



Policy: Disclosure of Financial Interests & Management of Conflicts of Interest (FCoIR), Public Health Service Research Awards

Effective: 02/06/24

Identifier: S-FW-LD-0004

Acute Care: ENC GR LJ MER

Ambulatory SHAS

I. PURPOSE, SCOPE, AND APPLICATION

The federal Department of Health and Human Services (DHHS) has determined, pursuant to 42 CFR Part 50, Subpart F and 45 CFR Part 94, as revised on August 25, 2011, that effective no later than August 24, 2012, Public Health Service (PHS)- sponsored Investigators shall be subject to specific requirements regarding the disclosure and management of conflicts of interest with regard to research in order to provide a reasonable expectation that PHS-sponsored research will be conducted free of bias resulting from Investigator financial conflicts of interest.

This policy for disclosure and management of conflicts of interest applies to all grants and cooperative agreements (other than Phase I SBIR and STTR applications) with an issue date of the Notice of Award on or after August 24, 2012 (including noncompeting continuations), and to solicitations issued and contracts awarded after August 24, 2012 that are submitted to PHS (NIH, CDC, FDA, etc.) and other non-federal sponsors that adopt the PHS policy for research.

Scripps Health is obligated to establish this policy consistent with these regulations to require disclosure, and identification and management of financial conflicts of interest for all Investigators supported by PHS (NIH, CDC, FDA, etc.) research awards and other non-federal sponsors that adopt the PHS policy (for example, American Heart Association and the American Cancer Society).

Consistent with PHS regulations, this policy will be made available via a publicly accessible website. All Scripps Health Investigators (that is, individuals who, regardless of position or title, are responsible for the design, conduct or reporting of PHS supported research, and Investigators seeking PHS research support) shall be informed where this policy is and relevant reporting requirements may be accessed via the web.

II. DEFINITIONS

- A. **Designated Institutional Official:** The individual(s) at Scripps Health responsible for implementing this policy. The responsibility includes ensuring completion of all disclosure of Significant Financial Interests per the outlined policy below, reviewing all disclosures of Significant Financial Interests, Conflicts of Interest and Conflicts of Commitment, and requiring all actions necessary to ensure that any Conflict of Interest or Commitment found will be managed, reduced, or eliminated in accordance with this policy.
- B. **Financial Conflict of Interest (FCOI):** A Significant Financial Interest that is related to the PHS-funded research activity in which the Investigator is engaged and that could directly and significantly affect the design, conduct, and/or reporting of PHS-funded research.
- C. **Independent Review Committee (IRC):** A committee which may be appointed by the RIO to review Investigator's significant financial interests related to PHS-funded research, and to serve as regulatory body who determines whether any of the significant financial interest constitutes a financial conflict of interest. At the RIO's discretion, this review may be conducted by the RIO or the IRC.
- D. **Institutional Responsibilities:** An Investigator's professional responsibilities on behalf of the Institution, which may include activities such as research, research

consultation, teaching, institutional committee memberships, and service on such panels as Institutional Review Boards or Data and Safety Monitoring Boards.

- E. **Key Personnel:** A PHS-funded research Project Director, Principal Investigator, and any other personnel considered essential to work performance and identified as Key Personnel in the contract proposal, grant, or contract.
- F. **Principal Investigator:** An Investigator who has primary responsibility for the scientific and technical conduct, reporting, fiscal, and programmatic administration of a sponsored project.
- G. **Research:** As used in this policy, any activity for which research funding is available from a PHS awarding agency, including but not limited to research grants, cooperative agreements, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects or research resources awards, conference grants, and Phase II Small Business Innovative Research (SBIR) and Phase II Small Business Technology Transfer Research (STTR) awards. Excluded from this policy, consistent with the underlying federal regulations, are Phase I Small Business Innovative Research (SBIR) and Phase I Small Business Technology Transfer Research (STTR) awards.
- H. **Research Integrity Officer (RIO):** The RIO is the primary designated institutional official responsible for implementing this policy. In the absence of a RIO, the Scripps Health OHRP Institutional Official or Corporate Compliance & Privacy Officer could act in place of the RIO.
- I. **Scripps Office for the Protection of Research Subjects (SOPRS):** The office that is responsible for training and education around this policy, collection of FCOI disclosure forms, adherence to federal regulations governing human subjects research, and disclosure of significant financial interests to the Scripps Institutional Review Board (IRB).
- J. **Significant Financial Interest (SFI):** Consistent with federal regulations (42 CFR Part 50.603 and 45 CFR Part 94.3), *significant financial interest* means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or registered domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - 1. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration (other than remuneration described in Paragraph 5, below) 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. Included are salary (other than salary described in Paragraph 5, below), consulting fees, honoraria, and the equity interest value at the date of disclosure as determined by public prices or other reasonable measure of fair market value.
 - 2. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration (other than remuneration described in Paragraph 5, below) 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, registered domestic partner, or dependent children) holds **any** equity interest (e.g. stock, stock option, or other ownership interest).
 - 3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 - 4. Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., 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, a U.S. institution of higher education, or a research institute, an academic medical center or hospital affiliated with an institution of higher education.

5. The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, a U.S. institution of higher education, or a research institute, an academic medical center or hospital affiliated with an institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, a U.S. institution of higher education, or a research institute, an academic medical center or hospital affiliated with an institution of higher education.

III. POLICY

- A. **Disclosure of Financial Interests:** All principal investigators and key personnel must disclose all potential conflicts of interest of themselves or of their spouses/domestic partners and dependent children on the appropriate FCOI disclosure form(s).
 1. At the time of application for PHS funding
 2. Annually during IRB renewal
 3. Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI. With the exception of travel described below.
 4. Before joining an ongoing PHS-funded research project as a new Investigator.
 5. Principal Investigators must identify all Investigators on the award who (that is, all individuals who will have responsibility for designing, conducting, or reporting the research to be funded by PHS) are required to disclose SFIs.
 6. Sponsored or reimbursed travel may be disclosed:
 - i. Prospectively listing all anticipated travel (including information about the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip, as well as any other information that may be required by the institution) for the 12-month period following the filing of the Investigator's annual disclosure form.
 - ii. Within 30 days of the occurrence of travel that either was not listed on the prospective annual travel report pursuant to paragraph 6.i. above or that significantly varied in the threshold reporting details from what was listed in the prospective report.
- B. **Review of Disclosures, Management Plans, Monitoring:** With each PHS proposal, progress report, incremental funding or extension, Investigators' SFI

disclosures will be reviewed by the RIO to determine whether there are any SFIs that reasonably appear to be related to the PHS-funded research activity in which the Investigator is engaged. Investigators shall have an opportunity to indicate whether they believe the SFI(s) they reported are related to their PHS-funded research activities.

If the RIO concludes that an Investigator's SFI reasonably appears to directly and significantly affect the design, conduct, or reporting of the PHS-funded research, or is in an entity whose financial interest could be affected by the research, the disclosure and appropriate documentation shall be forwarded to the IRC for consideration. When it is determined that there is a FCOI, the IRC shall make a final recommendation to the RIO about whether any conditions or restrictions should be placed on the project to eliminate or manage the FCOI before the support can be accepted.

The management plan is to be implemented prior to Scripps Health's expenditure of PHS funds awarded for the research project, and shall specify the actions that are required to manage the FCOI, and shall include:

- The role and principal duties of the conflicted Investigator
- Conditions of the management plan
- How the plan will safeguard objectivity in the research activity
- Confirmation of the investigator's agreement to the plan
- How the plan will be monitored

The management plan put in place by the RIO or IRC shall specify the way in which the Investigator's compliance with the management plan will be monitored on an ongoing basis until completion of the PHS-funded research project.

C. Training and Education Regarding Conflicts to Investigators: SOPRS makes all Scripps Health investigators aware of this policy, the disclosure requirement outlined below, provides links to federal regulations, and provides resources for them to complete an NIH-compliant training about the PHS financial conflicts of interest:

- prior to engaging in research related to any PHS-funded project
- at least every 4 years thereafter
- immediately upon changes to Scripps policy, required in accordance with DHHS regulations
- immediately for PHS-funded Investigators who are new to Scripps Health or who are joining from an ongoing PHS research activity.
- immediately when an Investigator is not in compliance with this policy or a management plan.

D. Sub-Recipients, Subcontractors, and/or Consortium Members: For PHS-funded research where Scripps Health is the awardee institution, Scripps Health will ask the subrecipient institution to certify that its policy is in compliance with DHHS conflict of interest regulations, and unless the subrecipient does not have a DHHS-compliant policy, will indicate that the recipient organization is responsible for reviewing the disclosures submitted by its Investigators and, if a FCOI is identified, for sending Scripps Health notification of the conflict and of the subrecipient institution's plan to manage, reduce, or eliminate the identified conflicts, in accordance with PHS reporting requirements.

Collaborators from other institutions, who share responsibility for design, conduct, or reporting research results, and who will be conducting research under a contract from Scripps Health, are expected to comply with the policies and procedures for disclosure and review of a SFI at the institution at which they are employed, or if their institution does not have a conflict of interest policy that complies with the DHHS regulations, they must comply with Scripps Health policies and procedures for disclosure and review of a SFI related to PHS sponsored awards.

- E. **Reporting:** Prior to Scripps Health's expenditure of any funds provided under a PHS award, the RIO must provide to the PHS funding agency an initial report regarding Investigator FCOI. If FCOIs are eliminated before research funds are expended, Scripps Health is not required to submit a report to the PHS funding agency.

During the period of the award, Scripps Health shall, within 60 days of receipt of disclosure of a new or newly discovered SFI, review the disclosure, determine whether it is related to PHS-funded research, determine whether it constitutes a FCOI, and if so, implement a management plan and report the FCOI to the PHS funding agency.

For any FCOI that Scripps Health reports to a PHS awarding agency, Scripps Health shall provide to the PHS awarding agency an annual FCOI report that addresses the status of the conflict and any changes to the management plan for the duration of the project. The annual report shall specify whether the financial conflict is still being managed or explain why it no longer exists.

Scripps Health must provide annual reports to the PHS awarding agency for the duration of the project period (including extensions with or without funds).

Within 60 days of determining that a FCOI exists for a new Investigator who joins an ongoing PHS-funded research activity, Scripps Health must implement a management plan and submit a report to the PHS funding agency.

In any case in which DHHS determines that a PHS-sponsored project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by Scripps Health as required by this policy and Federal regulations, Scripps Health shall require the Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

- F. **Retrospective Review and Mitigation Reports:** If during the course of an ongoing PHS-funded research project, Scripps Health identifies a SFI that was not disclosed in a timely manner by an Investigator or which was not previously reviewed, the RIO will, within 60 days, review the SFI to determine whether it is related to a PHS-funded research activity, determine whether a FCOI exists, and if so, implement a management plan on at least an interim basis.

In addition, whenever a FCOI is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose a SFI that was later determined to be a FCOI, or Scripps Health did not review or manage the FCOI, or the Investigator failed to comply with a previously implemented management plan, Scripps Health must, within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research. The purpose of this retrospective review is to determine if the ongoing PHS-funded research was biased in its design, conduct, or reporting.

Scripps Health will document the retrospective review. The documentation will include the project number, project title, name of Investigator with FCOI, name of the entity with which the Investigator has a FCOI, the reasons for the retrospective review, the detailed methodology used for the retrospective review, the findings, and conclusions.

1. Based on the results of the retrospective review, if appropriate, the previously submitted FCOI report should be updated to specify the actions that Scripps Health will take to manage the identified FCOI going forward.
 2. If bias was found during the retrospective review, Scripps Health will promptly notify the PHS funding agency and will draft a mitigation report, that at a minimum, documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines Scripps Health's plans to eliminate or mitigate the effect of the bias.
- G. **Records:** Official records regarding individual conflict of interest disclosures shall be maintained by the SOPRS and retained for three years after submission of the final expenditures report, or for awards that are renewed quarterly or annually, from the date of submission of the quarterly or financial report, or from other dates specified in 45 CFR 75.361 where applicable.
- H. **Public Access to Information:** The RIO shall identify one e-mail address and one office address as the recipient addresses for public requests for information under the PHS regulations and this policy and shall take action necessary to provide reasonable notice of those addresses to the public, including prominently posting this information on the Scripps Health web site.

The contact must respond within 5 business days to any request for information about SFIs held by Key Personnel when Scripps Health has determined that the disclosed SFIs are related to the PHS-funded research and constitute FCOI. The 5-day response time shall be measured from the date the request for information is received at the Scripps Health-designated address until the date a response is sent to the requestor.

Disclosure forms, disclosure update forms, and management plans including determinations of FCOI under this policy are public records, open to public inspection, under Federal and state law.

IV. REFERENCES

- A. [21 CFR Part 54 – Financial Disclosures by Clinical Investigators](#)
- B. [42 CFR Part 50 Subpart F – Promoting Objectivity in Research](#)
- C. [45 CFR Part 94 – Responsible Prospective Contractors](#)

V. RELATED FORMS

Research Conflict of Interest Disclosure Form; [SW-LD-0004](#)

VI. RELATED PRACTICE DOCUMENTS

Responding to Allegations of Research Misconduct; [S-FW-LD-1014](#)

VII. SUPERSEDED

Disclosure of Financial Interests & Management of Conflicts of Interest (FCOIR), Public Health Service Research Awards; S-FW-LD-0004, 02/21

Policy: Disclosure of Financial Interests & Management of Conflicts of Interest (FCOIR), Public Health Service Research Awards

Identifier: S-FW-LD-0004

Date: 01/24

Page: 7 of 7

Document Chronology		
Original: 12/08	Revised: 07/19, 02/21, 01/24	Reviewed:
Development Summary		
01/24 Revised: Updated to better align with federal requirements.		
Development Workgroup		
Representation	Member Name	Member Title/Discipline
Workgroup Leader	Stephanie Cammarata	Director, Research Compliance
Workgroup Member	Taunya Juliano	Sr. Director, Corporate Compliance & Privacy Officer
Workgroup Member	Jennifer Holmes	Manager, Scripps IRB
Workgroup Member	Gary Williams, MD	VP, Scripps Clinic Medical Grp.
Workgroup Member	Addie Fortmann	Sr. Director, Chief Research Officer
Endorsements & Approvals		
Function	Chair Name/Title/Position	Date
Executive Sponsor	Anil Keswani, MD, Corp. SVP, Chief Medical & Operations Officer, Ambulatory Care	01/16/24
Corporate Legal	Brad Ellis, Corp SVP, Chief Legal Officer	01/16/24
Audit, Compliance & Risk	Gerald Soderstrom, Corp SVP, Chief Audit, Compliance & Risk Officer	12/05/23
Executive Cabinet	Chris Van Gorder, President & CEO	01/23/24