POLICY STATEMENT

Subject: Policy For Financial Conflict of Interest (FCOI) in University Research

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Revision _X_ Originating Office: President's Approval

Deletion Researcj & Innovation (formerly SGSR)

New Item

1. PURPOSE: The purpose of this policy is to provide the members of this academic community a framework to promote objectivity in research by establishing standards to ensure that the design, conduct or reporting of research will not be biased by any conflicting financial interests of an investigator.

2. SCOPE: This Financial Conflict of Interest Policy applies to all investigators and their immediate family, who are in a position to affect the design, conduct, or reporting of externally funded research or scholarly activity. This policy also applies to all University personnel working in a key position on an externally funded project. All Investigators submitting applications for external funding of sponsored research or scholarly activity must disclose to the University any actual or potential financial conflict of interest (as defined herein).

3. OBJECTIVE: Federal regulations (42 CFR 50; 42 CFR 94) require that the University have established policies and procedures to ensure that the design, conduct, or reporting of externally-sponsored activity is not biased as a result of the personal financial holdings of the University personnel directing the activity. The University is mandated to manage, reduce or eliminate any actual or potential financial conflicts of interest. Before external funding proposals are submitted to the sponsor, the University is required to obtain, from University investigators, the written disclosure of any significant financial interest that could reasonably appear to affect the objectivity of their performance on the sponsored project.

4. POLICY: Conducting high quality research and instructional activities is integral to

the primary mission of the Indiana University of Pennsylvania. Active participation by faculty and other employees in external activities that enhance their professional skills or constitute public service can be beneficial to the University as well as the individual.

It is University policy that all Investigators submitting applications for external funding of sponsored research or scholarly activity disclose to the University any financial interests which the Investigator or the Investigator's immediate family hold, if these holdings could reasonably give the appearance that a financial conflict of interest might exist between the Investigator and the external sponsor of the research.

This policy sets forth assurances that all federal and state regulations regarding potential financial conflicts of interest will be followed and also establishes procedures that provide a process to manage, reduce, or eliminate potential financial conflicts of interest.

5. DEFINITIONS:

"Business entity" - any person or entity or organization, or any combination of one or more of them. A business entity includes, but is not limited to, a sole proprietorship, partnership, association, joint venture, corporation, firm, trust, foundation or other organization or entity used in carrying on a business, including parent organizations of such entities or any other arrangement in which an entity operates through a subsidiary.

"Conflict of Financial Interest Classifications" - the determinations of the Financial Conflict of Interest Review Board (FCIRB) issued following a review of a disclosed financial interest:

(1) Not a financial conflict of interest.
(2) A potential financial conflict of interest, with mandate of public disclosure.
(3) A potential financial conflict of interest, with mandate of additional project oversight.
(4) A potential financial conflict of interest, with mandate of divesture of relationship with sponsor.
(5) A financial conflict of interest, with mandate that the Investigator terminate involvement with the project.

"Financial Conflict of Interest" - a Significant Financial Interest as defined herein that could directly affect the design, conduct, or reporting of research and which, in the opinion of the University, is determined to be too significant to allow the Investigator to avoid giving the appearance that the financial interest could reasonably affect the Investigator's objectivity in the performance of the research. Abbreviated FCOI (financial conflict of interest).

"Financial Conflict of Interest Review Board (FCIRB)" - ad hoc committee comprised of the Research Integrity Officer (RIO) and

members selected from the University Senate Research Committee (USRC), at least two of whom are not from the same college as the investigator presenting a potential financial conflict of interest

"Financial interest" - anything of monetary value, whether or not the value is readily ascertainable (42 CFR 50.603)

"Immediate family" - parent, spouse, child, brother or sister (PASSHE Board of Governors Policy 2012-01: Conflict of Interest, January 2012).

"Institution" - any entity or organization that is applying for or receives PHS research funding (42 CFR 50.603)

"Institutional responsibilities" - an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts 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 (42 CFR 50.603)

"Intellectual property" - as defined in the APSCUF CBA.

"Investigator" - Any person who is in a position to affect the design, conduct or reporting of externally funded research or education activities, or who reasonably gives the appearance of being in such a position, and who is subject to the control and disciplinary processes of the University.

"PHS" - 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). (42 CFR 50.603)

"PHS Awarding component" - means the organizational unit of the PHS that funds the research that is subject to this subpart. (42 CFR 50.603)

"Potential financial conflict of interest" - any outside activity, commitment or interest that may reasonably give the appearance of adversely affecting, compromising, or being incompatible with, the University obligations of an Investigator.

"Research" - systematic investigation, study or experiment designed to develop or 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). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component

through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. (42 CFR 50.603)

"Research Integrity Officer (RIO)" –Vice Provost for Research and Innovation

"Resolution Plan" - an action plan agreed to by the University and the Investigator, outlining the steps that must be taken by the Investigator and/or the University to manage a potential financial conflict of interest situation.

"Significant Financial Interest" - [43 CFR 50.603) except as excluded below, anything of monetary value that reasonably appears to be related to the Investigator's University responsibilities, including, but not limited to, salary or other payments for services (e.g., consulting fees, honoraria, paid authorship, reimbursed or sponsored travel except as described in (4) below); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). "Significant financial interest" includes such interests held by an Investigator's immediate family member. "Significant financial interest" also includes all financial interests related to the Investigator's University responsibilities, not just those related to PHS-funded research.

Notwithstanding the foregoing, per 42 CFR 50.603, "significant financial interest" does not include:
(1) Salary, royalties, or other remuneration from the University.
(2) Income from seminars, lectures, or teaching engagements sponsored by federal, state, or local government agencies, institutions of higher education as defined at 20 USC 1001(a), academic teaching hospitals, medical centers, or research institutes that are affiliated with institutions of higher education.
(3) Income from service or advisory committees or review panels for federal, state, or local government agencies, institutions of higher education as defined at 20 USC 1001(a), academic teaching hospitals, medical centers, or research institutes that are affiliated with institutions of higher education.
(4) Travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
(5) An equity interest that, when aggregated for the Investigator and the Investigator's immediate family, meets both of the following tests: does not exceed $5,000 in value, including any equity interest in non-publicly traded entities, as determined through reference to public prices or other

reasonable measures of fair market value and does not represent more than a five percent ownership interest in any single entity.
(6) Salary, royalties or other payments that, when aggregated for the Investigator and the Investigator's immediate family over the next twelve months, are not expected to exceed $5,000.
(7) Financial interests held indirectly through funds, such as mutual funds and pension funds, in which the interested party does not control the selection of investments.

"Sponsor" - any non-University entity providing partial or full support of research or scholarly activity performed by University members utilizing University resources.

"University" -Indiana University of Pennsylvania

6. RESPONSIBILITIES:

It is the responsibility of investigators to disclose any potential financial conflicts of interest truthfully and accurately to the best of their knowledge and ability and to ensure the disclosure of any potential financial conflicts of interest held by their immediate families.

It is the responsibility of the Research Integrity Officer (RIO) (Vice Provost for Research and Innovation) to review disclosures of potential financial conflicts of interest, to convene the Financial Conflict of Interest Review Board (FCIRB), and to make the necessary notifications required by external sponsors.

It is the responsibility of the FCIRB to work with the RIO to determine if a financial conflict of interest exists and to resolve potential financial conflicts of interest.

It is the responsibility of IUP Research and Innovation, or designee, to provide training on financial conflicts of interest and to ensure compliance with statutorily mandated FCOI training requirements.

It is the responsibility of the Office of Human Resources to collect completed SEC-1 forms on an annual basis and retain record of completed forms and all records of actions taken to manage actual or potential financial conflicts of interest for at least three (3) years after the later of the termination of any award made to which the records relate or the resolution of any government action involving those records. [42 CFR 50.604(i)

It is the responsibility of the President or his or her designee to respond to appeals of decisions by the Research Integrity Officer and to take appropriate disciplinary action. If the RIO has been accused of violating this policy, then the President will appoint a substitute.

7. PROCEDURES: All Investigators specifically named in grant applications are required to complete the Financial Disclosure block on the University's "Authorization to Seek External Funding Form" and provide a signature that certifies their compliance with the University's Financial Conflict of Interest policy. All such investigators must disclose any significant financial interests and assure that a current SEC-I, "Statement of Financial Interest" disclosure form (Commonwealth of Pennsylvania form number SEC-I Rev. 1/93) is attached to the "Authorization to Seek External Funding Form" and will be placed on file with Human Resources [42 CFR 50.604(e)(1)].

In the event that a significant financial interest is held by the immediate family of the Investigator, it is the responsibility of the Investigator to ensure that a separate SEC-I form is completed by the immediate family member and submitted by the Investigator as an attachment to the Investigator's own SEC-I disclosure form.

If the proposal is funded as an award, the Investigator must submit an SEC-I annually on May 1 of every year that an award is in active status [42 CFR 50.604(e)(2)]. If the investigator or the Investigator's immediate family acquires new financial interests with potential conflict during the life of the award a new SEC-1 must be filed within 30 days [42 CFR 50.604(e)(3)].

All Investigators who are <u>not named</u> in submitted proposals, but who are subsequently hired as Investigators on grant proposals, are required to submit SEC-I forms to the Office of Human Resources within ten days (10) of being named to the grant funded position.

Each Investigator must complete training prior to engaging in sponsored projects related to any PHS-funded grant or contract and at least every four years, and immediately under any of the following circumstances: University FCOI policies change in a manner than affects investigator requirements; an Investigator is new to the University; and/or the University finds an Investigator non-compliant with the University's FCOI policy or resolution plan. [42 CFR 50.604 (b)]

The University reserves the right to not process grant applications if all required, certified University Authorization Forms and SEC-I forms are not submitted in compliance with this requirement. The University also reserves the right to take other actions as necessary. In each application for funding, the University must certify that it has in effect a written, up-to-date, and enforced administrative process to identify and manage FCOI; shall promote and enforce compliance with this policy; shall manage and provide initial and on-going FCOI reports to agencies as appropriate; and shall make available upon request by funding agencies any investigator disclosure of financial interests and the University's review of and response to such disclosures whether or not such disclosure resulted in the University's determination of a FCOI. [24

CFR 50.604(k)(1-4)]

The University will accept grant awards for funded proposals but will withhold expenditure authority until all required SEC-I forms are submitted in compliance with this requirement, except by written order of the President or the President's Designee. (The Public Health Service as research sponsor does not permit such an exception.)

Collaborators, subrecipients or subcontractors from other academic or not-for-profit institutions must either comply with this policy or provide a certification from their institutions that they are in compliance with Federal policies regarding Investigator significant financial interest disclosure and that their portion of the project is in compliance with their institutional policies. The determination of whether this policy or the policy of the collaborator, subrecipient, or subcontractor will apply must be incorporated as part of the written agreement between the parties and must include time periods to meet disclosure and/or FCOI reporting requirements. When PHS funds are involved, subrecipient institutions that rely on their FCOI policies must report identified FCOIs to the awardee institution in sufficient time to allow the awardee institution to report the FCOI to the PHS Awarding Component to meet reporting obligations. [42 CFR 50.604(c)]

Subcontractors from commercial firms need not make a certification, except when the prime award is from the Public Health Service (PHS). The PHS requires a certification from any subcontractor, including commercial firms, stating that it is in compliance with Federal policies regarding Investigator significant interest disclosure and that its portion of the project is in compliance with the subcontractor's company policies

The Research Integrity Officer shall serve as the University's designee to review all "Authorization to Seek External Funding Forms" and any attached or filed SEC-1 forms to determine if a potential financial conflict of interest exists. This review shall take place upon the RIO's receipt of the "Authorization to Seek External Funding Form" and SEC-1s, prior to the expenditure of funds, and/or within 60 days of a funded Investigator's disclosure of a previously undisclosed significant financial interest. [42 CFR 50.605(a)(2)] If no potential financial conflict of interest exists, the RIO shall document the results of the review and forward the original SEC-I(s) to the Office of Human Resources.

If the RIO determines that a potential financial conflict of interest does exist, the RIO shall convene the Financial Conflict of Interest Review Board (FCIRB). The FCIRB shall (1) review information presented by the RIO, (2) assign financial conflict of interest classifications, and (3) if necessary, mandate remedial action to resolve potential financial conflicts of interest through the implementation of a Resolution Plan.

The Resolution Plan shall be incorporated into an action plan for the University and the Investigator that shall be certified to by the Research Integrity Officer and the Investigator and shall be monitored by the Research Integrity Officer until the completion of the research project [42 CFR 50.605(a)(4)].

If remedial action is necessary to manage a financial conflict of interest situation, the FCIRB, in conjunction with the Investigator, shall determine a Resolution Plan that details the steps that must be taken to manage, reduce or eliminate any actual or potential financial conflict of interest situation. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to: (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research); (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants; (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest; (iv) Modification of the research plan; (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or (vii) Severance of relationships that create financial conflicts. [42 CFR 50.605(a)(1)(i-vii)]

The RIO shall oversee that the Resolution Plan is followed and make the necessary notifications required by external sponsors. This notification may, and in the case of PHS funds will, include: grant/contract number; project director/principal investigator contact, name of investigator with a financial conflict of interest (FCOI); whether the FCOI was managed, reduced, or eliminated; the name of the entity with which the Investigator has a FCOI; the nature of the FCOI (e.g. equity interest, consulting fees, travel reimbursement, honoraria); the value of the financial interest ($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 a value cannot be readily determined); description of how the financial interest relates to the funded research and the basis for the University's determination that the financial interest conflicts with such research; and key elements of the University's management plan. Additionally, the RIO will report annually to the sponsor the status of the FCOI and any changes to the management plan.[42 CFR 50.605(b)(1)]

Prior to the University's expenditure of any funds under a PHS funded research project, the University's Right to Know Officer shall ensure public accessibility, via a written response to any requestor within **five business days** of a request, of information concerning any significant financial interest disclosed to the University that meets the following three criteria: (A) The significant financial interest was disclosed and is still held

by the investigator as defined by this subpart; (B) The University determines that the significant financial interest is related to the PHS-funded research; and (C) The University determines that the significant financial interest is a financial conflict of interest [42 CFR 50.605(a)(5)]. The information that the University's Right to Know Officer makes available via a written response to any requestor within **five business days** of a request, shall include, at a minimum, the same information reported to PHS (described above) and shall be retained for at least three years from the date that the information was last updated [42 CFR 50.605].

The University shall follow Federal regulations regarding the notification of the Sponsor in the event an Investigator fails to comply with the terms of the resolution plan, or any other requirement of this policy. Specifically, for PHS-funded research, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the University's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. [42 CFR 50.605(a)(3) and (b)(2-3); 45 CFR 94.5(a)(3] The University will notify the PHS Awarding Component of the retrospective review per 42 CFR 50.605(b)(3) and 45 CFR 94.5(a)(3)(ii-iii) only in cases where bias is found. The Sponsor may take its own action, as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

If an unmanageable financial conflict of interest situation is determined, the RIO shall take the necessary action to assure that the Investigator's relationship with the project is severed.

Additionally, the University President, Provost, and the dean of the investigator's college or other supervisor, as well as the investigator him/herself must be notified in writing with a memo describing the identified financial conflict of interest and the basis for the determination that the financial conflict cannot be mediated. If the investigator is a member of a collective bargaining unit, his or her union chapter President shall also be notified. In addition, if the research was sponsored by any external agency, that agency will be notified if such notification is required.

Disputes on matters regarding financial conflict of interest, including the interpretation of this policy, shall be referred to the President, or the

President's Designee, for resolution.

Appeals of the decision of the FCIRB must be made to the President, or the President's Designee, within five (5) days of receipt by the Investigator of written notice of the decision of the FCIRB.

Non-compliance with this policy or resolution plan may result in disciplinary actions subject to any applicable collective bargaining agreement, or existing University rule or regulations such as the Board of Governors' Merit Principles Policy. [42 CFR 50.604U)]

After review and necessary action, all SEC-1s will be retained in the Office of Human Resources for a period of (5) five years from the date of receipt. All financial disclosure information shall be kept confidential, except to the extent required by law, and except to the extent necessary to review, consider, and resolve any conflicts.

8. RECISION: Not applicable.

9. PUBLICATION STATEMENT: Not applicable.

10. DISTRIBUTION: Code Description

All employees annually (by the Vice Provost for Research and Innovation) and via the IUP Research website (updated within 60 days of any modification of the policy) [43 CFR 50.604(a)].