

Financial Conflict of Interest for Public Health Service (PHS) Funded Research

Key Points:

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- (1). Personnel involved with research funded under Public Health Service grants or cooperative agreements will be free from bias resulting from financial conflicts of interest.
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- (2). A Principal Investigator (PI) that applies for PHS funded research must complete the Clinical Research Potential Conflict of Interest Disclosure Form and submit to the Designated Official at the same time as submitting the PHS funding application.
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- (3). If a PI receives PHS research funding, they must be trained by FMCNA Corporate Compliance on the applicable policies & procedures.
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- (4). FMCNA will determine if a Financial Conflict of Interest (FCOI) exists and if it does exist, take steps to manage the FCOI.
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- (5). FMCNA will maintain and enforce PHS Funded Conflict of Interest policies & procedures and post them on the publicly accessible company web site.
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- (6). Upon request from the public, FMCNA will provide a written report (within 5 business days) with information concerning an investigator's FCOI.
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Applies To The following when seeking or participating in PHS funded research:

Each FMCNA, or FMCNA affiliated:

- entity, that is applying for, or that receives, PHS research funding by means of a grant or cooperative agreement,
- investigator who is planning to participate in, or are participating in such research and,
- employee who is responsible for the contracting and management of clinical studies, and responsible prospective contractors.

Purpose To ensure that personnel involved with the design, conduct, and reporting of research funded under PHS grants, cooperative agreements or contracts will be free from bias resulting from financial conflicts of interest.

What is a Financial Conflict of Interest (FCOI)? A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Definitions

Conflict of Interest Committee (COIC) – committee comprised of representatives from Legal, Compliance and the Medical Office that determines and manages financial conflicts of interest for PHS-funded research.

Designated Official - the FMCNA Clinical Research Compliance Officer.

Entity – company or corporation.

Financial Conflict of Interest – significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

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Financial Interest – anything of monetary value, whether or not the value is readily ascertainable.

FMCNA Institutional Responsibilities - the Investigator’s professional responsibilities that the investigator performs for or on behalf of FMCNA. Such activities may include research, research consultation, teaching, professional practice and medical directorship, FMCNA committee memberships, Medical Advisory Boards and service on panels such as IRBs or data safety monitoring boards.

Investigator –the project director, principal investigator, co-investigator, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of PHS funded research (or applications of the same), which may include collaborators or consultants.

Key Personnel – includes the PD/PI and any other personnel considered to be essential to work performance, and identified as key personnel in the contract proposal and contract.

Manage – address financial conflict of interest, which can include reducing or eliminating the financial conflict of interest to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PHS or the U.S. Public Health Service - the unit within the Department of Health and Human Services that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

PHS funded research –research, financially supported by PHS (e.g., NIH, CDC, etc.) through grants, contracts, or cooperative agreements, and also

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includes applications for any of the same. Such research funding may be provided, for example, as a research grant, career development award, center grant, individual fellowship award, infrastructure award, FMCNA training grant, program project, or research resources award.

PHS Awarding Component – the organizational unit of the PHS that funds the research that is subject to the regulation.

Research - 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 encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test, medical device or drug).

Proprietary Interest - in the tested product includes, but is not limited to, a patent, trademark, copyright or licensing agreement.

PD/PI – 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.

**Significant
Financial
Interest (SFI)**

SFI is anything of monetary value of the Investigator (or those of the Investigator’s spouse and dependent children) that appears to be related to the Investigator’s FMCNA Institutional Responsibilities. This includes:

- Intellectual property rights and interests (e.g. patents, copyrights)
- Reimbursed or sponsored travel (i.e. paid on behalf of the Investigator and not reimbursed to the Investigator so the exact monetary value may not be known).

SFI does not include:

- Travel reimbursed or sponsored by a Federal state, or local government agency, Institution of higher education, an academic teaching hospital, or a research institute affiliated with an Institution

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of higher education.

- Salary, royalties, or other remuneration paid by FMCNA to the Investigator if the Investigator is currently employed or otherwise appointed by FMCNA.

| A Significant Financial Interest exists | If the value of remuneration received from the entity... |
|--|--|
| For a publicly traded entity | in the past twelve months and value of any equity interest when aggregated exceeds \$5,000 |
| For a non-publicly traded entity | in the past twelve months when aggregated exceeds \$5,000 or; Investigator (or the Investigator's spouse or dependent children) holds any equity interest (i.e. stock, stock option, or other ownership interest) in entity |

Significant Financial Interest vs. Financial Conflict of Interest

A SFI is not always a FCOI.

A Financial Conflict of Interest (FCOI) exists when the applicable FMCNA Conflict of Interest Committee (COIC) reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of the research project.

FMCNA will collect Investigator's financial arrangements with:

- FMCNA and affiliates
- Entities outside of FMCNA that could be reasonably related to FMCNA Institutional responsibilities
- Entities that could potentially be affected by the results of the research project

FMCNA will determine if the financial arrangements pose a financial conflict of interest.

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**Responsibilities
of Institutions
Regarding FCOI**

FMCNA will:

- Maintain an up-to-date, written, enforced policy on FCOI.
- Post the FCOI policy to a publicly accessible Web site, signifying that FMCNA is in full compliance with all the regulatory requirements.
- Enforce a written and administrative process and procedure to identify and manage, reduce or eliminate conflicting interests.
- Inform each Investigator of the Institution’s policy on financial conflicts of interest, the Investigator’s responsibilities regarding disclosure of significant financial interests, and of the applicable regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years.
- If HHS determines that a PHS-funded research project 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 financial conflict of interest that was not managed or reported by the Institution, then FMCNA requires the Investigator to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.
- Ensure public accessibility to FCOI information by responding within 5 business days to a request concerning an Investigator, PD/PI and Senior/Key personnel. The response shall include:
 - Investigator’s name
 - Investigator’s title and role with respect to the research project
 - Name of the entity in which the significant financial interest is held
 - Nature of the significant financial interest
 - Approximate dollar value of the significant financial interest.
 - Dollar ranges are permissible
 - \$0-\$4,999

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- \$5,000-\$9,999
- \$10,000-\$19,999
- \$20,000-\$100,000 in increments of \$20,000
- >\$100,000 in increments of \$50,000
- Or a statement that the interest cannot be readily determined through reference to public prices or other measures of fair market value.
- Statement that information is current as of the date on the letter is subject to be updated by the investigator at least annually or within 60 days of identifying a new financial conflict of interest.
- It is up to any requestor to ask for updated information.

Investigator Responsibilities

Each investigator must:

| | | |
|---|--|---|
| 1 | Submit an FMCNA financial disclosure statement to the FMCNA Designated Official <ul style="list-style-type: none"> • Complete the Clinical Research Potential Conflict of Interest Disclosure Form <p><u>Note:</u> all investigators listed on the grant must complete the disclosure form before the grant may be submitted.</p> | <ul style="list-style-type: none"> • No later than at the time of application for PHS-funded research • At least annually, by the anniversary date during the period of the award • Report any new Significant Financial Interests, or any changes to a previously disclosed interest, to FMCNA within 30 days of discovering or acquiring a new SFI |
| 2 | Complete training prior to engaging in PHS-funded research: | At least every 4 years, and within a reasonable time period if: <ul style="list-style-type: none"> • FMCNA Financial Conflict of Interest policies change in a manner that affects Investigator |

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| | | requirements. <ul style="list-style-type: none"> • An Investigator is new to a FMCNA entity. • FMCNA finds that an Investigator is not in compliance with FMCNA’s Financial Conflict of Interest policy or management plan. • If FMCNA performs PHS-funded research as a sub recipient. |
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Conflict of Interest Committee

FMCNA will establish a Conflicts of Interest Committee (COIC) for Fresenius Medical Services and a second COIC for the Renal Therapies Group/Renal Research Institute. They will include representation from:

- Legal
- Compliance
- Medical Office

The Medical Office representation must be different for the two committees.

FMCNA Entity Applying / Conducting PHS Research

Financial conflict of interest responsibilities:

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| Each FMCNA entity applying for and conducting PHS funded research will: |
| Solicit and review disclosure statements (FMCNA Clinical Research Potential Conflict of Interest Disclosure Form) from each Investigator planning to participate in federally-funded research. |

FMCNA Designated Official Responsibilities

The Designated Official is responsible for the following:

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| FMCNA Designated Official will: | |
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| | Establish guidelines to identify conflicting interests. |
| | Take action to ensure FCOI are reported, managed, reduced or eliminated. |
| | Report regularly to the Conflict of Interest Committee, including failure of an Investigator to comply with this policy or management plan. |
| | Review disclosures prior to the expenditure of funds after receipt of disclosures of significant financial interests and determine whether there appears to be any financial conflict of interest. |
| | Review disclosures for new investigators within 60 days after receipt of disclosures of significant financial interests and determine whether there appears to be any financial conflict of interest. |
| | Review disclosures for investigators that were received after the research project within 60 days after receipt of disclosures of significant financial interests and determine whether there appears to be any financial conflict of interest. |
| | Report failure of an Investigator to comply with this policy and or financial conflict management plan to the PHS Awarding Component |
| | After reviewing disclosures, if an FCOI appears to exist, present findings to the applicable COIC committee. |
| Note: If SFI is not reported or reviewed within a timely manner, perform a retrospective review of the investigator's actions and if applicable, report findings to the PHS Awarding Component | |

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Is the SFI a Financial Conflict of Interest?

If the applicable COIC determines that an SFI is a financial conflict of interest then the following must be done:

| If | Then |
|--|---|
| FMCNA determines that the SFI is a FCOI, FMCNA will: | 1. Notify the Investigator. 2. Create a management plan that specifies actions that have been, and shall be taken to manage the FCOI 3. Monitor compliance to the plan 4. Submit a FCOI report to the PHS Awarding Component and provide annual updates for the duration of the study. |
| Examples of an FCOI Management Plan may include, but is not limited to: <ul style="list-style-type: none"> • Public disclosure of financial conflicts of interest (i.e. when presenting or publishing research) • Disclosure of FCOI directly to human subjects in the study • Appointment of an independent monitor who can protect the design, conduct, and reporting of the research against bias • Modification of the research study • Change of personnel or disqualification of personnel from the study • Removal of relationships causing the financial conflicts | |
| The FMCNA Designated Official will monitor compliance to the management plan for the duration of the study and provide periodic updates to the applicable COIC. | |
| Note: If the FCOI is eliminated before the expenditure of funds, FMCNA is not required to submit a FCOI report to the PHS Awarding Component. | |

COI Report to PHS Awarding Component

A Financial Conflict of Interest report submitted to the PHS Awarding Component must contain, at a minimum, the following:

| | | |
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| 1 | Project number | |
| 2 | PD/PI or Contact PD/PI | If multiple used |
| 3 | Name of the Investigator | Name of the Investigator with the financial |

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| | | conflict of interest |
| 4 | Name of the entity | Name of the entity with which the Investigator has a financial conflict of interest. |
| 5 | Nature of the financial interest. | i.e. equity, consulting fee, honorarium, travel reimbursement. |
| 6 | Value of the financial interest. | Note that dollar ranges are permissible <ul style="list-style-type: none"> • such as \$5000-\$9,999; \$10-19,999; • amounts between \$20,000-\$100,000 by increments of \$20,000; • amounts above \$100,000 by increments of \$50,000) or • a statement that the interest is one whose value cannot be readily determined through reference to public prices or fair market value. |
| 7 | Description of how the financial interest relates to the PHS-funded research and; | The basis for FMCNA's determination that the financial interest conflicts with such research |
| 8 | Brief description of the key elements of FMCNA's management plan. | Includes; <ul style="list-style-type: none"> o Role and principal duties of the conflicted Investigator in the research project; o Conditions of the management plan; o How the management plan is designed to safeguard objectivity in the research project; o Confirmation of the Investigator's |

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| | | agreement to the management plan; o How the management plan will be monitored to ensure Investigator compliance; and o Other information as needed. |
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Retrospective Review for Non-compliance; Non-disclosure of FCOI

Important: Retrospective review must be completed within 120 days.

The Designated Official will conduct a retrospective review and report to the applicable COIC if:

- A financial conflict of interest is not identified or managed or not handled in a timely manner, or
- Investigator does not disclose significant financial interest; or
- Investigator fails to comply with the management plan.

Documentation of Retrospective Review

The FMCNA Designated Official will document the retrospective review and include at a minimum the following key elements:

| | |
|---|---|
| 1 | Project number |
| 2 | Project title |
| 3 | PD/PI or Contact PD/PI if multiple used |
| 4 | Name of the entity with which the Investigator with the FCOI. |
| 5 | Name of the entity with which the Investigator has a financial conflict of interest |
| 6 | Reason(s) for the retrospective review; |
| 7 | Detailed methodology used for the retrospective review; |
| 8 | Findings of the review; and |
| 9 | Conclusions of the review. |

Retrospective Based upon the results of the retrospective review, the COIC will:

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**Review –
Corrective
Actions**

- If bias is found, promptly notify the PHS Awarding Component and submit a mitigation report to the PHS Awarding Component including :
 - o The key elements documented in the retrospective review
 - o Description of the bias on the research project and FMCNA’s plan of action to eliminate or mitigate the effect of the bias.

- Recommend a corrective action plan for the Investigator including up to terminating future and current research privileges.

Continue to submit annual FCOI reports to the PHS Awarding Component outlining the status of the corrective action.

**PHS-funded
Research and
Sub-recipients**

PHS-funded research is performed through:

- Sub grantees/Sub-recipients,
- Contractors, or
- Collaborators

FMCNA Entity receiving the PHS grant, as the Awardee Institution, will ensure compliance of any sub-recipient by:

Establishing a written agreement with the sub-recipient determining if the FCOI policy of FMCNA or that of the sub-recipient will apply to the sub-recipient’s investigators.

| If | Then |
|--|--|
| Sub-recipient’s Investigator must comply with the Sub-recipient’s FCOI policy, | Sub-recipient shall: <ul style="list-style-type: none"> • certify as part of the agreement that its policy is compliant with 42 CFR Part 50 Subpart F (Grants and cooperative agreements), and 45 CFR Part 94 (contracts). <p>Note: The sub-recipient’s agreement must specify time periods for the sub-recipient to report all identified FCOI to the FMCNA Entity.</p> |
| Sub-recipient’s Investigator must | The agreement shall specify time period(s) for the sub-recipient to submit all Investigator |

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| comply with the FMCNA policy | disclosures of SFI to the FMCNA Designated Official. |
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Note: Provide FCOI reports to the PHS Awarding Component for all FCOI of all sub-recipient Investigators prior to the expenditure of funds and within 60 days of subsequently identified FCOI.

Reporting an Identified FCOI to HHS

Reports of an identified Financial Conflict of Interest in PHS funded research will include specified criteria.

Note:

- For NIH grants and cooperative agreements, all FCOI reports must be submitted to the NIH through the eRA Commons FCOI Module. [NIH Guide Notice NOT-OD-09-072; <http://grants.nih.gov/grants/quide/notice-files/NOT-OD-09-072.html>]
- For NIH contracts, reports should be sent to the appropriate Director, Office of Acquisitions.

Document Retention

All FCOI records:

- of disclosures, their review, determinations, and any subsequent actions
- must be retained for at least 3 years from the date of submission of the final expenditures report.

PHS funded or contracted studies records:

- HHS may inquire at any time (before, during, or after award) into any Investigator disclosure of financial interests.
- HHS may inquire regarding FMCNA's review (including retrospective review) and response to a disclosure, regardless of whether the disclosure resulted in FMCNA's determination of a FCOI, including a requirement to submit, or permit on site review of, all records pertinent to compliance with the regulation.

Related Documents

FMCNA Clinical Research Potential Conflict of Interest Disclosure Form

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