

POLICY: CONFLICT OF INTEREST IN RESEARCH	POLICY NUMBER:		PAGE: PAGE 1 OF 5				
	ORIGINATION:	1/1/2011					
	EFFECTIVE:	2019					
RESPONSIBLE DEPT./DIVISION/COMMITTEE: VP/COO AND CPHSR	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 regulations. No research activity at SPHS shall be adversely affected by the financial interests of persons involved in those activities. Prior to participating in a research activity, anyone having a significant financial interest related to the activity shall disclose the interest. Persons who have knowledge of a potential conflict of interest and fail to disclose same 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 an investigator's private interests and his/her professional obligations, such that an independent observer might reasonably question whether that investigator'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:

1. Investigators, co-investigators and 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 must complete a Research Conflict of Interest Disclosure Certificate (COI Certificate), attached. The principal investigator is responsible for ensuring that a COI certificate is completed by all such persons.
2. COI disclosure certificates are required to be completed annually by May 31st and updated within 30 days of any significant change in the disclosure.
 - a. The first annual COI disclosure due date will be effective the first full month after the policy revision is approved.
3. At appointment and annually thereafter, members of the CPHSR must complete a COI Certificate.

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4. New investigators, who join any research study in progress, must complete the COI Certificate before beginning any work on the study.
5. If a significant change occurs in the financial interests reported in a COI Certificate, an amended COI Certificate must be filed within thirty (30) days.
6. Exempt studies are not subject to this policy.
7. All COI Certificates may be submitted electronically to RCOI@saintpetersuh.com.
8. All disclosures are evaluated on a case by case basis by no less than three (3) voting members of the CPHSR (serving as institutional officials as per 42 CRF Part 50 subpart F), for the purpose of:
 - a. Reviewing the disclosure prior to the investigator taking part in any research conduct;
 - b. Assessing potential risk posed by outside financial interests;
 - c. Determining whether to permit a financially conflicted investigator to participate in the study; and
 - d. Development, assessment and approval of a plan to eliminate, mitigate or control the potential conflicts, which plan may include public disclosure requirements, limitations on the investigator's role in the study, oversight by independent reviewers, divestiture of financial interests, or periodic audits.
9. If a COI management plan is not submitted but is determined to be required by the reviewers, a formal request will be sent to the principal investigator via a letter from the CPHSR committee.

Attachment(s)

Research Conflict of Interest Disclosure Certificate

Joint Commission Chapter/Section:

LEADERSHIP 02.02.01 & 04.02.01

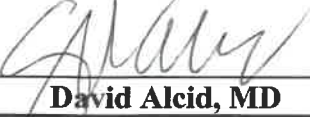
References:

42 CFR Part 50 subpart F

45 CFR Part 94

 Ethical & Religious Directives for Catholic Health Care Services, 6th Edition, ERD's 3 and 4

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APPROVAL BY: 		8/22/19
David Alcid, MD	Chair, CPHSR	Date

APPROVAL BY: 		8/22/19
BJ Welsh, CHC, FHFMA	VP/Chief Compliance Officer	Date

POLICY VERSION HISTORY	
Origination Date:	1/1/2011
Supersedes Date(s):	12/1/2013, 7/23/2015
Reviewed Date:	8/22/2019
Revised Date:	8/22/2019
Most Current Effective Date:	2019
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 clinical 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 clinical 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 clinical research.
Board Member, Steering Committee Member, Family Member Employment

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

You may complete a second page for additional disclosures as needed.

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 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 plans or 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 include a copy with 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 include a copy with your COI Disclosure Certificate.

Return the completed form:

ELECTRONIC SUBMISSION Print, Sign, Scan & E-mail to: RCOI@SaintPetersUH.com

RESEARCH CONFLICT OF INTEREST DISCLOSURE CERTIFICATE

1. Please 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 or collaborates on clinical trials (i.e. pharma, CRO, etc.).

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

1. Please 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 or collaborates on clinical trials (i.e. pharma, CRO, etc.).

Sponsor	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 Financial Interest:
	\$	<input type="checkbox"/> Stock	<input type="checkbox"/> Stock Options	<input type="checkbox"/> Patent	<input type="checkbox"/> Other Financial Interest:
	\$	<input type="checkbox"/> Stock	<input type="checkbox"/> Stock Options	<input type="checkbox"/> Patent	<input type="checkbox"/> Other Financial Interest:

2. Please 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 or collaborates on clinical trials (i.e. pharma, CRO, etc.).

Sponsor	Check if Active	Type of Position (one line/entry per type)			
	<input type="checkbox"/>	<input type="checkbox"/> Board Member	<input type="checkbox"/> Steering Committee Member	<input type="checkbox"/> Employment	<input type="checkbox"/> Other:
	<input type="checkbox"/>	<input type="checkbox"/> Board Member	<input type="checkbox"/> Steering Committee Member	<input type="checkbox"/> Employment	<input type="checkbox"/> Other:
	<input type="checkbox"/>	<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 during the period of this Research, update this disclosure on an annual basis and submit it with continuing review.
5. I also understand I must submit **AN UPDATE TO THIS FORM WITHIN 30 DAYS if there are changes in 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.
 - a. I agree to cooperate in the development of the management plan.
 - b. I agree to comply with the terms and conditions contained in any management plan.
7. If I serve as a Principal Investigator of a Research project, I will ensure that all key personnel are educated on Research Conflicts of Interest and complete a Research Conflict of Interest Disclosure Certificate.

Name: _____ Title: _____

Signature: _____ Date: _____

Roles (check all that apply):

- Principal Investigator
 Sub-Investigator
 Research Coordinator
 Other: _____