

<b>RHS - RE - Research - Conflict of Interest &amp; Financial Disclosure for Public Health Service (PHS) Funded Studies Policy</b>		<b>rPolicies# 2797</b>
<b>Riverside Health System (to include System Wide (RHS), RBHC, RDHW, RMG, RRM, RSMH, RTH, RWRH)</b>		
<b>Category Chapter: Research (RE), Regulatory</b>	<b>Distribution Group: All RHS Employees</b>	
<b>Policy Approver: Medical Director Research</b>	<b>Owner: Content Owner, Medical Director Research</b>	
<b>Effective Date: 4/14/2015</b>	Page 1 of 5	

<b>Revision Description</b>
7/2019 – converted to newly updated template.

## **PURPOSE:**

To describe requirements regarding Conflict of Interest & Financial Disclosure for studies funded by the U.S. Public Health Service and Riverside's process for meeting these requirements.

## **DEFINITIONS:**

*Disclosure of significant financial interests (SFI)* means an Investigator's disclosure of significant financial interests to an Institution.

*Financial conflict of interest (FCOI)* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

*FCOI report* means an Institution's report of a FCOI to a PHS Awarding Component.

*Financial interest* means anything of monetary value, whether or not the value is readily ascertainable.

*Institutional Official* means the individual within the Institution who is responsible for soliciting & reviewing of disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

*Institutional responsibilities* means an individual's professional responsibilities assumed/performed on behalf of Riverside. Such responsibilities include, but are not limited to: research, research consultation, teaching, professional practice, and service on institutional committees.

*Investigator* means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

*PD/PI* means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.

*PHS Awarding Component* means the organizational unit of the PHS that funds the research that is subject to this policy.

*Research* means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term includes any such activity for which research funding is available from a PHS Awarding Component.

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*Senior/key personnel* means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution.

*Significant financial interest (SFI)* means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears 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 (or the Investigator's spouse or dependent children) 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.

(2) 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.

(3) The term significant financial interest does not include the following types of financial interests:

(i) salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;

(ii) any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;

(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; or

(iv) income from seminars, lectures, or teaching engagements sponsored by, or from service on advisory committees or review panels for, 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.

**POLICY:**

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This policy, governing financial conflict of interest (FCOI), applies to all Investigators conducting Public Health Service (PHS) - sponsored research. Riverside is responsible for informing each Investigator of its policy on financial conflicts of interest, of the Investigator's responsibilities regarding disclosure of significant financial interests and the associated regulations, and of the requirements for training.

The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the FCOI is resolved or other action deemed appropriate by the Institutional Official

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is implemented. Violation of any part of this policy may constitute cause for disciplinary and/or other administrative action(s).

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with Riverside's Institutional Official, who is responsible for soliciting & reviewing disclosures of Significant Financial Interests (SFI).

Riverside's Institutional Official is designated as the Director of Internal Audit and Privacy, Lisa York, who can be reached at 757-369-3296 or [lisa.york@rivhs.com](mailto:lisa.york@rivhs.com).

**PROCEDURE:**

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**1) Investigator's Disclosure Requirements:**

(1) An investigator, who is planning to participate in PHS-funded research, must disclose to Riverside's Institutional Official their significant financial interests as defined above, by submitting Riverside's Financial Disclosure Certification form (See Job Aid for this policy below.), no later than the time of application for PHS research funding.

(2) Investigators participating in PHS-funded research must submit an updated disclosure of significant financial interests annually, in accordance with Riverside's annual request for such disclosure. Such disclosure shall include any information that was not disclosed previously, and shall include updated information regarding any previously disclosed significant financial interest.

(3) An investigator who is participating in PHS-funded research must submit an updated disclosure to Riverside's Institutional Official, within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

**2) Institutional Official:**

The Institutional Official shall receive investigators' disclosures of significant financial interests, and review them to determine if they may be related to the investigator's PHS-funded research, i.e., could be affected by the research or is in an entity whose financial interest could be affected by the research. The Institutional Official shall forward those financial interests determined to be potentially related to the Research Conflict of Interests Committee for action as described below.

**3) Research Conflict of Interests Committee:**

Riverside shall maintain a Research Conflict of Interests Committee, which shall:

- a. receive and review disclosures of significant financial interests that the Institutional Official has determined may be related to the investigator's PHS-funded research
- b. determine whether an Investigator's significant financial interest is related to their PHS-funded research and, if so related, whether the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research, creating a financial conflict of interest;
- c. recommend to the Institutional Official management plans for significant financial interests related to research that create Financial Conflicts of Interests;
- d. report Financial Conflict of Interests to all associated IRBs; and
- e. through the Institutional Official, implement and monitor compliance with management plans approved by the Institutional Official, and make reports of Financial Conflicts of Interests to the PHS Awarding Component as required by the HHS regulations on Promoting Objectivity in Research.
  1. Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution must provide to the PHS Awarding Component an FCOI report regarding any

Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with the regulations. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution must not submit an FCOI report to the PHS Awarding Component.

2. For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution must provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with the regulations.

The Research Conflict of Interests Committee shall cooperate with the Institutional Official to implement policies and procedures for investigators' disclosure and review of significant financial interests, management of financial conflicts of interests, reporting of interests to PHS, and record maintenance, as required by the HHS regulations on Promoting Objectivity in Research.

**4) PHS Investigator Training:**

Each investigator is required per federal regulations to complete training regarding disclosure of financial interests prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following apply:

(1) Riverside revises its financial conflicts of interest policies or procedures in any manner that affects the requirements of investigators;

(2) Riverside finds that an investigator is not in compliance with its financial conflict of interest policy or management plan.

**5) Research Carried Out Through Subcontracts:**

If PHS-funded research will be carried out through a sub-recipient (e.g., a subcontractor or consortium member): (a) the sub-recipient shall certify in a written agreement that its research conflict of interests policy complies with the HHS regulations on Promoting Objectivity in Research, and that it will report any financial conflicts of interests of its investigators to Riverside by dates sufficient for timely reporting by Riverside to PHS; or (b) if it is unable to certify compliance, the sub-recipient shall enter into a written agreement requiring its investigators to report significant financial interests to Riverside pursuant to this policy and associated procedures.

**6) Enforcement:**

Investigators who fail to comply with the requirements of this policy or with a FCOI management plan shall be subject to appropriate disciplinary action, up to and including suspension or termination of employment as provided in applicable Riverside policies. The Institutional Official shall conduct a retrospective review to determine if the non-compliance has resulted in any bias in the research and if so, shall implement a mitigation plan and do any required reporting.

**7) Responding to Public Requests for Information about PHS-Funded Research:**

Riverside shall respond in writing within five business days to requests from the public for information about financial conflicts of interest of senior/key personnel (the principal investigator or project director and any other person identified as senior/key in the PHS funding application or other reports to PHS) if such conflicts are related to PHS-funded research. The response will be made in writing, postmarked within five business days, and include the investigator's name, title and role with respect to the research project, a description of the interest, and its dollar value range as required by the HHS regulations on Promoting Objectivity in Research.

**8) Dissemination of Policy:**

Riverside shall make this policy publicly available on its website.

**9) Record Retention**

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditures report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period. In such case, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

**10) Confidentiality**

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to the PHS Awarding Component and/or HHS or to a requestor of information concerning FCOI related to PHS funding. If the Institution is required to provide such information to an outside entity, the Investigator will be informed of this disclosure.

**JOB AID(S):**

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Attachment:

1. [RHS - RE - Research - Financial Disclosure Certification \( PHS Funded Research \) Form](#)

**RELATED INFORMATION:**

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<i>Content References</i>	<ul style="list-style-type: none"><li>• 42 CFR 50 Subpart F &amp; 45 CFR 94</li></ul>
<i>Related Policies</i>	<ul style="list-style-type: none"><li>• None</li></ul>
<i>Related Forms</i>	<ul style="list-style-type: none"><li>• None</li></ul>

**POLICY DATES:**

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<b>Last Date Reviewed:</b>	<b>02/26/2021</b>
<b>Date Created:</b>	<b>04/14/2015</b>