s products or services.

THIS POLICY HAS BEEN REISSUED SINCE JULY 2004.

- Compensation- Compensation includes but is not limited to direct and indirect remuneration as well as gifts or favors that are substantial in nature.
- Discloser- An individual disclosing a Financial Conflict Of Interest.
- Family Member- A Family Member is an individual who is the spouse, parent, brother, sister, child, mother-in-law, father-in-law, son-in-law, daughter-in-law, grandparent, or grandchild of a person, or an individual claimed by a person or the person's spouse as a dependent for income tax purposes.
- Financial Conflict of Interest (FCOI)- A significant financial interest that could directly and significantly affect the design, conduct, or reporting of Public Health Service (PHS) -funded research.
- Financial Interest- Anything of monetary value, whether or not the value is readily ascertainable (e.g., salary, consulting fees, honoraria, gifts, dividends, distributions, rent, paid authorship, equity interests, intellectual property rights, etc.).

A person has a Financial Interest if the person or Family Member has, directly or indirectly through business, investment (excluding investments held in mutual funds), such as:

1. an ownership or investment in any entity with which GHS has a transaction or agreement,
2. a Compensation arrangement with GHS (excluding Compensation as a GHS employee) or with any entity with which GHS has a transaction or arrangement,
3. a potential ownership or investment interest in, or Compensation arrangement with, any entity or individual with which GHS is negotiating a transaction or arrangement, or
4. an economic interest distinct from that of the general public in any transaction or arrangement of an amount set forth in the GHS Business Ethics and Conduct policy.

A Financial Interest is not necessarily a conflict of interest.

An interest in a business consists of: (1) any stock, stock option or similar ownership interest in such Business, but excluding any interest arising solely by reason of investment in such Business by a mutual, pension, or other GHS investment fund over which the faculty member does not exercise control; or (2) receipt of, or the right or expectation to receive, any income from such Business (or from an agent or other representative of such business), whether in the form of a fee (e.g., consulting), salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology, technology transfer, patents, gifts, rent, capital gain, real or personal property, or any other form of Compensation, or any combination thereof whose value exceeds \$5,000.

- GHS Conflict of Interest Committee (GHS COIC)- The Committee comprised of the Chief of Medical Staff Affairs, the Executive Director of Corporate Integrity, the ORCA Medical Director, Deputy General Counsel, Corporate Compliance Officer, and the Institutional Official.
- GHS Management- For purposes of this policy, "GHS Management" means the GHS President, any vice president, administrator, department director, manager or supervisor.
- Health Care Organization- Any entity engaged in the business of providing

THIS INDIVIDUALLY ISSUED AND DISTRIBUTED POLICY DOES NOT CREATE A CONTRACT OF EMPLOYMENT BETWEEN GHS AND THE EMPLOYEE. EMPLOYMENT AT GHS IS AT WILL. ALL PREVIOUSLY ISSUED VERSIONS OF THIS POLICY ARE HEREBY REVOKED.

health care services including, but not limited to, imaging, diagnostic, physical or occupational therapy, infusion and ambulatory surgery centers, laboratories, and home health agencies.

- Interested Person- An Interested Person means any member of GHS Management or any other employee of Greenville Health System that has a Financial Interest (as defined above) and is duly authorized to conduct business or influence business decisions on behalf of GHS (and all entities affiliated with GHS) or on behalf of any entity with which GHS may do business. Financial Interests of a Family Member (as defined above) are considered to be the same as that of the Interested Person.
- Institutional Responsibilities- Institutional Responsibilities, including the Investigator's professional responsibilities on behalf of the GHS, and as defined by the GHS in its policy on Financial Conflict of Interest, which may include, for example, activities such as research, research consultation, teaching, professional practice, GHS committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

GHS will provide, or cause to be provided, education for appropriate employees and staff about disclosures and responsibilities related to Financial Conflict Of Interest.

1. Education is required prior to a possible FCOI and at least every four years and thereafter.
 2. Education is required immediately when:
 - a. Education is required prior to a possible FCOI and at least every four years and thereafter.
 - b. Education is required immediately when:
 - i. Financial Conflict Of Interest policies are revised in a manner that changes Investigator requirements.
 - ii. An Investigator is new to the organization.
 - iii. An Investigator is non-compliant with FCOI policies and procedures.
- Investigator- A principal Investigator, project director, co-Investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research (project) results, including collaborators and consultants.
 - Key Personnel- Project Director or Principal Investigator and any other person identified as senior/key personnel by GHS in the grant application, progress report, or any other report submitted to the Public Health Service (PHS) by GHS.
 - Medical Staff Committee- Any committee or task force that has been created at the direction of the organized medical staff of GHS.
 - Research- A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g. a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
 - Public Health Service (PHS)- PHS refers to the Public Health Service of the U.S.

Department of Health and Human Services (DHHS), and any components of the PHS to which the authority involved may be delegated, including the National Institute of Health (NIH).

- Significant Financial Interest- A Financial Interest held by an individual or his/her spouse or dependent children that reasonably appear to be related to the individual's Institutional Responsibilities and that consists of one or more of the following:
 1. Remuneration including, but not limited to salary, consulting fees, honoraria, and paid authorship received from a publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, and/or an equity interest (e.g. stock, stock options, or other ownership interest) held in such publicly traded company, if the aggregate value of such remuneration, plus the value of the equity interest as of the date of disclosure, exceeds \$5,000; or
 2. Remuneration (including, but not limited to, salary, consulting fees, honoraria and paid authorship) received from a non-publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, if the remuneration exceeds \$5,000; or
 3. Any equity interest in a non-publicly traded company or business, regardless of value; or
 4. Intellectual property rights and interests (e.g. patents and copyrights), upon receipt of income related to such rights and interests.
 5. Any reimbursed travel or travel expenses paid on an Investigator's behalf related to his/her GHS responsibilities, including circumstances when the exact monetary value of the travel is not readily available. This requirement does not apply to travel that is reimbursed by a Federal, state or local government, an Institution of higher education, an academic medical center or research institute (including GHS) that is affiliated with an Institution of higher education.
- Significant Financial Interest does not include:
 1. An Employee's salary or royalties received from the Greenville Health System; or
 2. Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency or an Institution of higher education; or
 3. Income from service on panels for a federal, state or local government agency or Institution of higher education.

An Investigator's Significant Financial Interest is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that the Significant Financial Interest could be affected by the PHS-funded research; or is in an entity whose Financial Interest could be affected by the research.

THIS POLICY HAS BEEN REISSUED SINCE JULY 2004.

- Significant Organizational Conflict of Interest- A Significant Organizational Conflict of Interest may exist when GHS has a Financial Interest that could cause a conflict with clinical care. Organizational conflicts of interest may include GHS's interests in the following:
 1. Licensing, technology transfer, and patents, when GHS owns the intellectual property
 2. Investments of GHS, in excess of \$500,000
 3. Gifts, when the donor has an interest in the research in excess of \$500,000
 4. Financial Interests of senior leadership in excess of \$250,000
 5. Other Financial Interests that are determined to be a conflict of interest

RELATED DOCUMENTS (optional):

S-015-03, Conflict of Interest Disclosure Requirements