

 VILLANOVA UNIVERSITY	Title: Financial Conflict of Interest in Research	
	University Division/Department: Office of the Provost	
Policy Number: ORA-002	Effective Date: 15 January 2015	Pages: 10

I. PURPOSE

This policy implements the disclosure and review requirements of financial interests and outside activities applicable to research, which requirements stem from federal regulations and the University’s existing general conflict of interest policies. It further describes the process Villanova University follows in reviewing and managing actual or potential conflicts of interest pertaining to research projects. This policy recognizes that faculty members and other University personnel engaged in research may have financial interests related to their research and, in accordance with applicable federal regulations, requires that these financial interests be disclosed and adequately managed, reduced or eliminated, as may be appropriate under the specific circumstances.

This policy is applicable to all University full-time and part-time faculty who are responsible for the design, conduct or reporting of research and who are currently participating in, or submitting proposals to participate in, human subject research or research funded by a) federal, state and/or local government agencies, b) commercial sponsors, and c) other organizations funding research at or on behalf of Villanova University (hereinafter “Investigators”). At times, staff and students may also be responsible for the design, conduct or reporting of research and, to the extent that they are, they are also deemed Investigators and are covered by this policy.

This policy is implemented by the requirement that each Investigator disclose his or her Significant Financial Interests (as defined herein) in the form prescribed by the University by no later than the time of proposal submission. If there is any new Significant Financial Interest or material change in previously disclosed Significant Financial Interests, the Investigator must disclose the new Significant Financial Interest within thirty (30) days of discovering or acquiring the new Significant Financial Interest. In addition, annually, by September 30, the Investigator must either certify that the Investigator has no Significant Financial Interests or disclose the Significant Financial Interests.

This policy recognizes that certain sponsoring agencies have adopted their own conflict of interest disclosure requirements which must be followed in connection with the specific research contract or award. For research funded by the Public Health Service of the U.S. Department of Health and Human Services (PHS), or any other sponsoring agency that has adopted the PHS’ regulations, this policy is not intended to exceed, but to closely mirror, the federal regulations in order to meet the minimum disclosure requirements.

II. SCOPE

This policy applies to all University faculty, staff, and students proposals having primary responsibility for a sponsored research regardless of whether the sponsor is a federal, state, local, corporate, non-profit, or foreign entity, and regardless of the primary purpose of the sponsored project.

III. DEFINITIONS

Conflict Review Committee (CRC) - Villanova University's appointed body to review all Investigator disclosures of Significant Financial Interests and determine whether they are related to the externally-funded research and could directly and significantly affect the design, conduct or reporting of that research. The CRC members are appointed by the Associate Vice Provost for Research and consist of the Director of the Office of Research Administration, the Dean (or his/her designee) from the College/School where the Investigator derives his or her primary Institutional Responsibilities, and the University Compliance Officer. For staff disclosures, the CRC will also include a representative from Human Resources. The CRC consults with the Office of the Vice President and General Counsel, as appropriate.

Disclosure of Significant Financial Interests - An Investigator's disclosure of significant financial interests to the University, made formally in writing using the proscribed process, defined herein.

Financial Conflict of Interest (FCOI) - Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of the externally- funded research.

HHS - The U.S. Department of Health and Human Services.

Institutional Responsibilities - An Investigator's professional responsibilities on behalf of the University which includes: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Intellectual Property - Inventions, discoveries, processes, methods, compositions, formulae, procedures, protocols, techniques, results of experimentation and testing, information, data, designs, utility models, know how, whether any of the foregoing are patentable or not, patents (whether registered or unregistered), works of authorship, mask works, database rights, copyrights (whether registered or unregistered), moral rights, trademarks, service marks and trade names (whether registered or unregistered), logos, brands and domain names, goodwill, trade secrets, rights in confidential information, rights of publicity, and any other intellectual or industrial property rights of any nature including, without limitation, all applications, registrations, renewals, reissues, extensions, divisions, assignments and continuations of, or licenses, waivers or settlements in connection with, any of the foregoing, together with all similar and analogous rights throughout the world.

Investigator - The principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or of proposed research, which may include, for example, collaborators or consultants. For purposes of this definition:

“Conduct of research” means the supervision or management of a study's execution. This is typically done by the principal investigator (PI) and co-investigators, but also may be performed by postdoctoral fellows and graduate students who have significant supervisory roles for junior researchers or technicians who are part of the study. For studies involving human subjects, this includes anyone who is responsible for explaining

the study, risk-benefit, and/or alternatives to potential participants, is listed on the 1572 or device agreement, and/or must complete a sponsor's conflict of interest disclosure form.

“Design of research” means the planning of the scientific strategy to test a research proposal.

“Reporting of research” means the authorship of: publications to journals or otherwise, reports to the research sponsor, or presentation at conferences or scientific meetings related to the research.

Manage - Taking action to address a financial conflict of interest to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

VPHS: the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component: the organizational unit of the PHS that funds the research that is subject to this subpart.

Principal Investigator or **(PI):** the University employee listed on the Office of Research Administration Proposal Review and Transmittal Form or the Applications for Review of Human Subjects Research as having primary responsibility for the overall conduct of the sponsored project, or if the research is not externally funded, the University employee having primary responsibility for the overall research project. The PI is a senior/key personnel and an Investigator.

Research: a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge in any academic discipline. 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).

Senior/key personnel: the PI and any other person identified as senior/key personnel on a grant application, progress report, or any other report submitted to the project sponsor.

Significant Financial Interest (SFI): a financial interest of the Investigator (and those of the Investigator's spouse and dependent children) that are set forth in federal regulation and which reasonably appear to be related to the Investigator's institutional responsibilities. The entire definition of Significant Financial Interest is contained in Section V, B below.

University – Villanova University.

IV. POLICY STATEMENT

Villanova University promotes objectivity in research by establishing and maintaining standards that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from the Investigators' financial interests. Villanova University and its Investigators often benefit from the Investigators' participation in both public and private outside activities. The University has no interest in setting forth detailed

rules that may interfere with Investigators' legitimate outside interests. Investigators, in turn, must also ensure that their outside obligations, financial interests, and activities do not conflict or interfere with their commitment to the University.

In those circumstances in which the University is engaged in, or intends to engage in, an externally funded research project, whether the external funding entity is public or private, or has subcontracted, or intends to subcontract to, an external entity under one of the University's sponsored projects, OR if the University is engaged in, or intends to engage in, research involving human subjects, each Investigator must disclose all Significant Financial Interests of each Investigator (including those of his or her spouse and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities.

The University, through its designated Conflict Review Committee (CRC), will review all Investigator disclosures of Significant Financial Interests and reasonably determine whether they are related to the Investigator's research. The CRC will also determine whether the disclosed interest constitutes a Financial Conflict of Interest (FCOI) in that it could directly and significantly affect the design, conduct or reporting of the research. If so, the CRC will develop and implement a Conflict Management Plan that must be followed by the Investigator in order to reduce, manage or eliminate the FCOI.

V. PROCEDURES

A. **Investigator Reporting Obligations - Who must report, when and how?** Each Investigator who is planning to participate, or who is participating in a research project, must disclose to Villanova the Investigator's Significant Financial Interests (which include those of the Investigator's spouse and dependent children):

1. no later than the time a proposal for a research project is submitted to the Office of Research Administration for review;
2. an updated disclosure of Significant Financial Interests no later than September 30 annually which shall include any Significant Financial Interests and also updated information regarding any previously disclosed Significant Financial Interest (e.g., the updated value of a previously disclosed equity interest); and
3. an updated disclosure of Significant Financial Interest within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

The above required disclosures are to be done by completing the applicable Significant Financial Interest/Conflict of Interest forms found online via ORA website at ora.villanova.edu. The non-PHS form is to be completed by all Investigators **EXCEPT** for those Investigators who participate in, or plan to participate in, any research subject to the PHS regulations. The PHS form is to be completed by all Investigators who participate in, or plan to participate in, **any** research subject to the PHS regulations (see a list of PHS agencies [here](#)). All individuals who meet the definition of Investigator must complete this form. Investigators who are not university employees (e.g., students, subcontractors, consultants or collaborators) must disclose using the applicable form.

B. What must be reported? Significant Financial Interest Defined

The items that must be disclosed are Significant Financial Interests (SFI) which are defined as the following interests of the Investigator and the Investigator's spouse and dependent children that reasonably appear to be related to the Investigator's Institutional Responsibilities:

1. Interest in publicly traded entities if the following interests, when aggregated among the Investigator and the Investigator's spouse and dependent children, exceed \$5,000:
 - a. any remuneration (e.g., salary and any payment for services not otherwise identified as salary such as consulting fees, honoraria, paid authorship) received from the publicly traded entity by the Investigator and/or the Investigator's spouse and dependent children in the twelve months preceding the disclosure plus
 - b. the value of any equity interest (including stock, stock options, or other ownership interest) in the publicly traded entity as of the date of the conflict disclosure.

2. Interest in non-publicly traded entities if:
 - a. the aggregated value of any remuneration received from any non-publicly traded entity by the Investigator and/or the Investigator's spouse and dependent children in the twelve months preceding the conflict disclosure exceeds \$5,000
OR
 - b. when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (including stock, stock options, or other ownership interest) in the non-publicly traded entity.

3. Intellectual Property Rights and Interests. Disclosure is required upon receipt of income related to such rights and interests except for royalties received from intellectual property assigned to the University as described below.

4. For all Investigators participating in, or planning to participate in, research subject to the PHS regulations, travel must be disclosed as follows:
 - a. If it is reimbursed or sponsored travel related to the Investigator's Institutional responsibilities and
 - b. The travel is sponsored or reimbursed from an entity that is not one of the following United States entities:
 - i. Federal, state, or local government agency;
 - ii. institution of higher education;
 - iii. an academic teaching hospital;
 - iv. a medical center; or
 - v. a research institute that is affiliated with an institution of higher education;

5. Disclosure is required both when the amount of reimbursement or payment for the travel is known and when the travel is paid on behalf of the Investigator and the exact monetary value is not known.

6. The details of travel disclosure must include, at a minimum:
 - a. the purpose of the trip;
 - b. the identity of the sponsor/ organizer;
 - c. the destination;
 - d. the duration; and
 - e. additional information (including a determination or disclosure of monetary value) if the Conflict Review Committee determines that the information is needed to determine whether the travel constitutes a FCOI.
- C. The following types of financial interests are not deemed to be Significant Financial Interests under the federal regulations and therefore need not be disclosed in connection with this policy:
1. Salaries, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
 2. 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 those vehicles;
 3. Income from seminars, lectures, or teaching engagements sponsored by one of the following United States entities: a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
 4. Income from service on advisory committees or review panels for one of the following United States entities: a Federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

If a Significant Financial Interest arises after the proposal was submitted to an external sponsor, then the Significant Financial Interest must be reported by the Investigator by submitting an amended Significant Financial Interest/Conflict of Interest form as soon as the Investigator becomes aware of the Significant Financial Interest.

VI. Review Process of Significant Financial Interest/Conflict of Interest Forms

A research project (regardless of funding source) may not commence unless the review of the disclosed Significant Financial Interest is finalized and the research is approved to commence, as set forth below.

The disclosure form is to be submitted in accordance with the procedures described in Section V above. Positive disclosures will be reviewed by the Conflict Review Committee (CRC) which will initially determine if the Significant Financial Interest is related to the research.

An Investigator's Significant Financial Interest is related to the research when the CRC reasonably determines that the Significant Financial Interest could be affected by the research, or is in an entity whose financial interest could be affected by the research.

If research related, the CRC must then determine whether the disclosed interest constitutes a Financial Conflict of Interest (FCOI) in that it could directly and significantly affect the design, conduct or reporting of the research.

In reviewing the positive disclosures, the CRC will be guided by the following practices and apply them as may be appropriate:

- A. Assure adherence to relevant University policies such as, the Faculty Handbook and other associated University documents including the University Conflicts of Interest and Business Ethics Policy, Villanova University Full-Time Faculty Handbook Conflict of Interest and Consulting, Outside Teaching, and Professional Work Policies.
- B. Consider the nature and extent of the financial interest in the relationship of the Investigator and the external organization.
- C. Give special consideration to the terms and conditions of sponsored project agreements that may mitigate or complicate the given situation.
- D. Consult with and obtain additional information that either the Investigator or the CRC determine may be helpful in resolving actual or potential conflicts.
- E. Conclude that the University may take one of the following actions:
 1. Accept the sponsored project award or protocol.
 2. Reject the sponsored project award or protocol.
 3. Accept the sponsored project or protocol subject to suitable modifications in the sponsored project award or protocol document, the role of the conflicted Investigator, or the external organizational affiliation(s) of the Investigator or Investigator's spouse or dependent children.
- F. The CRC may impose specific conditions or restrictions that will assist in the management, reduction or elimination of the conflict of interest which may include, without limitation:
 1. public disclosure of FCOIs;
 2. monitoring of research by independent reviewers;
 3. for research involving human subject research, disclosure of FCOI to the participants;
 4. modification of the research plan;
 5. disqualification from participation in the portion of the research that would be affected by Significant Financial Interests;
 6. divestiture of Significant Financial Interests; or
 7. severance or modification of relationships that create conflicts.

VI. Appeals of the CRC Determination

If the Investigator is dissatisfied with the decision of the Conflict Review Committee, the Investigator may appeal to the Vice Provost for Academics (VPA) in writing within five (5) days of receipt of the written determination from the CRC. The VPA shall review the Significant Financial Interest(s) and the decision of the CRC, and shall affirm, reject, or remand to the CRC. The decision of the VPA in this matter shall be final.

VII. Subawards on Sponsored Projects

Sponsored projects may permit the University to enter into one or more subcontracts or consulting agreements (“subawards”) with outside entities or persons. In those situations, the Investigator must disclose to the Office of Research Administration any SFI in relation to a proposed subaward, regardless of the project sponsor, before the subaward is executed. If the SFI arises after the subaward is executed, the PI shall disclose the SFI as soon as the Investigator learns of it.

In addition, if any part of a research project is funded by a Public Health Service (PHS) Awarding Component such as the National Institutes of Health (NIH), the subaward agreement will specify whether the subawardee has a conflict of interest policy that is compliant with the PHS regulations or, alternatively, whether it will comply with the University’s policy.

VIII. Training/Research Subject to PHS Regulations

If the research project is subject to the PHS regulations, each Investigator on the project must complete training on this policy, the Investigator’s responsibilities regarding disclosure of SFIs and the PHS regulations regarding financial conflicts of interest:

- A. prior to engaging in any PHS-funded research and
- B. at least every four years thereafter; and
- C. immediately when any of the following circumstances apply:
 1. the Investigator requirements of this policy are revised;
 2. an Investigator is new to an Institution; or
 3. The University finds that an Investigator is not in compliance with this policy or a management plan.

IX. Non-Disclosure Consequences/Sanctions

Violations of this policy, such as willful concealment of financial interests, may result in sanctions being imposed upon the violating individual. The Office of the Provost will review allegations of violations and will make recommendations regarding the imposition of sanctions, if any, to the VPA. The decision of the VPA with regard to the imposition of sanctions shall be final.

ORA and the University Compliance Office shall maintain the records pertaining to each disclosure in strict confidence, to the extent permitted by applicable law and regulation. Access to such records will be limited to the Investigator and representatives from the Office of Research Administration, the Department’s Chair and Dean’s Office, the University Compliance Office, the Associate Vice Provost for Research, the

VPA, the Office of the Vice President and General Counsel, Human Resources and others who have a legal right or business need to review the records.

X. Additional Requirements

Certain sponsors, particularly federal agencies, may have requirements that differ from this policy with regard to the timing and frequency of Investigator disclosures; the ability to conduct research even in the event of an unmanageable conflict of interest; the consequences of conducting research where a conflict of interest was not appropriately disclosed; and other conflict of interest considerations as well. In such cases, the sponsors' requirements will generally prevail. As it relates to confidentiality, the PHS regulations require public disclosure of Financial Conflicts of Interest of the Principal Investigator and other designated senior/key personnel on the research project upon request.

XI. Disclosure to and by ORA

When a proposal is submitted to ORA, each Investigator will indicate whether his or her disclosure of financial conflicts of interest has been completed for the previous calendar year and whether there are any additional financial interests in the sponsor or any other entity whose financial interests might reasonably be affected by the outcome of the research that he or she must disclose. If so, the Investigator will be guided to complete and/or update, as appropriate, the applicable Significant Financial Interest/Conflict of Interest Disclosure Form. The Director of ORA will make all information relevant to financial interest disclosures by the Investigators available to the CRC in connection with its review and determination.

With respect to sponsored research, prior to the expenditure of any funds under an award and on an ongoing basis as required, the University, through ORA, will report to the sponsor information regarding the identification, nature, and management of financial conflicts of interest as required by this Policy, by the sponsor's policy, or as required by law.

Upon request, the Associate Vice Provost for Research or designee will make information available regarding identified conflicts to those entities funding research or sponsors, as required by law.

XII. Subrecipients

When an award involves a subgrantee, a subcontract, or collaborators, Investigators working for these entities must comply with this Policy by completing the applicable Significant Financial Interest/Conflict of Interest Form or by otherwise providing acceptable evidence of compliance with these policies.

For research projects carried out through subrecipients, the University will incorporate as part of a written agreement terms that establish whether the COI policy of the University or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient Institutions who rely on their own COI policy must report identified financial conflicts of interest to the University in sufficient time to allow the University to report the matter to the sponsoring agency as required.

XII. RELATED INFORMATION/FORMS

Villanova University [Conflicts of Interest and Business Ethics Policy](#)
Villanova University Full-Time Faculty Handbook [Conflict of Interest](#) and [Consulting, Outside Teaching, and Professional Work Policies](#)

XIII. HISTORY

Revised November, 2016

XIV. RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT

Office of the Provost

XV. RESPONSIBLE ADMINISTRATIVE OVERSIGHT

Administrative Oversight Office:

Office of Research Administration
Middleton Hall Rm 1st
800 Lancaster Avenue
Villanova, PA 19085

General Telephone Number: 610-519-4220