Policy Statement: Virtua has adopted this policy for identifying and managing actual or perceived conflicts of interest that may arise in the conduct of research to ensure the integrity, objectivity, and freedom of inquiry of its Investigators, study personnel and the safety and welfare of human subjects who have volunteered to participate in research.

Objective: To promote objectivity and elimination of bias in the conduct of research. Describing the process and procedures for complying with the U.S. Department of Health and Human Services (HHS) final rule published September 26, 2011 in the Federal Register that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is sought (42 CFR, Parts 50, 56), Responsible Prospective Contractors (45 CFR Part 94) and to provide the reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from Investigator and study personnel financial conflicts of interest.

Applicable to Whom: This policy shall apply to all Virtua Investigators, study personnel, employees, students, and other individuals who, in the course of their association with Virtua (1) apply for or receive funds for any research or research training purpose, by grant or subgrant, or by contract or subcontract, or by cooperative agreement or (2) wish to conduct unsponsored (unfunded) research. This policy does not cover conflicts of commitment or institutional Conflicts of Interest.

Responsible Parties:

1. Institutional Official
2. General Counsel
3. Investigator(s)
4. Study Personnel
5. Director of Research Administration
6. Clinical Research Coordinators (CRC)
7. Clinical Research Nurses (CRN)
8. Clinical Research Medical Assistants (CRMA)
9. Director, Human Research Protection Program
10. Research Conflict of Interest Committee (RCOIC)

INTRODUCTION

This policy governing financial conflict of interest applies to all sponsored or unsponsored research. The Institutional 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 Institutional Official is implemented. Violation of any part of this policy may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy.

Virtua recognizes the importance of relationships between Researchers and outside organizations and seeks to encourage such relationships. These relationships can give rise to significant discoveries and translation of those discoveries into useful products. Productive relationships with outside organizations also inspire new avenues of inquiry and provide opportunities to test Research. However, the financial incentives that accompany such relationships may lead to Financial Conflicts of Interest. Such Conflicts of Interest have the potential to create real or apparent bias in research. Conflicts of Interest may affect research integrity and may place human research subjects at additional risk. Conflicts of Interest, and even the appearance of Conflict of Interest, may reduce public confidence in the research enterprise.

DEFINITIONS

Definitions of key terms are listed below. Throughout this policy, the term “reporting of financial interests” refers to the reporting of financial interests to Virtua. The term “disclosure of financial interests” refers to the disclosure of financial interests to peers, the public and others.

Business: (a) any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, limited liability company, trust or other for-profit commercial entity; and (b) any not-for-profit entity.

Conflict of Interest Training: required of all 'Investigators and study personnel' (defined below) prior to engaging in funded or unfunded research and every three years thereafter, and immediately under designated circumstances.

Family, with respect to any Investigator and study personnel, includes:

a. The Investigator's or study personnel's spouse or domestic partner

b. The Investigator's or study personnel's dependent child

Financial Conflict of Interest means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that Virtua reasonably determines could directly and significantly affect the design, conduct or reporting of unfunded or funded research.

Financial Interest means anything of monetary value received or held by an Investigator/Study Personnel or an Investigator's or study personnel'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 the Institution;
b) 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
c) 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.
d) 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. This does not include 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 and study personnel, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator/study personnel and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator/study personnel as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by 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.

Human Subjects Research: as defined in the Common Rule (45 CFR Part 46 and 21 CFR Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulations.

Interested Business: with respect to any Research conducted by an Individual, any Business that:

a. Funds such Research in whole or in part, whether through a Research agreement, gift or other arrangement;
b. Supplies drugs, devices, software, services, or other goods that are the subject of or used in connection to such Research, or other deliverables in connections with the Research, pursuant to a material transfer agreement, a Research agreement or otherwise'
c. Holds an Investigational New Drug application or Investigational Device Exemption for a Technology being investigated in such Research;

d. Owns, licenses or has any other contractual interest in a Technology being investigated in such Research; or
e. Acts for or on behalf of another Interested Business, directly or indirectly. Depending on the relationship, this could include some medical education companies and other similar entities.

Institutional official means the individual within Virtua that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's or Study Personnel's Family related to the Investigator's or Study Personnel's institutional responsibilities. For the purposes of this policy, the Institutional Official is designated as the Chief Clinical Officer.

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

Institutional Review Board (IRB): committee established in accordance with the Common Rule (45 CFR Part 46) with the authority to approve, require modifications in, or disapprove all University research activities involving human subjects.

Investigator: Principal Investigator, co-investigator(s), and any other Virtua personnel who, in the course of their association with Virtua are or will be responsible for the design, conduct and/or reporting of either funded research or unsponsored research activities. As used herein, the term 'Investigator" also covers collaborators, grantors, contractors or study personnel.

Public Health Service or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, 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: as defined in the Common Rule (45 Part 46), 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).

Research Conflict of Interest Committee (*RCOIC*) means the Institution's committee that advises the Institutional Official on conflict-of-interest matters. The Virtua Research Conflict of Interest Committee (RCOIC) serves as a resource with respect to matters involving conflicts of interest and the identification and management, mitigation, or elimination of specific conflicts of interest. The committee will work with the investigator(s) to resolve potential or apparent conflicts of interest by implementing reasonable controls which are commensurate with the potential conflict. The committee will also provide oversight for implementation of the Policy on Conflict of Interest and make recommendations to the Institutional Official on all future changes/modifications to the Policy.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator's/Study Personnel Institutional 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 related to intellectual property rights and interests not reimbursed through the Institution, or
e) is reimbursed or sponsored travel related to their institutional responsibilities.

Technology: any methodology, information, software, compound, drug, device, diagnostic, medical or surgical procedure, or composition of matter intended for public use or Research.

CONFLICT OF INTEREST:

This policy is predicated on the expectation that Investigator and study personnel should conduct their affairs to avoid or minimize conflicts of interest and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigator and study personnel about situations that generate conflicts of interest related to research, provides mechanisms for Investigator and study personnel and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator and study personnel has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raises any questions of conflict of interest, an Investigator/Study personnel should discuss the situation with the Institutional official.

1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigator and study personnel are required to disclose their outside Financial Interests as defined above, to Virtua on an annual and an ad hoc basis, as described below. The Institutional official or his/her appointed designee is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

a) Disclosure at the Time of Submission

Prior to (i) the submission of applications to sponsors for funds, (ii) the commencement of unsponsored research, (iii) approval of an IRB protocol, (iv) the execution of a licensing agreement with a publicly-traded company, specific to research, or (iv) the execution of a licensing agreement with a non-publicly traded company, specific to research, (v) the execution of a licensing agreement with a non-publicly traded company, specific to research, all investigators and study personnel must complete a disclosure form. If the investigator/study personnel has no such interest, the investigator/study personnel must certify as such. Virtua will not permit submission of a research proposal for a funded study or allow an investigator/study personnel to begin a non-funded study unless the Investigator(s)/study personnel have submitted such disclosures.

b) **Ad hoc Disclosures**

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigator must disclose their Significant Financial Interests to the Virtua Institutional Official, through the Human Research Protection Program, within 30 days of their initial employment.

In addition, all Investigator must submit to the Institutional official, via the Human Research Protection Program, 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 the Significant Financial Interest.

In addition, all Investigators and study personnel must submit to the Institutional official, via the Human Research Protection Program, 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 the Significant Financial Interest.

c) **Travel**

Investigators and study personnel must also disclose reimbursed or sponsored travel related to their institutional 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

Institutional 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.

Composition of the Research Conflict of Interest Committee

This committee shall consist of (i) four investigators and/or study personnel who have either participated in research funded through federal grants/contracts and/or conducted industry-sponsored research studies and (ii) someone with a nursing background for a total of five voting members. Representation will be determined by the Vice President of Clinical Learning and Research in consultation with the Executive Vice President & Chief Clinical Officer. The following will serve as liaison (non-voting) members of the committee: Director Research Administration, Director Human Research Protection Program, Vice President Internal Audit and Compliance, and General Counsel, or his/her designee.

2) Assessment of Significant Interests by a Research Conflict of Interest Committee

It is the responsibility of each member of the RCOIC to divulge any potential conflict of interest. If any member of a RCOIC has any real or apparent personal or professional conflicts of interest or bias with respect to the disclosure being considered, that member shall be recused. Such conflicts include, but are not limited to, involvement with the research in question, competition with the investigator, and a previous or ongoing close professional or academic relationship with the investigator, the sponsor, or competitor of the sponsor.

RCOIC will review all Disclosures of significant financial interests and determine whether or not there is a conflict and if there is, whether or not it can be managed.

3) REVIEW OF SIGNIFICANT FINANCIAL INTEREST RELATED TO CLINICAL RESEARCH

Subrecipient institutions of Virtua must comply with either Virtua's FCOI policy or their own, and must report any identified FCOIs to Virtua (when Virtua is the awardee institution) in sufficient time for Virtua to report the FCOI to the PHS Awarding Component (e.g. NIH, through the eRA commons FCIO module) to meet reporting obligations.

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.

4) REPORTING TO PHS

The Institutional 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.

5) INVESTIGATOR NON-COMPLIANCE

a) **Disciplinary Action**

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented. Non-compliance shall be reported by any knowledgeable individual to the RCOIC or the Director of the Human Research Protection Program. Non-compliance shall be investigated by the Human Research Protection

Program, a conclusion reached and sanctions or dismissal may be recommended to the Institutional Official. The Institutional Official shall have the final decision regarding sanctions or dismissal. Recommendations may also include notification to the sponsor and/or journal editors if non-compliance may have resulted in compromise of the integrity of the research and/or resulting publications or other communications.

Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the Investigator, RCOIC and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. The institution will promptly notify the PHS Awarding Component, as applicable, 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 Institutional 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, a committee appointed by the Institutional Official will complete a retrospective review of the Investigator's activities and research project within 120 days 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, PI, 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 Institutional 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.

6. RECORD RETENTION AND REPORTING

The Director, Human Research Protection Program shall maintain records of all disclosures of financial and other personal interests in, RCOIC determinations and recommendations, final decisions, actions taken to resolve conflicts of interest and the outcomes thereof for at least three (3) years from the date of submission of the final expenditure report of the project, or from the conclusion of unsponsored research, or until the resolution of any governmental or legal actions involving these records, whichever is longer.

Annually in January, the Director, Human Research Protection Program shall summarize for the Institutional Official all disclosures of significant interests, Committee determinations and recommendations, final decisions, actions taken and the outcomes thereof during the previous calendar year.

7. CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to the PHS Awarding Component, HHS or a sponsor, of information concerning financial conflict of interest related to funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

8. PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, the Institution 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.

The information to be made available shall be consistent with the requirements of the PHS regulation. It should include at a minimum the investigator name, title, role in the research, the name of the entity in which the significant financial interest is held, the nature of the financial interest, the approximate dollar value in ranges ($0-$4,999; $5,000-$9,999; $10,000-$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 references to public prices or other reasonable measures of fair market value.

9. **REGULATORY AUTHORITY**

This policy implements the requirements of 42 CFR 50 Subchapter D and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence. Standards set by governmental agencies will be monitored and considered in Virtua's routine review of this policy.