

**TITLE: Conflict of Interest, Research**

IDENTIFIER: S-FW-LD-0004

APPROVED: Executive Cabinet 12/11/12  
ORIGINAL FORMULATION: 12/08REVISED: 12/12  
REVIEWED: 06/12**EFFECTIVE:**

<input checked="" type="checkbox"/> Acute Care:	ENC: <u>12/17/12</u>	GH: <u>12/17/12</u>
	LJ: <u>12/17/12</u>	MER: <u>12/17/12</u>
<input checked="" type="checkbox"/> Home Health:	<u>12/17/12</u>	
<input checked="" type="checkbox"/> SHAS:	<u>12/17/12</u>	
<input checked="" type="checkbox"/> SMF:	SC: <u>12/17/12</u>	SCMC: <u>12/17/12</u>
	CVTSC: <u>12/17/12</u>	

**KEYWORDS: Disclosure, Financial Disclosure, Gifts, Kickback, Payment****I. PURPOSE**

This policy establishes standards and procedures to ensure that the design, conduct and reporting of research activities will not be compromised by any conflicting financial interest on the part of the principal investigator(s) or key personnel by implementing a system for the disclosure, evaluation, management, reduction, and/or elimination of potential conflicts of interest. This policy is intended to comply with Federal regulations regarding objectivity in research ([21 C.F.R. Part 54](#), [42 C.F.R. Part 50](#) and [45 C.F.R. Part 94](#)), and the [Final Rule on Financial Conflict of Interest Regulations, revised regulations, – Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought, dated August 25, 2011 and effective August 24, 2012 \(42 CFR Part 50, subpart F, 50.601-50.607, and 45 CFR Subpart F, 94.1-94.6.](#)

**II. POLICY****A. Requirements for the Disclosure of Financial Interests:**

1. All principal investigators and key personnel must disclose their financial interests and the interests of their spouses/domestic partners and dependent children on the appropriate disclosure form(s).
2. All principal investigators and key personnel involved in projects sponsored by the Federal government must update their financial interests and the interests of their spouses/domestic partners and dependent children at least annually and upon any change in their financial interest or that of their spouse/domestic partner or dependent children.
3. If a PI has a significant change in a financial relationship with a related entity that occurs during the course of a clinical trial that has already been reviewed for potential conflict of interest, he/she must make that new financial relationship known to the Research Conflicts of Interest Committee, within 30 days by submitting a new COI form.

**B. When a research project or research program is sponsored by a nongovernmental entity or a governmental entity that is not described in C (below):**

1. All principal investigators must disclose their financial interests in or with the sponsor of the research.
2. If the project involves human subjects, principal investigators and key personnel must disclose any significant financial interests related to

the research project or that could reasonably appear to be affected by the sponsored research project.

- C. When a research project, a research program or an educational activity is sponsored by the Federal government or Federal government entity:
  - 1. Principal investigators and key personnel must disclose their significant financial interests that are related to the sponsored research project or educational activities or that could directly and significantly affect the design, conduct, or reporting of Public Health Service (PHS)-funded research.
- D. When it is determined that a sponsored research project may reasonably appear to be affected by a financial interest disclosed pursuant to III.A or III.B, Scripps Research Conflict of Interest Committee may require steps to reduce, manage or eliminate the conflict to assure objectivity.
- E. Scripps will maintain a current, enforced policy on financial conflicts of interest that complies with subpart F, and make such policy available via a publicly-accessible website.
- F. Scripps will inform each Investigator of this Policy, and of the Investigator's responsibilities regarding the disclosure of significant financial interests and the applicable regulations, and require each Investigator to complete training regarding same, prior to engaging in research related to any PHS-funded grant and at least every 4 years.
- G. If Scripps carries out PHS-funded research through a sub-recipient (subcontractor or consortium member), the awardee Institution must take reasonable steps to ensure that any sub-recipient Investigator complies with financial COI's by incorporating as part of a written agreement with the sub-recipient, whether the COI policy of the awardee Institution or that of the sub-recipient will apply to the sub-recipient Investigators.
- H. Prohibited Activities. The following activities are prohibited because they present conflicts of interest that are contrary to the Scripps policy and mission:
  - 1. Academic Freedom Restrictions
    - a. Investigators may not enter into secrecy or confidentiality agreements if the agreement delays the protection of Intellectual Property Rights.
    - b. Investigators may not agree to arrangements that permit a sponsor to interfere in the scientific analysis or publication of research results or conclusions.
  - 2. Human Subjects Research

Principal investigators and key personnel involved in research with human subjects may not:

    - a. Directly or indirectly accept any gifts or payments from the sponsor of the research except for payments that are commensurate with their efforts on behalf of the sponsor.
    - b. Buy or sell common stock (as opposed to mutual funds) in the sponsor of the research until their involvement in the research ends and the results of the research are published or otherwise disseminated to the public.
  - 3. Intellectual Property

- a. An investigator who is involved in negotiating a license on behalf of Scripps Health may not have a significant financial or other interest in the business entity that is a party to the negotiations.
- b. An investigator shall not accept a position on the board of directors of a licensee in which Scripps holds an equity interest.

I. Records

Official records regarding individual conflicts of interest shall be maintained by the Office of Research and retained for seven years, or as otherwise required by state and Federal law.

J. Violations

1. Failure to file disclosures or provide information required by this policy or to comply with any conditions or restrictions imposed by the Research Conflict of Interest Committee, a monitor, or management sub-committee, constitutes violations of this policy, which may be grounds for exclusion from current and future research relating to Scripps or performing Research at a Scripps' facility.
2. State and/or Federal regulations may require reports to the project sponsor regarding violations of this policy. Project sponsors may impose additional sanctions including the suspension or termination of an award or debarment from receiving future awards.

### III. DEFINITIONS

- A. Conflict of Interest—a situation that occurs when the conduct of research could be compromised, or appear to be compromised, by a related financial interest of the principal investigator or key personnel.
- B. Disclosure of Significant Financial Interests—means an Investigator's disclosure of significant financial interests to an Institution.
- C. Financial Interest—includes any of the interests in a private sponsor of research, held by the principal investigator or the principal investigator's spouse, domestic partner and/or dependent children within the 12 months prior to the date of the offer of research funding. Under 42 CFR 50.603 and PHS-funded research, Financial Interest means *anything of monetary value, whether or not the value is readily ascertainable*.
- D. Financial Conflict of Interest (FCOI)—means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- E. Financial COI Report—means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
- F. HHS—means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- G. Institution—means any domestic or foreign, public or private, entity or organization (excluding a Federal Agency), that is applying for, or that receives, PHS research funding.
- H. 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 services on panels such as IRBs or DSMBs.

- I. Investigator—means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- J. Key Personnel—any person, other than the principal investigator, who is independently responsible for the design, conduct or reporting of sponsored research or educational activities conducted in whole or in part at a Scripps' Health facility.
- K. Manage—means taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- L. Management Plan—the written plan created by the Research Conflict of Interest Committee for the management, reduction or elimination of a potential or actual conflict of interest.
- M. Principal Investigator—the investigator primarily responsible for the design, conduct or reporting of sponsored research or educational activities conducted in whole or in part at Scripps. PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under Subpart F, 45 CFR Part 50.
- N. PHS—means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the NIH. The PHS Awarding Component means the organizational unit of the PHS that funds the research that is the subject to this subpart.
- O. Research—a systematic investigation, experiment, study, evaluation, demonstration or survey 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 (diagnostic test or drug). As used in Subpart F, the term includes any such activity for which research funding is available from a PHS awarding component through a grant or co-operative agreement.
- P. Senior/key personnel—means the PD/PI and any other person identified as such by the Institution in a PHS grant application, progress report, or any other report submitted to the PHS by the Institution under Subpart F.
- Q. Significant Financial Interest—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: anything of significant monetary value, including but not limited to salary or other payments for services; equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights); or holding a position as an

officer, director, agent, or employee of a business entity.

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 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 (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.
2. 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 12 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 (stock, stock option, or other ownership interest); or
3. Intellectual Property rights and interests (patents, copyrights) upon receipt of income related to such rights and interests.
4. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (e.g., 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, a medical center, or a research institute that is affiliated with an Institution of higher education. The Investigator will disclose the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS-funded research.

Significant financial interest does NOT include:

- a. Salary, royalties, or other remuneration from Scripps if the Investigator is currently employed or otherwise appointed by Scripps, including Intellectual Property rights assigned to Scripps and agreements to share in royalties related to such rights;
- b. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- c. Income from service on advisory committees or review panels for public or nonprofit entities;
- d. Income from mutual funds and/or pension funds, as long as the Investigator does not directly control the investment decisions made in these vehicles.

**IV. RESPONSIBILITIES****A. Research Conflict of Interest Committee**

1. The Research Conflict of Interest Committee shall review the positive disclosures of financial interests from principal investigators and key personnel to determine if a conflict of interest exists, and if so, how to manage, reduce, or eliminate the conflict.
2. The Research COI Committee shall review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial COI exists, and, if so, develop and implement a management plan that shall specify the actions that will be taken to manage the financial COI. The committee may consider:
  - a. Public disclosure of financial conflicts of interest which may include disclosure in the research publication or other appropriate means;
  - b. For research projects involving human subjects, disclosure of financial COIs directly to the participants;
  - c. Appointment of an independent monitor to take measures to protect the design, conduct, and reporting of the research against any bias thought to result from the COI;
  - d. Modification of the research plan;
  - e. Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the research;
  - f. Reduction or elimination of the financial interest;
  - g. Severance or modification of relationships that create financial conflicts including limiting the scope of speaking engagements and other appropriate limitations.
3. During a PHS-funded research project if a significant COI is disclosed, the Research COI Committee shall, within 60 days, review the disclosure, determine whether it is related to PHS research, and, if so, implement a management plan that shall specify the actions taken to manage such COI.
4. If the Research COI Committee becomes aware that an Investigator has failed to disclose a COI that is later determined by the Committee to constitute a financial COI, Scripps shall, within 120 days of the determination of noncompliance:
  - a. Complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research was biased in the design, conduct, or reporting of such research;
  - b. Document the retrospective review by project number, title, PI, name of Investigator with the COI, reasons for the review and a detailed methodology used for the review, findings of the review, and conclusions;
  - c. If bias is found, Scripps will notify the PHS awarding component promptly and submit a mitigation report, including Scripps' plan of action or actions taken to eliminate or mitigate the effect of the bias;
  - d. The PHS awarding component may determine that imposition of special

award conditions under 45 CFR 74.14 and 92.12 or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43 are necessary until the matter is resolved.

5. Whenever Scripps implements a management plan to manage a COI, Scripps shall monitor Investigator compliance with the plan until the PHS-funded research is completed.
  6. The Research Conflict of Interest Committee members are appointed by the Scripps CEO for three-year terms.
  7. The Committee shall be comprised of between 4-6 voting members to include the Chief Medical Officer, the Vice President of Clinical Research, the General Counsel, and the Chief Compliance Officer. The Committee may include non-voting, ex-officio participants.
  8. Recusal. A committee member shall be recused from discussion and voting on a particular case if:
    - a. The committee member has a compelling personal interest in the case (such as research or academic collaboration with the individual whose case is under consideration); or
    - b. The committee member has a financial interest in the case under consideration.
- B. Director—Regulatory Services, Clinical Research Services
- The Director is responsible for supporting the Research Conflict of Interest Committee, the individual monitors, ensuring that the Committee's decisions, recommended actions and reasons therefore are fully documented and implemented, and that Scripps complies with its obligations under state and Federal law and this policy.
- C. Vice President—Clinical Research
- The Vice President—Clinical Research is responsible for ensuring that no Federal funds are expended before the Federal sponsor receives notification when it is determined that a conflict of interest exists.
- D. Institutional Review Board (IRB)
1. The IRB cannot receive for review any research involving human subjects where the principal investigator or a key personnel member has submitted a positive financial disclosure until the Conflict of Interest Committee reviews the disclosure and provides its recommendations to the IRB.
  2. The IRB will review recommendations it receives from the Conflict of Interest Committee regarding the management, reduction or elimination of conflicts of interest to ensure that the recommended course of action will adequately protect study participants and the credibility of the human research protection program.
- E. Principal investigators are responsible for the following:
1. Disclosing financial interests as required by this policy.
  2. Ensuring disclosure by key personnel when required by this policy.
  3. Complying with the provisions in Section F below.
- F. Principal investigators and key personnel are responsible for the following:

1. Disclosing financial interests as required by this policy, the applicable regulations as noted in this Policy.
2. Upon request, preparing a statement for an individual monitor or management sub-committee regarding how they intend to manage, reduce, or eliminate a conflict when it is determined to be necessary by the Research Conflict of Interest Committee.
3. Cooperating with the Research Conflict of Interest Committee and any monitor or management sub-committee in providing reports and documents as requested.
4. Conducting the sponsored research or educational activity in a manner that will avoid a perception that the project could be influenced or biased by conflicts of interest.
5. Delaying IRB submission where the principal investigator or a key personnel member has submitted a positive financial disclosure until a recommendation is made by the Research Conflict of Interest Committee.
6. Fulfilling all conditions necessary to manage a conflict of interest as determined by the Research Conflict of Interest Committee, and in the case of research involving human subjects, the IRB.

## **V. RELATED FORMS**

Research Conflict of Interest Disclosure Form; SW-LD-0004

## **VI. REFERENCES**

- A. [21 C.F.R. Part 54](#)
- B. [42 C.F.R. Part 50](#)
- C. [45 C.F.R. Part 94](#)
- D. [45 C.F.R. Subpart F 50.601-50.607 and Part 94.1-94.6.](#)

## **VII. SUPERSEDED**

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