

SAPIEN HEALTH LLC

FINANCIAL CONFLICT OF INTEREST POLICY DOCUMENT

INTRODUCTION

The Federal government requires that entities receiving federal funding maintain a written policy on financial conflict of interest which is consistent with 42 CFR Part 50 Subpart F and 45 CFR Part 94.50 entitled “Responsibility of Applicants for Promoting Objectivity in Research.” These regulations describe the actions an individual and an organization must take to promote objectivity in PHS-funded research. The regulations apply to all Public Health Service (PHS) (e.g., National Institutes of Health [NIH])-funded grants, cooperative agreements, and research contracts. This policy implements the regulatory requirements for Sapien Health LLC provided in the grant and cooperative agreement regulation at 42 CFR Part 50 Subpart F

DEFINITIONS

Financial conflict of interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. **Financial Interest:** means anything of monetary value, whether or not the value is readily ascertainable.

Investigator: 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 award or proposed for such funding, which may include, for example, collaborators or consultants.

Research: means a systematic investigation, study, or experiment 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 (e.g., a diagnostic test or drug). For PHS-Funded Research, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.

Institutional responsibilities: are the professional activities an Investigator performs on behalf of Sapien Health LLC (e.g., activities such as administration, research, research consultation, institutional committee memberships, etc.).

Sapien Health LLC has designated Dr. Tara Thiagarajan and Robert Carter to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests and identifying FCOIs per the regulatory criteria provided in 42 CFR 50.604(f) and as stated within the policy below.

PHS: 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 National Institutes of Health (NIH).

NIH: the biomedical research agency of the PHS.

Senior/key Personnel: means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS/NIH by the

Institution. This term is defined only as it relates to the public accessibility requirements described under the section labeled “Public Accessibility to Information Related to Financial Conflict of Interest”.

SIGNIFICANT FINANCIAL INTEREST MEANS

1. 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 appear to be related to the Investigator’s institutional responsibilities (e.g., research, research consultation, administrative, etc.) performed on behalf of Sapien Health LLC

- 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 (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- iii With regard to intellectual property rights and interests (e.g., patents, copyrights), a significant financial interest exists upon receipt of income of greater than \$5,000 related to such rights and interests.

2. Investigators must disclose the occurrence of any foreign or domestic reimbursed or sponsored travel that exceeds \$5,000 (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. The initial disclosure of reimbursed or sponsored travel should include income received over the previous twelve months. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The travel disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- a federal, state, or local government agency located in the United States,
- a United States Institution of higher education,
- an academic teaching hospital,
- a medical center, or
- a research institute affiliated with a United States Institution of Higher Education.

3. The term significant financial interest DOES NOT include any of the following types of financial interests; therefore, the Investigator does not disclose these types of financial interests to the institution:

- i Salary, royalties, or other remuneration paid by Sapien Health LLC to the Investigator if the Investigator is currently employed or otherwise appointed by Sapien Health LLC, including intellectual property

rights assigned to Sapien Health LLC and agreements to share in royalties related to such rights, any ownership interest in Sapien Health LLC held by the Investigator since Sapien Health LLC is a commercial or for-profit organization and such interest is excluded in the SFI definition of the regulation.

- ii 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.
- iii Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States (U.S.), a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.
- iv Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States (U.S.), a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.

Foreign Financial Interests: Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (i.e., income in excess of \$5,000).

DISCLOSURE REQUIREMENTS

At the time of application, the Principal Investigator and all other individuals who meet the definition of “Investigator” must disclose their SFIs to Sapien Health LLC’s designated officials, Dr. Tara Thiagarajan and Robert Carter. Any new Investigator who plans to participate in the project at any time during the period of PHS/NIH funding must similarly disclose their SFI(s) to the designated officials promptly and prior to participation in the project.

Each Investigator who is participating in research under an NIH award must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to Sapien Health LLC pursuant to this Policy or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on an NIH-funded project directly as an NIH Grantee and/or indirectly through a sub-award that was transferred from another Institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest). Each Investigator participating in PHS/NIH-funded research must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). In addition, Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

REVIEW OF SFI DISCLOSURES BY SAPIEN HEALTH LLC’S DESIGNATED OFFICIALS

The designated officials, Dr. Tara Thiagarajan and Robert Carter, will review any SFI that has been identified in a disclosure; these interests will be compared to each PHS/NIH research application and/or award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the

SFI is related to the PHS/NIH-funded research and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award.

GUIDELINES FOR DETERMINING “RELATEDNESS” OF SFI TO PHS/NIH-FUNDED RESEARCH AND A FINANCIAL CONFLICT OF INTEREST

The designated officials will determine whether an Investigator’s SFI is related to the research under an PHS/NIH award and, if so, whether the SFI is a financial conflict of interest.

An Investigator’s SFI is related to the research when it is reasonably determined that the SFI:

- could be affected by the PHS/NIH-funded research; or
- is in an entity whose financial interest could be affected by the PHS/NIH-funded research.

The designated officials may involve the Investigator in determining whether an SFI is related to the research supported by the award.

A financial conflict of interest exists when it is reasonably determined that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. (“Significantly” means that the financial interest would have a material effect on the research).

MANAGEMENT OF SIGNIFICANT FINANCIAL INTERESTS THAT POSE FINANCIAL CONFLICT(S) OF INTEREST

If a conflict of interest exists, the designated officials will determine what management conditions and/or strategies will be put in place to manage the FCOI.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- I. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to the Institution’s Institutional Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board, etc.);
- II. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document;
- III. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- IV. Modification of the research plan;
- V. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- VI. Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- VII. Severance of relationships that create financial conflicts;

If the designated officials determine that a conflict exists, they will communicate their determination and the means they have developed for managing the FCOI. No expenditures on an NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the designated officials necessary to manage the Financial Conflict of Interest. The designated FCOI SO of Sapien Health LLC will submit the FCOI report to NIH via the eRA Commons FCOI Module.

PUBLIC ACCESSIBILITY TO INFORMATION RELATED TO FINANCIAL CONFLICTS OF INTEREST

Prior to the expenditure of any funds under an NIH award, Sapien Health LLC will ensure public accessibility as follows:

1. This policy will be publicly available on the SAPIEN HEALTH's public website .
2. In addition to this policy, information concerning any SFI disclosed that meets the following criteria will be made available to the public within 5 business of a written request:
 - The SFI was disclosed and is still held by the senior/key personnel for the PHS-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH or other PHS agency.
 - The Institution determines that the SFI is related to the research funded by NIH or other PHS agency.
 - The Institution determines that the SFI is a Financial Conflict of Interest
3. The following information will be provided:
 - i Investigator's name
 - ii Investigator's title and role with respect to the research project
 - iii Name of the entity in which the Significant Financial Interest is held
 - iv Nature of the Significant Financial Interest
 - v Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
 - vi Name and address of contact person for obtaining written requests.

REPORTING OF FINANCIAL CONFLICTS OF INTEREST

Prior to the expenditure of any funds under an award funded by NIH, Sapien Health LLC will provide to NIH an FCOI report compliant with NIH regulations regarding any Investigator's Significant Financial Interest found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan. Sapien Health LLC will assign an institutional official to serve as the FCOI SO within the eRA Commons FCOI Module. The FCOI SO has the authority to submit FCOI reports to the NIH. The FCOI Module User Guide is available at

https://www.era.nih.gov/files/fcoi_user_guide.pdf.

While the award is ongoing (including any extensions with or without funds), Sapien Health LLC will provide NIH with an annual FCOI report that addresses the status of the FCOI (i.e., an indication whether the FCOI is still being managed or if it no longer exists) and any changes in the management plan, if applicable.

For any Significant Financial Interest that is identified as conflicting subsequent to an initial FCOI report during an ongoing NIH-funded research project (e.g., a new SFI is identified for an Investigator who is participating in the NIH-funded research, upon the participation of an Investigator who is new to the research project, etc.), Sapien Health LLC will provide to NIH within 60 days of identifying an FCOI, an FCOI report regarding the financial conflict of interest and ensure that Sapien Health LLC has implemented a management plan and the Investigator has agreed to the relevant management plan.

The Original (initial) FCOI report will include the information required in the regulation at 42 CFR Part 50.605(b)(3) or as outlined in NIH's FAQ H.5. at.

<https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52888>. Additional information on FCOI reporting can be found under this reference: Types of FCOI Reports Summary Chart for NIH at (https://grants.nih.gov/grants/policy/coi/required_FCOI_reports_through_era_commons.docx)

TRAINING REQUIREMENTS

Each Investigator will be informed about Sapien Health LLC's Financial Conflict of Interest Policy and be trained on the Investigator's responsibility to disclose foreign and domestic SFIs per this policy and of the FCOI regulation at 42 CFR Part 50 Subpart F. FCOI training will occur prior to an Investigator engaging in PHS/NIH-funded research, at least every four years and immediately (as defined below) when any of the following circumstances apply:

- i Sapien Health LLC revises this Policy, or procedures related to this Policy, in any manner that affects the financial interest disclosure requirements of Investigators;
 - ii An Investigator is new to Sapien Health LLC research under an NIH award (training is to be completed prior to his/her participation in the research);
- or
- iii Sapien Health LLC finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training is to be completed within 30 days in the manner specified by the designated official).

In fulfillment of the FCOI training requirement of the FCOI regulation, Sapien Health LLC, requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at: NIH FCOI Tutorial at (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html).

All investigators must print a certification of completion at the end of training and retain it for audit purposes.

FAILURE TO COMPLY WITH SAPIEN HEALTH LLC'S CONFLICT OF INTEREST POLICY APPLICABLE TO PHS FUNDED AWARD

When an FCOI is not identified or managed in a timely manner, including:

- failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a FCOI,
- failure by the Institution to review or manage such an FCOI; and
- failure by the Investigator to comply with a management plan;

Sapien Health LLC will within 120 days of determining noncompliance:

- i. Complete a retrospective review of the Investigator's activities and the PHS/NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the period of the noncompliance was biased in the design, conduct, or reporting of research;
- ii. Document the retrospective review consistent with the regulation at 42 CFR 50.605(a)(3)(ii)(B) or as described in NIH's FAQ I.2. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52895>.

If bias is found, Sapien Health LLC shall notify NIH promptly and submit a mitigation report to NIH via the eRA Commons FCOI Module that shall address the following:

- Impact of the bias on the research project, and
- Sapien Health LLC's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, Sapien Health LLC shall submit FCOI reports annually to NIH in accordance with the regulations and terms and conditions of the award agreement. Depending on the nature of the Financial Conflict of Interest, Sapien Health LLC may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of Sapien Health LLC's independent retrospective review. If bias is not found, no further action is required.

CLINICAL RESEARCH REQUIREMENTS

If HHS 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 Sapien Health LLC, Sapien Health LLC 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.

SUBRECIPIENT REQUIREMENTS

A subrecipient relationship is established when federal funds flow down from or through Sapien Health LLC to another individual or entity, and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to Sapien Health LLC for programmatic outcomes and compliance matters. Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees, are subject to Sapien Health LLC's terms and conditions, and as such, Sapien Health LLC will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation at 42 CFR Part 50 Subpart F.

Sapien Health LLC will incorporate, as part of a written agreement with the subrecipient, terms that establish whether Sapien Health LLC's FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator(s). See the NIH Grants Policy Statement Section 15.2.1 Written agreement at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15.2_administrative_and_other_requirements.htm.

If the subrecipient's FCOI policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with Sapien Health LLC that its policy is in compliance with the federal FCOI regulation. In this situation, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to Sapien Health LLC in sufficient time to enable Sapien Health LLC to provide timely FCOI reports, as necessary, to the PHS/NIH as required by the regulation (i.e., prior to the subrecipient's expenditure of funds and within 60 days of the subrecipient's identification of an FCOI during the period of an award). Therefore, the written agreement will establish a reporting requirement of FCOIs identified during the period of an award to be submitted to Sapien Health LLC within 50 or 55 days, for example, of the subrecipient's identification of an FCOI to allow Sapien Health LLC to report the FCOI within the 60-day period. The Sapien Health LLC assigned FCOI SO will submit the FCOI report (subrecipient report) to the NIH via the eRA Commons FCOI Module.

If the subrecipient cannot provide the certification of compliance with the FCOI regulation, the agreement shall state that the subrecipient Investigator is subject to Sapien Health LLC's FCOI Policy for disclosing SFI(s) that are directly related to the subrecipient's work for Sapien Health LLC. Therefore, Sapien Health LLC will require the submission of all Investigator disclosures of SFIs to Sapien Health LLC. The agreement will include sufficient time period(s) to enable Sapien Health LLC to comply timely with its review, management, and reporting obligations under the regulation. When an FCOI is identified, Sapien Health LLC will develop a management plan, monitor subrecipient Investigator compliance with the plan, and submit an FCOI report (subrecipient report) to the NIH through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient Investigator.

MAINTENANCE OF RECORDS

The Institution will keep all records of all Investigator disclosures of financial interests and the Institution's review of, or response to, such disclosure (whether or not a disclosure resulted in the Institution's determination of a Financial Conflict of Interest), and all actions under the Institution's policy or retrospective review, if applicable. Records of financial disclosures and any resulting action will be maintained by the Institution for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361 for different situations. Sapien Health LLC will retain records for each competitive segment as provided in the regulation.

FAILURE TO COMPLY WITH THIS POLICY

Compliance with this policy is a condition of employment and/or participation for all applicable Investigators. Therefore, such Investigators who fail to comply with this policy are subject to discipline, including letters of reprimand, restriction on the use of funds, termination of employment, or disqualification from further participation in any PHS/NIH-funded research, etc., as may be deemed appropriate.

USEFUL FCOI AND NIH RESOURCES:

FCOI Regulation 42 CFR Part 50 Subpart F: <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>

FCOI Webpage: <https://grants.nih.gov/grants/policy/coi/index.htm>

FCOI Training Webpage: <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>

FCOI FAQ: <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm>

NIH Guide Notices Related to FCOI: <https://grants.nih.gov/grants/policy/coi/guide-notices.htm>

Subscribe to the NIH Guide to Grants and Contracts: <https://grants.nih.gov/funding/subscribe.htm>

Subscribe to the NIH Nexus: <https://nexus.od.nih.gov/all/subscribe/>

Foreign Grant webpage: [Information For Foreign Grants | grants.nih.gov](#) and [Important Highlights of FCOI Regulatory Requirements for Foreign Institutions | grants.nih.gov](#)

NIH's Welcome Wagon Letter: <https://grants.nih.gov/grants/funding/welcomewagon.htm> and

FCOI information within the Welcome Wagon letter:
<https://grants.nih.gov/grants/funding/welcomewagon.htm#fcoi>