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| POLICY: CONFLICT OF INTEREST IN RESEARCH | POLICY NUMBER: | | PAGE: PAGE 1 OF 12 | | | |
| | ORIGINATION: | 1/1/2011 | | | | |
| | EFFECTIVE: | 3/2022 | | | | |
| RESPONSIBLE DEPT./DIVISION/COMMITTEE: VP/CCO | VERSION: | | NEW | X | REVISED | REVIEWED |
| | SCOPE: | X | SPUH | X | SPHCS | X SPPA |

POLICY:

All human subject research activities undertaken at Saint Peter's Healthcare System (SPHS) shall be conducted in compliance with federal financial conflict of interest regulations. No research activity at SPHS shall be adversely affected by the financial interests of persons involved in research activities. Prior to participating in a research activity, anyone involved in the research as defined in this policy shall submit a conflict of interest disclosure certificate. Persons who have knowledge of a potential conflict of interest and fail to disclose it in accordance with this policy shall be subject to sanctions by applicable SPHS and Medical Staff policy, up to and including dismissal or severance of relationship with SPHS.

PURPOSE:

A conflict of interest arises when there is a divergence or potential divergence between a researcher's private interests and his/her professional obligations, such that an independent observer might reasonably question whether that researcher's actions or decisions are determined by consideration of personal gain, financial or otherwise. This policy is intended to protect the integrity and credibility of research activities and maintain the reputation, public trust and confidence in SPHS and its staff. This policy and its attachment provide a means for researchers to disclose potential conflicts of interest, and for SPHS, through its designated institutional officials (reviewers), to manage or eliminate reported conflicts.

PROCEDURE:
Notification & Training

- Information about this policy will be conveyed on an annual basis to all researchers (physicians, medical residents, research staff and nursing staff). The policy will be published on the employee internal network, the public facing webpage and presented as noted in the table below.

| Group | Training Forum |
|-------------------|--|
| Physicians | Multiple forums including research leadership committee, monthly division meetings, etc. |
| Medical Residents | Presented at Noon Meeting for Pediatrics, Ob-gyn, Internal Medicine and others as appropriate. |
| Research Staff | Presented Annually at a Monthly Research Meeting |
| Nursing Staff | Presented Annually at a Nursing Research Council Meeting |
| IRB Committee | Presented Annually at an IRB Monthly Meeting |

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2. Researchers engaging in federal or state funded research (grants) as well as members of the Institutional Review Board (IRB) will be required to complete the CITI Program's Conflicts of Interest training module and re-certify every 4 years.
3. A report from the CITI website will be run annually and/or as-needed by the IRB Administrator and furnished to Corporate Compliance to confirm completion of the COI training module by applicable researchers. Non-compliance with CITI training requirements will be addressed by Corporate Compliance with the applicable researcher and may include IRB intervention for the research, suspension of research privileges or other appropriate remedies as determined by Corporate Compliance.
4. Any revisions to this policy will be conveyed to all persons engaging in research.

Disclosure Process

1. All researchers must complete a research Conflict of Interest Disclosure Certificate (COI Certificate), attached.
2. COI disclosure certificates are required to be completed annually at the request of Corporate Compliance. Researchers are responsible for updating their COI disclosure within 30 days of a change that results in a new or modification to a significant financial interest.
3. New researchers to the organization (or new to research) that will be engaging in research are required to submit a COI disclosure and complete the CITI COI module training prior to engaging in any research activities at the institution.
4. IRB committee members must complete a COI Certificate at the time of appointment to the committee, annually and within 30 days of a change that results in a new or modification to a significant financial interest.
5. COI disclosures are to reflect the Compensation, Ownership and/or Positions of the researcher and that of their direct family as noted on the COI form and the instruction page.
6. COI Certificates may be submitted to RCOI@saintpetersuh.com.
7. The Institutional Review Board IRB Administrator will be provided with access to the COI disclosure file to ensure a COI certificate is on-file for all researchers requesting to engage in research prior to the IRB's initial review of a study or prior

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to the review of an amendment to add new study staff. The review of IRB applications will be held until all COI certificate have been submitted and reviewed if a potential significant financial interest is disclosed.

8. Corporate Compliance will review the COI disclosures on an annual basis and/or as-needed for new researchers or changes to existing COI disclosures. Non-compliance with the COI disclosure will be addressed by Corporate Compliance with the applicable researcher and may include IRB intervention for the research, suspension of research privileges or other appropriate remedies as determined by Corporate Compliance.
9. Any researcher participating in a PHS funded research grant with a significant financial interest will have the significant financial interest disclosed on the institution's public facing website in accordance with federal regulations (see Public Posting / Disclosure section of this policy for more information).
10. Any researcher applying for a PHS-funded grant is required to have a COI certificate filed with the institution from the current year prior to the submission of a PHS grant application.
 - a. The Office of Grant Administration will be provided access to the COI disclosure file to ensure all researcher's engaging in federally support grants have a current COI disclosure, and management plan if applicable, on-file prior to submitting grant applications or extensions.

Management of Conflict of Interests

1. COI disclosures with a significant financial interest are evaluated on a case by case basis by Corporate Compliance (serving as the designated institutional official),
2. Corporate Compliance will review all researchers who have disclosed a significant financial interest for the purpose of:
 - a. Reviewing the disclosure prior to the researcher taking part in any research conduct;
 - b. Assessing potential risk posed by outside financial interests;
 - c. Determining whether to permit a financially conflicted researcher to participate in the study;
 - d. Development, assessment and approval of a management plan to eliminate, mitigate or control the potential conflicts, which may include public disclosure requirements, limitations on the researcher's role in the study,

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| | oversight by independent reviewers, divestiture of financial interests, or periodic audits; and |
| | e. Determining if the financial interest relates to PHS-funded research and if that interest represents a financial interest that could be affected by the research. |
| 3. | Corporate Compliance will consider the following factors when determining if the significant financial interest constitutes a conflict of interest: |
| | a. Degree to which the researcher's significant financial interest relates to the proposed research project (if the significant financial interest is with the study sponsor or an engaged third-party vendor, etc.); |
| | b. Risk of the significant financial interest impacting research participant's safety, the integrity of the research program, the reputation of the institution or the reputation of the researcher; |
| | c. Value and Type of the significant financial interest (if the interest is an annual compensation, whether it can be divested, etc.); and |
| | d. Possibility of the significant financial interest influencing the research (role of the researcher as it relates to the project, whether the researcher's contributions could impact the outcome, built in safeguards within the research project, etc.). |
| 4. | If a significant financial interest constitutes a conflict of interest Corporate Compliance may exclude the person from engaging in the research OR develop a management plan that will mitigate the conflict. A copy of the management plan will be provided to the Principal Investigator, researcher and presented to the IRB committee. |
| | a. Persons engaging in research submit a COI certificate prior to being added to a research project and therefore in advance of any fund expenditures. Corporate Compliance will review and issue a management plan, as needed, for any significant financial interests prior to the IRB issuing any approval. |
| 5. | A COI management plan may include any of the following or additional restrictions: |
| | a. Public disclosure of the significant financial interests; |
| | b. Monitoring of research by independent reviewers; |
| | c. Modification of the research plan; |
| | d. Disqualification from participation in all or a portion of the research funded by the PHS; |
| | e. Divestiture of significant financial interests; or |
| | f. Severance of relationships that create actual or potential conflicts. |

All policies are intended as a guidelines to assist in the delivery of patient care or management of the system or hospital services and are not intended to replace professional judgment in patient care or administrative matters.

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6. Corporate compliance will review and issue a management plan within 60 days of becoming aware of a significant financial interest due to a new researcher submitting a new COI certificate, a researcher submitting a change to their COI certificate or upon becoming aware of a researcher's previously unknown conflict.
7. All COI management plans will be reviewed annually by Corporate Compliance to ensure the researcher's adherence to the management plan's requirements.
8. Non-compliance with a management plan will be addressed by Corporate Compliance with the applicable researcher and may include IRB intervention for the research, suspension of research privileges or other appropriate remedies as determined by Corporate Compliance.

Reporting to NIH

1. Institution will report to the NIH and/or coordinate with the primary grant recipient to report to the NIH any FCOI (new, modified or discovered) or mitigation report in accordance with federal regulations and this policy.
2. Any FCOI report submitted to the PHS Award Component (initial, modified, discovered) shall include the following information:
 - a. Project number;
 - b. PD/PI or Contact PD/PI if multiple PD/PI model is used;
 - c. Name of the research with the financial conflict of interest;
 - d. Name of the entity with which the research has a financial conflict of interest;
 - e. Nature of the financial interest (speaking fees, stock, positions, etc.);
 - f. Value of the financial interest:
 - \$0 - \$4,999;
 - \$5,000 - \$9,999;
 - \$10,000 - \$19,999;
 - \$20,000 - \$100,000 in \$20,000 increments;
 - \$100,000+ in \$50,000 increments; or
 - A statement that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
 - g. Description of how the financial interest related to the PHS-funded research and the basis for the institution's determination that the financial interest conflicts with such research; and

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| <p>h. A description of the key elements of the institution's management plan including:</p> <ul style="list-style-type: none"> • Role and principal duties of the conflicted research in the research project; • Conditions of the management plan; • How the management plan is designed to safeguard objectivity in the research project; • Confirmation of the research's agreement to the management plan; • How the management plan will be monitored to ensure the researchers compliance; and • Other information as needed. <p>3. For research funded through PHS grants, the Institution will provide to the PHS Awarding Component an initial FCOI report regarding the researcher's significant financial interest found by the Institution to be conflicting and a copy of the Institution's management plan prior to the expenditure of any funds.</p> <p>a. A significant conflict of interest identified by the institution and eliminated prior to the expenditure of PHS-awarded funds does NOT require the institution to submit an FCOI report to the PHS Awarding Component.</p> <p>4. For on-going PHS-funded research grants with a documented conflict of interest, the institution will provide the PHS Awarding Component with an annual FCOI report until the project period end date including the following information:</p> <p>a. The status of the financial conflict of interest and any changes to the management plan and</p> <p>b. Specify whether the financial conflict of interest is still being managed or explain why it no longer exists.</p> <p>5. If during the course of Corporate Compliance's annual review of researcher's significant financial interests and/or management plan, a new conflict of interest for a PHS-funded research grant is discovered, the institution will, within 60 days, implement a COI management plan and provide the PHS Awarding Component a FCOI report noting that the management plan has been implemented.</p> <p>a. If the Department of Health and Human Services determines that a researcher's significant financial interest for a PHS-funded research grant was not reported by the researcher or was not managed or reported by the institution, the researcher must disclose the significant financial interest in any public presentation of the research project's results and an addendum must be requested for any previously published presentations.</p> |
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6. For any significant financial interest that was not disclosed in a timely manner including; failure by the researcher to disclose a significant financial interest that the institution determines is a conflict of interest; or failure by the institution to review or manage such a conflict of interest; or failure by the researcher to comply with the COI management plan (i.e. noncompliance); the institution will, within 120 days of the determination of noncompliance, perform a retrospective review to determine if any of the PHS-funded research that was conducted prior to the identification and management of the conflict of interest was biased in the design, conduct or reporting of such research.

a. The retrospective review will document the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if multiple PD/PI model is used;
- Name of the researcher with the FCOI;
- Name of the entity with which the researcher has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (i.e. methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

7. If bias is found, the institution will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Award Component. At a minimum, the mitigation report will include the following key elements:

- a. Criteria noted above under section 6 a – i);
- b. Description of the impact of the bias on the research project; and
- c. Institution's plan of action to eliminate or mitigate the effect of the bias (i.e. impact on the research project, extent of harm done including any qualitative and quantitative data to support any actual or future harm and analysis of whether the research project is salvageable).

Record Retention

1. All COI disclosures, management plans and mitigation reports will be retained indefinitely by the institution in electronic format on a restricted-access secured network that is backed up routinely.

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Enforcement

1. Enforcement mechanisms are incorporated within this policy to address non-compliance with the institution and federal requirements for COI training, COI disclosure and COI management plans. This includes safeguards such as an annual collection cycle and hard stops (i.e. IRB review will not occur without a COI certificate on-file).

Subrecipient Requirements

1. Not Applicable. Institution serves as a sub-recipient but is not a primary grant recipient of federal funding or issuing funding to third party sub-recipients. This policy will be amended if the institution becomes a primary recipient or will be issuing payment to sub-recipients.

Public Posting / Disclosure

1. This policy is publicly posted on Saint Peter's website in accordance with federal regulations.
<https://www.saintpetershcs.com/About-Us/Office-of-Research/Contact-Us>
2. Prior to the expenditure of any funds under a PHS-funded research grant, the Institution will post on its publicly facing website the information for any researcher for which the following three criteria are met:
 - a. A significant financial interest has been disclosed and is still held by the senior/key personnel;
 - b. The institution has determined that the significant financial interest is related to a PHS-funded research grant; and
 - c. The institution has determined that the significant financial interest is a financial conflict of interest.
3. In compliance with federal regulations, the public posting on the institution's website for disclosures meeting the criteria listed above under section 2 a – c for a PHS-funded research grant will be performed as follows:
 - a. Initially posted within 60 days of becoming aware of a new, revised or discovered financial conflict of interest.
 - b. Corporate Compliance will review all existing significant financial interests annually and the website updated to reflect a statement noting the most recent

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review date.

- c. Information concerning the significant financial interest of a researcher will remain available for at least three years from the date that the information was most recently updated.
- d. The public posting will include the following information:
 - Name of the researcher
 - Title of the researcher
 - Role of the research with respect to the research grant
 - Name of the entity in which the significant financial interest is held
 - Nature of the significant financial interest
 - Dollar amount of the significant financial interest (use range):
 - \$0 - \$4,999;
 - \$5,000 - \$9,999;
 - \$10,000 - \$19,999;
 - \$20,000 - \$100,000 in \$20,000 increments;
 - \$100,000+ in \$50,000 increments; or
 - A statement that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

DEFINITIONS:

1. A **significant financial interest (“SFI”)** is defined as a person (the researcher) or a member of the person’s direct family hold a financial interest meeting any of the following criteria:
 - a. Compensation from a company that engages in healthcare related research that exceeds \$5,000 over the most recent 12-month period for services such as consulting fees, honoraria and paid authorship;
 - b. Ownership in a company that engages in healthcare related research that exceeds \$5,000 in value over the most recent 12-month period such as stock ownership, stock options, patents or other financial interests; or
 - c. Holding a position with a company that engages in healthcare related research over the most recent 12-month period such as board member, steering committee member, family member employment.
 - d.
2. A **researcher** is defined as an investigator, co-investigator, research staff or any other person who designs or directs research protocols, enrolls research subjects or makes decisions related to eligibility to participate in research, analyzes or reports research data, or submits reports or manuscripts for publication.

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| <p>3. A direct family member is defined as a spouse, domestic partner or dependent child.</p> <p>4. A PHS grant is a grant supported by funding from the Public Health Services of the U.S. Department of Health and Human Services (“PHS”).</p> |
| <p>ATTACHMENT(S):</p> <p>Research Conflict of Interest Disclosure Certificate</p> <p>REFERENCES:</p> <p>42 CFR Part 50 subpart F 45 CFR Part 94 NIH 15.2.1 Ethical & Religious Directives for Catholic Health Care Services, 6th Edition, ERD’s 3 and 4</p> |

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| APPROVAL BY:  | | 3/14/2022 |
| BJ Welsh, CHC, FHFMA | VP/Chief Compliance & Privacy Officer | Date |

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| POLICY VERSION HISTORY | |
| Origination Date: | 1/1/2011 |
| Supersedes Date(s): | 12/1/2013, 7/23/2015, 8/22/2019 |
| Reviewed Date: | 8/22/2019 |
| Revised Date: | 3/2022 |
| Most Current Effective Date: | 3/2022 |
| Retired/Inactive Date: | |

RESEARCH CONFLICT OF INTEREST DISCLOSURE CERTIFICATE

FORM COMPLETION INSTRUCTIONS

Question # 1 Disclose any Compensation that you (or your direct family*) have received over the past 12 months with a value greater than or equal to \$5,000 with any company engaged in healthcare research.

Speaking Fees, Honoraria, Gifts, etc.

Question # 2 Disclose any Ownership that you (or your direct family*) have with a value greater than or equal to \$5,000 with any company engaged in healthcare research.

Stock, Stock Options, Patents, Other Financial Interest

Question # 3 Disclose any Positions held by you (or your direct family*) with any company engaged in healthcare research.

Board Member, Steering Committee Member, Family Member Employment

*** Direct Family = Spouse, Domestic Partner or Dependent Child**

Complete a second page as needed for additional disclosures.

It is your responsibility to update and submit this form within 30 days if you have any significant change to your disclosure.

If you have a conflict of interest, you may require a management plan that may or may not impose limitations on what functions you can perform to eliminate and/or manage any actual or potential conflicts of interest.

- If you have any recommendations to eliminate, reduce or manage perceived/potential conflicts of interest or if a conflict of interest management plan already exists for your conflict, please provide it when submitting your COI Disclosure Certificate.
- If there are compelling circumstances, such as unique investigator expertise, unique institutional resources (e.g. equipment, facilities, personnel), unique access to particular patient populations, level of risk for human subjects and degree to which financial interests and research are linked, outline the compelling circumstances and provide a copy when submitting your COI Disclosure Certificate.

Return the completed form

ELECTRONIC SUBMISSION

Completed PDF, Print / Sign & Date / Scan and E-mail to:
(Electronic signature accepted if you have Digital ID configured)

RCOI@SaintPetersUH.com

RESEARCH CONFLICT OF INTEREST DISCLOSURE CERTIFICATE

1. **Disclose any Compensation with a cumulative value greater than or equal to \$5,000 that you (or a member of your direct family) have received over the last 12 months from any entity that sponsors, conducts, supports or collaborates on research trials (i.e. pharmaceutical, CRO, etc.).**

Check Box if No Compensation to disclose

| Sponsor/Company | Amount | Type of Compensation (one line/entry per type) | | | |
|-----------------|--------|--|--|--|--|
| | \$ | <input type="checkbox"/> Consulting Fees | <input type="checkbox"/> Honoraria for Lectures/Paper/Teaching | <input type="checkbox"/> Officer/Director Fees | <input type="checkbox"/> Gift/Gratuities |
| | \$ | <input type="checkbox"/> Royalty Payment | <input type="checkbox"/> Compensation for Advisory Board | <input type="checkbox"/> Other: | <input type="checkbox"/> Gift/Gratuities |
| | \$ | <input type="checkbox"/> Consulting Fees | <input type="checkbox"/> Honoraria for Lectures/Paper/Teaching | <input type="checkbox"/> Officer/Director Fees | <input type="checkbox"/> Gift/Gratuities |
| | \$ | <input type="checkbox"/> Royalty Payment | <input type="checkbox"/> Compensation for Advisory Board | <input type="checkbox"/> Other: | <input type="checkbox"/> Gift/Gratuities |

2. **Disclose any Ownership with a cumulative value greater than or equal to \$5,000 that you (or a member of your direct family) have held within the last 12 months with any entity that sponsors, conducts, supports or collaborates on research trials (i.e. pharmaceutical, CRO, etc.).**

Check Box if No Ownership to disclose

| Sponsor/Company | Value | Type of Ownership (one line/entry per type) | | | |
|-----------------|-------|---|--|---------------------------------|--|
| | \$ | <input type="checkbox"/> Stock | <input type="checkbox"/> Stock Options | <input type="checkbox"/> Patent | <input type="checkbox"/> Other Interest: _____ |
| | \$ | <input type="checkbox"/> Stock | <input type="checkbox"/> Stock Options | <input type="checkbox"/> Patent | <input type="checkbox"/> Other Interest: _____ |
| | \$ | <input type="checkbox"/> Stock | <input type="checkbox"/> Stock Options | <input type="checkbox"/> Patent | <input type="checkbox"/> Other Interest: _____ |

3. **Disclose any Position(s) that you (or a member of your direct family) have held within the past 12 months with any entity that sponsors, conducts, supports or collaborates on research trials (i.e. pharmaceutical, CRO, etc.).**

Check Box if No Position(s) to disclose

| Sponsor/Company | Check if: | Type of Position (one line/entry per type) | | | |
|-----------------|---------------------------------|--|--|-------------------------------------|---------------------------------------|
| | <input type="checkbox"/> Active | <input type="checkbox"/> Board Member | <input type="checkbox"/> Steering Committee Member | <input type="checkbox"/> Employment | <input type="checkbox"/> Other: _____ |
| | <input type="checkbox"/> Active | <input type="checkbox"/> Board Member | <input type="checkbox"/> Steering Committee Member | <input type="checkbox"/> Employment | <input type="checkbox"/> Other: _____ |
| | <input type="checkbox"/> Active | <input type="checkbox"/> Board Member | <input type="checkbox"/> Steering Committee Member | <input type="checkbox"/> Employment | <input type="checkbox"/> Other: _____ |

Attestation; I certify that:

1. I have read the Saint Peter's Healthcare System Conflicts of Interest in Research Policy.
2. I hereby attest that the information contained in this disclosure certificate is accurate and complete to the best of my knowledge and does not omit or misstate any facts.
3. I will provide any additional information as requested by the COI disclosure reviewers and/or Corporate Compliance Office.
4. I will update this disclosure on an annual basis and submit it as requested or as amended.
5. I also understand **I must submit AN UPDATE TO THIS FORM WITHIN 30 DAYS if there are changes impacting my Significant Financial Interests.**
6. I understand that any conflict may require a management plan to reduce, manage or eliminate actual or potential conflicts of interest and I agree to comply with the terms and conditions of any such management plan.
7. If I am serving as a Principal Investigator of a research project I will ensure that all key personnel are educated on the research Conflicts of Interest policy and submit a COI Disclosure Certificate prior to engaging in any research activity.

Name: _____ **Title:** _____

Signature: _____ **Date:** _____

Roles (check all that apply):

- Principal Investigator
 Sub-Investigator
 Research Coordinator
 IRB Committee Member
 Other: _____