LEGACY HEALTH

ADMINISTRATIVE

Policy #: **100.88**
Origination Date: **08/2012**
Last Revision Date: **03/15**

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 42CFR50 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. **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.
3. **Institutional Animal Care & Use Committee (IACUC) –** A board charged with ensuring the humane use of animals in research activities and to ensure compliance with applicable Legacy policies as well as state and federal regulations.
4. **Institutional Review Board (IRB) -** A board charged with protecting the rights and welfare of human research subjects and to ensure compliance with applicable Legacy policies as well as state and federal regulations.
5. **Investigator –** For the purposes of this policy, the "Investigator" includes all Senior and Key Personnel directly named in PHS grant applications. That will include the principal investigator, co-investigator, and other Legacy employees, or any Legacy research collaborator, including visiting scientists, responsible for the design, conduct or reporting of research results or responsible for preparing a proposal for research funding. For this policy "Investigator" also includes the Investigator's spouse and dependent children.
6. **Public Health Service (PHS) –** All Agency Divisions of Health and Human Services which includes but not limited to the following agencies: National Institutes of Health, Agency for Healthcare Research and Quality, Centers for Disease Control, Food and Drug

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

7. **Significant Financial Interest (SFI) –** One or more of the following:
    a. With regard to any publically traded entity, if the value of any renumeration received within the 12 months preceding the disclosure exceeding $5000. For the purposes of this definition, renumeration 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-publically traded entity, SFI exists if the value of any renumeration received from the entity in the twelve months preceding the disclosure exceeds $5000 or when the investigator holds any equity interest (e.g. stock, stock option, or other ownership interest); or
    c. Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interests.

PROCEDURE

1. **Applicability**

    This policy applies to investigators, senior and key personnel, and any others named in grants that are funded by any PHS agency. In most cases these grants will fund research studies but in other cases they will involve demonstration projects, supplemental funding for clinical programs and quality initiatives. This policy does not apply to Phase I Small Business Technology Transfer and Small Business Innovative Research grants. In the case of the Institution receiving a sub-award, the Institution may choose to manage the SFI, share management of the SFI with the institution receiving the primary award, or request that the institution receiving the primary award manage the SFI.

2. **Disclosures**

    Disclosures will be made at least on an annual basis by all investigators whose work is funded by any PHS agency and within 30 days of acquiring an SFI. Disclosures and updates of disclosures can be made at the time of IRB or IACUC review or at any other time using the form in Attachment A.

    a. What must be disclosed:
        - Any renumeration received from an entity within the 12 months preceding the disclosure and the value of any equity interests as of the date of the disclosure, when aggregated, exceeds $5,000
        - Intellectual property rights on receipt of income from those rights
        - All SFIs related to an investigator's institutional responsibilities; for instance, an investigator who is paid to consult for a pharmaceutical company because of the nature of their clinical practice, not their research interest, must disclose the consulting income
        - Sponsored or reimbursed travel related to institutional responsibilities whether it is paid by a for-profit or non-for-profit organization of any amount
    b. What is exempted from disclosure:

- Income derived from intellectual property owned by the grantee institution if the investigator is employed by the institution
- Payments for seminars, lectures or teaching engagements or service on advisory committees or review panels from federal, state or local government agencies, institutions of higher education, academic teaching hospitals, medical centers, and research institutes affiliated with institutions of higher education
- Income derived from vehicles such as mutual funds and retirement accounts

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3. COI Committee

Upon receipt of a disclosure to the IRB, IACUC or Legacy Legal Services, an ad hoc COI committee of three individuals will be formed drawn from one or all of those bodies, or qualified individuals inside and outside Legacy Health, to examine the disclosure. That committee may be named by the Clinical VP of Research, Chief Medical Officer, or the Senior VP of Legal Services. When a potential conflict is disclosed the IRB or IACUC, or Legacy Legal Services may propose a preferred method of managing the conflict to the Investigator and to the COI Committee. The Committee shall review in a timely manner proposals for which a SFI has been disclosed to determine whether the interest may represent a FCOI and reasonably be thought to directly and significantly affect the design, conduct, or reporting of the sponsored research or other PHS funded activity. 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 shall inform the Investigator of the decision. An Investigator who disagrees with the decision of the Committee may appeal to the Senior VP of Legal Services. Such an appeal shall be in writing only and must be made within (10) days of the decision of the Committee. An appeal to the Senior VP of Legal Services 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. The Senior VP of Legal Services shall make a decision within (10) ten working days of the date of the Investigator's appeal and the Senior VP of Legal Service's decision shall be final.

4. Management of FCOI

The COI Committee may impose conditions to manage a FCOI involving PHS sponsored research or other activities including but not limited to:

a. Public disclosure of the FCOI (eg. in the consent form)
b. Monitoring of the project by independent reviewers
c. Modification of research proposal or the PHS funded activity
d. Disqualification of the Investigator from participating in all or a portion of the PHS funded activity (eg. remove the Investigator from recruiting and/or consenting human subjects or bar from analyzing outcome date)
e. Divestiture of the financial interest

f. Severance of any relationship between the Investigator and the Institution which may create actual or potential conflicts of interest

5. Public Accessibility

Legacy is responsible for making its policy on COI publically accessible on its publically accessible website. Prior to Legacy's expenditure of PHS funds the Institution shall ensure public accessibility, via a publically accessible website or written disclosure within (5) working days, of information concerning any FCOI disclosed to the Institution that will include at a minimum:

a. Investigator's name
b. Investigator's title and role in the PHS funded activity
c. Name of the entity in which the SFI is held
d. Nature of the SFI
e. Approximate dollar value of the SFI 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

In order to receive PHS funding Legacy all 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 their 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 the FCOI within (60) days after its determination that an FCOI exists. After the initial report of an FCOI reports will be provided to the granting agency annually or more often to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.

Those disclosures will include:

a. Grant number
b. Name of the Investigator with the FCOI
c. Role and principle duties of the conflicted Investigator in the research project
d. Whether the FCOI has been managed, reduced or eliminated
e. Conditions of the management plan
f. Confirmation of the Investigator's agreement to the management plan
g. How the management plan will be monitored to ensure Investigator compliance

8. Record Retention

Legacy shall maintain records identifiable to each award for at least (3) years beyond the termination or completion of the PHS award or until resolution of any action by any federal agency involving the records, whichever is longer.

9. Non-Compliance

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 Compliance Committee Executive Council
Owner:	Research

ATTACHMENT A

TO BE COMPLETED BY INVESTIGATORS OR KEY PERSONNEL	
PHS Agency:	Grant Number:
Name:	
Name of grant:	
Information collected at: ☐ Initial disclosure	☐ Interim time point

TO BE COMPLETED BY CLINICAL INVESTIGATOR (named on line 2 above)

Indicate by marking YES or NO if any of the financial interests or arrangements described below apply to you, your spouse, or dependent children.

Are you a part-time or full-time employee of the sponsoring company? *This employment could include such services as speaking engagements sponsored by the company, teaching classes related to the company's products, serving as a scientific advisor or other formal relationships even if payment is under USD 5,000 per year.*

☐ Yes *Please provide details:* ☐ No.

YES	NO	**Significant Financial Interests**
☐	☐	A significant equity interest in company or parent company of the sponsor of the study or grant. This would include, for example, any ownership interest, , or other financial interest whose value cannot be easily determined through reference to public prices, or an equity interest exceeding USD 5,000. If yes, please specify dollar amount and period covered:
☐	☐	Significant payments of other sorts, the total of which exceeds USD 5,000, EXCLUDING the costs of conducting the grant. *This could include, for example, payments made to the investigator or the institution to support activities (i.e., a grant to fund ongoing research, compensation in the form of equipment, or retainers for ongoing consultation or honoraria).* If yes, please specify dollar amount and period covered:
☐	☐	A proprietary or financial interest in the test product such as a patent, trademark, copyright, or licensing agreement. If yes, please describe:
☐	☐	Financial arrangements whereby the value of the compensation could be influenced by the outcome of the trial. This could include, for example, compensation that is greater for a favorable outcome, or compensation to the investigator in the form of an equity interest (stock) in the sponsor or in the form of compensation tied to sales of the product, such as a royalty interest. If yes, please describe:

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Investigator Signature **Date**