

Financial Conflicts of Interest Policy and Procedures

(in accordance with 42 CFR Part 50
- Subpart F, and 45 CFR Part 94.)

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I. Introduction

A. General Policy

At Truven Health, nothing is more important than the trust of the company's customers. In order to maintain that trust, Truven Health employees are instructed to deal honestly and fairly with each other and with every customer, business partner and competitor. Essential to maintaining this trust is Truven Health's dedication to excellence and to compliance with the laws and ethical standards everywhere the company does business.

All employees are required to read and acknowledge the company's "Code of Business Conduct and Ethics" each year. The "Code of Conduct and Ethics" is required reading so all employees understand the conduct that is expected of them. This Code tells the employees who to consult for guidance on complex issues. It's vitally important to the company to continue the long-established record of integrity.

In addition to the Code of Conduct and Ethics, Truven Health employees are responsible for reading and abiding by any supplemental policies and guidelines that apply to them. For those engaged in applicable research, Truven Health has a Financial Conflict Conflicts of Interest Policy designed to be compliant with 42 CFR Part 50, Subpart F and 45 CFR Part 94.

B. Scope

This statement of policy and procedures is intended to carry out Truven Health's responsibilities under the Public Health Service (PHS) Policies on Financial Conflicts of Interest, 42 CFR Part 50, Subpart F and 45 CFR Part 94.

These standards and procedures are intended to ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements, or contracts will be free from bias resulting from Investigator FCOIs. Truven Health's Conflict of Interest Policy and this procedure implement the requirements of these federal regulations.

Definitions

Terms used have the same meaning as given them in the Public Health Service Policies For the purposes of this procedure, the following definitions apply:

Agreement refers to Truven Health's contract, cooperative agreement, or grant for a Public Health Service (PHS) research project.

FCOI Client Report means the Truven Health disclosures (initial and annual) to the PHS client of a Financial Conflict of Interest (FCOI) with respect to a particular PHS research project. This report must be provided in advance of spending PHS funds.

FCOI Management Plan means the Truven Health actions addressing an FCOI, which can include reducing or eliminating the FCOI, to ensure that the design, conduct, and reporting of the PHS research project will be free from bias.

FCOI Public Disclosure Form means the document used to make information related to FCOIs publicly available upon request. The completed form must be available for release in advance of spending PHS funds.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research as determined by the Truven Health Compliance Director.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable, including remuneration, salary, other payments for services (e.g., consulting fees, paid authorship or honoraria), equity interests (e.g., stocks, stock options, or other ownership interest), intellectual property rights (e.g., patents, copyrights, and royalties from such rights), and reimbursed or sponsored travel unless the sponsored travel is paid for by a 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.

Investigator means the principal investigator, project manager, or other person, regardless of title or position, who is responsible for the design, conduct, or reporting of a PHS research project, as specified in the relevant Agreement or as additionally defined by the Truven Health project manager, including any persons who are Sub-recipients.

Project Scope and Roster Form means the form describing the project scope and listing investigators that is used used in conjunction with the SFI Disclosure Form to determine if an FCOI exists in the context of a particular PHS research project.

SFI Disclosure Form is the document used to identify and transmit SFIs to the Truven Health Compliance Director.

Significant Financial Interest (SFI) is defined as one or more of Investigator Financial Interests (and those of the Investigator’s spouse and dependent children) that reasonably appears related to the Investigator’s institutional responsibilities, and where the value of such Investigator Financial Interest exceeds \$5,000, existing at the date of SFI disclosure and going back 12 months. For avoidance of doubt, SFI does not include: (1) salary, royalties, or other remuneration from Truven Health, (2) salary, royalties, or other payments from any source other than Truven Health that, when aggregated for the Investigator and spouse and dependent children in the 12 months preceding disclosure, are not expected to exceed \$5,000, (3) income from seminars, lectures, or teaching engagements, service on advisory committees or review panels sponsored by federal, state or local government agencies, 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, (4) an equity interest that, when aggregated for the Investigator/Project Director and spouse and dependent children, does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, or (5) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not control such fund’s or account’s investment decisions.

Sub-recipient means any party that has entered into an Agreement with Truven Health as a subgrantee, subcontractor, collaborator, contractor, or consultant.

I. Responsibilities

A. PHS-Funded Investigators

- Must complete FCOI training prior to engaging in a PHS research project and thereafter, every four years.
- Must complete and submit to the Truven Health Compliance Director a Statement of Financial Interest Disclosure Form prior to working on PHS-funded projects.
- Must update the Statement of Financial Interest Disclosure Form annually or within 30 days of a change in financial status (acquisition of new financial interest), whichever occurs first.
- If serving as Truven Health’s project manager/principal investigator, PHS-funded investigators must complete and submit to the Truven Health Compliance Director Project Scope and Roster forms, describing the project scope and the names of all other investigators.

B. Truven Health Compliance Director

- Must record and review all Statement of Financial Interest Disclosure forms from PHS-funded researchers at Truven Health.
- Must determine whether a Truven Health researcher working on a PHS-funded research project has an FCOI.
- Must provide required information concerning FCOIs to the expenditure of PHS funds, and must update such information at least annually and within 60 days of changes to Statement of Financial Interest Disclosure forms, whichever occurs first.
- Must prepare the Public Financial Conflict of Interest Disclosure Form, including the following information, for reported FCOIs such that it can be made publicly available upon request:
 - Investigator's name
 - Investigator's title and role with respect to the research project
 - Name of the entity in which the relevant SFI is held
 - Nature of the relevant SFI (e.g., equity, consulting fees, travel reimbursement, honoraria, etc.)
 - Approximate dollar value of the relevant SFI (dollar ranges are permissible: \$5,000-\$9,999; \$10,000-\$19,999; etc.)
- Must prepare FCOI Client Reports including the following information:
 - Agreement number and title
 - Name of project manager
 - Name of Investigator with the FCOI
 - Name of the entity with which the Investigator has an FCOI
 - Nature of the SFI
 - Value of the SFI
 - Description of how the SFI relates to the PHS funded project and the basis for Truven Health's determination that the SFI constitutes an FCOI
 - Description of Truven Health's FCOI Management Plan, including role and principal duties of the Investigator with the FCOI; how the FCOI Management Plan is designed to safeguard objectivity in the PHS research project; confirmation that Investigator agrees with the FCOI Management Plan; and how the FCOI Management Plan will be monitored
- Must maintain for three years records of all Statement of Financial Interest Disclosure form records and FCOI Management Plans.
- Maintains Truven Health's FCOI Policy and Procedure on the Truven Health external website.

C. Truven Health Compliance Officer

- Ensures compliance with FCOI policy and procedures.
- In cases where the Compliance Director determines that a potential FCOI exists, develops and coordinates implementation of FCOI Management Plan in consultation with the Truven Health project manager. The FCOI Management Plan must be completed and provided to the Compliance Director, in advance of Truven Health expending PHS funds – and a summary of the management plan must be included in the FCOI Client Report (see Exhibit A).
- Coordinates the submission of annual reports related to the FCOI Management Plans through the Office of Contracts.

D. Contract Administration

Certifies in all PHS research project proposals that Truven Health (1) has in effect at Truven Health an up-to-date, written, and enforced administrative process to identify and manage FCOIs with respect to all

PHS research projects; (2) shall promote and enforce Investigator compliance with FCOI requirements, including those pertaining to disclosure of significant financial interest; (3) shall implement FCOI Management Plans; (4) agrees to make information available, promptly upon request, relating to any FCOI; and (5) shall fully comply with the FCOI requirements contained in the referenced regulations in the context of PHS research projects.

Obtains assurances (where such assurances are not otherwise included in a Teaming Agreement) from Sub-recipients (if PHS research project proposal involves Sub-recipient Investigators) that such Sub-recipients: (1) have an FCOI policy that complies with the PHS requirements contained in the referenced regulations and will ensure the disclosure of Sub-recipient Investigator FCOIs to the Truven Health Compliance Director, or (2) agree to comply with Truven Health's FCOI policy and procedure and will ensure the disclosure of Sub-recipient Investigator SFIs to the Truven Health Compliance Director.

Obtains certification from Sub-recipients (if PHS research project involves Sub-recipient Investigators) that such Sub-recipients: (1) have an FCOI policy that complies with the FCOI requirements contained in the referenced regulations and will ensure the disclosure of Sub-recipient Investigator significant financial interest to the Truven Health Compliance Director, or (2) agree to comply with Truven Health's FCOI policy and procedure and will ensure the disclosure of Sub-recipient Investigator significant financial interest to the Truven Health Compliance Director.

E. Sales Support Director and Proposal Managers

Remind Truven Health Client Services and Sales proposal leaders to ensure that Truven Health staff members expected to work as Investigators on a PHS research project complete and submit the significant financial interest disclosure form prior to proposal submission

II. General Policy and Principles

A. Disclosure Requirements

By the time a proposal is submitted to PHS, all investigators/project directors requesting PHS funding—whether grant, cooperative agreement, or contract—are required to have submitted to the Compliance Director a **Significant Financial Interest (SFI) Disclosure Form**. These completed forms either indicate that the investigator/project director has no Significant Financial Interests (SFIs) or includes a listing of known SFIs (and those of the spouse and dependent children) in entities whose financial interests would reasonably appear to be affected by the research for which PHS funding is sought. Financial disclosures must be updated by all investigators/project directors on an annual basis during the award period or as new reportable SFIs are obtained, whichever occurs first.