Researcher Conflict of Interests Policy

Responsible Office:
Office of Research

POLICY STATEMENT AND PURPOSE

The purpose of this Researcher Conflict of Interests Policy (hereinafter, the "Policy") is to define the process for identifying, reporting, evaluating, and managing investigators' financial relationships that have or may have an impact on the objectivity and integrity of research conducted at Virginia Commonwealth University

WHO SHOULD READ THIS POLICY

All University Members involved in the design, conduct, review, reporting, or supervision of research should read this Policy.

RELATED DOCUMENTS

Objectivity in Research – Public Health Service (PHS) Rules
Conflict of Interest – National Science Foundation (NSF) Rules
21 CFR 54 – FDA regulation for Financial Disclosure by Clinical Investigators
Virginia State and Local Government Conflict of Interests Act

Institutional Conflict of Interests in Human Subjects Research (URL Pending)

Conflict of Interests Policy within the VCU Financial Policies
Outside Professional Activity and Employment, Research, and Continuing Education
Policies and Procedures for Misconduct in Research and Scholarly Activities

VCU Institutional Review Board (IRB) Written Policy and Procedure #VIII-10 *Evaluating Investigator Conflicts of Interest*

CONTACTS

VCU Office of Research officially interprets this policy and will prepare revisions, as needed, to meet the changing needs of Virginia Commonwealth University. All revisions shall be subject to University Board of Visitors approval following review by university leadership (Vice Presidents, Council of Deans, University Council, and Faculty Senate).

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DEFINITIONS

Conflicts of Interest exist when financial or other personal interests or considerations of the researcher, or members of his or her immediate family, may directly and significantly affect, or have the appearance of directly and significantly affecting, a researcher's professional judgment in exercising any University duty or responsibility, including the design, conduct or reporting of research. Researcher financial Conflicts of Interests occur when the researcher, or any member of that person's immediate family (spouse, or domestic partner, and any other person residing in the same household as the researcher, who is a dependent of the researcher or of whom the researcher is a dependent, possesses a prohibited financial interest in a research activity that involves his or her University responsibilities. For some activities, such as human subjects research, any financial interest will be deemed to give rise to a Conflict

of Interests whereas in other situations, only a Significant Financial Interest (as that term is defined in this Policy) will give rise to a prohibited Conflict of Interests.

Conflict of Interests Committee *(for research)* is a standing committee of the University, composed of faculty and administrative personnel, as needed, and convened under the authority of the Vice President for Research by his or her designee. The Committee is charged to evaluating investigator reports of financial conflicts of interest and determines an appropriate resolution, including the development/recommendation of a management strategy, as appropriate. Committee members are responsible for adhering to applicable rules of privacy and confidentiality when commencing conflict of interests assessments.

Financial Interest (for the purposes of this policy) includes anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees, honoraria, or payments for serving on a corporate Board of Directors or Scientific Advisory Board); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). It does not include salary, royalties, or other remuneration originating from VCU or the VCU Health Systems, income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities, or income from service on advisory committees or review panels for public or nonprofit entities.

Financial Interest Related to the Research, under FDA regulations, means a financial interest in the sponsor, product, or service being tested, or competitor of the sponsor or product or service being tested.

Investigator* or *Researcher describes any individual who is responsible for the design, conduct, or reporting of a research project. The roles of individuals with such research responsibilities may be, but are not limited to, key personnel, co- or sub-investigator, medical investigator, student, trainee, or research coordinator.

Significant Financial Interest *(or Personal Interest, as termed in the Virginia Code)* includes Financial Interest, as defined above, at an income level exceeding $10,000 per year and/or equity interests of 3% or more, individually or in aggregate, accruing to the researcher or any member of the researcher's immediate family.[1] In the case of NIH sponsorship, this term does not include investigator ownership interests in the institution,

[1] A Significant/Personal Interest also may exist by virtue of ownership of real estate or personal property, the value of which exceeds $10,000, or personal liability (e.g., debt) assumed on behalf of a business if the liability exceeds 3% of the net assets of the business.

if (1) the institution is an applicant under the Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer Program (SBTT), and (2) the funding is for Phase I support. To the extent to which state law deviates from, and imposes more strict criteria than federal law and/or regulations, VCU, as a public instrumentality of the Commonwealth of Virginia, necessarily must defer to state law.

INTRODUCTION

Conflicts of Interests exist in many forms and frequently are inherent to the nature of the research enterprise. A Conflict of Interest can arise in situations in which there exists discord between a primary duty and a secondary interest. While such interests can be either financial or non-financial, they, nevertheless, can yield conscious or subconscious bias in the conduct and/or interpretation of research, and, potentially can adversely impact the safety of human or animal research subjects. Often financial Conflicts of Interest will simply present an appearance of compromising an investigator's professional judgment in conducting or reporting the results of research. Accordingly and whether real or only perceived, all identified conflicts of interests must be addressed. Investigators and participants in the research enterprise must be able to recognize real or perceived conflicts and report them as required by this Policy. Where appropriate, Conflicts of Interests must be managed in keeping with recommendations of the Institutional Conflict of Interests Committee.

Faculty and non-faculty employees generally are encouraged to engage in outside professional activities and relationships so long as such relationships and activities are consonant with the objectives of the University and are mutually beneficial to participants as well as to society, at large. While Conflicts of Interests also may involve institutional relationships with for-profit or non-profit entities that may need to be addressed, this Policy focuses on Conflicts of Interests involving individual Investigators and members of the research team.

This policy is largely governed by the Virginia State and Local Government Conflict of Interests Act., which may be found in the Code of Virginia, beginning with Section 2.2-3100 Faculty and non-faculty employees should be aware of the provisions of State law as well as VCU's Policy on Outside Professional Activity and Employment, Research, and Continuing Education and the University's Conflict of Interests Policy, included within the University's Financial Policies.

POLICY

Researcher Conflicts of Interests

Conflicts of Interest may exist in situations in which financial or other personal considerations may directly and significantly affect, or have the appearance of directly and significantly affecting, a Researcher's professional judgment in exercising any University duty or responsibility, including the design, conduct or reporting of research. A Researcher at VCU may be considered to have a Conflict of Interest when he or she, or a member of that person's immediate family, as previously defined, possesses a personal or Financial Interest in an activity that involves his or her University responsibilities.

University policy expects Researchers at VCU to avoid Conflicts of Interests that may, or may appear to, (1) compromise objectivity in carrying out University research responsibilities; (2) adversely affect the University's interests; or (3) otherwise compromise the performance of University responsibilities, unless such conflicts are managed, reduced or eliminated in accordance with this Policy. Research activities and responsibilities are meant to be all-inclusive under this policy and include research design and proposal writing, applying for research funding, performing research, reviewing research proposals and protocols, reporting Intellectual Property (IP) resulting from research activities, entrepreneurship and new venture creation as they relate to the results of research, and reports of research results in any form.

PROCEDURE

Reporting by the Researcher

The Principal Investigator, or Researcher, and all other involved investigators must submit a completed Conflict of Interests Reporting Form and a Supplement Form, as appropriate, with (1) each new, continuation, or revised grant or contract application submitted to the Office of Sponsored Programs, (2) each new protocol involving animal or human subjects, and (3) whenever there is a change in status from the previous report. The Financial Interests of each Investigator, as well as those of the immediate family, are subject to financial Conflict of Interests reporting.

In the event an Investigator is the applicant who submits a marketing application for FDA approval, the applicant is responsible for submitting the appropriate certification and reporting statements to the FDA, in addition to those submitted to VCU. Information about such statements appears in Part 54 of the FDA federal regulations.

Conflict of Interests reporting, assessment, and management is addressed in federal regulations pertaining to federal funding agencies, such as NIH or NSF, and for research seeking FDA approval. VCU policies for reporting and dealing with financial Conflicts of Interest reflect the stricter requirements of the Commonwealth of Virginia in areas where federal regulations differ.

Review by the Conflict of Interests Committee

If a real or apparent Conflict of Interest is reported on the part of an Investigator or a member of his/her immediate family, it will be referred to the Conflict of Interests Committee (COIC), which will evaluate the report. Once referred to the COIC, an Investigator may not proceed in research, nor may he/she assign students, post-doctoral fellows or other trainees to the research, without prior approval of the COIC if:

- The Investigator has any Financial Interest and the research involves human subjects or is being conducted for the purpose of regulatory approval (by the FDA, for example); or
- The Investigator has a Significant Financial Interest even though the research neither involves human subjects nor is being conducted for the purpose of regulatory approval.

Additional approval is required if the sponsor of the research is a business in which a University employee has a Significant Financial Interest.

Members of the COIC who have financial or non-financial interests in a particular proposal or IRB or IACUC protocol shall recuse themselves from review of said protocol.

Managing Conflicts of Interest

If a Conflict of Interest exists that would reasonably appear to compromise the objectivity of the research, the COIC requires that a strategy for managing, reducing, or eliminating the conflict must be adopted prior to expenditure by VCU of any part of any sponsored research award or contract and/or before the research begins. The Investigator reporting a Conflict of Interest on the Reporting and/or Supplement Forms may propose a management strategy for ensuring research objectivity that will be considered by the COIC. Possible strategies for management of Conflicts of Interest include, but are not limited to:

- public disclosure of the financial interest;
- written affirmation of the VCU COI and/or IP Policy;
- monitoring of research by independent reviewers;
- modification of the research plan;
- disqualification of an Investigator(s) from participation in all or a portion of the research;
- divestiture of the Financial Interest;
- severance of relationships that create Conflicts of Interest; or
- VCU declining the award.

For management plans that require monitoring of the research, individuals reporting financial or non-financial Conflicts of Interest in the project shall not be assigned as independent reviewers.

In circumstances wherein a VCU researcher has a Significant Financial Interest, or personal interest (termed as such in state law), in a contract between VCU and research and development or commercialization of intellectual property, or a business, the COIC will require additional consultation in dealing with the conflict of interests, as provided in Virginia Code.

The COIC has the authority to modify and approve, or disapprove, the Investigator's proposed management strategy, if submitted. A final management strategy developed by the COIC must be accepted in writing by the Investigator.

The signed management strategy notice must be shared with the appropriate academic Dean. It must also be submitted to:

1. the *Office of Sponsored Programs* prior to expenditure by VCU of any part of the affected award. The management

strategy will become part of the sponsored program record maintained by VCU.

2. the *Office of Research Subjects Protection,* as applicable, for review by the IRB or IACUC. The COIC-approved management strategy may not be altered by the IRB or IACUC but it may be augmented to ensure the optimal protection of research subjects. For example, the IRB may require disclosure in the informed consent form or the IACUC may require additional safeguards to protect the well-being of laboratory animals. The research protocol cannot be approved until the IRB or IACUC have reviewed the COIC management plan. The COIC management strategy, together with any additional requirements by the IRB or IACUC, will become part of the approved protocol record maintained by VCU.

The Investigator must provide the COIC and appropriate academic Dean with an annual update on the fulfillment of the management strategy. Monitoring compliance with the agreed strategy shall be the responsibility of the Dean.

An appeal of a COIC determination can be made directly to the COIC Chairperson who may call for reconsideration by the COIC if additional supporting information has become available since the initial review. The conflicted individual may be required to attend the reconsideration session. The decision of the COIC re-review may be further appealed to the Vice President for Research (VPR) by an Investigator. The Investigator must notify the VPR of any intended appeal within 5 days of receiving notice of the management plan. The VPR will form an *ad hoc* Appeal Panel comprised of three senior faculty, and other consultants as needed, who will have 30 work days to review the relevant materials. The Appeal Panel's recommendation is made to the VPR who will render a decision within 10 work days. The decision of the VPR will be final and there shall be no further appeal within the University.

Reporting Significant Conflicts of Interest by VCU

Significant Financial Conflicts of Interest must be reported to PHS (Public Health Service) sponsors, as required by the relevant federal agencies, by the Office of Sponsored Programs. A reported conflict must be certified as having an appropriate management plan. In the event a Significant Financial Conflict of Interest is identified subsequent to the initial report under the award, the conflict also must be reported to sponsors, as appropriate. All information regarding reported Significant

Financial Conflicts of Interest must be made available upon request by the PHS-funding agency, along with how those conflicting interests have been managed, reduced, or eliminated.

Records of reports and management plans of significant financial Conflicts of Interest are to be maintained as follows: 1) in the case of grants or cooperative agreements, for a period of at least five years after submission of the final expenditures report, unless otherwise directed, or 2) in the case of research contracts, for at least five years after final payment, unless otherwise directed.

Policy Implementation and Policy Breaches

The Vice President for Research, or his/her designee, is responsible for the implementation of this Policy, including the process and mechanism for Conflict of Interests reporting and management, and the appointment of members to the COIC. The Vice President for Research, or his/her designee, will oversee all identified breaches of Conflict of Interests reporting, review, and approval process, including:

- failure to comply with the process (e.g., failure of Investigators to report Conflicts of Interest, failing to respond to COIC, IRB, or IACUC inquiries, or responding with incomplete or knowingly inaccurate information);
- failure to remedy conflicts; and
- failure to comply with a prescribed monitoring plan.

Violation of the Conflict of Interests policy is subject to action, as appropriate, under University policies and procedures, including the University's Outside Professional Activity and Employment, Research, and Continuing Education policy or under VCU's Policies and Procedures for Misconduct in Research and Scholarly Activities.

Approved Board of Visitors 5-15-09