

LEGACY HEALTH

ADMINISTRATIVE

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SECTION: ADMINISTRATION & MANAGEMENT
TITLE: CONFLICT OF INTEREST IN PUBLIC HEALTH SERVICE FUNDED RESEARCH

PURPOSE: The objectivity of research and other activities funded by the Public Health Service (PHS) is of paramount importance and the basis for obtaining and maintaining public trust. All such activities must be free of any potential undue influence arising from the private financial interests of those involved in the design and conduct of PHS research. This policy is designed to comply with the federal regulation 42 CFR 50, Subpart F: Promoting Objectivity in Research.

DEFINITIONS

1. **Conflict of Interest (COI)** – Those circumstances (actual or potential) in which a competing personal interest could affect, or could appear to affect, an individual's judgment or could cause the individual's impartiality to be questioned.
2. **Entity** – Any domestic or foreign, public or private organization (excluding a Federal agency) from which an Investigator (including his/her spouse/partner and dependent children) receives remuneration or in which any person has an ownership or equity interest.
3. **Financial Conflict of Interest (FCOI)** – A financial conflict of interest exists when the grantee's designated official(s) reasonably determines that an investigator's significant financial interest (SFI) could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
4. **Institution** – Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or that receives PHS research funding.
5. **Institutional Responsibilities** – Any activities that arise from an Investigator's professional standing or expertise, and activities within the investigator's field of scientific expertise or medicine carried out on behalf of Legacy Health (Legacy). These can include, but are not limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
6. **Investigator** – 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 (e.g., NIH), or proposed for such funding, which may include, for example, collaborators, visiting scientists, contractors, or consultants. For this policy "Investigator" also includes the Investigator's spouse/partner and dependent children.
7. **Public Health Service (PHS)** – All Agency Divisions of the Department of Health and Human Services, which includes but is not limited to, the following agencies: National Institutes of Health, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration,

Administration for Children and Families, Administration on Aging, and the Indian Health Service.

- 8. Significant Financial Interest (SFI) – One or more of the following:**
- a. With regard to any publicly traded entity, if the value of any remuneration received within the 12 months preceding the disclosure exceeds \$5,000. For the purposes of this definition, remuneration includes salary (excluding the costs of conducting the grant), any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest including stock, stock options or other ownership interest.
 - b. With regard to any non-publicly traded entity, SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure exceeds \$5,000 or when the Investigator holds any equity interest (e.g., stock, stock option, or other ownership interest).
 - c. Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
 - d. Sponsored travel or reimbursements made to, or on behalf of, the Investigator and/or his/her family, exceeding \$5,000 during the 12 months preceding disclosure.
- Note: Reimbursed or sponsored travel with a value of less than \$5,000 is disclosed on the Legacy Travel Approval Form. 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.

The term “SFI” does **not** include the following types of financial interests:

- a. Salary, royalties, or other payments made by Legacy to an Investigator who is currently employed by Legacy.
- b. Income from seminars, lectures, teaching engagements, travel reimbursement, or service on advisory committees or review panels 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. Income from investment vehicles, such as mutual funds and retirement funds, in which the Investigator does not directly control investment decisions.

PROCEDURE

1. Applicability

- a. This policy applies to investigators, senior and key personnel, and all other investigators, regardless of title or position who are responsible for the design, conduct, and reporting of PHS-funded research.
- b. In most cases PHS-funds will be used for research studies, but may involve demonstration projects, supplemental funding for clinical programs, and quality initiatives.
- c. This policy does not apply to Phase I Small Business Technology Transfer and Small Business Innovative Research grants.
- d. In the case of Legacy issuing a sub-award, the institution of the external recipient will manage the FCOI process, providing assurance to Legacy that its COI policy meets all requirements of the regulation.
- e. In the case of a Legacy receiving a sub-award, Legacy will manage the FCOI process per this policy unless otherwise noted in the Letter of Intent to Establish a Sub-award.

2. Disclosures

Using the form in Attachment A, Financial Conflicts of Interest must be disclosed to the Grants Management Office at the following times:

- a. When initially hired as a Legacy Investigator on a PHS-funded project.
- b. If the Investigator does not already have a COI declaration on file and he or she agrees to be part of a new proposal/application (including any subcontract agreement) to be submitted for PHS funding.
- c. At least annually while PHS-funded (at the beginning of each calendar year).
- d. Within thirty (30) days of acquiring or discovering any new Significant Financial Interest(s).

What must be disclosed:

- i. Publicly-Traded Entities: Income received from an entity in the 12 months preceding disclosure, and value of any equity interests in entity as of date of disclosure, exceeding \$5,000 when combined, for an Investigator and his/her spouse/partner and dependent children.
- ii. Privately Held or Not-For-Profit Entity: Any remuneration received from an entity in 12 months preceding disclosure, or when an Investigator or his/her spouse/partner and dependent children holds any equity interest (e.g., stock, stock option, or other ownership interest; stipends and honorariums), which when combined exceeds \$5,000.
- iii. Intellectual property rights and interests: Upon receipt of income exceeding \$5,000 during the 12 months preceding disclosure from such rights and interests.
- iv. Travel: Sponsored travel or reimbursements exceeding \$5,000 made to, or on behalf of, the Investigator and/or his/her spouse/partner and dependent children, during the 12 months preceding disclosure, from a for-profit or non-profit entity related to the Investigator's Institutional Responsibilities.

Note: All SFIs related to an investigator's institutional responsibilities should be disclosed; for example, an investigator who is paid to consult for a pharmaceutical company because of the nature of clinical practice, not research interest, must still disclose the consulting income.

What is exempted from disclosure:

- 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.
- ii. Income derived from intellectual property owned by the grantee institution if the investigator is employed by the institution.
- iii. Travel reimbursements and payments for seminars, lectures or teaching engagements or service on advisory committees or review panels when the entity one of the following: federal, state or local government agencies; institutions of higher education; and academic teaching hospitals, medical centers, and research institutes affiliated with institutions of higher education.
- iv. Income derived from vehicles such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

3. Disclosure Process and COI Committee

- a. Upon receipt of a disclosure to the LRI Grants Management Office, the Senior Grants Specialist will review the submission and complete the FCOI Determination Checklist (attachment B). If the interest(s) may reasonably represent an FCOI and be thought to directly and significantly affect the design, conduct, or reporting of the sponsored research or other PHS-funded activity, the disclosure will be referred to the ad hoc COI Committee (Committee) for review.

- b. The Committee will consist of a minimum of three individuals: Director of Research, Senior Regulatory Specialist and Senior Outcomes Specialist. Other qualified individuals inside and outside Legacy may also be invited as needed.
- c. The Committee shall review in a timely manner the COI disclosure and the PSH funding of the Investigator.
 - i. If the interest is not determined to be an FCOI, which has the potential to adversely affect the -funded activity, a summary of the finding will be placed in the Investigator's COI file in the Grants Management Office.
 - ii. If an FCOI is identified that has the potential to adversely affect the PHS-funded activity, the Committee shall determine how to manage, reduce, or eliminate the conflict and inform the Investigator of the decision in writing.
 - iii. If the conflict can be eliminated no Management Plan or further reporting is needed.
 - iv. If the conflict needs to be managed/reduced a Management Plan will be issued and the matter will be reported to the PHS-funding agency.
- d. An Investigator who disagrees with the decision of the Committee may appeal to the Vice President of Research. Such an appeal shall be in writing only and must be made within (10) days of the decision of the Committee.
- e. An appeal to the VP of Research may only be made upon grounds of procedural irregularity that resulted in prejudice to the Investigator, new material information that could not have been presented to the Committee or that the decision is in conflict with applicable laws, rules or Legacy policies.
- f. The VP of Research shall make a decision within (10) ten working days of the date of the Investigator's appeal and the VP of Research's decision shall be final.

4. Management of FCOI

The Management Plan produced by the Committee may impose conditions to manage an FCOI involving PHS-funded research or other activities, including but not limited to:

- a. Public disclosure of financial conflicts of interests (e.g., to staff members working on the project, and when presenting or publishing the research, etc.)
- b. For research projects involving human subjects, disclosure of financial conflicts of interest directly to participants using, for example, the consent form.
- c. Monitoring of the project by independent reviewers.
- d. Modification of the research plan.
- e. Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research.
- f. Reduction or elimination of the financial interest (e.g., sale of an equity interest).
- g. Severance of relationships that create financial conflicts.

5. Public Accessibility

Legacy's COI policy for PHS-funded projects shall be available on its publicly accessible website. Prior to Legacy's expenditure of PHS funds, information concerning any FCOI disclosed to the Institution will be available, upon request, via written disclosure within five (5) working days of the request being received. At a minimum, this will include:

- a. Investigator's name.
- b. Investigator's title and role in the PHS-funded activity.
- c. Name of the entity in which the FCOI is held.
- d. Nature of the FCOI.

- e. Approximate dollar value of the FCOI or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value

6. Training Requirements

To receive PHS funding all Legacy Investigators must complete COI training through the Collaborative Institutional Training Initiative (CITI) web-based training program. New Legacy Investigators will be required to complete training prior to initiating PHS-funded research at Legacy. COI training will be required every four years, or more often if an Investigator is not in compliance with the policy or Management Plan.

7. Reporting Requirements

Prior to the Institution's expenditure of PHS funds, the Institution must provide the granting agency with a report of any FCOIs discovered. Subsequently, reports will be submitted within 60 days of the determination that an FCOI exists.

After the initial report of an FCOI, reports will be provided to the granting agency at least annually, at the time of progress report submission, to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.

All reports and disclosures in this section will include, but are not limited to:

- i. Grant number.
- ii. Name of the Investigator with the FCOI.
- iii. Role and principle duties of the conflicted Investigator in the research project
- iv. Details of the FCOI (entity, value, how it conflicts with the research, etc.).
- v. Whether the FCOI has been managed, reduced or eliminated.
- vi. Conditions of the Management Plan.
- vii. Confirmation of the Investigator's agreement to the Management Plan.
- viii. How the Management Plan will be monitored to ensure Investigator compliance.

8. Record Retention

Legacy shall maintain records of financial disclosures and any resulting action for at least three (3) years from the date of submission of the final expenditures report.

9. Non-Compliance

Legacy will, within 120 days of a determination of noncompliance, complete a retrospective review of the Investigator's research activities and the PSH-funded research project to determine whether any PSH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting.

Non-compliance with this policy will be reported to the PHS funding agency which may determine that suspension of funding is necessary until the matter is resolved.

Approvals: Research
 Legal Services
 Finance
 Compliance Committee
 Operations Council

Owner: Research

ATTACHMENT A



FCOI DISCLOSURE FOR PHS-FUNDED RESEARCH

Show/Hide
Instructions and
Definitions

LRI INVESTIGATOR INFORMATION

Investigator Name:	Calendar Year: <input type="text"/>	Disclosure Type: <input type="text"/>
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Have you completed the CITI COI Training Module within the last four years? Yes No

DETAILS OF FINANCIAL INTERESTS - Complete all sections

NOTE: For the purposes of this form, the questions below refer to significant financial interests related to your Institutional Responsibilities. These are defined as teaching/education, research, outreach, clinical service, training, and public service on behalf of Legacy Health System/Legacy Research Institute, and directly related to those credentials, expertise and achievements upon which the Investigator's Legacy position is based. 'Family' refers to your spouse, registered domestic partner and/or dependent children.

1. Publicly Traded Entities

Equity Interest + Compensation Exceeding \$5,000

Do you or your family have a financial interest in a publicly traded entity that exceeds \$5,000? *Add the value of any equity interest held as of the date of this disclosure and any compensation received from the entity in the twelve months preceding this disclosure.*

Use the 'Show/Hide Instructions and Definitions' button for more information regarding what to include in this section.

Yes No

2A. Privately Held or Not-For-Profit Equity

Equity Interest - Do you or your family own, or have held in the past 12 months, an equity interest in **any** Privately Held Entity?

Use the 'Show/Hide Instructions and Definitions' button for more information regarding what to include in this section.

Yes No

2B. Privately Held or Not-For-Profit Compensation

Compensation - Have you or your family received any compensation, in the past 12 months, exceeding \$5,000, from **any** Privately Held or Not-For-Profit Entity? *This includes income or honoraria received for outside activities.*

Use the 'Show/Hide Instructions and Definitions' button for more information regarding what to include in this section.

Yes No

3. Intellectual Property Rights and Interests

Have you or your family received any payments in excess of \$5,000 during the twelve months preceding this disclosure for any intellectual property rights and interests (e.g., patents, copyrights assigned or licensed to a party other than Legacy Health)?

Use the 'Show/Hide Instructions and Definitions' button for more information regarding what to include in this section.

Yes No

4. Travel Reimbursement/Sponsorship

In the past 12 months, has any organization sponsored or reimbursed you for any travel, in excess of \$5,000, that is related to your work for Legacy Health/Legacy Research? **Note: Honorarium payments should be listed in section 2B**

Yes No

ACKNOWLEDGMENT AND CERTIFICATION

I acknowledge that by signing or typing my name below that it is my responsibility to disclose, within 30 days, any new significant financial interests obtained. I certify, to the best of my knowledge, that this disclosure of significant financial interests related to my Institutional Responsibilities is complete and accurate.

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Investigator Signature

Note: Typed names and signature images are acceptable if you return this form via a valid work-based email address

Date

SAVE & SUBMIT

In order to expedite future disclosures, please save this form before submitting it. Submitting by email sends the form to jcouchman@lhs.org.

1. Save Form

2. Submit by Email