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Departments	Policy, Posted on Internet

PSJH-CPP-724 Conflict of Interest in Research

Executive Sponsor:	David Lane, VP, Chief Compliance Officer
Policy Owner:	Darshita Sheth, Senior Manager, Compliance
Policy Contact:	Darshita Sheth, Senior Manager, Compliance

Scope:

This policy applies to all individuals participating in research activities at Providence and/or its Affiliates[i] (collectively known as "Providence") and their caregivers (employees) and employees of affiliated organizations. Subcontractors, subgrantees and collaborating investigators must also comply with this policy as stated herein.
This is a management level policy reviewed and recommended by the Policy Advisory Committee to consider for approval by senior leadership which includes vetting by Executive Council with final approval by the President, Chief Executive Officer or appropriate delegate.

Purpose:

The purpose of this policy is to promote objectivity and maintain public trust in research by establishing guidelines and procedures for reporting and managing conflicts of interest related to research. For purposes of this policy, a conflict of interest in research (COIR) exists when it is determined that an investigator has a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research or what may be perceived as a significant conflict in the eyes of the public, including those individuals that may participate in a research study. Providence intends, by this policy, to comply with applicable federal and state requirements.

Definitions:

As used in this policy, the following terms mean:

1. *The Conflicts of Interest in Research Committee* (COIRC) - there will be a central COIRC comprised of research leadership and, as applicable, with representation from each region, ministry and/or facility where research is conducted. The COIRC will include representatives in the areas of business, legal, ethics, and research disciplines to serve as an advisory body on conflicts of interest issues, as provided in this policy. The COIRC shall include the COIR Office and ad-hoc specialists as needed. COIRC will meet as determined by COIR Office.
2. *Conflict of Interest in Research Officer (COIR Officer)* - the person(s) designated to receive conflict of interest in research disclosure information. COIR Officer will be the Executive Director of Research Compliance. As used herein, the term COIR office shall mean the COIR Officer and their staff.
3. *Department of Human and Health Services (HHS)* - Federal Executive Department of which the U.S. Public Health Service (PHS) is a component and the National Institutes of Health (NIH) is an agency of the Public Health Service.
4. Dependent Child(ren) – means a natural or adopted child of the investigator who is under the age of 18.
5. *Electronic Research Administration (eRA) Commons* - NIH's online interface where signing officials, principal investigators, and grant staff can access and share administrative information relating to research grants.
6. *Financial interest* - anything of monetary value, whether the value is easily determined.
7. *Financial Conflict of Interest (FCOI)* - A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.
8. *Financial Conflict of Interest (FCOI) Report* - The FCOI Report is submitted through eRA Commons FCOI module when the conflict involves PHS funds and includes the information listed below. FCOI Report is not required when PHS funds are not involved in the conflict.
    - Project number;
    - Project title;
    - Project Director (PD)/Principal Investigator (PI) or contact PD/PI if a multiple PD/PI model is used;
    - Name of the investigator with the FCOI;
    - Name of the entity with which the investigator has a FCOI;
    - Nature of the financial interest (equity, consulting fee, travel reimbursement, honorarium);
    - Dollar value (in ranges) of SFI, or justification of why value cannot easily be determined;
    - Description of how the SFI relates to PHS-funded research and the basis for

Providence determination that SFI conflicts with the research;

- Detailed management plan as established by COIR Office and COIRC.

9. *Institution* - any domestic or foreign, public or private, entity or organization that is applying for, or that receives, PHS research funding.
10. *Institutional Responsibility(ies) – means an Investigator's professional responsibilities on behalf of Providence. Examples include, but are not limited to:*
    - *Research (regardless of whether or not it is funded);*
    - *Research consultation;*
    - *Teaching;*
    - *Outreach;*
    - *Professional practice (e.g., clinical medical practice);*
    - *Medical Directorship;*
    - *Committee memberships (e.g., Purchasing Committees); and*
    - *Service on panels, such as an Institutional Review Board or Data and Safety Monitoring Boards.*
11. I*ntellectual property* - any ideas, inventions, technology, creative expression, and embodiments thereof, in which a proprietary interest may be claimed, including but not limited to and without limitation, patents, copyrights, trademarks, know-how, and biological materials.
12. Principal Investigator (PI) -- means an individual who actually conducts a research investigation. In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team.
13. *Investigator (for PHS funded studies)* -- means the project director, principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research.
14. *Public Health Services (PHS) Awarding Component* - the organizational unit of the Public Health Service that funds federal research subject to 42 CFR 50.601-607.
15. Remuneration – means salary and any payment for services not otherwise identified as salary, including, but not limited to, consulting fees, honoraria, and paid authorship.
16. *Research* - a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research.
17. *Significant Financial Interest (SFI)* -
    a. A financial interest consisting of one of more of the following interests that reasonably appear to be related to the investigator's (and those of the investigator's spouse and dependent child(ren)) institutional responsibilities:
        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, as defined herein, holds any equity interest (e.g., stock, stock option, or other ownership interest); or

iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

b. Significant financial interest does NOT include:

i. Salary, royalties, or other remuneration paid by Providence to the investigator if the investigator is currently employed or otherwise appointed by Providence;

ii. Intellectual Property Rights assigned to Providence and agreements to share in royalties related to such rights;

iii. 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. If the investigator is able to exert direct control over the decisions made in any such investment vehicle, the investigator must either (a) provide a note from the investment company confirming that the investigator (or those of the investigator's spouse and dependent child(ren)) cannot exert control over the investment decisions; or (b) disclose all individual investments;

iv. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or

v. Income from service on advisory committees or review panels for a federal, state, or local government agency, institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

c. **For investigators participating in PHS funded research:**

i. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (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 their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

ii. PHS funded investigators or researchers that receive income, travel expenses or any type of reimbursement over $5,000 from a foreign entity (includes companies, foreign institutions/universities and foreign governments) in the prior twelve month time period, must disclose the financial interest.

18. *Other Conflicts of Interest* - Any significant role in a publicly or non-publicly traded entity. Examples include appointment in an advisory role, heading a department, influential position that determines or impacts writing protocol, research decisions, etc.
19. *Signing Official* - individual(s) with institutional authority to legally bind the institution in research administration matters as delegated by Chief Executive or designee.
20. *Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs* - An award designed to support projects from small businesses ultimately having commercial viability. The federal requirements for FCOI do not apply to SBIR/STTR program Phase 1 applications.
21. *Sub-investigator (Sub-I)* - means any individual designated by the principal investigator to perform critical research-related procedures and/or make important trial-related decisions
22. *Subrecipient* - also referred to as subcontractor, subgrantee, collaborator, or consortium member. Subrecipient relationship is established when research funds flow through Providence to another individual or entity and the subrecipient will be conducting a substantive portion of the research project and is accountable to Providence for programmatic outcomes and compliance matters. Accordingly, Subrecipient investigator and institution must comply with the Financial Conflict of Interest regulation.

Policy:

Investigators shall certify as part of a formal COIR process that they have read the Providence COIR policy and shall conduct their research in a manner that promotes objectivity in research. To the extent there is the appearance of, potential for, or actual SFI or Other Conflict of Interest, investigators shall disclose the SFI or Other Conflict of Interest in accordance with the procedures of this policy and shall fully participate in a COIR management plan.

Reporting Requirements:

For PHS-funded studies, *reporting individual* includes Investigators (see above definition)

For non PHS-funded studies, *reporting individual* includes PI & Sub-I only

1. Any individual conducting sponsored and/or funded research at Providence must comply with the Providence COIR Policy and complete a Providence COIR disclosure form. The COIR disclosure form must be completed at a minimum annually and prior to submitting research studies through a Providence IRB or non-Providence IRB of record, or prior to submitting a grant, regardless of the source of funding. Contact the Risk and Integrity Services Compliance department (RISComplianceServices@providence.org) if you have a question about a research conflict of interest.
2. If a reporting individual discovers or acquires a new SFI or Other Conflict of Interest, or if the value of a previously-disclosed interest changes such that it constitutes a SFI or Other Conflict of Interest, or if a previously-disclosed interest increases in a significant manner it is the individual's responsibility to update the COIR Disclosure within thirty (30) days, providing any information that was not disclosed previously.
3. An individual must complete training on the Providence COIR Policy and federal FCOI regulations. Training is required prior to engaging in research and must be updated at least every three (3) years.

Sanctions:

Failure of an individual to file a complete and truthful annual disclosure, to update the disclosure when a new SFI or Other Conflict of Interest is discovered or acquired, or to comply with any conditions or restriction directed or imposed, including failure to cooperate with appointed award monitoring bodies, will be grounds for sanctions and/or corrective action pursuant to Providence policy. In addition, federal regulations may require reports be made to the federal sponsor of any violations of federal regulation or Providence policy.

Institutional Responsibilities:

Accountability

A. The COIR Office is responsible for soliciting and reviewing COIR financial disclosure forms according to the process set forth in this policy and may engage COIRC in an advisory capacity at its discretion. The COIR Office shall keep and maintain records, of disclosures of relationships between investigators and potential research sponsors and actions taken to manage any actual or potential conflicts of interests for at least three (3) years beyond the termination or completion of the award or until resolution of any action by any federal agency involving the records, whichever is longer. The COIR office or designee will submit FCOI Reports to PHS via eRA Commons according to this policy. The COIRC will meet as determined by COIR Office to evaluate submitted COIR financial disclosure forms and assist in determining actions required to manage any actual or potential conflicts.

B. For studies submitted to a Providence IRB or non-Providence IRB, the Providence HRPP Office is responsible for certifying that each investigator submitting clinical research

studies has a current COIR disclosure on file at the time of IRB submission and that COIR training is documented and current.

C. The signing official or designee is responsible for certifying that each investigator submitting a grant, either federal or non-federal, has current COIR disclosure on file at the time of submission and that COIR training is documented and current. When submission involves subrecipients, signing official will certify that a written agreement is established with subrecipient institution to include terms set forth in this policy.

Public Accessibility

Prior to Providence's expenditure of any research funds, Providence shall assure public accessibility as follows:

A. Maintain current Providence COIR Policy on Providence's public website, under Integrity and Compliance (currently: http://www2.providence.org/phs/integrity/Pages/default.aspx)

B. Respond in writing within five (5) business days to any request for information concerning an SFI or Other Conflict of Interest disclosed by Providence investigators that meets all of the following criteria:

- SFI or Other Conflict of Interest was disclosed and is still held by the investigator;
- Providence determines that the SFI or Other Conflict of Interest is related to research being conducted at Providence; and
- Providence determines that the SFI or Other Conflict of Interest is a FCOI.

Information provided will be limited to the investigator's name, investigator's title and role in the research, name of entity in which SFI or Other Conflict of Interest is held, nature of the SFI or Other Conflict of Interest, and dollar value (in ranges) of SFI or Other Conflict of Interest or justification of why value cannot easily be determined.

Subrecipients

Investigators who are subrecipients of Providence research will be subject to the subrecipient institution's COIR policy. If Providence cannot ensure subrecipient institution's compliance with FCOI regulations, subrecipient will be subject to Providence COIR Policy.
Providence will establish a written agreement or other documentation, prior to submission of funding, with the subrecipient institution, certifying that subrecipient institution complies with current FCOI regulations and that subrecipient investigator has a current disclosure on file and that FCOI training is documented and current. If a FCOI involves PHS funds, Providence will report identified FCOI of subrecipient to PHS prior to expenditure of any funds. If funding is awarded, the subcontract agreement between Providence and subrecipient institution will include specific terms regarding responsibilities of each party relative to FCOI disclosure and reporting.

Review of Disclosures

Prior to expenditure of any funds and during the course of an initiated project within 60 days of a new/updated disclosure, the COIR Office must review an investigator's disclosure of SFI and determine if a FCOI exists based on Providence policy. The COIR Office may conduct investigations and consult with others as necessary. As needed, the COIR Office will consult with members of the COIRC for further evaluation and will report the results of the COIRC determinations to the signing official, research leadership, and Providence HRPP Office.

Management Plan

For all determined FCOI involving research, the COIR Office will establish a management plan to determine how objectivity in research will be maintained. The COIR Office and COIRC may work with the investigator, signing official, and/or research leadership to implement a plan to manage determined FCOI.

The management plan will also describe the role and principal duties of the investigator with the FCOI the conditions of the management plan, how the management plan is designed to safeguard objectivity in the research project, provisions for monitoring compliance to the COIR management plan, and other information as deemed advisable by the COIR Office. The management plan must be signed by the investigator and others as appropriate. Additionally, documentation of all proceedings will be kept by the COIR Office.

Management plans may be provided to sponsor based on sponsor requirements. The reviewing IRB may require additional requirements to ensure protection of rights and welfare of research participants.

FCOI Report to PHS is required for PHS-funded research only

A. Initial: For PHS-funded research, prior to expending any PHS funds, the Providence Sponsored Projects Office in collaboration with COIR Office will submit an FCOI Report for determined FCOI to the PHS granting agency. If the determined FCOI is eliminated prior to expenditure of PHS funds, an FCOI Report is not required, provided, however the records relating to the review of the FCOI shall reflect how the FCOI was eliminated. FCOI regulations do not apply to PHS Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Phase 1 programs; FCOI regulations do apply to SBIR/STTR Phase 2 programs.

B. Annual: For ongoing PHS-funded research, Providence will submit annual reports to the PHS for FCOI previously submitted. These updates will provide status of FCOI and any changes to the management plan for the duration of the PHS-funded research project. The report should specify whether the conflict is still being managed or explain why it no longer exists. Providence will submit reports in the time and manner established by the PHS.

C. New/Updated: If FCOI is identified subsequent to initial FCOI Report during an ongoing PHS-funded project, Providence will submit an FCOI Report within sixty (60) days of determination.

D. Bias: If the failure of the investigator to comply with the Providence COIR policy or management plan has biased any PHS-funded research, Providence must promptly notify the PHS of the corrective action taken or to be taken.

Noncompliance with PHS-Funded Research

A. The COIR Office in conjunction with the applicable research department will, within 120 days of the determination of non-compliance, complete and document a retrospective review of the investigator's activities and research to determine if there was bias in the design, conduct, or reporting of the research.

B. Documentation of the retrospective review will include the following information:

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

C. In those cases where, through a retrospective review, bias is determined to have occurred in the course of the federally-funded research, Providence will promptly notify and submit a report to the PHS Awarding Component. The report will address the impact of the bias on the research project and the corrective actions taken, or to be taken, to eliminate or mitigate the effect of the bias. In those cases where it is determined that bias has not occurred and/or for research that is not funded by the PHS, Providence is not required to notify the PHS.

D. The PHS may require further corrective action to ensure appropriate objectivity in PHS-funded research.

E. In the case of a PHS-funded project of clinical research 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 conflicting interest that was not managed or reported by an investigator with a FCOI that was not managed or reported by Providence as required by the regulation, Providence will require the investigator(s) involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

References:

21 CFR 54.1-6 *Financial Disclosure by Clinical Investigators*
42 CFR 50.601-607 - *Responsibility of Applicants for Promoting Objectivity in Research for Which*

PHS Funding is Sought 45 CFR 94.1-6 - *Responsible Prospective Contractors* 45 CFR 74.62 - Uniform Administrative Requirements for Awards and Subawards – Enforcement Providence Code of Conduct PSJH-CPP-733 Non-Retaliation PSJH-CPP-851 Privacy Sanctions Policy see also, *Counseling and Corrective Action Policy* available on the Caregiver Services Portal
Applicability:

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[i] For purposes of this policy, "Affiliates" is defined as any not-for-profit or non-profit entity that is wholly owned or controlled by Providence St. Joseph Health (PSJH), Providence Health & Services, St. Joseph Health System, Western HealthConnect, Kadlec, Covenant Health Network, Grace Health System, Providence Global Center*, NorCal HealthConnect, or is a not-for-profit or non-profit entity majority owned or controlled by PSJH or its Affiliates and bears the Providence, Swedish Health Services, St. Joseph Health, Covenant Health, Grace Health System, Kadlec, or Pacific Medical Centers names (includes Medical Groups, Home and Community Care, etc.). *Policies and/or procedures may vary for our international affiliates due to regulatory differences.

Approval Signatures

Step Description	Approver	Date
Site Admin Only	Naomi Margolis: Compliance Specialist	11/2025

Applicability

AK - Credena Health, AK - Providence Alaska MC, AK - Providence Kodiak Island MC, AK - Providence Medical Group, AK - Providence Seward MC, AK - Providence St. Elias Specialty Hospital, AK - Providence Valdez MC, CA - Credena Health, CA - Healdsburg Hospital, CA - Petaluma Valley Hospital, CA - Physician Enterprise Northern, CA - Physician Enterprise Southern, CA - Providence Cedars-Sinai Tarzana MC, CA - Providence Holy Cross MC, CA - Providence LCM MC San Pedro, CA - Providence LCM MC Torrance, CA - Providence Mission Hospitals, CA - Providence Queen of the Valley Medical Center, CA - Providence Redwood Memorial Hospital, CA - Providence Saint John's Health Center, CA - Providence Saint Joseph MC, Burbank, CA - Providence Santa Rosa Memorial Hospital, CA - Providence St. Joseph Hospital - Eureka, CA - Providence St. Joseph Hospital Orange, CA - Providence St. Jude Medical Center, CA - Providence St. Mary Medical Ctr Apple Valley, MT - Credena Health, MT - Providence St. Joseph MC, Polson, MT - St. Patrick Hospital, NM - Covenant Hobbs Hospital, OR - Credena Health, OR - Providence

Ctr for Medically Fragile Children, OR - Providence Health Oregon Labs, OR - Providence Hood River Memorial Hospital, OR - Providence Medford MC, OR - Providence Medical Group, OR - Providence Medical Group, OR - Providence Milwaukie Hospital, OR - Providence Newberg MC, OR - Providence Portland MC, OR - Providence Seaside Hospital, OR - Providence St. Vincent MC, OR - Providence Willamette Falls MC, PACE, PHCC - Home & Community Care, PHCC - Home Health, PHCC - Home Medical Equipment, PHCC - Hospice, PHCC - Infusion/Pharmacy, PHCC - Palliative Care, Providence, Providence Express Care, Providence Physician Enterprise, Providence Traditional Health Workers, TX - Covenant Children's Hospital, TX - Covenant Health - ACO, TX - Covenant Health Partners, TX - Covenant Hospital Levelland, TX - Covenant Hospital Plainview, TX - Covenant Medical Center, TX - Covenant Medical Group, TX - Covenant Specialty Hospital, TX - Grace Clinic, TX - Grace Surgical Hospital, WA - Credena Health, WA - EWA Providence Medical Group, WA - Kadlec Regional Medical Center, WA - NWR Providence Medical Group, WA - PacMed, WA - PacMed - ASC, WA - Providence Centralia Hospital, WA - Providence DominiCare, WA - Providence Holy Family Hospital, WA - Providence Mt. Carmel Hospital, WA - Providence Regional MC Everett, WA - Providence Sacred Heart Med Ctr & Children's, WA - Providence St. Joseph's Hospital, WA - Providence St. Luke's Rehabilitation Medical, WA - Providence St. Mary MC, WA - Providence St. Peter Hospital, WA - SWR Providence Medical Group, WA - Skilled Nursing / AL, WA - Swedish Medical Center, WA - Swedish Medical Group, WA - USFHP

Standards

No standards are associated with this document