



FCOI DISCLOSURE FOR PHS-FUNDED RESEARCH

This form is used to ensure compliance with the federal regulation 42 CFR 50, Subpart F: Promoting Objectivity in Research. For instructions and definitions see page 5.

LRI INVESTIGATOR INFORMATION

Investigator Name: _____ Calendar Year: _____ Disclosure Type: _____

Have you completed the CITI COI Training Module within the last four years? Yes No Training Completion Date: _____

DETAILS OF FINANCIAL INTERESTS - Complete all 4 sections, add any additional info on page 4, then sign on page 3

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.

Answer 'Yes' or 'No' for each question, please provide details if any of the answers are Yes.

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.

No Yes - Please give details, if more than one source, please provide required information on page 4 & reference 'Section 1'

Entity Name: _____ Area of Business Activity: _____

Entity Address: _____

Equity Equity %: _____ Equity \$ Amount Received: _____

Compensation Compensation \$ Amount Received: _____

Please describe the nature and frequency of the recompensed activities:

Are the above recompensed activities/equity holdings related to a research project? Yes No

Please give details for both 'yes' and 'no' answers:

If 'Yes', how do you propose to mitigate this conflict?

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?

No Yes - Please give details, if more than one source, please provide required information on page 4 & reference 'Section 2A'

Entity Name: _____ Area of Business Activity: _____

Entity Address: _____

Equity Equity %: _____ Equity \$ Amount Received: _____

Are the above equity holdings related to a research project? Yes No

Please give details for both 'yes' and 'no' answers:

If 'Yes', how do you propose to mitigate this conflict?



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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.*

No Yes - Please give details, if more than one source, please provide required information on page 4 & reference 'Section 2B'

Entity Name: _____ Area of Business Activity: _____

Entity Address: _____

Compensation Compensation \$ Amount Received: _____

Please describe the nature and frequency of the recompensed activities:

Are the above recompensed activities related to a research project? Yes No

Please give details for both 'yes' and 'no' answers:

If 'Yes', how do you propose to mitigate this conflict?

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)?

No Yes - Please give details, if more than one source, please provide required information on page 4 & reference 'Section 3'

Entity Name: _____ Area of Business Activity: _____

Entity Address: _____

IP Type: _____ Amount of Royalties Received: _____

Is the above IP Interest related to a research project? Yes No

If 'Yes', please give details:

Is the IP Interest being tested, used, or further developed as part of the research project? Yes No

Please give details for both 'yes' and 'no' answers:

If 'Yes', how do you propose to mitigate this conflict?



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4. Travel Reimbursement/Sponsorship

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

No Yes - Please give details below (if more than 9 trips, please provide required information on page 4 & reference 'Section 4')

Entity Name	Benefits Received (\$ amt/description)	Travel Start Date	Travel End Date	Destination	Purpose

Other information/comments:

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.

Before signing, please make sure you have complete all relevant sections of the form, including any additional information required for a section (use page 4).

Investigator Signature (Please type your full name)



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Use this page to provide additional information. Indicate which section the information is for, e.g. 'Section 2A'

INSTRUCTIONS AND DEFINITIONS

Who must submit this form? All PHS-funded investigators (i.e., the Project Director/Principal Investigator, any other person identified as Senior/Key personnel in a grant application, progress report, or other report submitted to the PHS, and others who direct or can materially influence the research, or who are responsible for the design, conduct, and reporting of such research) will be required to disclose any Significant Financial Interests related to their institutional responsibilities. This requirement also extends to the spouse, registered domestic partner and dependent children of such personnel (family).

When should this form be submitted?

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

What must be disclosed? All Significant Financial Interests related to an Investigator's Institutional Responsibilities.

What are Institutional Responsibilities? They 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.

What is classed as a Significant Financial Interest? One or more of the following interests of the Investigator (and those of the Investigator's family, as defined above) that reasonably appears to be related to the Investigator's institutional responsibilities:

- **Publicly-Traded Entities:** Any income received from entity in 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 their family from a single Entity (Business, Public or Nonprofit). This includes salary, consultant payments, honoraria, royalty payments, dividend, loan, or any other payments or consideration with value during the prior twelve months. 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;
- **Privately Held or Not-For-Profit Entity:** Any remuneration received from entity in 12 months preceding disclosure, when combined, exceeds \$5,000; or when Investigator or their family holds any equity interest (e.g., stock, stock option, or other ownership interest). **Exclude** 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;
- **Intellectual property rights and interests,** upon receipt of income, exceeding \$5,000 during the twelve months preceding disclosure from such rights and interests. However, **Significant Financial Interests do NOT** include royalties received from Legacy Health System/Legacy Research Institute.
- **Travel:** Sponsored travel or reimbursements made to or on behalf of, the Investigator and/or their family, exceeding \$5,000 during the twelve months preceding disclosure, from a for-profit or non-profit entity related to the Investigator's Institutional Responsibilities. However, Significant Financial Interests do **NOT** include travel reimbursed or paid by a federal, state, or local government agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education.

Examples of disclosable Significant Financial Interests: Providing expert testimony or consulting services; Serving on a board of directors, scientific advisory board, committee, panel or commission, including professional or scholarly societies; Acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals; Salary received outside of Legacy Health System/Legacy Research Institute; Any equity interest in a company that is developing, manufacturing or selling products or providing services used in an Investigator's clinical practice, teaching, research, administrative or committee responsibilities; Royalties from any organization other than Legacy Health System/Legacy Research Institute, including for use or sale of patented or copyright intellectual property, such as software, textbooks, or other scholarly works; Travel reimbursed or sponsored by a professional society, foreign university or a company for which the Investigator provides recompensed advice.

Significant Financial Interests do NOT include: Payments made by Legacy Health System/Legacy Research Institute (salary, royalties, honoraria, expense reimbursement or any other remuneration); 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; An investment by a mutual fund, pension fund or other investment fund over which the investigator or his/her immediate family member does not exercise management of fund investment.