

POLICY: Financial Conflicts of Interest in Research - Investigator Significant Financial Interest Disclosure Policy for the Assurance of Objectivity in Research Applicable to Project Proposals Submitted to any Sponsor (Federal or Non-Federal)

Responsible Office: HyQ RS GM

Adopted: June 01, 2016

Responsible Official: President (HyQ RS)

Last Revision: November 31, 2016

PROCEDURES

The following provisions support the Financial Conflicts of Interest in Research policy.

What is required:

Federal regulations require institutions to have policies and procedures in place that ensure that Investigators disclose any significant financial interests that may present an actual or potential conflict of interest in research projects. Such disclosures must be made prior to the submission of a proposal for funding, and institutions must develop specific mechanisms by which conflict of interest will be satisfactorily managed, reduced or eliminated prior to the expenditure of any funds on an award. HYQ RS requires that disclosure forms be completed for all projects applying for external funding and for non-competing continuation grant applications (renewals).

Who is covered:

Investigator: The investigator means the physician or employee who is the project director or principal investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposed research. This may include collaborators or consultants. For research funded by the PHS, the term investigator includes, but is not limited to all key personnel.

Scope:

This policy is applicable to each investigator who will participate in HyQ RS research grants or cooperative agreements. The term “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.

The responsibilities of an investigator include the following:

1. Become familiar with the HYQ RS policies related to conflict of interest.
2. Complete training on conflict of interest before November 31, 2016 and no less than every four years.
3. Annual Disclosures-Faculty and Investigators shall disclose Significant Financial Interest (SFI) annually and within 30 days of discovering or acquiring a new SFIs.
4. Project Specific Disclosures with Research Application-Faculty/Investigators/Key Personnel shall disclose all SFIs in the Research Project application when it is initially submitted.
5. Project Specific Disclosure of SFIs prior to expenditure of funds required by Faculty, Investigator (including Project Manager and Programmer) and updated within 30 days of discovery or acquiring a new project specific SFI.

6. Comply with any management plan issued by HYQ RS and retain documentation that demonstrates compliance.

The term “significant financial interest” is defined as anything of monetary value, whether the value is readily ascertainable, that:

- Is related to the Investigator’s professional responsibilities on behalf of HYQ RS.
- Belongs to the investigator or the investigator’s spouse or dependent children.

Significant Financial Interests (SFI) include:

1. Income in excess of \$5,000 from publicly-traded entity (a company whose stock is available for purchase by the general public) during the past twelve months.
2. Stock valued in excess of \$5,000 the time of disclosure in a publicly traded entity.
3. A combination of the above two items (stock and income) that exceeds \$5,000.
4. Any amount of equity (stock, stock options, or other ownership interest) in a non-publicly traded entity (such as a start-up company).
5. Compensation that exceeds \$5,000 from a non-publicly traded entity in the past twelve months.
6. Income related to intellectual property rights paid by any source other than the investigator’s current institution.
7. Any reimbursed or sponsored travel paid by an entity, including non-profit organizations, but excluding travel sponsored by or reimbursed by a government agency, a U.S. institution of higher education or a research institute affiliated with such, a medical center, or an academic teaching hospital. The specific details that must be disclosed are: the name of entity sponsoring the travel and purpose, destination, and duration of the travel.
8. Any other interests required under the institution’s policy.

The following are not required to be disclosed by the investigator:

1. Salary, royalties, or other remuneration paid to the investigator from the institution that currently employs the investigator. Any ownership interest in the Institution held by Investigator if the Institution is a commercial for-profit organization.
2. Income from investments in mutual funds or retirement accounts, if the Investigator does not make the investment decisions.
3. Income for services (honoraria, advisory committees, review panels, etc.) and travel expenses paid by a federal, state, or local government agency, a U.S. institution of higher education or a research institute affiliated with such, a medical center, or an academic teaching hospitals.

Research Project Disclosures

- When submitting a proposal to any funding entity, all Investigators must affirm that they have read this policy and must disclose any significant financial interests. HYQ RS Investigators should submit the Significant Financial Interest Disclosure (SFID) form (with relevant supporting documentation attached). The completed form and attachments, if any, must be submitted to the by the proposal’s submission date. Supporting documentation should be submitted in a sealed envelope marked “confidential” to VP of Research.
- Project Managers and Programmers need to disclose prior to expenditure of funds.
- All Key personnel need to disclose within 30 days of acquiring a new SFI during research project.

Review Process:

If the disclosure form reveals a Significant Financial Interest (SFI), it will be reviewed promptly by the Institutional Official (VP of Research or designees (i.e., Director of Operations and/or Assoc. Director of Research)) for determination of whether the SFI could directly and significantly affect the design, conduct or reporting of the research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must require and approve a written management plan before any related research goes forward. The affected Investigator and the Institutional Official (or designee) are responsible for developing a proposed management plan. This involves proposing appropriate Management plan, including, but not limited to:

1. public disclosure of significant financial interests;
2. review of research protocol by independent reviewers; and
3. monitoring of research by independent reviewers.
4. modification of the research plan;
5. disqualification from participation in all or a portion of the research funded;
6. divestiture of significant financial interests; or
7. severance of relationships that create actual or potential conflicts of interest.

Resolution Process:

Resolutions to FCOI will be incorporated into a Management Plan between the Investigator(s) and the Institutional Official prior to expenditure of any award funds.

Required Reporting of Financial Conflict of Interest for Funded Projects:

REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THORUGH eRA COMMONS FOR FCOI MODULE		
REPORT	CONTENT	REQUIRED WHEN?
New FCOI Report (Initial submission)	Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	<ol style="list-style-type: none"> 1. Prior to expenditure of funds 2. Within 60 days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable.	Annual report due at the same time as when the Institution is required to submit annual progress report, multi-year progress report, or at time of extension.
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to originally submitted FCOI report.	Following the completion of a retrospective review when there is non-compliance with the regulation, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail	When bias is found as a result of a retrospective review.

	Methodology, Findings and Conclusion.	
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Summary of FCOI Noncompliance and FCOI Reporting	
FCOI Report (within 60 days of identification)	Whenever an Institution identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) shall within 60 days: review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH.
Retrospective Review (to determine bias)	If an FCOI exists, complete and document a retrospective review within 120 days of the Institution’s determination of noncompliance. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward.
Update/Revise FCOI Report (following retrospective review)	If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update previously submitted report.
Mitigation Report (promptly after retrospective review)	If bias is found, <ul style="list-style-type: none"> • Notify NIH promptly • Submit mitigation report through FCOI Module
Annual FCOI Report	Submit annual FCOI report thereafter through FCOI Module

Records of Investigator financial disclosures and of actions taken to manage significant financial interests shall be retained until three (3) years after the termination or completion of the award to which they relate, or until the resolution of any outstanding issues involving those records, whichever is longer.

Public Accessibility

HYQ RS will respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

1. The Significant Financial Interest was disclosed and is still held by the Investigator;
2. A determination has been made that the Significant Financial Interest is related to the funded research; and
3. A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS policy

Subcontracts:

Investigators at other institutions who will be subcontractors to HYQ RS must certify in the contractual agreement between HYQ RS and their institution that their institution is in compliance with federal conflict of interest regulations.