

<b><u>MANUAL TITLE</u></b> Administrative Leadership Manual		<b><u>POLICY NAME</u></b> Virtua Public Health Service (PHS) Research Financial Conflict of Interest Policy		
<b><u>MANUAL OWNER</u></b> Office of Research Administration	<b><u>DATE OF ISSUE</u></b> 07/01/2013	<b><u>DATE OF LAST REVIEW</u></b> 03/08/2018	<b><u>DATE OF REVISION</u></b> 03/08/2018	<b><u>EFFECTIVE DATE</u></b> 07/01/2013
<b><u>REVIEW INTERVAL</u></b> 24 Months	<b><u>REVIEWED / APPROVED BY: (Committees)</u></b> Office of Research Administration			
<b><u>THIS POLICY IS APPLICABLE TO:</u></b> Virtua - Memorial Hospital Burlington County, Inc. Virtua - West Jersey Health System, Inc. Virtua Medical Group				

Objective: To promote objectivity and elimination of bias in research. Describing the process and procedures for complying with the Public Health Service’s requirements for Financial Conflict of Interest Requirements for Research.

Responsible Parties:

1. Institutional Official
2. General Counsel
3. Principal Investigator (PI)
4. Sub-Investigator (Sub-I)
5. Director of Research Administration
6. Clinical Research Coordinators (CRC)
7. Clinical Research Nurses (CRN)
8. Clinical Research Medical Assistants (CRMA)

**INTRODUCTION**

This policy governing financial conflict of interest applies to all PHS-sponsored Investigators of Virtua. 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 these policies 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.

**PERSONS AFFECTED:**

This is a Virtua-wide policy that applies to all Investigators as defined below who conduct federally-funded research at Virtua. This policy does not cover conflicts of commitment or institutional Conflicts of Interest.

**ATTACHMENTS:**

1. Virtua Public Health Service (PHS) Research Financial Conflict of Interest (FCOI) Process
2. Virtua Public Health Services Research Financial Conflict of Interest Training Form
3. Disclosure Statement for Financial Conflict of Interest in Research for Projects Funded by the Public Health Service (PHS)

## **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 Committee (COI Committee)* means the Institution’s committee or individual that advises the Institutional Official on conflict of interest matters. The committee consists of the Chief Medical Officer, Virtua General Counsel, the IRB Administrator, the AVP of Clinical Learning and Academic Affiliations, Corporate Compliance Officer, and the Director of Research Administration. The Director of Research Administration will be the Chair of the committee.

*Family*, with respect to any Investigator, includes:

- a. The Investigator’s spouse or domestic partner
- b. The Investigator’s dependent child

*Financial Interest* means 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 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.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional 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 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* means a Financial Interest that reasonably appears to be related to the Investigator’s 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.

*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 PHS-sponsored research.

*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 Family related to the Investigator'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 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.

*Investigator* means any individual who is responsible for the design, conduct, or reporting of PHS sponsored 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* 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.

- a. Remuneration includes: Salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship) from any person or entity other than Virtua;
- b. 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, as long as the Investigator does not directly control the investment decisions made in these vehicles.

*Research* means 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).

*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 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 Institution 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 Institutional official.

### **1) DISCLOSURE OF FINANCIAL INTERESTS**

All Investigators are required to disclose their outside financial interests as defined above to Virtua on an annual and on an ad hoc basis, as described below. The Institutional official or his or her appointed designee is responsible for the distribution, receipt, processing, review and retention of disclosure forms. The COI Committee will assist with the distribution and review of those forms and processes.

#### **a) Annual Disclosures**

All Investigators must disclose their Significant Financial Interests that are related to the investigator's institutional responsibilities to the Virtua by submitting Virtua's Annual Public Health Service Conflict of Interest Questionnaire to the Institutional Official, via the Office of Research Administration on an annual basis. All forms should be submitted to the Institutional official or designee by March 1 for the previous calendar year.

#### **b) Disclosure at the Time of Submission**

All Investigators are required to disclose their Significant Financial Interests or update their disclosure at the time of submission of a protocol or application for PHS funded research. Virtua will not permit submission of a research proposal to the PHS unless the Investigator(s) have submitted such disclosures.

#### **c) Ad hoc Disclosures**

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Virtua Institutional Official, through the Office of Research Administration, within 30 days of their initial appointment or employment.

In addition, all Investigators must submit to the Institutional official, via the Office of Research Administration, 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.

**d) Travel**

Investigators 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.

**2) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL**

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional 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 Institutional 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 Institutional 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 Institutional 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.

**3) REVIEW OF SIGNIFICANT FINANCIAL INTEREST RELATED TO CLINICAL RESEARCH**

Subrecipient institutions of Virtua must comply with either Virtua's PHS FCOI policy or their own, and must report any identified FCOIs to the 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.

A 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, COI Committee 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 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 the PHS-sponsored 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) 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 Institutional 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 Virtua, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

### **7) RECORD RETENTION**

The Institutional 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.

## **8) 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 and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS 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.

## **9) 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 reference to public prices or other reasonable measures of fair market value.

## **10) REGULATORY AUTHORITY**

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.

# **VIRTUA PUBLIC HEALTH SERVICE (PHS) RESEARCH FINANCIAL CONFLICT OF INTEREST (FCOI)**

## **Process**

### Notification of Policy

The Virtua PHS FCOI policy will be published on the Virtua.org website. The PHS FCOI Institutional Official (the Chief Clinical Officer) will send an email (or letter) on an annual basis to all Virtua employees to notify all that Virtua has a PHS FCOI that can be accessed through the [www.Virtua.org](http://www.Virtua.org) website, as well as through the Office of Research Administration. The letter will instruct potential investigators that they must complete the PHS FCOI training, both general and institutional, prior to submitting a request for research funding to any Public Health Service funding source. The letter will also instruct potential investigators to contact the Office of Research Administration for additional information. In addition, the IRB submission form requires the investigator to reveal the funding source of each research trial. Any investigator who submits a trial to the Virtua General IRB, where a PHS funding source is indicated, will be directed to contact the Office of Research Administration for information regarding the Research PHS FCOI policy.

### Training

PHS FCOI training for investigators will comprise of both general and institution-specific training. The training must be completed according to the timelines set out in the Virtua Research PHS FCOI Policy. The general training will be the Conflicts of Interest – Stage 1 module available online at [www.citiprogram.org](http://www.citiprogram.org). The investigator will be required to submit a copy of the completion certificate to the Director of Research Administration.

The institution-specific training will require a review of the Research PHS FCOI policy by the investigator, followed by a discussion between the investigator and the Director of Research Administration to ensure that the investigator thoroughly understands the policy. The investigator will then be required to complete a Virtua Public Health Services Research Financial Conflict of Interest Training Form, documenting both comprehension and agreement to follow the policy. All paperwork will be distributed by the Office of Research Administration. All completed documents and certificates will be sent directly to the Director of Clinical Research for review and tracking. The Office of Research Administration will contact the appropriate investigators 60 days prior to any subsequent training completion date, and will send out renewal forms necessary to complete ongoing training 60 days prior to the date due, to encourage compliance with the policy.

### Disclosure, Review and Monitoring

An investigator applying for PHS funding for research, must contact the Office of Research Administration regarding PHS FCOI prior to applying for the funding. The Office of Research Administration will ensure that all required training has been completed and will collect all training documentation. The Office of Research Administration will provide the investigator with the PHS FCOI forms to be completed. Once completed by the investigator, the forms will be forwarded to the Office of Research Administration which will track all forms and due dates for subsequent form submissions. Approximately 60 days prior to any subsequent due date of an FCOI form, the Office of Research Administration will contact the investigator by phone and/or email to request completion of the new FCOI form.

All FCOI forms will first be reviewed by the Director of Research Administration for completeness. Form will be reviewed by at least two members of the COI Committee for any potential related Financial Conflict of Interest. Any forms found to have a possible related Financial Conflict of Interest will be forwarded to the Institutional Official for final review within 30 days of the completion date of any PHS FCOI form. The Institutional Official will determine whether there is a true FCOI that requires management. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The Institutional Official may consult with the COI Committee to determine whether a Significant Financial Interest (SFI) is a FCOI. If the Institutional Official determines that an FCOI does exist, he or she will develop and implement a management plan within 30 days, to mitigate or remove the impact of the FCOI. Once a management plan is implemented, the Institutional Official will monitor the compliance of the investigator through the completion of the project.

If the Institutional Official identifies an SFI that was not disclosed in a timely manner by an investigator, the Institutional Official will initiate a management plan within 60 day so of the discovery, and monitor the compliance of the investigator through the completion of the project. A retrospective review will be performed if applicable.

#### Reporting to Public Health Services (PHS)

The Institutional Official and the Director of Research Administration will provide the PHS with all PHS FCOI required reporting elements:

- Prior to the expenditure of funds
- Within 60 days of identification for an investigator who is newly participating in a project
- Within 60 days for new, or newly identified, FCOIs for existing investigators
- At least annually (at the same time as when the Institution is required to submit the annual progress report, if applicable, or at the time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project
- Following a retrospective review to update a previously submitted report, if appropriate

If bias is determined to have occurred with the design, conduct or reporting of PHS-funded research, the Director of Research Administration will notify the Institutional Official who will report the bias, with all required reporting elements, to the PHS promptly. Within 30 days of any such discovery, the Institutional Official will complete and submit a Mitigation Report to the PHS, in accordance with regulation 42 CFR 50.605 (a)(3)(iii).

If it is discovered that an investigator has failed to comply with Virtua's PHS Research FCOI policy, or if an FCOI management plan appears to have biased the design, conduct or reporting of PHS-funded research, the Institutional Official will notify the PHS of discovery within 30 days, and will take corrective action for noncompliance, which will be documented and provided to the PHS.

#### Reconsideration

If an investigator objects to the FOCI decision or management plan they will have fifteen days to compose an appeal explaining their objection. The Institution Official may choose to complete a second review or he may deny it.

#### Maintenance of Records

Virtua will retain all Research PHS FCOI-related records for a minimum of 3 years from the date that the final expenditures report is submitted to the PHS (NIH) or for a minimum of the dates specified in 45 CFR 74.53(b) and 92.42(b), where applicable.

#### Enforcement Mechanisms, Remedies and Noncompliance

The Institutional Official will take necessary enforcement actions, and provide for any necessary employee sanctions or administrative actions in order to ensure investigator compliance.

In cases where it is determined that SFIs were not disclosed in a timely manner or an FCOI is not identified or managed in a timely manner or reviewed appropriately, or an FCOI is not identified or managed in a timely manner, the Virtua Compliance Officer will conduct a retrospective review, and will document the review consistent with regulation 42 CFR 50.605(a)(3).

In any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research 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 an FCOI that was not managed or reported by the Virtua as required by the regulation, Virtua shall require the Investigator to disclose the FCOI in each public presentation of the results of the research, and to request an addendum to previously published presentations.

#### Subrecipient Requirements

Subrecipient institutions of Virtua must comply with either Virtua's PHS FCOI policy or their own, and must indicate in writing which Institution's policies they will follow. If following their own FCOI policies, the subrecipient Institution should indicate via a written agreement that they will report identified FCOIs for its Investigators in a time frame that allows Virtua to report identified FCOIs to the NIH as required by regulation. Alternatively, if following Virtua's PHS FCOI policies, the subrecipient Institution should indicate via a written agreement that they will allow Virtua to solicit and review subrecipient Investigator disclosures that enable the awardee Institution to identify, manage and report identified FCOIs to the NIH.

#### Public Accessibility

In addition to posting the Virtua PHS FCOI policy on the [www.Virtua.org](http://www.Virtua.org) website within 30 days of enacting the policy, Virtua will make available information concerning identified FCOIs held by senior/key personnel (as defined by regulation 42 CFR 50.605(a)(5)(i)-(iv), publically accessible prior to the expenditure of funds. The information will include the minimum elements as provided in the above-mentioned regulation, will be posted on the [www.Virtua.org](http://www.Virtua.org) website, and will be updated at least annually. The information will be updated within 60 days of any newly identified FCOI and will remain available on the website for a minimum of three years from the date the information was most recently updated.

Virtua Public Health Services Research  
Financial Conflict of Interest Training Form

I hereby certify that I have read and understand Virtua's Public Health Services Research Financial Conflict of Interest Training policy. I will comply with any conditions or restrictions imposed by Virtua to manage, reduce, or eliminate potential conflicts of interest in Public Health Services (PHS)-sponsored research.

---

Print Name

---

Date

---

Signature

## Virtua

### Disclosure Statement for Financial Conflict of Interest in Research for Projects Funded by the Public Health Service (PHS)

For complete information, see the Virtua Policy on Public Health Services (PHS) Research Financial Conflict of Interest at [www.Virtua.org](http://www.Virtua.org) or request a written copy from the Office of Research Administration. Please contact the Office of Research Administration at 856-761-3904.

In compliance with Virtua's policy on Public Health Services (PHS) Research Financial Conflict of Interest, prior to Virtua submitting an application for research funding to a PHS agency, each investigator responsible for the design, conduct, or reporting of the research activities must disclose to Virtua all his/her significant financial interests, and those of his/her spouse/domestic partner, and dependent children, that are related to the investigator's institutional responsibilities (see list of definitions at the end of this form).

1. **Name:**
2. **Position:**
3. **Department/Center:**
4. **Email/Phone:**
5. **Institution :**
6. **If you are not a Virtua employee, who is the Virtua employee who is the Principal Investigator for the PHS award?**
7. **Title of project/proposal:**
8. **Does any of your research involve use of human subjects?** \_\_\_\_ No \_\_\_\_ Yes
9. **This disclosure is an:**
  - a.  Initial disclosure for a new application to a PHS agency for research funding
  - b.  Initial disclosure for an ongoing PHS-funded project
  - c.  Ongoing update to an existing disclosure
  - d.  Annual update to an existing disclosure

#### 10. Financial interests:

<b>A. Only for updates (i.e., 9 c or d) to existing disclosures:</b> There have been no changes since my last disclosure.	Yes <input type="checkbox"/>
B. In the twelve months preceding this disclosure, did you, your spouse/domestic partner and/or your dependent children receive remuneration related to your institutional responsibilities from a publicly traded entity? (E.g., salary; payment for services; consulting fees; honoraria; paid authorship; compensation for service on advisory committees or review panels or for providing expert testimony; gifts; gratuities, etc.)	Yes <input type="checkbox"/> No <input type="checkbox"/>
C. Do you, your spouse/domestic partner, and/or your dependent children hold any equity interest in a publicly traded entity related to your institutional responsibilities? (E.g., stock, stock option, other ownership interest.)	Yes <input type="checkbox"/> No <input type="checkbox"/>
D. If Yes to question 10, part B and/or C (above), does the value of the remuneration received in the twelve months preceding this disclosure, aggregated with the value of any equity interest as of the date of this disclosure, exceed \$5,000?	Yes <input type="checkbox"/> No <input type="checkbox"/>
E. In the twelve months preceding this disclosure, did you, your spouse/domestic partner, and/or your dependent children receive remuneration related to your institutional responsibilities from a non-publicly traded entity, that when	Yes <input type="checkbox"/> No <input type="checkbox"/>

aggregated, exceeds \$5,000? (E.g., salary; payment for services; consulting fees; honoraria; paid authorship; compensation for service on advisory committees or review panels or for providing expert testimony; gift; gratuities.)	
F. Do you, your spouse/domestic partner, and/or your dependent children hold any equity interests related to your institutional responsibilities in a non-publicly traded entity? (E.g., stock, stock option, other ownership interest.)	Yes <input type="checkbox"/> No <input type="checkbox"/>
G. Have you received income related to intellectual property rights and interests not assigned to Virtua, and/or royalty income other than from Virtua, related to your institutional responsibilities? (E.g., patents, copyrights.)	Yes <input type="checkbox"/> No <input type="checkbox"/>
H. In the twelve months preceding this disclosure, did you, your spouse/domestic partner and/or your dependent children engage in travel related to your institutional responsibilities that is paid for on your behalf (and not reimbursed to you so that the exact monetary value may not be readily known) by a sponsoring/ reimbursing entity other than a/an: <ul style="list-style-type: none"> <li>i. Federal, state, or local government agency,</li> <li>ii. Institution of higher education as defined at 20 U.S.C. 1001(a),</li> <li>iii. Academic teaching hospital,</li> <li>iv. Medical center, or</li> <li>v. Research institute that is affiliated with an institution of higher education?</li> </ul>	Yes <input type="checkbox"/> No <input type="checkbox"/>

If you answered “Yes” to A, or “No” to B-H, you are finished with this form. Please sign and date the form, and submit as instructed below.

**If you answered “Yes” to questions D, E, F, G, or H, please:**

- Sign and date this form;
- Complete, sign, and date a Disclosure Attachment (following document) providing the requested information for **EACH** applicable entity;
- Attach a description of your proposed/ongoing research proposed for funding or funded by a PHS-agency;
- Attach a description of your role and principal duties in the research proposed for funding/ funded by a PHS-agency; and,
- Submit as instructed below.

In signing and submitting this form, I certify that:

- The information provided above is true to the best of my knowledge.
- The information provided above conveys an accurate and current statement of all financial interests held by me and/or my family member(s) that reasonably appear to be related to my institutional responsibilities.
- I will update this disclosure during the period of the award as new reportable significant financial interests are obtained per the Virtua policy on Public Health Services (PHS) Research Financial Conflict of Interest (within 30 days of discovering/acquiring a new SFI, and at least annually during the award period).
- I will comply with any conditions or restrictions imposed by Virtua to manage, reduce, or eliminate actual or potential conflicts of interest, or forfeit the award.
- If a financial conflict of interest is identified, a conflict management plan will fully executed prior to expenditure of any funds on a PHS-funded project.

Signed: \_\_\_\_\_ Date \_\_\_\_\_

Please submit all documentation in a sealed envelope marked confidential to: Director of Research Administration, Virtua Office of Research Administration, Center for Learning, 1200 Howard Blvd., Suite 100, Mount Laruel, NJ, 08054.

**Virtua**  
**Disclosure Statement for Financial Conflict of Interest in Research for Projects**  
**Funded by the Public Health Service (PHS)**

**Part A ~ Publicly Traded Entities**

Please complete this Disclosure Attachment Part A to further describe a "Yes" answer *for each publicly traded entity* on your Financial Conflict of Interest in Research in PHS-Funded Projects Disclosure Statement.

- For each entity, complete the following tables for all that apply for the 12 months preceding this disclosure.
- Use the Passive Stock Ownership table for publicly traded companies in which you own stock solely as an outside investor and none of the elements of personal involvement listed in the Other Financial Interests table applies (add lines to the table as necessary).
- Use the Other Financial Interests charts to break out details of any interest you may have that involves or results from an active role or relationship with a publicly traded company for which you received direct or indirect remuneration (reproduce the table on the form as necessary).

Passive Stock Ownership		
Name of Stock	Fair Market Value	Check to Indicate No Personal Involvement

Other Financial Interests							
Name of Entity:				Name of Entity:			
Type of remuneration	You	Related Party	Amount/ Value		You	Related Party	Amount/ Value
Salary				Salary			
Payment for services				Payment for services			
Consulting fees				Consulting fees			
Paid authorship				Paid authorship			
Service on advisory Committee				Service on advisory committee			
Service on review panel				Service on review panel			
Expert testimony				Expert testimony			
Gifts				Gifts			
Gratuity				Gratuity			
Stocks				Stocks			
Stock options				Stock options			
Other ownership interests				Other ownership interests			
Royalty payments				Royalty payments			
Other (specify):				Other (specify):			
Sponsored Travel:				Sponsored Travel:			
Purpose of trip:				Purpose of trip:			
Destination:				Destination:			

Dates of trip:		Dates of trip:	
----------------	--	----------------	--

Financial Conflict of Interest in Research in PHS-Funded Projects Disclosure Attachment:

**Part B ~ Non-Publicly Traded Entities**

▪ Please complete this Disclosure Attachment Part B to further describe a "Yes" answer **for each non-publicly traded entity** on your Financial Conflict of Interest in Research in PHS-Funded Projects Disclosure Statement. Reproduce this form as needed.

- 1. What is the name of the external entity in which you, your spouse/domestic partner, and/or dependent children has/have a significant financial interest?**

- 2. Briefly describe the primary business of this entity.**

- 3. Explain who (you, your spouse/domestic partner, and/or dependent children) holds the financial interest, and describe the role(s) of you, your spouse/domestic partner, and/or dependent children with this entity (e.g., shareholder, director, officer, employee, consultant).**

- 4. If applicable, describe the nature of the work that you, your spouse/domestic partner, and/or dependent children perform for this entity.**

- 5. Indicate the aggregate annual amount of remuneration (including, but not limited to: consulting fees, honoraria, and paid authorship) received from this entity in the 12 months preceding the date of this disclosure by checking the appropriate box:**

- Less than \$5,000
- More than \$5,000
- Not applicable

**6. Indicate the type of financial interest you, your spouse/domestic partner and/or dependent children has/have regarding this entity (check all applicable items):**

- a.**  Stock, stock option, partnership share or other ownership interest

**i.** Please state the fair market value of the ownership interest as of the date of this disclosure: \$

**ii.** Please state the percentage of ownership interest as of the date of this disclosure: %

- b.**  Intellectual property, such as pending patent applications (including provisional applications), issued patents, trademarks, or copyrights, or royalties received for intellectual property. Do not include information on intellectual property rights and interests assigned to Virtua, nor royalty income received from Virtua. Please describe the intellectual property to which these interests are related, and any associated agreements with Virtua, including licenses.

- c.**  Consulting income from entity
- d.**  Service in an executive position for a business, or compensation for service on boards
- e.**  Salary as an employee
- f.**  Payments for authorship, editing, lectures, teaching, commissioned papers, or expert testimony
- g.**  Gifts, gratuities, favors or anything of monetary value
- h.**  Other financial interest(s) that may affect or be perceived to affect the results of the research activities funded or proposed for funding.

Please explain items **c** through **h**.

**7. For any travel in the twelve months preceding this disclosure by you, your spouse/ domestic partner and/or your dependent children related to your institutional responsibilities that is paid for on your behalf by this entity (and not reimbursed to you so that the exact monetary value may not be readily known), please provide the following information:**

1. Purpose of the trip:
2. Destination of the trip:
3. Duration of the trip:

**8. Does/will this entity or any of its employees use Virtua space/facilities or equipment on behalf of the entity? \_\_\_\_ No \_\_\_\_ Yes. If Yes, describe the resources to be used and indicate whether there is a written agreement between Virtua and the entity to manage their use (if yes, please attach a copy of the agreement).**

**9. Please describe how the disclosed relationship with this entity relates, or appears to relate, to your Virtua institutional responsibilities.**

**10. Please describe how the disclosed relationship with this entity relates, or appears to relate, to the proposed research.**

In signing and submitting this form, I certify that:

- The information provided above is true to the best of my knowledge.
- The information provided above conveys an accurate statement of all financial interests held by me and/or my family member(s) that would reasonably appear to affect or be affected by the proposed research.

- Per the Virtua policy on Financial Conflict of Interest in Research for PHS-Funded Projects, I will update this disclosure during the period of the award as new reportable significant financial interests are obtained (within 30 days of discovering/acquiring a new SFI, and at least annually during the award period).
- I will comply with any conditions or restrictions imposed by Virtua to manage, reduce, or eliminate actual or potential conflicts of interest, or forfeit the award.
- If a financial conflict of interest is identified, a conflict management plan will be fully executed prior to expenditure of any PHS project funds.

Signed: \_\_\_\_\_ Date \_\_\_\_\_

## Financial Conflict of Interest in Research for PHS-Funded Projects Frequently Asked Questions

### Who is required to complete this disclosure form?

Any individual, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. This may include, for example, collaborators or consultants.

### What is a financial conflict of interest (FCOI)?

A financial conflict of interest is caused by any significant financial interest that could directly and significantly affect the design, conduct, or reporting of Public Health Service (PHS)-funded research. A conflict is identified when it can be reasonably determined that the significant financial interest could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research.

### What is a significant financial interest (SFI)?

When concerning PHS-funded projects, a significant financial interest is any financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse or domestic partner, and dependent children) that reasonably appears to be related to the investigator's institutional responsibilities:

#### Publicly traded entities:

A SFI exists if the value of any **remuneration** received from the entity **in the twelve months preceding the disclosure** aggregated with the **value of any equity interest** in the entity **as of the date of disclosure exceeds \$5,000**. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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.

#### Non-publicly traded entities:

A SFI exists if the value of any **remuneration** received from the entity **in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000**, or when the investigator (or the investigator's spouse or domestic partner or dependent children) holds **any equity interest** (e.g., stock, stock option, or other ownership interest).

#### Intellectual property rights and interests (e.g., patents, copyrights):

A SFI exists upon **receipt of income related to such rights and interests**.

#### Sponsored Travel:

A SFI exists when the investigator (and/or investigator's spouse/domestic partner and dependent children) in the twelve months preceding the disclosure engages in travel related to his/her institutional responsibilities which is paid for on his/her behalf by an entity and not reimbursed to the investigator so that the exact monetary value may not be readily known. This does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

### How should individuals decide if an equity interest in a publicly traded company may reasonably appear to be related to their institutional responsibilities?

Individuals must make an educated attempt at deciding whether an equity interest, such as a stock, would reasonably appear to be related to their Virtua responsibilities, including service responsibilities. For example, a health economist would probably not need to disclose ownership of stock in Boeing Aircraft, but should disclose stock owned in Johnson & Johnson. When in doubt, it is safest and least time-consuming to err on the side of disclosure.

## **How should individuals decide if their disclosed relationship with the entity relates, or appears to relate, to the proposed research?**

Individuals should think broadly when trying to decide if their disclosed relationship with the entity relates, or appears to relate, to the proposed research. For example, an individual has a consulting relationship with an entity that is centered on project X and has submitted a grant proposal to a federal agency for project Y; project X and project Y are not related and require different skills and knowledge. The individual should consider whether there is any way that the results of the research project could affect the entity positively (creating an appearance of conflict because of the individual's interest in future consulting work) or negatively (creating an appearance of conflict because the work might dampen the individual's prospects for future consulting work). If so, there may be an appearance of a conflict of interest even though the consulting work for the entity is not related in any way to the research proposal.

## **When do I submit this disclosure?**

### Initial Disclosure Process for New PHS-Funded Projects:

*No later than the time of Virtua's submission of a proposal for research funding to a PHS agency, each individual responsible for the design, conduct, or reporting of research activities funded or proposed for funding by PHS must disclose to Virtua all his/her SFIs related to his/her institutional responsibilities, along with any SFI's of his/her spouse or domestic partner and dependent children.*

### Initial Disclosure Process for Addition of an Investigator to an Ongoing PHS-Funded Project:

*Before commencing any activities on the project, each individual responsible for the design, conduct, or reporting of research activities who joins an ongoing PHS-funded project must disclose to Virtua all his/her SFIs related to his/her institutional responsibilities, along with those of his/her spouse or domestic partner and dependent children.*

### Updates of Existing Disclosures:

*Within thirty (30) business days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest, each investigator who is participating in PHS-funded research must submit an updated disclosure of SFIs.*

## **To whom do I submit this disclosure?**

Please submit all documentation in a sealed envelope marked confidential to: Director of Research Administration, Virtua Office of Research Administration, Center for Learning, 1200 Howard Blvd., Suite 100, Mount Laurel, NJ 08054.