



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

Effective Date: 3/9/21

Identifier: S-FW-LD-0004

Acute Care: ENC  GR  LJ  MER

Ambulatory  SHAS

## PURPOSE, SCOPE AND APPLICATION

The federal Department of Health and Human Services (HHS) has determined, pursuant to 42 C.F.R. Part 50, Subpart F and 45 C.F.R. 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).

- I. 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 and relevant reporting requirements may be accessed via the web.

## II. DEFINITIONS

- A. **Designed 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 any and 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:** 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 activity.

- 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. **Key Personnel:** A PHS 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.
- E. **Principal Investigator:** An Investigator who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a sponsored project.
- F. **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 (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.
- G. **Research Integrity Officer (RIO):** The RIO is 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 department could act in place of the RIO.
- H. **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 or the Investigator's spouse or registered domestic partner<sup>1</sup> and dependent children for the following categories, except in the case of travel:
  - 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.

3. Intellectual property rights and interests, upon receipt of income, exceeding \$5,000 during the twelve months preceding disclosure from such rights and interests.
4. In the case of travel, sponsored travel or reimbursements made to or on behalf of, the Investigator, regardless of amount, by a for-profit or non-profit entity related to the Investigator's Institutional Responsibilities. However, Significant Financial Interests do not include travel reimbursed or paid by a federal, state, or local government agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education.
5. Scripps Office for the Protection of Research Subjects (SOPRS): The office that is responsible for training and education around this policy, FCOIR, adherence to federal regulations governing human subjects' research, and disclosure of significant financial interests to the Scripps Institutional Review Board.

### **III. POLICY**

- A. **Disclosure of Financial Interests:** All principal investigators and key personnel must disclose any and all potential conflicts of interest of themselves or 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 Significant Financial Interest. With the exception of travel described below.)
  4. Before joining an ongoing PHS-funded research project new Investigators
  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 Significant Financial Interests
  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 campus) 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 a) 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' Significant Financial Interests disclosures will be reviewed by the RIO to determine whether there are any Significant Financial Interests 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 or not they believe the Significant Financial Interest(s) they reported are related to their PHS-funded research activities.

In the event that the RIO concludes that an Investigator's Significant Financial Interest 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 financial conflict of interest, 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 Financial Conflict of Interest 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 Financial Conflict of Interest, 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 same review process takes place when an Investigator reports a new Significant Financial Interest.

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

- C. **Training and Education Regarding Conflicts to Investigators:** Scripps Office for the Protection of Research Subjects (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 revisions, 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 policy or management plan
- D. **Sub-Recipients, Subcontractors and/or Consortium Members:** For Public Health Services (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

Financial Conflict of Interest 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. For collaborators from other institutions who share responsibility for design, conduct or reporting research results, and who will be conducting research under a contracts from Scripps Health are expected to comply with the policies and procedures for disclosure and review of a Significant Financial Interests 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 Significant Financial Interests 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 Financial Conflict of Interest. If Financial Conflicts of Interest 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 Significant Financial Interest, review the disclosure, determine whether it is related to PHS-funded research, determine whether it constitutes a Financial Conflict of Interest, and if so, implement a management plan and report the Financial Conflict of Interest to the PHS funding agency.

For any Financial Conflict of Interest that the Scripps Health reports to a PHS awarding agency, Scripps Health shall provide to the PHS awarding agency an annual Financial Conflict of Interest 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 Financial Conflict of Interest 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 the Department of Health and Human Services (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 Financial Conflict of Interest that was not managed or reported by Scripps Health as required by this policy and Federal regulation, Scripps Health shall require the Investigator to disclose the Financial Conflict of Interest 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:**

When during the course on ongoing PHS-funded research project, Scripps Health identifies a Significant Financial Interest 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 Significant Financial Interest to determine whether it is related to PHS funded research activity, determine whether a Financial Conflict of Interest exists, and if so, implement a management plan on at least on an interim basis.

In addition, whenever a Financial Conflict of Interest is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose an SFI that was later determined to be a Financial Conflict of Interest, or Scripps Health did not review or manage the Financial Conflict of Interest, 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.

The Scripps Health will document the retrospective review; such documentation will include the project number; project title; name of Investigator with the Financial Conflict of Interest; name of the entity with which the Investigator has a Financial Conflict of Interest; the reasons for the retrospective review; detailed methodology used

1. for the retrospective review; findings; and conclusions.
2. Based on the results of the retrospective review, if appropriate, the previously submitted Financial Conflict of Interest report should be updated to specify the actions that Scripps Health will take to manage the identified Financial Conflict of Interest going forward.
3. 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 conflicts of interest disclosures shall be maintained by Scripps Office for the Protection of Research Subjects (SOPRS) 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 campus web site.

The contact must respond within 5 business days to any request for information about Significant Financial Interests held by Key Personnel when Scripps Health has determined that the disclosed Significant Financial Interests are related to the PHS funded research, and constitute Financial Conflicts of Interest. The 5- day response

time shall be measured from the date that the request for information is received at the campus-designated address until the date a response is sent to the requestor.

Disclosure forms, Disclosure Update forms, and Management Plans including determinations of Financial Conflicts of Interest under this policy are public records open to public inspection, under federal and state law.

### **III. 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.](#)

### **IV. RELATED FORMS**

- A. Research Conflict of Interest Disclosure Form; [SW-LD-0004](#) (2012)

### **V. RELATED PRACTICE DOCUMENTS**

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

### **IV. SUPERSEDED**

Formerly Titled: Conflict of Interest, Research; S-FW-LD-0004, 07/19