

 Spartanburg Regional Healthcare System	SRHS Policy Manual	
	Title: Conflicts of Interest in Research	
	Policy #: IM1600.503	Policy Effective Date: 09/01/19
Document Owner (title): IRB & Research Compliance Manager		
Corporate Required Reviewer(s) (title): VP Corporate Integrity		

SCOPE:

Applies to all District Entities

DEFINITIONS:

Definitions for the following terms used in this document may be found in HRPP Policy 1700.103 Definition of Terms.

- Close Relation**
- Conflict of Commitment**
- Conflicts of Interest**
- Conflict of Interest Committee (CIC)**
- Disfavored Conflict**
- Equity Interests**
- Funding and Compensation (in the context of Conflicts of Interest in Research)**
- Institutional Responsibilities**
- Investigator**
- IRB**
- Management Role (in the context of Conflicts of Interest in Research)**
- Research**
- Research Team Member**
- Significant Conflict**
- Spartanburg Regional Healthcare System (SRHS)**
- Student Conflicts of Interest**

POLICY STATEMENT:

1. **Introduction:** This document describes the policy regarding conflicts of interest that may arise in connection with participation by SRHS associates, medical staff, and students in professional relationships with industry and other private partners in the conduct of research, and outlines the procedures related to those individuals’ duties to identify and disclose such conflicts, and the review and management of any conflict to ensure that it does not improperly influence, or appear to improperly influence, how SRHS research is proposed, conducted or reported.

This policy applies to all research conducted within SRHS, including all sponsored projects, government and non-government funded projects (such as industry or foundation sponsors), SRHS-funded projects, gift funded projects, clinical trials and to unfunded research projects.

2. **Responsibilities:**
 - 2.1. All associates, medical staff members, investigators, Research Team Member(s), and students who propose, conduct or report research on behalf of SRHS, regardless of funding source, are responsible for identifying and disclosing actual or potential conflicts of interests, receiving a

written determination from the VCPI as to how to manage the conflict, updating their disclosures, and providing timely and accurate information in response to the CIC.

3. Background and Related Principles:

- 3.1. Conflicts of Interest include non-financial as well as financial conflicts, because non-financial interests can conflict with a researcher's primary commitment to maintain scientific objectivity.
 - 3.1.1. Investigators should not only consider situations that are set forth in this policy, but also gray areas that might create the appearance of a conflict of interest.
 - 3.1.2. Conflicts of interest include the following types of interests maintained by an investigator, Research Team Member(s) or close relations: Equity Interests (including private equity interests and certain publicly traded equity interests of \$5000 or more), Management Roles in a research sponsor or company having an interest in the research, certain Funding and Compensation (including any travel reimbursed or sponsored by a sponsor or organizer other than SRHS).
- 3.2. Written Determination Regarding Conflict Management Required Before Beginning a Research or External Activity.
 - 3.2.1. Investigators are not permitted to begin any research activity when there is an actual or apparent conflict of interest before they receive a written determination from the VCPI as to how to manage the conflict.
 - 3.2.2. Investigators are not permitted to begin an external activity that would create a conflict of interest relative to ongoing research activity before they receive a written determination from the VCPI as to how to manage the conflict.
- 3.3. Times to Identify a Potential or Actual Conflict.
 - 3.3.1. Investigators and/or Research Team Member(s) should evaluate and disclose conflicts of Interest at the outset of their research (e.g., new study submission).
 - 3.3.2. Investigators and/or Research Team Member(s) should evaluate and disclose conflicts of interest when a change occurs in their relationship with an outside entity. This may occur at the time a new proposal is submitted, when a new relationship is established with an outside entity, or when a prior relationship with an outside entity changes.
 - 3.3.3. Investigators and/or Research Team Member(s) should evaluate and disclose conflicts of interest at the time of continuing review.
 - 3.3.4. Investigators and/or Research Team Member(s) should evaluate and disclose conflicts of interest at the time a new researcher is added.
 - 3.3.5. Investigators and/or Research Team Member(s) should evaluate and disclose conflicts of interest on an annual basis.
 - 3.3.6. SRHS may also require identification of conflicts at other times.
- 3.4. Updating Disclosures.
 - 3.4.1. Investigators, Research Team Member(s) and their close relations are responsible for updating their disclosures whenever there is a change to the information contained in the initial disclosure.
 - 3.4.2. Investigators must submit an annual disclosure of financial interests related to their institutional responsibilities (regardless of whether the interest creates a conflict of interest in research) when mandated by a research sponsor (e.g., the Department of Health and Human Services [HHS]), in accordance with the schedule established by SRHS.
 - 3.4.2.1. Investigators who are seeking support from HHS must have a current annual disclosure at the time of proposal submission. Investigators with HHS sponsored funding must update their annual disclosures within 30 days of the time they obtain

a financial interest with an entity that was not disclosed at the time of the most recent annual disclosure.

- 3.4.2.2. All changes to financial interests with entities disclosed in the annual disclosure must be updated at the time of the next annual disclosure.
- 3.4.3. SRHS may also require updating disclosures at other times.
- 3.5. Compliance.
 - 3.5.1. Investigators and Research Team Member(s) must comply with all of the elements of the CIC's management plan, as approved by the VPCI.
 - 3.5.2. All investigators must complete training relating to conflicts of interest in research as prescribed by SRHS.
 - 3.5.3. Each investigator is responsible for confirming that Research Team Member(s) under investigator's supervision who are involved in proposing, conducting or reporting research on the investigator's project identify and disclose any potential conflict of interest.
- 3.6. Significant Conflicts include situations when a principal investigator and/or principal investigator's close relation maintains any of the following interests:
 - 3.6.1. Private equity interests (e.g., stocks, stock options, or other ownership interests) in a non-publicly traded research sponsor or remuneration from the non-publicly traded entity that in the aggregate exceed \$5,000 in the twelve months prior to the disclosure; and/or
 - 3.6.2. Publicly traded equity interests in and remuneration from a research sponsor in the aggregate exceed of \$5,000 (except when the interest is maintained in an investment vehicle, such as mutual funds and retirement accounts, where the investigator does not directly control the investment decisions made) in the twelve months prior to the disclosure; and/or
 - 3.6.3. Management Roles in a research sponsor, including both original sponsor and any third party entity receiving the funding (e.g., a director, officer, or other position that has significant decision-making authority); and/or
 - 3.6.4. Receipt of payment for services related to promoting, marketing or selling products (e.g., paid public appearances, endorsements or speaking engagements aimed to encourage purchase or use of products) on behalf of a company for whom the investigator has also conducted (or intends to conduct) SRHS research as an independent evaluator of the company's products.
- 3.7. Disfavored Conflicts.
 - 3.7.1. Disfavored Conflicts should be avoided in order for the investigator to participate in related research.
 - 3.7.2. If a Disfavored Conflict is not avoided, the investigator must disclose the Disfavored Conflict, even if the Disfavored Conflict does not involve remuneration valued in the aggregate of more than \$5,000 in the twelve months prior to the disclosure.
 - 3.7.3. Exceptions may be made in compelling circumstances to allow the investigator to participate in the related research. The exceptions will depend in each case upon the nature of the science, the nature of the financial interest, how closely the interest is related to the research, and the degree to which the interest may be affected by the research. The investigator will have the opportunity to rebut the presumption against participating in research involving disfavored conflicts by demonstrating to the CIC that, for example, the investigator is uniquely qualified because of the investigator's expertise and experience and the research could not otherwise be conducted as safely or effectively without the investigator's participation.



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3.7.4. Disfavored Conflicts include:

- 3.7.4.1. Participating in a paid “speakers bureau” (i.e., contractual relationships to give talks in which the topic(s) and/or content are provided by the company) for any company that has sponsored the investigator’s research, or that of their close relations; and/or
- 3.7.4.2. Any personal incentive payments, bonus payments, finder fees, or any type of payment or incentive based on outcome that are made directly to the researcher relating to the proposal, conduct, supervision, or reporting of research (e.g., additional personal payments by research sponsors to investigators or Research Team Member(s) who enroll a certain number of participants in a project within a certain period of time), or with respect to the evaluation of a product or service intended for a commercial market (e.g., a clinical trial for a pharmaceutical company), regardless of the amount of compensation or payments received; and/or
- 3.7.4.3. Any sponsored agreement in which publication rights are restricted, except for reasonable delays in order to protect proprietary rights (i.e. patent rights), in combination with the investigator, Research Team Member(s) or close relation holding a conflict of interest; and/or
- 3.7.4.4. Accepting personal gifts, gratuities or special favors from an actual or prospective sponsor of an investigator’s research, other than occasional gifts, including meals, having a retail value of no more than \$100 per item or \$1,200 in the aggregate on an annual basis.
 - 3.7.4.4.1. Investigators and/or Research Team Member(s) who are healthcare providers and/or associates of SRHS are subject to additional requirements under IM1000.707 Gifts, Gratuities, and Business Courtesies.

PROCEDURE (Click on link below):

[Spartanburg Regional Health Services District, Inc., Procedures](#)

ASSOCIATED FORMS:

Conflict of Interest in Research Questionnaire

COMMITTEE APPROVAL:

Research Compliance Committee

POLICY REFERENCES:

Department of Health and Human Services. (2004). Financial Conflict of Interest: HHS Guidance [Guidance], Retrieved from <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/financial-conflict-of-interest/index.html>.

IM1000.707 Gifts, Gratuities, and Business Courtesies

IM1000.718 Conflicts of Interest

Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought, 45 CFR § 50, Subpart F (2011).

Responsible Prospective Contractors, 45 CFR § 94, (2011).

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SPARTANBURG REGIONAL HEALTH SERVICES DISTRICT, INC., PROCEDURES

ROLES AND RESPONSIBILITIES:

All Associates in the District

PROCEDURE:

1. Identifying and Disclosing Potential or Actual Conflicts

- 1.1. Investigators and Research Team Member(s) must identify and disclose conflicts of interest (including any Disfavored Conflict(s)):
 - 1.1.1. At the time of proposal submission.
 - 1.1.2. In connection with human subjects research, at the time of submission of the initial review application to the Institutional Review Board (IRB).
 - 1.1.3. At any point when the Investigator and/or Research Team Member(s) establish a new outside relationship, or change an existing relationship that creates a potential conflict under this policy.
 - 1.1.4. In connection with human subjects research, at the time of continuing review by the IRB.
 - 1.1.5. In connection with human subjects research, at the time a new researcher is added.
 - 1.1.6. Annually.
 - 1.1.7. When required at other times by SRHS.
- 1.2. Conflicts of Interest in Research Questionnaire (COIRQ).
 - 1.2.1. All Research Team members must complete and submit a COIRQ at the times described in 1.1. including simultaneously with submission of a research application for a study that is to be conducted at SRHS.
 - 1.2.2. The COIRQ will require the Investigator and/or Research Team Member(s) to describe the research, the nature of the potential conflict, and to propose how the conflict should be managed, reduced, or eliminated.
- 1.3. Sponsor Requirements.
 - 1.3.1. Research sponsors (such as Health and Human Services) may also require that Investigators make an annual disclosure (e.g., prior to a designated date each year) of all outside relationships maintained by them or their Close Relations that relate to the Investigator's Institutional Responsibilities to SRHS, regardless of whether the relationship creates a potential conflict of interest.
 - 1.3.2. Investigators must adhere to sponsor-specific disclosure requirements.
 - 1.3.3. Investigators must submit an annual disclosure to SRHS of all outside interests related to the Investigator's Institutional Responsibilities. If a potential conflict is first identified through an annual disclosure, the Investigator shall be required to submit a conflict disclosure, as described in Section 1.2.
- 1.4. Additional disclosures may be needed under other SRHS policies.

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2. Managing Conflicts

- 2.1. Given the complexity of financial and non-financial relationships within SRHS, disclosures will be evaluated on a case-by-case basis to determine whether the disclosure constitutes a conflict of interest and, if so, to determine an appropriate action.
- 2.2. Conflicts of interest generally do not require full CIC review and may be handled administratively if the conflict is not a Significant Conflict, does not involve students or human subjects, and/or is not a Disfavored Conflict. However, the VPCI, or VPCI's designee, reserves the right to require CIC review if appropriate. A conflict is handled administratively, as described in Section 2.1 of these procedures.
- 2.3. When a disclosure reveals a potential conflict requiring full CIC review, the pre-review will be forwarded to the CIC, which is charged with reviewing disclosures and formulating recommendations to manage, reduce, or eliminate conflicts of interest, as appropriate. The CIC shall meet as determined by the VPCI.
 - 2.3.1. The VPCI and the Institutional Official, or their respective designees, must approve the portions of a management plan designed to manage an identified Student Conflict of Interest.
 - 2.3.2. When a disclosure reveals a Significant Conflict, the CIC will make an assessment of whether compelling circumstances exist that justify allowing the research to proceed despite the presence of the conflict.
 - 2.3.3. The CIC will make a recommendation to the VPCI as to whether a potential conflict is manageable and, if so, the management plan that should be implemented. The VPCI will make the final determination.
- 2.4. All management plans will contain, at a minimum, the following elements:
 - 2.4.1. All relevant publications, proposals and presentations must contain a statement disclosing support received from, or financial interests in, any source outside of SRHS;
 - 2.4.2. All informed consent documents in the context of human subjects research must disclose support received from, or financial interests in, any source outside of SRHS. Conflicted investigators and/or Research Team Member(s) are not permitted to consent human subjects;
 - 2.4.3. The investigator and/or Research Team Member(s) and their close relations will not represent the SRHS in any intellectual property negotiations, or other contractual negotiations, between SRHS and the outside entity;
 - 2.4.4. Investigators must notify students of the presence of a conflict of interest if the student is to perform as a research assistant on the research, along with a notification to the student and student's advisor of the student's rights, and the appointment of a third party faculty member as a monitor of the situation.
 - 2.4.4.1. An independent faculty member (student research) must also be designated to monitor the student's progress and protect student's interests.
- 2.5. Management plans may contain a variety of additional options for the investigator to pursue, including:
 - 2.5.1. Monitoring and oversight by the CIC or by an individual delegated to monitor by the CIC;
 - 2.5.2. Referral to an independent faculty member (for student research), supervisor or CIC appointed subcommittee for oversight.

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- 2.5.3.Reformulation of the research workplan;
- 2.5.4.Restrictions on the analysis of data:
- 2.5.5.Close monitoring of the research project by independent reviewers;
- 2.5.6.Termination or reduction of involvement in the relevant research project;
- 2.5.7.Termination of inappropriate student involvement in projects;
- 2.5.8.Where the investigator and/or Research Team Member(s) are healthcare providers, compliance with SRHS's Relationships with Funders policy;
- 2.5.9.Where the investigator and/or Research Team Member(s) receive payments for personal services related to research involving human subjects (e.g., consulting arrangements, non-managerial scientific or technical appointments, and payments for lectures and similar public appearances), the IRB may require written disclosure of such payments during the informed consent process, regardless of dollar amount:
- 2.5.10. Removal from the research project of an investigator and/or Research Team Member(s) with an apparent or actual conflict of interest;
- 2.5.11. Creation of an escrow account and/or blind trust to hold equity interests or intellectual property interests that create an actual or apparent conflict of interest:
- 2.5.12. Divestiture of relevant financial interests;
- 2.5.13. Severance of outside relationships that pose a conflict of interest.
- 2.5.14. The CIC may also consider steps taken by the investigator and/or Research Team Member(s) to minimize potential bias and include protective factors in the design of the study, such as using multiple investigators, blinding, or establishing objective endpoints. Possible management recommendations may apply to the monitoring of research, conduct of research, or the individual's outside interests.
- 2.6. In cases where the CIC's review of a disclosure raises a potential Conflict of Commitment, the CIC will notify the investigator and/or Research Team Member(s)'s supervisor, department chair or department director as appropriate. The investigator and/or Research Team Member(s)'s supervisor, department chair or department director must provide a copy of all documentation reflecting their decision with respect to the conflict of commitment to the VPCI.
- 2.7. Once the VPCI makes a final determination, the VPCI will notify the following individuals and/or entities in writing, as appropriate:
 - 2.7.1.The individual(s) who has the potential or actual conflict of interest. If this individual(s) is someone other than the investigator, the investigator will be notified as well;
 - 2.7.2.The relevant faculty member (for student research);
 - 2.7.3.If the conflict of interest involves human subjects, the chair of the relevant IRB:
 - 2.7.4.If the conflict of interest has been identified in connection with research conducted at Medical Group of the Carolinas (MGC), the VPCI will notify the Chief Medical Officer of MGC of the VPCI's determination;
 - 2.7.5.Other individuals on campus who have a "need to know"
- 2.8. It is the responsibility of the investigator and/or Research Team Member(s) to comply with each element of a required management plan. This includes any requirement that the investigator and/or Research Team Member(s) provide a follow-up disclosure at a reasonable time interval after the initial disclosure (but no less frequently than once per year) that updates the CIC and

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the VPCI on the status of the conflict of interest, and investigator and/or Research Team Member(s)'s compliance with the measures put in place to manage it.

3. Violations and Sanctions

- 3.1. Failure to report a conflict of interest or to submit an accurate required disclosure, or refusal to cooperate in the management of a conflict of interest, may be cause for disciplinary action.
 - 3.1.1. Possible violations of this policy include, but are not limited to, failure to file a disclosure form; furnishing false, misleading, or incomplete information on a disclosure form; or failure to follow a management plan.
 - 3.1.2. The CIC may recommend suspension of research on the part of any individual who has violated this policy.
 - 3.1.3. The VPCI will make the final determination on whether to adopt CIC recommended sanctions and how to execute the recommended sanctions.
- 3.2. In addition, in the case of HHS-funded research, if the investigator fails to disclose or update a conflict in a timely fashion, or to comply with the management plan, SRHS will review the investigator's activities and the research project to determine whether any research conducted during the period of noncompliance was biased in the design, conduct, or reporting of such research. SRHS will document the review and notify the sponsor promptly in the event bias is found. The report will include:
 - 3.2.1. Project number;
 - 3.2.2. Project title;
 - 3.2.3. Principal investigator or contact principal investigator if a multiple PI model is used;
 - 3.2.4. Name of the investigator with the conflict;
 - 3.2.5. Reason(s) for the retrospective review;
 - 3.2.6. Methodology used for the retrospective review, and
 - 3.2.7. Findings and conclusions of the review.
- 3.3. If actual bias is found, SRHS will notify the sponsor promptly and submit a mitigation report.
 - 3.3.1. The mitigation report will include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project.
 - 3.3.2. The mitigation report will also outline SRHS's plan to eliminate or mitigate the effect of the bias.

4. Government Reporting and Appeals

- 4.1. An associate, medical staff member, or student seeking review of the decision by the VPCI has a right to a hearing under SRHS's grievance provisions on any of the grounds on which a reappointment or promotion decision may be grieved. The decision of the VPCI will remain in full force and effect throughout the review process.
- 4.2. When a conflict of interest has been identified in connection with HHS-funded awards, the VPCI, or VPCI's designee, will notify the sponsor and submit a report in accordance with HHS requirements, documenting the conflict and how it will be managed.
- 4.3. SRHS is required to respond to requests for information about conflicts of interest on HHS funded research within five business days of receipt of the request. Requests should be directed to the VPCI or Office of Research Compliance.

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4.4. Records relating to disclosures of actual or apparent conflicts of interest and the determinations of the CIC will be kept by the VPCI or designee for three years after the termination or completion of the project, or from other dates specified in 45 CFR 75.361, whichever is later.

ASSOCIATED FORMS:

Conflict of Interest in Research Questionnaire

PROCEDURE REFERENCES:

Department of Health and Human Services. (2004). Financial Conflict of Interest: HHS Guidance [Guidance], Retrieved from <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/financial-conflict-of-interest/index.html>.

IM1000.707 Gifts, Gratuities, and Business Courtesies

IM1000.718 Conflicts of Interest

Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought, 45 CFR § 50, Subpart F (2011).

Responsible Prospective Contractors, 45 CFR § 94, (2011).