



POLICY

Title:	Financial Conflict of Interest Related to Research
Effective Date:	November 25, 2020
Approved By:	President's Council
Responsible Party:	Dean of Research
History:	8/24/12; 12/1/19

I. PURPOSE

POLICY STATEMENT

Salus University is committed to overseeing the conduct of research in a manner that ensures the integrity of the research process and maintains the public trust and that of sponsors in the integrity and credibility of its faculty, its staff, and its research programs. This commitment requires the University to ensure that there is no reasonable expectation that research results are biased by the external commitments and financial interests of persons who are responsible for the design, conduct, reporting, or direct administration of University research. Such individuals are, for the purposes of this policy, referred to as "research personnel." Research, for the purpose of this policy, includes all sponsored projects and all non-sponsored University research.

This policy identifies and addresses the real or apparent financial conflicts of interest presented by the intersection of research activities and personal financial interests, and defines the requirements of all research personnel to ensure that those activities are conducted objectively and without consideration of personal financial gain.

REASON FOR POLICY

The integrity of Salus University's research is of the utmost importance. The principles and procedures of this policy assure that University research personnel will report their external commitments and financial interests in a timely manner and that the real and apparent financial conflicts of interests of research personnel will be identified and responsibly managed. This policy establishes the structure for how Salus University will receive real or apparent conflicts of interest from research personnel and describes how the University will evaluate and/or manage those conflicts of interests. It promotes compliance with all applicable federal and state laws, regulations, and policies regarding financial conflicts of interest.

WHO SHOULD READ THIS POLICY

- All University research personnel
- All Administrative managers

WEB ADDRESS FOR THIS POLICY

<http://www.salus.edu/About/University-Policies/University-Policies.aspx>

CONTACTS

Direct any general questions about this policy to the Conflict of Interest Officer at:

fcoiofficer@salus.edu

II. DEFINITIONS

These definitions apply to terms as they are used in this policy.

Conflict Management: Measures taken to address the risk of bias or the appearance of bias, protect research subjects, and maintain public trust in Salus University's research and its personnel when research personnel may have a real or apparent financial conflict of interest.

Conflict Commitment: When an employee of the University engages in an outside activity that burdens or interferes with their fulfillment of primary commitments and obligations to the University, even if the outside activity is valuable to the University or contributes to their professional development and competence.

Design, Conduct, or Reporting of Research: Oversight, decision-making, or participation in research that includes creating the structure, roles, and/or protocol of a research project; participating in the execution of the research roles and protocol; participating in the publishing, presentation, or discussion of the research results.

Direct Administration of Research: Oversight or decision-making impacting research that includes, selection of vendors, determining the allocation of funds, sponsor negotiations for the research project, protocol review and approval, or managing resulting intellectual property and licensing opportunities.

Disclose/Disclosure: To provide relevant information about research personnel's financial interests related to a research project to parties inside and outside the institution to assure full awareness of potential conflicts and institutional efforts to address them. Compare with Report.

External Commitment: An obligation or activity (e.g., management, employment, advisory, or consulting role) that is not related to primary commitments or obligations to the University.

External Entity: An entity other than the University.

Financial Conflict of Interest – Real, Apparent: A Real Financial Conflict of Interest arises when a financial interest, or other opportunity for personal financial gain, is likely to compromise or influence the objective design, conduct, reporting, or direct administration of research. An Apparent Conflict of Interest arises when there is a reasonable apprehension, which reasonably well-informed persons are likely to have, that an individual's opportunity for personal financial gain could compromise or influence the design, conduct, reporting, or direct administration of research.

Financial Interest: A monetary interest or relationship, including, but not limited to, compensation for management, advisory, or consulting roles; gifts, services, loans; payments or in-kind gifts for services; licensing, patent, royalty, and other intellectual property agreements; equity interests (e.g., stocks, stock options, bonds, property interests, dividends, convertible securities); and legal partnership interests.

Human Subject Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, involving a living individual about whom an investigator (whether professional or student) conducting the research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Institutional Responsibilities: A researcher's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on Financial Conflict of Interest, which may include, for example, 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.

Key Personnel: Any individuals responsible for the design, conduct, or reporting of a research study, including the following:

- (1) Principal investigators, co-principal investigators, co-investigators, and any other individual named in a sponsored or non-sponsored project budget, narrative, key personnel list, by CV attachment, or noted anywhere else by name in a proposal or award, and (2) Anyone who during the course of a sponsored or non-sponsored project assumes a role synonymous with the roles above.

Management Plan: See Conflict Management.

Non-Sponsored University Research: The pursuit of professional interests through research that is Research supported by University funds including, but not limited to, internal allocations, gifts, endowment income, fellowships, licensing income, and cost sharing.

Report: To provide information to the University concerning one's external commitments and financial interests. Compare with Disclose.

Report File: Information submitted on a report, and any pertinent information gathered in relation to a report required for a complete review of external commitments and financial interests.

Research: Research, for the purpose of this policy, includes all sponsored projects and all non-sponsored University research.

Research Personnel: Any individual responsible for the design, conduct, or reporting of research, including key personnel, as well as those responsible for the direct administration of research.

Research-Related: An external commitment or financial interest that is likely to bias the outcome of research.

Significant Financial Interest (SFI): Any monetary value or potential monetary value held by the researcher (including the researcher's spouse and dependent children) that reasonably appears to be related as follows:

- a. For publicly traded companies, if income in excess of \$5000 (in the aggregate) is received during the twelve months preceding the disclosure. Examples of income include salary, consulting fees, honoraria, paid authorship, stock, stock options, or other ownership interests (based on public prices or other reasonable measures of fair market value).
- b. For non-publicly traded companies, if income in excess of \$5000 (in the aggregate) is received during the twelve months preceding the disclosure, or when any equity interest is held (e.g., stocks, stock options, or other ownership interests).
- c. If any income is received from intellectual property rights and interests (e.g., patents, copyrights).

- d. Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by 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. Disclosure of this interest will include, at a minimum, the purpose of the trip, identity of the sponsor/organizer, destination, and duration.

Significant financial interest does not include the following types of financial interests:

- a. Salary, royalties, or other remuneration paid by Salus University to the investigator if the investigator is currently employed or otherwise appointed by Salus University,
- b. Intellectual property rights assigned to Salus University and agreements to share in royalties related to such rights.
- c. 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.
- d. Income from seminars, lectures, or other teaching engagements, or from service on advisory panels or review panels from 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.

Sponsor: An external entity that funds or supports research. Sponsors include federal, state, and local governments and private entities, both non-profit and for profit.

Sponsored Research: Research funded by a sponsor through a grant, contract, or agreement.

III. POLICY

PRINCIPLES

Overview: The research, scholarship, and other professional activities of the University's faculty, students, and staff are governed both by principles of academic freedom with responsibility and codes of academic integrity and ethical conduct. The principles outlined below protect academic freedoms, assure open publication of research results, and encourage a spirit of entrepreneurship. At the same time, University research personnel must exercise these ideals within the bounds of legal and ethical restraints. The conduct of research in compliance with applicable regulations and free from any reasonable expectation that the research results are biased by the financial self-interest of research personnel ensures the integrity of the research process, protects the public's investment, and engenders and maintains the public trust in the integrity of the University's research and education mission.

Principle 1 – External Relationships and Research: The University recognizes the value of engagement in external organizations and activities. Such activities and relationships enable the transfer of knowledge and skills that enhance teaching, research, service, and the administration of University programs, as well as inspire solutions to benefit the world. Entrepreneurial endeavors and productive relationships with businesses can stimulate inquiry and provide opportunities to further academic research. However, the financial interests that accompany such relationships may lead to real or apparent financial conflicts of interest.

Principle 2 – Legal Compliance: This policy promotes compliance with all applicable federal and state laws and regulations regarding financial conflicts of interest, including the National Institutes of Health, the National Science Foundation, the Food and Drug Administration and the Office for Human Research Protections (OHRP). It incorporates these requirements and extends them to all research conducted at Salus University, whether externally sponsored or not. In addition, it provides for agency- or contract-specific requirements where applicable.

Principle 3 – Open Publication of Research Results: One mission of the University is the pursuit of knowledge for the benefit and use of society. Accordingly, the University vigorously protects the free and open publication, presentation, and discussion of research results.

Principle 4 – Entrepreneurship: The University contributes to the economic development of the State of Pennsylvania and the nation and brings important scientific and medical discoveries to the marketplace for the benefit of the public. Consistent with the Bayh-Dole Act of 1980, the University strongly encourages and supports the efforts of its research personnel to participate in the development and dissemination of intellectual property by entering into relationships with existing business entities or by starting their own. These relationships, however, also present situations where some degree of real or apparent financial conflict of interest is inevitable. These situations are appropriately managed, therefore, to ensure the integrity of the research process, the unbiased and effective development of University intellectual property, and the appropriate entrepreneurial participation and external engagement of its research personnel.

Principle 5 – Human Subject Research: Research involving human subjects is critical in developing knowledge and discoveries that will benefit society. Protecting the rights and welfare of human research subjects is of the utmost importance and a requirement of all research personnel and the University. Of particular concern, therefore, are external commitments and financial interests that compromise or appear to compromise the rights and well-being of human research subjects. The University scrutinizes the roles in such research and of research personnel who have external commitments and financial interests with a sponsor or with an external entity that is related to, or can be affected by, the research. As described in this policy, the University has instituted a rebuttable presumption that research personnel who are involved in the design, subject selection, informed consent process, or the clinical management of a trial cannot have a financial interest in an entity whose interest could be affected by the research. In other words, the default position is that participation in human subject research by conflicted research personnel is not allowed. However, there may be compelling circumstances in which conflicted research personnel would be permitted to participate in the research. In these cases, the management strategies for the involvement of conflicted researchers must be carefully adjusted to the level of anticipated risk. All financial interests and external relationships related to human-subject research that are not eliminated must be disclosed to all subjects in the related research. The management plan must be implemented before research personnel can participate in the design or conduct of the research, enrollment of subjects, or analysis of the results.

Principle 6 – Full and Accurate Reporting: Real and apparent financial conflicts of interest may arise from any number and type of external commitments and financial interests, and particular expertise is required to determine whether they could affect, or could be perceived to affect, research activities and results. University research personnel are required to report to the Financial Conflict of Interest Officer, as defined below, fully and accurately all external commitments and all research-related financial interests in accordance with the procedures in this policy, in order to provide sufficient information for the identification of real and apparent financial conflicts of interest. Research personnel must include the external commitments and financial interests of his/her spouse and dependent child(ren) in accordance with the procedures in this policy.

Principle 7 – Timely Reporting: Reports of external commitments and financial interests must be made at regular intervals, as required by University policy and federal regulation, to allow the University to identify and manage real and apparent financial conflicts of interest in a timely manner. Additional reporting events are prescribed by federal regulation, agency- and award-specific terms, and human subject protocol submission requirements. All research personnel must report (1) annually, (2) when external commitments and financial interests materially arise or change, (3) when submitting a proposal or IRB protocol, (4) when required by the specific terms of an award, (5) upon appointment, (6) when newly assigned to a research personnel role, (7) when initiating licensing activity, and (8) when otherwise required by federal or state law.

Principle 8 – University Oversight: Three principles are accounted for in the process of University review of reports of external commitments and financial interests: (1) respecting the confidentiality of reported information to the extent possible under federal or state law, (2) managing rigorously both real and apparent financial conflicts of interest, and (3) achieving consistency across the University in the way that financial conflicts of interest are identified and managed.

A financial conflict of interest review committee, in accordance with the procedures of this policy, will identify situations in which external commitments and financial interests may potentially compromise, or appear to compromise, the professional judgment of research personnel in conducting or reporting research, including the collection, analysis, and interpretation of data, the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human subjects, and the use of statistical methods.

Principle 9 – Management of Conflicts: Real or apparent financial conflicts of interest are addressed through a management plan. The plan must be designed to remove the bias, or the reasonable perception of bias, in research that the conflict raises, while allowing that degree of personal financial and professional freedom that is consistent with research integrity, the public trust, and the protection of human subjects.

Real and apparent financial conflicts of interest often can be managed, in whole or in part, by disclosing the implicated external commitments and financial interests to, as applicable, the University, journal publishers, granting agencies, conference organizers, audiences at presentations, colleagues, collaborators, students, human subjects, or to any extent required by federal or state law. Other possible management plan measures include, but are not limited to, the monitoring by independent reviewers of the related research and/or of the student participation; modification of the research plan; and disqualification of the research personnel's participation in all or a portion of the research project.

Special attention is paid when research personnel have academic oversight responsibilities for undergraduates, graduate students, or postdoctoral associates who are working on projects that are funded by, or conducted in collaboration with, an external entity in which the research personnel have a financial interest.

Principle 10 – Reporting and Management Plan Compliance: Persons subject to this policy are required to report fully and accurately their external commitments and financial interests and to comply with any plans developed to manage their real or apparent financial conflicts of interest. Disciplinary measures and sanctions will be imposed, consistent with University policy, when they fail to report as required or when they fail to comply with management plans.

Principle 11 – Confidentiality and Sharing of Financial Information: The University is committed to maintaining the confidentiality of reported information as far as is practicable and consistent with its legal obligations. All information and written materials provided to the campus review committee are shared only with committee members and staff who are

involved in the processing and review of the information, as well as those who create and implement management plans. Other individuals receive this information only on a need-to-know basis.

ADMINISTRATIVE STRUCTURES

Financial Conflicts of Interest Review Committee (FCOIC)

- a. **Authority:** The FCOIC has authority for reviewing external commitments and financial interests reported or disclosed under this policy, in order to identify real or apparent financial conflicts of interest related to research, and address them in accordance with this policy and federal regulations. The FCOIC has the authority to promulgate binding FCOI management plans.
- b. **Scope of Responsibility:** The FCOIC is responsible for ensuring that all real or apparent financial conflicts of interest are identified and that a management plan is provided. The FCOIC reviews reported information, requests additional material as needed, identifies real or apparent financial conflicts of interest, devises an appropriate plan to manage the conflict, communicates the plan to the research personnel, and monitors compliance with the plan.
- c. **Committee Membership:** The FCOIC is appointed by Dean of Research and includes Salus faculty, as voting members, with no fewer than 3 members of the Salus faculty. No member of the FCOIC who holds a significant financial interest in a project may participate in the review of interest or the development of a management plan for that project.
- d. **Financial Conflicts of Interest Committee Training:** FCOIC members receive appropriate training and continuing education in the identification and management of financial conflicts of interest, including related University policies and procedures and federal regulations.
- e. **Confidentiality:** As far as is practicable and consistent with legal obligations, Salus University protects the confidentiality of financial conflicts of interest information. Information and written materials provided to the FCOIC and its administrators are shared to the most limited degree possible with those committee members and staff who are involved in the processing and review of reported information and the creation and implementation of management plans and others on a need to-know basis. FCOIC review meetings are closed to the public.

Financial Conflicts of Interest (FCOI) Officer

- a. **Appointment:** The FCOI Officer is a University official appointed by the Dean of Research.
- b. **Duties:** The duties of the FCOI Officer include (1) coordinating the reporting and collection of annual and event-based reports of external commitments and financial interests and providing those reports and disclosures to the FCOIC, (2) conducting preliminary reviews of reports and disclosures to assess completeness, and consulting with the reporters and others as required to obtain clarifications and additional information required for making an FCOI determination, (3) providing administrative support to the FCOIC including, but not limited to, additional information related to a disclosure or report and/or information that will assist the FCOIC in rendering a determination of whether a financial conflict of interest is real, (4) assisting the FCOIC in developing and monitoring management plans for financial conflicts of interests identified, and (5) assisting and advising research personnel, University management, and others as appropriate on FCOI management, regulations, policy, and procedures.

IV. PROCEDURES

REPORTING

Who Must File and When:

Research Personnel: All University research personnel, including key personnel, are required to report their external commitments and financial interests annually and on an event-required basis for themselves and their spouse and dependent children (hereinafter called "family").

What must be reported:

- a. Irrespective of dollar amount, a reporter's external commitments or financial interests with an external entity that could constitute a conflict of commitment, such as, but not limited to, employment, service or consulting, travel expenses, intellectual property, licensing, or the like.
- b. Irrespective of dollar amount, a reporter's family's financial interest or commitments with an external entity, whose activities could be related to the reporter's Salus duties.
- c. Significant financial interest, as defined in this policy, for a reporter or family with any external entity whose activities could be related to the reporter's duties at Salus University.
- d. Any financial interests or external commitments not explicitly stated in the reporting form.

Annual Reports

- a. **Required Reporting:** All research personnel must update their reports of external commitments and financial interests annually ("annual report").
- b. **Handling of Annual Reports:** The FCOI Officer will coordinate the solicitation and collection of the annual reports and will review reports for the purpose of identifying real and apparent conflicts of interest related to research. Reports indicating FCOI will be sent to the FCOIC for review and management plan development.
- c. **Timely Reporting Requirement:** All research personnel must complete and submit his or her annual reports by the required deadlines.

Event-based Reports

- a. **New Appointments:** Upon the appointment of a new faculty member, academic staff member, or other employee, the FCOI Officer determines whether he or she is responsible for the design, conduct, reporting, or direct administration of research and is subject to this policy. If responsible, the new appointee must complete the annual report within one month of his or her Salus start date. The FCOI Officer is responsible for ensuring that these individuals are identified and complete their reports within the required timeframe.
- b. **Newly Assigned Responsibilities:** Individuals who become newly responsible for the design, conduct, reporting, or direct administration of research are required to complete annual reports within one month of their assumption of such responsibilities. The FCOI Officer is responsible for ensuring that these individuals are identified and complete their reports within the required timeframe.
- c. **Material Change in Circumstances:** All research personnel must amend their annual reports within 30 days of any material changes to their responses. Material changes include but are not limited to: the initiation or elimination of a reportable

external commitment or financial interest for the reporter and family, a change in a sponsor, or any change that might affect a current management plan.

- d. **Proposal-Specific Report:** All research personnel, who are identified by the principal investigator, for a proposal must report proposal-specific external commitments and financial interests, including any sponsor-required information, at the time the principal investigator submits the proposal to the Director, Sponsored Programs Administration. Principal investigators are responsible for ensuring that research personnel submit FCOI reports prior to proposal submission. Any resulting award may be distributed only after the reported proposal-specific information has been reviewed and any management plan has been implemented.
- e. **Protocol-Specific Report:** Principal investigators and key personnel on IRB protocols are required to report their project-related external commitments and financial interests at the time they submit a protocol to the IRB. Principal investigators are responsible for ensuring that key personnel submit FCOI reports prior to protocol submission. The protocol-specific reports must be reviewed and any required management plans implemented prior to protocol approval.
- f. **Initiating Licensing Activity:** Research personnel are required to report to the FCOI Officer their external commitments and financial interest at the time a license for technologies is negotiated or for which the research personnel is named as an inventor.

MANAGEMENT PLAN DEVELOPMENT AND MONITORING

- a. **Management Plan Development:** Where the FCOI Officer has determined that a financial conflict of interest exists, the FCOIC will develop a management plan. The FCOIC will consider the nature of the research, the nature and size of the interest, the degree to which the conflict is related to the research, the extent to which the interest could be affected by the research, and any management strategies that would mitigate or eliminate the conflict. The FCOIC may consult with others on an as needed basis only, including campus administrative offices, as well as the research personnel in developing the management plan.

Examples of management strategies include, but are not limited to, one or a combination of the following:

- i. Public disclosure of the external commitment and/or financial interest to human subjects, fellow researchers, students involved in the research activity, journal publisher, and/or others as required by federal or state law;
 - ii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, or the appearance of bias, resulting from the external commitment or financial interest (If the management plan prescribes monitoring of the activity, it will describe specifically how the monitoring shall be performed, who shall perform it, what records are to be kept, and what reports are made to the FCOIC);
 - iii. Modification of the research plan (including the assignment of responsibilities);
 - iv. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - v. Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
 - vi. Severance of relationships that create actual or potential financial conflicts.
- b. **Management Plan Notification:** The FCOIC communicates the FCOIC decision and management plan to the research personnel, who must accept the requirements of the management plan in writing before beginning the project. Copies of the signed management plan will also be provided to those responsible for implementation of the management plan, the Assistant Director for Research and Academic Finance, and for

research involving human subjects, the IRB and the Associate Dean for Clinical Research.

- c. **Appeals Process:** Within two weeks of notification of the FCOIC decision, research personnel may submit a written request for reconsideration to the FCOIC, which has the authority to review and affirm the previous decision or amend the management plan. The FCOIC will notify the research personnel and the FCOI Officer of the result of the appeal. Research personnel who do not agree with the FCOIC decision may submit a written request for reconsideration to the Dean of Research, who may make recommendations to the FCOIC. The FCOIC issues a final binding decision.
- d. **Specific Provisions Applicable to Human Subjects Research:** As a general policy, Salus University will not allow research personnel with a financial conflict of interest to conduct a clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment. In such cases, disclosure or standard conflict management strategies may be inadequate and adequate monitoring plans may be difficult or impossible to implement. This prohibition applies not only to principal research personnel of a clinical research project, but also to any research personnel involved in the design, conduct, or reporting of the research. A principal investigator would thus be prohibited not only from serving in that role, but in any research role on the study.

The University may waive this prohibition only where the research personnel provides a compelling justification for its waiver. In considering the research personnel's request for waiver, the FCOIC, at a minimum, will require the research personnel to address the following points:

- i. The nature of the research project (including whether it is early- stage or closer to commercial application);
- ii. The size and nature of the research personnel's financial interest;
- iii. The degree to which the financial interest is related to the research;
- iv. The extent to which the interest is or may be affected by the research;
- v. The degree of risk to subjects in the research;
- vi. The research personnel's proposed role in the research, including protocol design, selection of subjects, administration of informed consent, performance of protocol- mandated clinical procedures, evaluation of the effectiveness of the drug, device, or treatment, and evaluation of adverse effects; and
- vii. The existence of unique circumstances that would require the research to be performed at this institution as opposed to another (such as the unique qualifications of the research personnel and/or unique resources/capabilities of the University).

If the FCOIC finds a compelling justification for waiver of the prohibition in a particular case, a stringent management plan, including a plan for rigorous oversight of the study, will be implemented to ensure the safety of study subjects and the integrity of the research

- e. **Specific Provisions Applicable to PHS-funded Research:** In addition to the requirements of this policy outlined above, Salus University will apply the following specific provisions to research funded by the Public Health Service (PHS):
 - i. Monitoring – For PHS- funded research, the research personnel's management plan will be monitored on an ongoing basis until the completion of the research project.

- ii. Subrecipients – If the University carries out the PHS- funded research through a subrecipient, as defined in 45 C.F.R. Part 94, the University will incorporate as part of a written agreement with the subrecipient terms that establish whether the University’s or the subrecipient’s policy on conflict of interest in research will apply to the subrecipient research personnel.

If the subrecipient’s policy will apply, the subrecipient will certify as part of the agreement that its policy complies with the PHS regulations on Objectivity in Research. Additionally, the agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the University to enable the University to provide timely reports to PHS.

Alternatively, if the University’s policy on conflict of interest will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient research personnel disclosures of significant financial interests to the University. Such time periods shall be sufficient to enable the University to comply with timely review, management, and reporting obligations under the PHS regulations.

- iii. Public Access of Disclosed Significant Financial Interest – The University will make available to the public upon request information concerning any significant financial interest disclosed to the University that meets the following three criteria:
 - (1) The disclosed significant financial interest is still held by the key personnel of the active PHS project;
 - (2) The University determines that the significant financial interest is related to the PHS-funded research; and
 - (3) The University determines that the significant financial interest is a financial Conflict of Interest.

The information request must be made to the FCOI Officer who will respond within five (5) business days of receipt of the request. Disclosed information will be provided to the extent required by applicable PHS regulations and state law

- iv. Institutional Reporting Requirements – For PHS-awarded grants and cooperative agreements, the University must submit all FCOI reports to the NIH as required by the regulation:
 - (1) Prior to the expenditure of funds
 - (2) Within 60 days of identification for key personnel who are newly participating in the project
 - (3) Within 60 days for new, or newly identified, FCOIs for existing key personnel
 - (4) At least annually (at the same time as when the University is required to submit the annual progress report, multi-year progress report, if applicable, or at 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.
 - (5) Following a retrospective review to update a previously submitted report, if appropriate.

All FCOI reports must include sufficient information to enable the NIH to understand the nature and extent of the Financial Conflict of Interest and to assess the appropriateness of the University’s management plan. The following key elements that must be included in the FCOI report to NIH:

- (1) Name of the Investigator with the Financial Conflict of Interest;
- (2) Name of the entity with which the Investigator has a Financial Conflict of Interest;
- (3) Nature of the financial interest (e.g., equity, consulting fee, travel

- reimbursement, honorarium);
- (4) Value of the financial interest 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;
- (5) A description of how the financial interest relates to the NIH-funded research and why the University determined that the financial interest conflicts with such research;
- (6) A description of the key elements of the University's management plan, including:
 - a. Role and principal duties of the conflicted Investigator in the research project;
 - b. Conditions of the management plan
 - c. How the management plan is designed to safeguard objectivity in the research project;
 - d. Confirmation of the Investigator's agreement to the management plan;
 - e. How the management plan will be monitored to ensure Investigator compliance; and

Other information as needed.

- f. **Retrospective Review:** In the event the University identifies a financial interest, a significant financial interest, or the like that was not disclosed in a timely manner by a research personnel or, for whatever reason, was not previously reviewed by the University during an ongoing research project, and where the FCOIC has determined that the undisclosed significant financial interest constitutes a financial conflict of interest, whether related to funded or unfunded research, the FCOIC will review the financial conflict of interest and will implement a management plan for the project within 60 days of identification of that interest. In addition, the FCOIC will, within 120 days of its determination of noncompliance, complete a retrospective review of the research personnel's research activities associated with the project to determine whether the research conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such research. If bias is found and if the research is funded by the PHS, the University will notify The PHS promptly and submit a mitigation report to the PHS. The mitigation report will include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the University's plan of action or actions taken to eliminate or mitigate the effect of the bias.
- g. **Mitigation Plan:** If the FCOIC determines in the conduct of its retrospective review of research that the research or any part of it was biased, the FCOIC will recommend a mitigation plan to the Dean of Research to address any such issues. The University will notify the sponsor, if any, to the extent required in accordance with the award or under federal or state law of its determination and subsequently follow up with the mitigation report for the project.

SANCTIONS FOR NONCOMPLIANCE

Annual Report of External Commitments and Financial Interests

Failure to file a complete and truthful disclosure as required by this policy or to comply with the conditions or restrictions imposed in the resolution, management, or elimination of FCOI constitutes a violation of University policy and may violate state and/or federal law. Failure of an individual to comply with reporting requirements may result in one or more of the following sanctions, until the report is submitted:

- a. The individual will be deemed ineligible to maintain principal investigator status on sponsored projects;
- b. The individual will be deemed ineligible to enter into technology transfer agreements;
- c. The University may suspend ongoing research projects;
- d. The University may halt the expenditure of funds, if applicable.

In addition, where such failure is not remedied, the non-compliance must be reported to federal agencies, sponsors, and/or other regulatory bodies and disciplinary action may be commenced, including academic misconduct proceedings, and, in severe cases, termination. Any academic misconduct or termination proceedings will be conducted in accordance with the applicable University policies and codes, including those set forth in Policy 3001 on Appointments, Tenure, Renewable Tenure and Termination.

PHS Funded Research

If the failure of an Investigator to comply with University policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the University shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken, and the University will comply with any corrective action dictated by the PHS Awarding Component.

In any case in which the HHS determines that a PHS-funded 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 a financial conflict of interest that was not managed or reported by the University as required by the regulations, the University shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations .

TRAINING

Prior to engaging in any research or research project, whether sponsored or not, all research personnel must complete training on the research personnel obligations under this policy. FCOI training must be repeated at least every four years. It also must be completed immediately if this policy is revised so as to affect the research personnel obligations, if new research personnel are hired by the University, or if the University finds a violation of this policy or any applicable management plan by research personnel.

AUDIT

The FCOI Officer and/or FCOIC may conduct:

- i. investigations of potential non-compliance with reporting requirements, management plans, or other policy related issues, when necessary.
- ii. audits and process and compliance reviews to identify needed improvements to the financial conflicts of interest process.

Audit reports are reviewed by the Dean of Research, who will act on as required in accordance with this policy.

RECORD RETENTION

The FCOI Officer will maintain the records regarding the financial conflicts of interest process, in accordance with University policy and sponsors' requirements. For PHS-funded research, the FCOI Officer will maintain the records for at least three years from the date the final expenditures report is submitted to the PHS, or from other dates specified in 45 CFR 75.361, where applicable.

FEDERAL CONFLICT OF INTEREST REGULATIONS

NIH Public Health Service: <http://grants.nih.gov/grants/policy/loi/index.htm>

National Science Foundation: <http://nsf.gov/policies/conflicts.jsp>

Food and Drug Administration

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>

Office of Human Research Protections (OHRP) guidance:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/financial-conflict-of-interest/index.html>

Federal register: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

RELATED UNIVERSITY POLICIES

Faculty Handbook of Salus University

300 University Policies: 304 Conflict of Interest and Outside Employment

3003 Faculty Advancement Program (FAP)

3004 Research Advancement Program (RAP)

Administrative and Professional Staff Handbook of Salus University

304 Conflict of Interest and Outside Employment

902 Involuntary Termination of Employment