

Swedish Health Services

FAQ's for Swedish/Providence Conflict of Interest in Research Policy and Disclosure Process

(Effective 8/24/12; Based on 2011 revised DHHS regulations)

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General

1. What is the purpose of the federal Financial Conflict of Interest (FCOI) regulation?

The 2011 revised regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. This regulation is commonly referred to as the Financial Conflict of Interest (FCOI) regulation.

(<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>).

2. What is the most significant difference between the previous regulation and the new revised regulation effective 8/24/12?

The 2011 revised regulation includes comprehensive changes, focusing on these areas in particular:

- i. Definition of Significant Financial Interest
- ii. Extent of Investigators' disclosure of information to Institutions regarding their Significant Financial Interests;
- iii. Institutions' management of identified Financial Conflicts of Interest
- iv. Information reported to the Public Health Service funding component (e.g., NIH);
- v. Information made accessible to the public (i.e., Institutional FCOI policy and FCOIs of senior/key personnel);
- vi. Investigator training requirement

3. The revised regulations apply only to NIH-funded research. Why does Swedish/Providence COIR Policy apply to all research, federal and non-federal?

Our leadership believes that it is in the best interest of the organization to ask all Investigators involved in research in any capacity under our oversight to complete the disclosure. While our liability may be greater with federally funded research, our approach is to promote objectivity and maintain public trust with all research.

4. What information will be made available to the public by the new regulations?

The regulations require that the organization maintains its COIR Policy on a public Internet site; located on the Integrity and Compliance page <http://www2.providence.org/phs/integrity/Pages/default.aspx>.

Additionally, Swedish must respond in writing within five (5) business days to any request for information concerning an SFI disclosed by our investigators that meets all of the following criteria:

- SFI was disclosed and is still held by the investigator;
- Institution determines that the SFI is related to research being conducted at Swedish; and
- Institution determines that the SFI is a FCOI.

Information provided will be limited to: investigator's name; investigator's title and role in the research; name of entity in which SFI is held; nature of the SFI; and dollar value (in ranges) of SFI, or justification of why value cannot easily be determined.

Applicability

5. Who is covered by the regulation?

The regulation is applicable to all institutions that apply for, or receive, NIH research funding by means of a grant or cooperative agreement. At Swedish and Providence, the regulation applies to each Investigator who is planning to participate in, or is participating in, any research, regardless of the source of funding. The regulation, however, does not apply to Phase I Small Business Innovative Research or Small Business Technology Transfer applications. For purposes of financial disclosure only, the regulation covers interests held by the Investigator's spouse and dependent children.

6. Who is considered an "Investigator" for the purpose of our COIR Policy?

"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 a government agency or other entity, or proposed for such funding, or who participates in research activities conducted in whole or in part at or through Swedish, funded or not. Investigator may include subrecipients, collaborators, consultants, staff, post-docs, fellows, residents or students.

7. What are "institutional responsibilities?"

"Institutional responsibilities" are defined as an investigator's professional responsibilities on behalf of an organization, including medical directorships, all research activities, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Board, Research Steering Committee, and Institutional Biosafety Committee.

8. Does the regulation apply to subrecipients, subgrantees and collaborators?

Yes. A subrecipient relationship is established when research funds flow through Swedish to another individual or entity and the subrecipient will be conducting a substantive portion of the research project and is accountable to Swedish for programmatic outcomes and compliance matters. Swedish/Providence's COIR policy states that Investigators who are subrecipients of Swedish research will be subject to the subrecipient institution's COIR policy. If Swedish/Providence cannot ensure subrecipient institution's compliance with FCOI regulations, subrecipient will be subject to our COIR Policy.

Swedish will establish a written agreement or other documentation, prior to submission of funding, with the subrecipient institution, certifying that subrecipient institution complies with current FCOI regulations and that subrecipient investigator has a current disclosure on file and that FCOI training is documented and current. Swedish will report identified FCOI of subrecipient to PHS prior to expenditure of any funds. If funding is awarded, the subcontract agreement between Swedish and subrecipient institution will include specific terms regarding responsibilities of each party relative to FCOI disclosure and reporting.

For cooperative group studies: investigators who rely upon Swedish IRB review on their behalf are considered collaborators and fall under our policy.

Definitions

9. What is a "Financial Conflict of Interest?"

A Financial Conflict of Interest exists when Swedish, through its Conflict of Interest in Research Committee, reasonably determines that an Investigator's Significant Financial Interest is related to a research project and could directly and significantly affect the design, conduct or reporting of the research.

10. What is a Significant Financial Interest (SFI)?

- (a) a financial interest consisting of one or more of the following interests that reasonably appear to be related to the Investigator's Institutional Responsibilities:
 - (i) With regard to any **publicly traded entity**, a significant financial interest exists if the value of any remuneration 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. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., 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;

(ii) 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 twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator, as defined herein, holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) **Intellectual property rights** and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests

- (b) Investigators also 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, 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.
- (c) Significant financial interest does **NOT** include:
- (i) Salary, royalties, or other remuneration paid by Swedish to the investigator if the investigator is currently employed or otherwise appointed by Swedish;
 - (ii) Intellectual Property Rights assigned to Swedish and agreements to share in royalties related to such rights;
 - (iii) 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;
 - (iv) Income from seminars, lectures, or teaching engagements 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; or
 - (v) Income from service on advisory committees or review panels for a federal, state or local government agency, 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.

11. How is a “new” Significant Financial Interest (SFI) defined?

A new SFI is a different type or nature of SFI (e.g., royalty payment versus consulting fees) than what had previously been disclosed from the same source that meets or exceeds the threshold. In addition, a “new” SFI is also considered to be the same type or nature of SFI (e.g., royalty payment) from a different source (e.g., company A versus company B).

12. How long does an Investigator have to disclose a newly acquired or discovered Significant Financial Interest?

Investigators must submit an updated disclosure of Significant Financial Interests within thirty (30) days of acquiring or discovering a new Significant Financial Interest or a Significant Financial Interest that was not disclosed timely.

Disclosure

13. How often do Investigators need to complete COIR disclosure?

COIR disclosure must be completed annually, or more frequently if requested by COIRC. A current COIR disclosure must be on file prior to submitting Research studies through a Swedish IRB or non-Swedish IRB of record, prior to submitting a grant; regardless of the source of funding. If an investigator discovers or acquires a

new SFI, or if the value of a previously-disclosed financial interest changes such that it constitutes a SFI, or a previously-disclosed SFI increases in a significant manner, it is the investigator's responsibility to update COIR Disclosure within 30 days, providing any information that was not disclosed previously.

14. Who reviews the disclosures?

Investigator disclosures are received and reviewed initially by Swedish's Conflict of Interest in Research Officer (COIR Officer). As needed, the disclosure will also be reviewed by the Conflicts of Interest in Research Committee (COIRC), a committee representing the areas of business, legal, ethics, and research disciplines that serves as an advisory body on conflicts of interest issues

15. Are Investigators required to disclose interests in mutual funds or retirement accounts?

No, as long as the Investigator does not directly control the investment decisions made in these vehicles.

16. What type of travel do Investigators need to disclose on their annual disclosure and throughout the reporting period?

The COIR Policy requires Investigators to 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 the Investigator's institutional responsibilities.

Investigator's COIR disclosure must be updated within 30 days of travel or risk non-compliance. However, the disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- i. a federal, state, or local government agency,
- ii. an Institution of higher education as defined at 20 U.S.C. 1001(a),
- iii. an academic teaching hospital,
- iv. a medical center, or a research institute that is affiliated with an Institution of higher education

17. Does an Investigator need to disclose all reimbursed or sponsored travel, no matter the dollar level, if it is reimbursed or sponsored by sources other than those excluded from disclosure (i.e., Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education)?

Yes. The COIR policy does not provide a de minimis threshold for the disclosure of reimbursed or sponsored travel. Basic information to be disclosed about the travel includes the purpose of the trip, the sponsor/organizer, the destination and the duration, but not the dollar amount.

COIRC will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI.

Travel to scientific meetings and to present Investigator's research to colleagues and other interested parties is an integral part of the scientific research enterprise and affords many important opportunities for forging relationships and collaborations among researchers. The provisions in the revised regulations are not intended to discourage this type of travel but require the disclosure of the occurrence of any reimbursed or sponsored travel related to the Investigator's institutional responsibilities.

18. How do Investigators submit new travel outside of the annual disclosure?

A form has been developed to assist with reporting travel throughout the reporting period and is located on the Swedish Research internet site. Investigators and/or their administrative assistants should complete the form when scheduling travel. Completed forms should be submitted to research.center@swedish.org **Investigator's COIR disclosure must be updated within 30 days of travel or risk non-compliance.**

Training

19. How do I complete the Investigator training required in the Swedish/Providence COIR Policy?

Swedish will use CITI for mandatory Investigator training. There are 2 required Conflict of Interest modules: (1) Financial Conflicts of Interest: Overview, Investigator Responsibility, and COI Rules and (2) Institutional Responsibilities as They Affect Investigators. Investigators can use their existing CITI login, or if new to CITI, they can self-register. Access CITI at <https://www.citiprogram.org/Default.asp>? To access the new COI modules, click on [Add a course or update your learner groups](#), then click the Conflict of Interest module option.

20. How often do Investigators need to complete the training?

Investigators must complete training prior to engaging in research and at least every four years, and immediately under the designated circumstances:

- i. Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements
- ii. An Investigator is new to an Institution
- iii. An Institution finds that an Investigator is not in compliance with the Institution's Financial Conflict of Interest policy or management plan.

Non-Compliance

21. What happens if an Investigator fails to comply with the Swedish/Providence's Conflict of Interest in Research policy or management plan?

When an Investigator fails to comply with Swedish/Providence's COIR policy (or subsequent management plan), Swedish must conduct the following steps within 120 days of discovery of non-compliance:

- a) complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine any bias in the design, conduct or reporting of research;
- b) document the retrospective review consistent with the regulation; and
- c) document Swedish's determination as to whether any NIH-funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with the COIR policy or management plan, was biased in the design, conduct, or reporting of such research.

22. What happens if Swedish finds bias in the design, conduct, or reporting of the research?

If bias is found, Swedish must notify the NIH promptly and submit a mitigation report to the NIH that shall address the following: (1) impact of the bias on the research project and (2) Swedish's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, Swedish shall submit FCOI reports annually, in accordance with the regulation. Depending on the nature of the Financial Conflict of Interest, Swedish may determine that additional interim measures are necessary with regard to the Investigator's participation in any research project between the date that the Financial Conflict of Interest is identified and the completion of the Institution's independent retrospective review, in accordance with 42 CFR 50.605(a)(3) and 42 CFR 50.605(b)(3).

In addition, if the NIH determines that one of its funded clinical research projects 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 Swedish, Swedish shall require the Investigator involved 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.