

<b>Policy Name:</b>	Financial Conflicts of Interest in Research: Disclosure, Management, and Reporting
<b>Category / Dept.:</b>	Leadership/Governance
<b>Policy #:</b>	1000.46
<b>Working Owner:</b>	<b>Lisa Leiden</b>
<b>Executive Owner:</b>	<b>Jim Lindsey</b>
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<b>Approved By:</b>	Charles J. Barnett, President & CEO

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## Policy Statement

The primary responsibility of a covered individual (as defined in the definitions section of this policy) must be at all times to his or her institutional responsibilities at Seton Healthcare Family. No covered individual may engage in any outside relationship with a business entity if that relationship improperly influences decisions related to the covered individual's institutional responsibilities, leading to personal financial gain or advantage, or causing or appearing to cause bias in the design, conduct, or reporting of research. Covered individuals must disclose and structure their outside relationships with business entities to enable the review and management of any possible conflicts of interest with their institutional responsibilities. Covered individuals whose appointments are less than full-time are expected to devote full professional loyalty, time and energy to their institutional responsibilities according to their agreed-upon time commitments.

All covered individuals shall read this policy, comply with all of its requirements, and fully adhere to any management plans developed under this policy. This policy applies in addition to, and not instead of, general Seton Healthcare Family policies, such as policies on standards of conduct, as well as other policies or statutes governing disclosure of activities and financial interests.

**If a specific law or regulation provides different requirements than this policy, the more stringent requirement applies.**

## Purpose & Scope

Seton Healthcare Family has a responsibility to the public to promote an environment that endorses the highest standards of integrity, honesty, and objectivity in its research activities. At the same time, independent relationships with business entities established by faculty, staff, and students can enhance the institution's research and educational

missions, while also presenting opportunities for personal financial gain. Additionally, Seton has an obligation to commercialize technologies derived from faculty research for the public good, and these activities frequently result in royalty income for the faculty inventors.

Faculty and staff engagement in outside relationships with business entities is not in principle unacceptable and commercialization activities can align with Seton's missions, but in practice, such interactions must be carefully managed. Yet, if the potential or actual conflicts of interest created by these relationships and activities are not appropriately disclosed, reduced, managed, or eliminated, they will undermine the public's trust in the research and business conducted at Seton, and may violate applicable federal or state law and regulations, as well as other Seton policies

This policy applies to ALL individuals conducting research at Seton including but not limited to: faculty members, study team members (including students and post-graduate trainees); individuals who may influence the negotiation or execution of research or technology licensing agreements; Institutional Review Board (IRB) members; and Conflict of Interest Committee (COI Committee) members.

## Definitions

**Business Entity** - any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal entity organized for profit or non-profit (charitable) purposes, except for (a) the Seton Healthcare Family affiliated hospitals or (b) any non-profit health-care corporation or any other entity controlled by, controlling, or under common control with Seton Healthcare Family or an affiliated hospital.

**CITI Training** – refers to the Collaborative Institutional Training Initiative (CITI) available on the internet at [www.citiprogram.org](http://www.citiprogram.org) where registered users take designated classes and are issued certificates of completion.

**Conflict of Interest Program Manager** – person within the Office of Research Administration responsible for posting this policy on the internet and making management plans developed for a covered individual available to the public.

**Conflict of Interest** – refers to any situation in which a significant financial interest has the opportunity to influence decisions related to institutional responsibilities in a way that could lead to personal financial gain or advantage, or cause or appear to cause bias in the design, conduct, or reporting of research.

**Covered Family Member (of a Covered Individual)** – includes any of the following:

- A spouse;

- A dependent child or stepchild;
- Any other person financially dependent on the covered individual; and
- Any other person with whom the covered individual has joint financial interests, such that an objective third party could reasonably conclude that the covered individual's decisions or other exercise of institutional responsibilities could be influenced by their effect on the other person's financial interest.

Any person may meet the above definition and be identified as a covered family member without regard to whether a legal or biological family relationship exists with the covered individual.

**Covered Individual** – All individuals conducting research at Seton including but not limited to: faculty members, study team members (including students and post-graduate trainees); individuals who may influence the negotiation or execution of research or technology licensing agreements; Institutional Review Board (IRB) members; and Conflict of Interest Committee (COI Committee) members

**Faculty Member** – any individual who holds a full-time or part-time academic appointment with Seton Healthcare Family, including any individual who holds an academic appointment with an adjunct title (with or without pay). This definition does not include individuals holding volunteer faculty appointments or emeritus faculty appointments.

**Financial Interest** – anything of monetary value, including without limitation salary or other payments for services (e.g., compensation for consulting; speaking; advising; serving on a Board of Directors or as an officer, trustee, or other executive or management position; editorial compensation; etc.); investment interests (e.g., common or preferred stock, options or other derivatives, partnership interests or shares, etc.); intellectual property rights (e.g., patents, copyrights, royalties from such rights, etc.); reimbursements including travel expenses; gifts; or other income (e.g., any other compensation or benefit from a single business entity not otherwise described above).

**Human Participant Research** – all research meeting the definition of “research” performed with “human participant” as these terms are defined in the federal Common Rule (45 C.F.R. Part 46 and 21 C.F.R. Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulations.

**Institutional Responsibilities** – any of the professional responsibilities of a covered individual on behalf of Seton Healthcare Family, including research, research consultation, teaching, administrative responsibilities, professional practice, institutional committee membership, or service on an institutional panel such as an IRB, the COI Committee or a Data Safety and Monitoring Board.

**Investment Interest** – means common or preferred stock (in any form or class), warrants, options or other derivatives, partnership interests or shares, etc., where the selection or disposition of the interest is directly controlled by the individual.

**Research** – means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.

**Significant Financial Interest** – a financial interest consisting of one or more of the following interests of a covered individual or covered family member:

- *From any single, publicly traded business entity* – any salary, consulting fees, honoraria, paid authorship or other payments for services received in the preceding 12 months, and any investment interests as valued on the date of disclosure by reference to public prices or other reasonable measures of fair market value, all of which, when aggregated for the covered individual and covered family members, is  $\geq$  \$5,000;
- *From any single, non-publicly traded business entity* – any salary, consulting fees, honoraria, paid authorship, or other payments for services received in the preceding 12 months, all of which, when aggregated, is  $\geq$  \$5,000, and/or any investment interest in the business entity;
- *Intellectual property and royalties* – any royalties, license fees, or other compensation (including investment interests), or agreements to share in royalties, license fees or other compensation (including investment interests) with respect to intellectual property, excluding royalties from publishing;
- *Gifts* – A single gift to a covered individual from a business entity received in the preceding 12 months that exceeds \$250 in value, or multiple gifts from a single business entity that in the aggregate exceed \$250 in value, other than gifts from a covered family member; or
- *A fiduciary position held by the covered individual or a covered family member in a business entity in the preceding 12 months*, including a position as a member of the board of directors, an officer, or other executive or management position, for which the covered individual received any form of remuneration or reimbursement for expenses.
- Significant financial interests do not include salary, royalties, or other remuneration paid by Seton Healthcare Family (if the covered individual is currently employed or otherwise appointed by Seton Healthcare Family); income from seminars, lectures, teaching engagements, or service on an advisory committee or review panel sponsored by a federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. 1001(a), an

academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education; income from investment vehicles such as mutual funds or retirement accounts in which the covered individual does not directly control investment decisions made in those vehicles; or travel reimbursed or sponsored by a federal state or local government agency, an institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

**Statement of Financial Interests (or Statement)** – the financial disclosure form that identifies all financial interests of the covered individual and covered family members related to any health care entity, drug, device, biological or medical suppliers, or to human participant research, and also identifies whether the covered individual is engaged in research sponsored by or is evaluating the products or devices made by the business entities in which financial interests were reported.

**Study Team Members** – all principal investigators, sub-investigators, or other persons listed on a research project, regardless of title or position, who are responsible for the design, conduct, or reporting of research.

## Regulatory and / or Legislative Context

### I. Covered Individual [\[back to top\]](#)

1. Each covered individual must acknowledge annually receipt of this policy, and must agree he or she is responsible for fully complying with this policy.
2. Each covered individual must complete specified training regarding this policy and any other applicable policies, regulations, and laws before engaging in research at Seton Healthcare Family and at least once every four years thereafter. A covered individual new to Seton Healthcare Family must complete the CITI Conflicts of Interest (COI) training course before engaging in research, or must provide evidence of having completed the COI training at Seton within the last four years. The covered individual must provide proof of CITI COI training by sending a copy of the course completion certificate to [COI@seton.org](mailto:COI@seton.org). A covered individual must complete the training immediately if it is found that the covered individual is not in compliance with this policy or a management plan, or if the policy is revised in a manner that affects the covered individual's duties.
3. A covered individual's primary responsibility is to his or her institutional responsibilities. No covered individual shall conduct research or engage in any

other institutional responsibilities under circumstances in which a reasonable person could infer that the research or institutional responsibilities could have been influenced by the desire for or expectation of direct or indirect personal financial gain.

4. A covered individual must disclose any and all financial interests related to any business entity, including but not limited to all health care entities, drug, device, biological or medical suppliers, or to human participant research as required in this policy and structure any outside relationship with a business entity to enable the review and management of any possible conflict of interest.
5. A covered individual must demonstrate compelling circumstances to the satisfaction of the COI Committee or COI Official in order to hold or continue to hold a significant financial interest or any investment interests in any business entity that supports in any way human participant research or that is a health care entity, drug, device, biological or medical supplier.
6. No covered individual may receive compensation from any person or business entity if such compensation is conditioned upon a particular research result.
7. Conflicts of interest in supervision are prohibited. No covered individual will be responsible for oversight or approval of an individual's request to engage in an outside relationship with a business entity if the covered individual has a significant financial interest with the same business entity. In the event a covered individual is disqualified from oversight or approval, such responsibilities must be assigned to an alternative decision-maker.
8. Faculty members are responsible for the academic development of students, residents, and other trainees under their direction. Faculty members should not permit students, residents, or other trainees to participate in any research (including human participant research) supported by a business entity if any of the terms or conditions of participation would prevent the student, resident, or trainee from meeting any applicable degree or residency/fellowship training requirements.
9. No member of the IRB, CRSC or COI Committees of Seton Healthcare Family may participate in an initial or continuing review of any project in which that member may have a significant financial interest, except to provide information requested by the reviewing committee.
10. Covered individuals must fully and promptly comply with the provision of this policy. Timely, complete, and accurate disclosure of activities and financial interests consistent with this policy is a condition of employment and/or research at Seton Healthcare Family.

- a. Instances of deliberate breach of this policy, including failure to submit a statement of financial interests as required in this policy; failure to provide additional information requested by Seton Healthcare Family; knowingly filing an incomplete, erroneous, or misleading statement; knowingly violating applicable federal and state law, or this policy; failure to comply with a management plan; or failure to complete required training may subject the covered individual to disciplinary action under Seton Healthcare Family policies, as well as possible enforcement actions mandated by a granting agency.
  - b. Disciplinary action may include termination of employment, non-renewal of appointment, debarment from eligibility for federal funds, or possible prosecution under state or federal law.
11. For a covered individual who is not an employee of Seton Healthcare Family, compliance with this policy is a condition of participating with Seton Healthcare Family in the capacity that qualifies the person as a covered individual. Seton Healthcare Family may require the individual to execute a document certifying that the individual knows that compliance with this policy is a condition of participation.

## **II. COI Official, the COI Committee, and the ORA Office [\[back to top\]](#)**

1. The Conflict of Interest Official (or COI Official) for Seton Healthcare Family is the Senior Vice President for Medical Affairs. The COI Official is responsible for development, implementation and enforcement of this policy, ensuring covered individuals participate in required training, and other duties as assigned by the CEO. Service as the COI Official is in addition to any other capacities in which the person serves Seton Healthcare Family. The COI Official may delegate his or her authority to one or more designees.
2. The CEO or designee shall appoint a COI Committee and committee chair to assist the COI Official in developing policy, reviewing conflict of interest or conflict of commitment issues, developing management plans for potential conflicts of interest, monitoring compliance with management plans, and any other such tasks as assigned by the President or the COI Official.
3. The COI Official may provide additional procedures and supplementary forms, as appropriate, consistent with this policy and applicable sponsor regulations.
4. The Office of Research Administration Office (or ORA Office) shall assist the COI Official and COI Committee in administering and enforcing this policy.

## **III. Seton Healthcare Family [\[back to top\]](#)**

1. Federal regulations require Seton Healthcare Family to notify the PHS of instances in which a covered individual's failure to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research. The PHS awarding component may take enforcement action or require Seton Healthcare Family to take action appropriate to maintaining objectivity in research. Seton Healthcare Family will make information available to the Department of Health and Human Services (HHS) or the PHS awarding component as required by federal regulations.
2. If HHS determines human participant research funded by PHS to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a covered individual with a significant financial interest that was not managed or reported by Seton Healthcare Family by federal regulations, Seton Healthcare Family will require the covered individual involved to disclose the conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Seton Healthcare Family will provide for regular audits of statements to determine individual and Seton Healthcare Family compliance with this policy.

## Procedures

### **I. Required Disclosure of Financial Interest by Covered Individuals** [\[back to top\]](#)

1. Every covered individual shall complete or update a statement of financial interests using the TOPAZ Elements system annually as determined by ORA and with the following clarifications:
  - a. Not later than the 30th day of initial employment, covering the 12 months preceding the date of submission;
  - b. Before engaging in research or submitting research proposals;
  - c. No later than the 30th day after acquiring a new financial interest that requires disclosure; or
  - d. At the request of the CEO of Seton Healthcare Family, the Office of Research Administration Office (ORA Office), the Conflict of Interest Committee (COI Committee) or the Conflict of Interest Official (COI Official).

The TOPAZ Elements system is available on the Seton Healthcare Family intranet under Web Applications. Users who do not have intranet access will access the system at: <http://txaussmcwwapp01/TOPAZElements/Default.aspx>

2. On a statement, a covered individual must report any financial interest (as defined in

this policy) received by the covered individual or covered family member related to any health care entity, drug, device, biological or medical suppliers, or to human participant research or which reasonably appears related to the covered individual's institutional responsibilities, such as:

- a. Consulting and/or serving on a scientific advisory board, speaking, or any other activities for a business entity;
  - b. Serving as a member of the board of directors, an officer, a trustee, or any other executive or management position for a business entity within the preceding 12 months;
  - c. Creating, producing, or editing publishable content (regardless of the medium for expression) for or on behalf of a business entity (NOTE: This does not include activities that would normally be considered part of academic duties, e.g., writing scholarly or educational journal articles, books or book chapters, teaching grand rounds, serving on study sections, or serving as an editor of a scientific journal unless the covered individual is paid to do these activities);
  - d. Intellectual property (e.g., royalties, license fees or other compensation, or agreements to share in royalties, license fees, or other compensation), excluding royalties from publishing;
  - e. Investment interests (e.g., common or preferred stock in any form or class, warrants, options or other derivatives, partnership interests or shares, etc.) held in or promised from a business entity;
  - f. Gifts (e.g., entertainment tickets, meals, gift certificates, items, etc.) received by the covered individual or a covered family member from a single business entity that, when aggregated, exceed \$250 (Note: Gifts from covered family members are not required to be reported);
  - g. Reimbursed or sponsored travel (Not by Seton or the Federal Government) within the preceding 12 months, including the purpose of the trip, the sponsoring business entity, the destination, and duration; and
  - h. Other income (e.g., any other compensation or benefit from a single business entity not otherwise described above) that reasonably appears related to the covered individual's institutional responsibilities.
3. In disclosing financial interests, the interest of any legal entity, including a foundation or a trust controlled or directed by the covered individual and/or a covered family member, is considered to be the interest of the covered individual and/or covered family member as if the separate legal entity did not exist.
  4. In determining whether to disclose a research or a financial interest, the covered

individual must resolve all doubt in favor of disclosure.

5. If a covered individual discloses any compensation received under item (2) in this section, the covered individual must provide a copy of any related agreement, contract, offer letter, or other documentation of the relationship with the business entity upon request. Requests may be made by the CEO of Seton Healthcare Family, the ORA Office, the COI Committee, the COI Official, or any other person or entity with administrative responsibility for reviewing statements or approving a related management plan.
6. Timely, complete and accurate disclosure of activities and financial interests consistent with this policy is a condition of employment and/or research at Seton Healthcare Family, and a covered individual who does not comply with this policy is subject to disciplinary action, up to and including termination of employment or non-renewal of appointment.
7. The COI Official, ORA Office, COI Committee, or CEO of Seton Healthcare Family may request further information about the reimbursed or sponsored travel of a covered individual, including the monetary value of the travel, in order to determine whether the travel constitutes a conflict of interest.

## **II. Review of Statements of Financial Interests – General [\[back to top\]](#)**

1. The Conflict of Interest (COI) Program Manager will review and triage completed statements of financial interests into two categories:
  - a. Statements that report no possible conflicts of interest because there is no relationship between the disclosed financial interest and the covered individual's ongoing research or institutional responsibilities; or
  - b. Statements that report possible conflicts of interest regarding research, including human participant research.
2. Statements that report no possible conflicts of interest do not require review by the COI Committee and will be reviewed and managed through the ORA Office. Examples of such statements include the following:
  - a. Those reporting royalties for publishing scholarly work;
  - b. Those reporting financial interests in business entities that do not support in any way the covered individual's research; or
  - c. Those reporting royalties for a technology licensed by Seton Healthcare Family for which the covered individual is neither conducting nor directing any further research related to the technology.
3. Statements that report possible conflicts of interest related to research, including

human participant research, will be initially assessed by the ORA Office for determination of whether any significant financial interest disclosed is related to the research in which the covered individual is engaged, and if so, whether a conflict of interest exists.

- a. When a conflict of interest is identifiable and management of the conflict is routine, the ORA Office may recommend a management plan directly to the COI Official or designee for approval.
  - b. At the ORA Office's discretion, the office may refer the review of a statement to the COI Committee or its chair for determination of whether a conflict of interest exists. If the COI Committee or its chair finds a conflict of interest, the COI Committee or chair either will determine that the conflict is not permissible, or will develop for the COI Official's approval a management plan (if possible) for that conflict of interest in cooperation with the covered individual and other individuals necessitated by the situation.
4. The ORA Office will document and maintain records showing that review of a statement has taken place. If required by a granting agency, the ORA office will forward a notice of review in accordance with the agency's policy.
- a. For statements reporting no possible conflicts of interest, the ORA Office will document its review and that no further action is required unless circumstances arise requiring an update of the covered individual's statement before the next annual statement is due.
  - b. For statements reporting possible conflicts of interest, records will be maintained, identifiable to any grant awarded to the covered individual, showing that review has taken place and that a management plan has been developed and implemented.
5. Neither Seton Healthcare Family nor a covered individual may expend research funds unless the COI Official and/or COI Committee have determined no conflict of interest exists or that any conflict of interest is manageable in accordance with the terms of an adopted and implemented management plan.

### **III. Review of Statements Involving Human Participant Research [\[back to top\]](#)**

1. In conducting human participant research, Seton Healthcare Family and covered individuals have an added ethical responsibility to protect the safety and well-being of research participant. Financial or other interests held by covered individuals conducting human participant research may compromise or appear to compromise this ethical responsibility. Examples of such interests include, without limitation, the

following:

- a. Serving as a study team member on a clinical study supported by or evaluating the products or devices of a business entity, and receiving (or a covered family member receiving) salary, consulting or speaking fees, honoraria, gifts, or other payments from the same business entity;
  - b. Serving as a study team member on a clinical study supported by or evaluating the products or devices of a business entity, and holding (or a covered family member holding) an investment interest in the same business entity; or
  - c. Serving as a study team member on a clinical study supported by or evaluating the products or devices of a business entity, and holding (or a covered family member holding) a position as a member of the board of directors, an officer, or other executive or management position of the same business entity.
2. Accordingly, there is a strong presumption against permitting any covered individual with related significant financial interests or any investment interests from participating in the human participant research, especially if the protocol involves more than minimal risk. To overcome this presumption, a covered individual must assert and demonstrate to the COI Committee that compelling circumstances exist for the covered individual's participation in the human participant research in question.
  3. In considering whether compelling circumstances exist, the COI Committee will evaluate the nature of the human participant research; the magnitude of the financial interest and its relation to the research; the extent to which the research could directly and substantially influence the financial interest; the degree of risk to the research participant inherent in the protocol; the extent to which the financial interest is amenable to effective oversight and management; the question whether the covered individual is uniquely qualified by virtue of expertise and experience such that the research could not be otherwise conducted safely or effectively without the covered individual; and any other factor deemed relevant.
  4. Significant financial or other interests related to human participant research must be reviewed by the COI Committee or its chair. The ORA Office will notify the responsible IRB when a financial disclosure statement must be included in an informed consent document. In developing additional management plans for human participant research, the IRB may refer review to the COI Committee; however, the IRB retains the final decision-making authority on conflict of interest management for human participant research. Such IRB decisions are final. When the COI Committee has recommended a conflict of interest management plan and the plan has been

agreed to by the covered individual, the covered individual may be permitted to conduct IRB-approved human participant research.

#### **IV. Review of Statements Related to Commercialization Activities** [\[back to top\]](#)

1. Seton Healthcare Family works to create relationships with business entities – via licensing, sponsored research agreements, supporting new start-up companies, or other means – to commercialize intellectual property developed from the research activities of Seton Healthcare Family faculty for the public good. Inventor participation in these commercialization activities can be critical to the success of these activities. It is just as important that these activities do not compromise or appear to compromise the integrity of the underlying research. Examples of such inventor participation include, without limitation, the following:
  - a. Participating in sponsored research supported by a business entity which also has licensed technology related to the sponsored research from Seton Healthcare Family, for which the covered individual is entitled to or has received royalty income under Seton Healthcare Family’s intellectual property policy; or
  - b. Participation as a scientific advisory board member for a start-up business entity which has licensed technology from Seton Healthcare Family, holding a founder investment interest in the same business entity, and participating in research on the same licensed technology.
2. Consequently, any research conducted in association with commercialization activities must be reviewed and subject to a management plan developed by the COI Committee and approved by the COI Official.
3. The Intellectual Property Committee at Seton is the designated group responsible for commercializing the intellectual property developed from research activities of Seton Healthcare Family faculty for the public benefit. The committee may consult with a covered individual who is an inventor concerning the development or commercialization of that invention. Final decisions concerning whether or how Seton Healthcare Family develops and commercializes an invention rest in the sole discretion of Seton Healthcare Family. Decision-making authority for management of related conflicts of interest resides with the COI Official and the COI Committee.

#### **V. Management of Conflicts of Interest** [\[back to top\]](#)

1. A management plan may impose any condition and prescribe any action necessary to manage a conflict of interest, including an action reducing or eliminating the conflict of interest, to ensure that the design, conduct, or reporting of research is free from bias or the appearance of bias. In addition to public disclosure of the conflict of interest in presentations and publications, examples of conditions or actions that may

be prescribed include, without limitation, the following:

- a. Disclosure of the conflict to students, trainees, staff, and/or patients;
  - b. For human participant research, direct disclosure of the conflict of interest to research participants;
  - c. Appointment of an independent monitor with authority to take measures to protect the design, conduct, and reporting of research against bias, or the appearance of bias, resulting from the conflict of interest;
  - d. Modification of the research plan;
  - e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - f. Divestiture or reduction of the financial interest;
  - g. Severance of the relationships that create an actual or potential conflict of interest; or
  - h. Disallowing the conduct of the research at Seton Healthcare Family.
2. A management plan must be in the form of a written agreement, and must:
    - a. Provide that the covered individual acknowledges receipt of the plan and understands the requirements of this policy and the required actions and other terms of the plan, including time frames for required actions; and
    - b. Clearly identify each specific person responsible for monitoring compliance with the management plan.
  3. Each covered individual conducting research under a management plan shall comply fully and promptly with the plan, and each person identified in the management plan as having full responsibility for monitoring compliance with the plan shall carefully and fully monitor that compliance.
  4. If circumstances warrant, it may be necessary to implement an interim management plan or other interim measures before development of a final management plan. With respect to human participant research, the IRB may consult with the COI Committee or chair, but has final decision-making authority on conflict of interest management for human participant research. These IRB decisions are final.
    - a. If research is ongoing and a new covered individual discloses a significant financial interest related to the research, or any other covered individual discloses a new significant financial interest related to the research, then as soon as possible but no later than the 60<sup>th</sup> calendar day after the filing of the revised statement (as required by Public Health Service [PHS] regulation), the interest shall be reviewed to determine if a conflict of interest exists and, if so,

an interim management plan or other interim management measures must be implemented to ensure the objectivity of the research.

- b. If the ORA Office or the COI Official learns of a significant financial interest that was not timely disclosed or reviewed, then as soon as possible but no later than the 60<sup>th</sup> calendar day after learning of the significant financial interest (as required by PHS regulation), the interest shall be reviewed to determine if a conflict of interest exists and, if so, an interim management plan or other interim management measures must be implemented to ensure the objectivity of the research. In addition, if a conflict of interest was not timely identified or managed, or if a covered individual fails to comply with a management plan, the COI Official shall, as soon as possible but no later than the 120<sup>th</sup> calendar day after determining non-compliance (as required by PHS regulation), (i) complete and document a retrospective review and determination as to whether research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research, and (ii) implement any measures necessary with regard to the covered individual's participation in the research between the date the non-compliance is identified and the date the retrospective review is complete.
- c. Any retrospective review under this section shall cover key elements as specified by federal regulations and may result in updating the Financial Conflict of Interest Report described in Section VII, notifying the PHS, and submitting a mitigation report as required by federal regulations.

#### **VI. Web-Posting of Information Regarding Specific Conflicts of Interest** [\[back to top\]](#)

1. This policy, or its updates, must be publicly accessible through the Internet.
2. When a conflict of interest is found and a management plan is developed for a covered individual, Seton Healthcare Family will make the following information available to the public by request or through the Internet with regard to that covered individual:
  - a. The covered individual's name;
  - b. The covered individual's title and role with respect to the research;
  - c. The name of the business entity in which the significant financial interest is held;
  - d. The nature of the significant financial interest that constitutes a conflict of interest; and
  - e. The approximate dollar value of the significant financial interest by range or, if the dollar value cannot be determined by reference to public prices or

other reasonable measures of fair market value, a statement to that effect.

To the extent dollar values can be determined by reference to public prices or other reasonable measures of fair market value, the following ranges will be used in making information available:

1. \$0 to \$4,999;
  2. \$5,000 or more but less than \$10,000;
  3. \$10,000 or more but less than \$20,000;
  4. \$20,000 or more but less than or equal to \$100,000, by increments of \$20,000; or
  5. More than \$100,000, by increments of \$50,000.
3. Seton Healthcare Family will update the information posted in this section annually, and information posted under (2) in this section will be available for three years after its most recent update.
  4. For any conflict of interest of a covered individual whose information must be posted under (2) in this section and for which information was not previously posted, the information must be posted as soon as possible but not later than the 60<sup>th</sup> calendar day after the determination that a conflict of interest exists.
  5. The web site on which the information under (2) in this section is posted must note that the information is current as of the date listed and is subject to updates.
  6. For PHS-funded research, information required to be posted by this section must be made available before the expenditure of the related PHS research funds.

## **VII. Certification and Reports to the Public Health Service (PHS) [\[back to top\]](#)**

1. Federal regulations require that each application for funding to the PHS include specific certifications and agreements in regard to this policy and conflicts of interest. Federal regulations also require that Seton Healthcare Family make reports required by this policy related to PHS-funded research.
2. Before the expenditure of any funds under a PHS-funded research project, the COI Official or designee will make the Financial Conflict of Interest Report to the PHS awarding component in compliance with 42 CFR Part 50, Subpart F, and 45 CFR Part 94. In general, those regulations require a Financial Conflict of Interest Report regarding those interests that Seton Healthcare Family determines are conflicts of interests, including conflicts of interest of sub-recipients.
  - a. The reporting will include specific information sufficient to enable the awarding

component to understand the nature and extent of the conflict of interest and to assess the appropriateness of the management plan related to the conflict of interest.

- b. The federal regulations require reporting within a specified period of conflicts of interest identified after an earlier report, and require annual updating of reports regarding previously disclosed conflicts of interest.

#### **VIII. Records and Confidentiality** [\[back to top\]](#)

1. Records regarding disclosure of financial Interests and the management of a conflict of interest, including statements, the COI Committee's or COI Official's determination, and other records of institutional actions, shall be retained for the longer of at least three years after:
  - a. The date of creation;
  - b. The date of termination or completion of a research award or contract, or the submission of the final expenditure report, for research identified in a disclosure statement; or
  - c. The date of final resolution of any investigation, audit, or similar action involving the records.
2. The central repository for records related to conflicts of interest will be the ORA Office, and records will be maintained in paper or electronic form.
3. To the extent permitted by law and the requirements of this policy, all statements, other records, and information submitted to the COI Official or the COI Committee will be maintained confidentially. However, any statements, other records, or information will be made available upon written request to the agency funding research of the covered individual, and as otherwise required by law. Where human participant research is contemplated and a potential or actual conflict exists, the statement(s), other records and information may be shared with the appropriate IRB.

#### **IX. Collaborators and Contractors** [\[back to top\]](#)

1. If research is conducted in cooperation with or through a subcontractor, contractor, or collaborator, including a person identified under applicable federal regulations as a "sub-recipient," Seton Healthcare Family must enter into a written agreement with the contracting party that provides legally enforceable terms which establish whether this policy or the financial conflicts of interest policy of the contracting party applies to the investigators of the contracting party.
2. If the policy of the contracting party applies to its investigators, the contracting party must certify that its policy is consistent with the requirements of any applicable

regulations. If the contracting party cannot so certify, the agreement must state that the investigators are subject to this policy as covered individuals for disclosing financial interests that relate to the investigators' research at Seton Healthcare Family.

3. If the policy of the contracting party applies to its investigators, the agreement must specify the time periods for the contracting party to report identified financial conflicts of interest to Seton Healthcare Family. The time periods must be sufficient for Seton Healthcare Family to make any reports required by applicable federal regulations.
4. If this policy applies to the investigators of the contracting party, the agreement must specify the time periods for the researchers to submit a statement of financial interest. The time periods must be sufficient for Seton Healthcare Family to comply with its review, management, and reporting obligations under federal regulations and this policy.

#### **X. Challenging Decisions of ORA Office or COI Committee**

1. Covered individuals may challenge a decision of the ORA Office or COI Committee with respect to the review or management of a conflict of interest. The covered individual challenging a decision must do so in writing to the COI Committee chair within five working days of the decision being challenged. The written challenge should clearly state the decision being challenged, the facts upon which the covered individual is relying, the reason(s) why the decision should be changed, and the change sought.
2. The COI Committee chair may review the challenge as well as the facts and reasoning of the ORA Office or COI Committee, or may defer review of the challenge to the COI Committee (or a subcommittee thereof). The COI Committee (or chair) may, but is not required to, consult with the covered individual in review of the challenge. The COI Committee (or chair) may seek the guidance of other relevant Seton Healthcare Family personnel as appropriate in reviewing the challenge.
3. The COI Committee chair should provide a written decision to the covered individual within 45 calendar days of receipt of the challenge.
4. If the covered individual disagrees with the COI Committee's (or its chair's) decision with respect to the challenge, the covered individual may appeal the decision to the COI Official. The covered individual challenging a decision must do so in writing to the COI Official within five working days of receipt of the challenge decision. The written appeal should clearly state the facts upon which the covered individual is relying, the reason(s) why the decision should be changed, and the change sought.
5. The COI Official will review the appeal as well as the facts and reasoning of the COI Committee (or its chair). The COI Official may, but is not required to, consult with the covered individual, the ORA Office or the COI Committee (or chair) in review of the appeal. The COI Committee chair may seek the guidance of other relevant Seton

Healthcare Family personnel as appropriate in reviewing the challenge.

6. The COI Official should provide a written decision to the covered individual within 30 calendar days of receipt of the appeal. The decision of the COI Official is final in all respects.
7. Failure of the covered individual to meet the deadline for challenging a decision will constitute waiver by the covered individual of that challenge. A covered individual may request an extension for submitting a challenge or appeal within five working days of the decision or appeal being challenged. It is within the sole discretion of the COI Committee chair (for challenges) or COI Official (for appeals) whether to grant or deny such an extension. Where time limits are indicated in this section, “day one” will be the next working day.
8. Copies of the challenge and decision of the COI Official shall be maintained by the ORA Office.

## Supporting Documentation

42 CFR Part 50 & 45 CFR Part 94

Section 51.912, Texas Education Code

Chapter 572, Texas Government Code

## Document History

Version	Date	Author	Change Description
A	2/25/13		Policy Updated/Reviewed
B	2/27/12		Policy Updated / Reviewed
C	1/25/12		Legal Review/Approval
D	1/25/12		Network Accreditation Review/Approval

## Approval History