

HR005B – Conflict of Interest Related to Research

		Policy and Procedure	
Title: Conflict of Interest Related to Research	P&P #: HR-005B	Page: 1 of 10	
Scope: Organization wide	Originating Department: Human Resources		
Original Date:	Effective Date:		

POLICY: Employees and independent contractors of Quality Insights, hereafter referred to as Investigators as defined below, will exercise due care in identifying, understanding, and responding to financial conflicts of interest in order to protect the credibility and objectivity of their work and contract deliverables related to Research funded by the Public Health Service (PHS) of the U.S. Department of Health and Human Services (DHHS).

PURPOSE: The purpose of this policy is to set forth the framework for identifying, evaluating, and managing financial conflicts of interest related to Research activities funded by the PHS, controlling Investigator's ability to create bias and thus maintaining integrity, credibility, and respect for their work related to PHS-funded Research.

DEFINITIONS:

Clinical Trial: means any Research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

Corporate Official: means the individual within the company that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's corporate responsibilities. For the purposes of this policy, the Corporate Official is designated as the Compliance Officer.

Corporate responsibilities: means the Investigator's professional responsibilities associated with his or her corporate appointment or position, such as research, teaching, clinical activities, administration, and corporate, internal and external professional committee service.

Family: Any member of the Investigator's immediate family, specifically, any dependent children and spouse.

Financial Interest: Anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a. salary, royalties, or other remuneration from Quality Insights;
- b. income from the authorship of academic or scholarly works;
- c. income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d. equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, Financial Interest also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her corporate responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by Quality Insights, U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest: A Financial Interest that reasonably appears to be related to the Investigator's Corporate Responsibilities, and:

- a. if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b. if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c. if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d. is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through Quality Insights, or
- e. is reimbursed or sponsored travel related to their corporate responsibilities.

Financial Conflict of Interest: A Significant Financial Interest (or, where the Corporate Official requires disclosure of other Financial Interests, a Financial Interest) that the company reasonably determines could directly and significantly affect the design, conduct or reporting of Research.

Investigator: Any individual who is responsible for the design, conduct, or reporting of Research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service or PHS: The Public Health Service of the U.S. Department of Health and Human Services (DHHS), and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children

and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research: A systematic investigation, study, or experiment designed to 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 or drug).

APPLICABLE STATUTES/REGULATIONS/OTHER REFERENCES:

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

INTRODUCTION:

This policy governing financial conflict of interest applies to all PHS-sponsored Investigators of the corporation. The Corporate Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Corporate Official is implemented. Violation of any part of this policy may also constitute cause for disciplinary or other administrative action pursuant to this policy.

CONFLICT OF INTEREST:

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the company to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Corporate Official.

I. DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests as defined above to the company on an annual and on an ad hoc basis, as described below. The Corporate Official, or his/her designee, is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

a. Annual Disclosures

All Investigators must disclose their Significant Financial Interests that are related to the investigator's responsibilities to the company, through the Corporate Official, on an annual basis.

b. Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the company, through the Corporate Official (or designee), within 30 days of their initial appointment or employment.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Corporate Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Corporate Official an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, inheritance, etc.) the Significant Financial Interest.

c. Travel

Investigators must also disclose reimbursed or sponsored travel related to their company responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Corporate Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

II. REVIEW AND DECISION OF THE CORPORATE OFFICIAL

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Corporate Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Corporate Official will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate.

A Financial Conflict of Interest will exist when the Corporate Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored Research. If the Corporate Official determines that there is a Financial Conflict of Interest that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored Research goes forward.

The Corporate Official will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely

dissemination of the Research results, and to otherwise oversee compliance with the management plan.

III. CLINICAL TRIALS

Review of Significant Financial Interests Related to Clinical Trials

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.

- a. In the event of non-compliance with reporting and/or management of a financial conflict of interest involving a PHS-sponsored clinical Research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this Policy, the investigator must disclose the financial conflicts of interest in each public presentation of the results of the affected PHS-sponsored Research and request an addendum to previously published presentations.

IV. REPORTING TO PHS

The Corporate Official will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS.

V. INVESTIGATOR NON-COMPLIANCE

a. Disciplinary Action

In the event of an Investigator's failure to comply with this policy, the Corporate Official may impose appropriate disciplinary actions pursuant to policy number HR040-Disciplinary Procedures and Policies.

The company will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the Research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

b. Retrospective Review

In addition, if the Corporate Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Corporate Official or designee will complete a retrospective review of the Investigator's activities and the PHS-sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, principle investigator, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Corporate Official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the institution will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

VI. TRAINING

Each Investigator must complete training on this Policy, the investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Corporate Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the investigator is new to the institution, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

VII. RECORD RETENTION

The Corporate Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

VIII. PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, the company will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a. The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
- b. A determination has been made that the Significant Financial Interest is related to the PHS-funded Research; and

- c. A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.
- d. The information to be made available shall be consistent with the requirements of the PHS regulation.

ATTACHMENTS:

A-Quality Insights Research Financial Conflict of Interest Declaration

B-Independent Contractor Agreement Addendum

REVISION HISTORY

Version	Change Date	Change By	Description	Review By
HR-005B		Human Resources	Original	
HR-005B	2013-03-20		Approved	HRC Committee
HR-005B	2013-04-25		Approved	Quality Council
HR-005B	2014-12-29	Human Resources	Reviewed	
HR-005B	2015-12-31	Human Resources		
HR-005B	2016-02-05	Human Resources	Corporate Logo Change Only	
HR-005B	2016-22-22	Human Resources	Company Name Change Only	

INQUIRIES:

Direct inquiries about this policy to:

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