Subject: Conflict of Interest in Research	**Policy Number:** PROV-ICP-724	
Department: Enterprise Risk Management Services	☐ New ☒ Revised ☐ Reviewed	**Date:** 02/27/2015
Executive Sponsor: SVP/Chief Risk Officer	**Policy Owner:** AVP Compliance and Information Security	
Approved by: Rod Hochman, MD - President/CEO	**Implementation Date:** 8/24/2012	

Scope: This policy applies to all individuals participating in research activities at Providence Health & Services and/or its Affiliates[1]. Subcontractors, subgrantees and collaborating investigators must also comply with this policy as stated herein. This is a management level policy approved by the Leadership Council and signed by the President /CEO.

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. 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) - in each Providence region, ministry or facility where research is conducted, the Chief Executive or designee will appoint a committee representing 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(s) typically reside in compliance departments. As used herein, the term COIR office shall mean the COIR Officer and his/her 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. *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.
5. *Financial interest* - anything of monetary value, whether or not the value is easily determined.

[1] For purposes of this policy, "Affiliates" is defined as any entity that is wholly owned or controlled by Providence Health & Services or Western HealthConnect (for example, Swedish Health Services, Swedish Edmonds, Kadlec Regional Medical Center, PacMed Clinics and Inland Northwest Health Services).

6. *Financial Conflict of Interest (FCOI)* - A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.

7. *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.

8. *Institution* - any domestic or foreign, public or private, entity or organization that is applying for, or that receives, PHS research funding.

9. *Signing Official* - individual(s) with institutional authority to legally bind the institution in research administration matters as delegated by Chief Executive or designee.

10. *Institutional Review Board (IRB)* - The National Research Act, Public Law 93-348, mandates that an Institutional Review Board, or human subjects committee, must be established by any institution that receives federal funding for biomedical or behavioral research. Providence requires all research studies involving human subjects being conducted through its facilities be approved by the IRB of record. This includes studies involving non-investigational and investigational drugs, devices, procedures and tests, as well as behavioral research. The review process is designed to protect the rights and welfare of human research participants by selecting them equitably, obtaining informed consent, minimizing risks, and ensuring their privacy and confidentiality.

11. *Intellectual 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. This policy is intended to affect only that Intellectual Property owned, in whole or in part, by Providence. It does not alter or affect other Providence policies that determine ownership of Intellectual Property.

12. *Investigator* - the PD or PI and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research, funded by a government agency or other entity or proposed for such funding, or who participates in research activities conducted in whole or in part at Providence, funded or not. Investigator includes the investigator's spouse and dependent child/children and may include sub-recipients, collaborators, consultants, staff, post-docs, fellows, residents or students. For purposes of this policy, others living in a residence

owned by the investigator are included under this definition (e.g., a significant other or foster children).

13. *Investigator's Institutional Responsibilities* - an investigator's professional responsibilities on behalf of Providence, including medical directorships, all research activities, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards, Institutional Animal Care and Use Committee, Institutional Biosafety Committee.
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. *Research* - a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied (clinical) research, and product development. As used in this policy, the term includes any such activity for which external funding is available, both federal and non-federal. Examples include, but are not limited to, research grant/agreement, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, research resources award or industry sponsored projects.
16. *Research Department Manager* - caregiver/employee(s) or employee(s) of affiliated organizations designated by Providence to fulfill the responsibilities of operational oversight and administrative representation of the research program. Titles for this responsibility may vary.
17. *Research Program* - Entities, departments or functions conducting research within Providence, including clinical, pre-clinical, outcomes, and registry research.
18. *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 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) 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.

(c) 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;
(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 defied 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.

19. *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.
20. *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 COIR, investigators shall disclose the apparent, potential or actual COIR in accordance with the procedures of this policy and participate in a COIR management plan.

Investigator Responsibilities:

1. Any investigator conducting research at Providence must comply with the Providence COIR Policy and complete a Providence COIR disclosure form (Attachment A). 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.

2. If an investigator discovers or acquires a new SFI, or if the value of a previously-disclosed financial interest changes such that it constitutes a SFI, or a previously-disclosed SFI increases in a significant manner, it is the investigator's responsibility to update COIR Disclosure within 30 days, providing any information that was not disclosed previously. Examples include: new COIR identified on a research project that was transferred from another institution; updated value of a previously disclosed equity interest.

3. An investigator 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 four (4) years. More frequent training updates may be assigned to an investigator if the Providence COIR policy changes significantly; if an investigator is new to Providence; or if Providence finds that investigator is not compliant with applicable policies or a management plan. An investigator will be made aware of the availability of such training by Providence personnel.

Sanctions - Failure of an individual to file a complete and truthful annual disclosure or disclosure when a new SFI is discovered or acquired, or failure 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. A research department manager or designee is responsible for enforcing policy within a respective research program and ensuring that all investigators complete disclosures and COIR training according to the process set forth in this policy. A research department manager is responsible for ensuring that subrecipients comply with COIR policy of subrecipient institution. When a non-Providence IRB is used, the research department manager is responsible for ensuring investigator has a current COIR disclosure on file at the time of IRB submission and that COIR training is documented and current.

B. 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 his/her 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. COIR Office shall prepare an annual summary report to research department leadership including number of

disclosures received, key findings and results, and conclusions. 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.

C. For studies submitted to a Providence IRB, the Providence IRB 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. When a non-Providence IRB is used, the research department manager is responsible for ensuring investigator has a current COIR disclosure on file at the time of IRB submission and that COIR training is documented and current.

D. 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 disclosed by Providence investigators that meets all of the following criteria:

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

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

Investigator Training

Providence will provide mandatory COIR training for investigators. Training covers Providence policy and overview of the federal regulations. Training is required at least every four (4) years, and immediately under the following circumstances:

- Providence COIR policies change in a manner that affects investigator requirements
- An investigator is new to Providence

- Providence finds an investigator noncompliant with Providence COIR policy or management plan.

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

A. COIR process

The COIR Office will solicit and review COIR financial disclosure forms for investigators at a minimum annually or as new SFIs are disclosed by an investigator. 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, investigator's research department manager and/or the IRB. The research department manager or designee will inform those sponsors that require notification of the conflict and actions taken.

The COIR Office will maintain records relating to an investigator's disclosures of financial interests and the review of, and response to, such disclosures (whether or not a disclosure resulted in the determination of a FCOI) and actions under this policy or retrospective review, if applicable, for at least three (3) years from the date the final expenditures report is submitted to the sponsor.

B. COIRC

The COIRC will meet as needed to discuss issues as presented by a COIR Office, including the results of any investigations and determine conditions and restrictions for the proper level of management of conflicts.

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 research department manager to impose a plan to manage determined FCOI including, but not limited to the following conditions:

a) Public disclosure of FCOI (i.e. when presenting or publishing the research);
b) For research projects involving human subjects research, disclose FCOI in IRB approved informed consent document;
c) Monitoring of any research project by independent reviewers;
d) Modification of the research proposal or plan;
e) Disqualification or change of personnel or personnel responsibilities from participating in all or a portion of the sponsored research;
f) Divestiture by an investigator of the financial interest in any research sponsor; or
g) Severance of any relationship between an investigator and a research sponsor which may create financial conflicts.

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.

FCOI Reporting Requirements to PHS

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

A. Initial: For PHS-funded research, prior to expending any PHS funds, the COIR office in collaboration with research department manager or designee will submit an FCOI Report for determined FCOI to the PHS via eRA Commons. 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
- Conflict of Interest in Research Form