

UICOMP Investigator Conflict of Interest Disclosure Policy for Human Subjects Research

Effective 8/24/12

INTRODUCTION:

The University of Illinois College of Medicine at Peoria (UICOMP) revised its University Policy on Conflict of Commitment and Interest and the campus processes in August 2012 to comply with the Public Health Services (PHS) Regulation, Department of Health and Human Services 42 CFR Part 50 and 45 CFR Part 94, on Financial Conflicts of Interest (FCOI). The revised policy and processes increase accountability, add transparency, enhance regulatory compliance and effective Institutional management of Investigators' FCOI. The primary goal is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Investigator FCOI. The UICOMP Investigator Conflict of Interest Disclosure Policy for Human Subjects Research applies the University policy and processes for FCOI to ensure the protection of human subjects enrolled in research.

POLICY:

- I. Federal regulations (PHS, National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control (CDC), Agency for Healthcare Research and Quality (AHRQ)) and University policies require that investigators disclose significant financial interests (SFIs) that are reasonably related to the research or to an investigator's responsibilities that in any way could bias the design, conduct or implementation, management, and reporting of research data. The regulations further require that the University have a mechanism for the investigators to disclose SFIs and University designated officials to determine if a SFI represent a FCOI which requires the development of a University approved management plan to manage or eliminate the FCOI. The disclosure and management of the FCOI must occur before any funds are released to investigators for expenditure.
- II. The IRB must consider in its review the disclosure of conflicts of interest that may affect the human subjects enrolled in the research, the integrity of the research, or the integrity of the human subjects protection program (HSPP.) For the HSPP and the IRB, the disclosure of conflicts goes beyond investigator financial conflicts, and includes institutional conflicts of interest, real or apparent, that could affect the research, the rights or safety of the research subjects, or the integrity of the HSPP. The HSPP standards regarding conflicts of interest apply equally to all research whether the study is sponsored (i.e., funded by an external organization) or non-sponsored.

DEFINITIONS:

- I. **INVESTIGATOR:** any person responsible for the design, conduct, or reporting of the research. This includes, but is not limited to, the Principal Investigator (PI), Faculty Sponsor, Co-Investigators, or other Key Research Personnel. An investigator may be a faculty member (including those with the title of visiting, clinical, or adjunct), staff member (including those with the title instructor or lecturer), fellow (including post-doctoral associates), student, trainee, administrator, unpaid personnel (including volunteers) or other individual who is engaged in research involving human subjects pursuant to the review and

approval of the PIRB; or is otherwise identified as involved in research by a PI, Chair or Department/Unit Head, or other administrative officer responsible for research activities.

For purposes of this policy, "Investigator" includes the investigator's family members.

- II. **FAMILY MEMBERS:** Includes the investigator's spouse or domestic partner, parents, siblings, and children.
- III. **FINANCIAL CONFLICT OF INTEREST (FCOI):** The possibility that an investigator's SFI is reasonably related to the research or the investigator's university responsibilities so that the SFI might compromise or be perceived to affect the design, conduct or reporting of the research, including the protection of the human research subjects.
- IV. **SIGNIFICANT FINANCIAL INTEREST (SFI) (42 CFR 50.603):** Identified when:
 - A. The value of any remuneration received from an external entity at present or in the 12 months preceding the disclosure that when aggregated for the investigator and family members totals or exceeds \$5,000. The \$5,000 threshold also applies to salary, royalties, and other payments aggregated for the investigator and family members.
 - B. The value of a publicly-traded equity (plus any remuneration) meets or exceeds \$5,000.
 - C. Any level of ownership in a privately-held equity regardless of the dollar value.
 - D. Intellectual property rights (e.g., patents, trademarks, copyrights, licensing agreements, and royalties from such rights)
 - E. Any other relationships that might present a conflict of interest, such as fiduciary interests (paid or unpaid positions as director, officer, or other management role in a for-profit or not-for-profit entity sponsoring or related to the research) or interests in which compensation or the value of equity or property rights or the combination of interests might affect the outcome of the research.

The following SFIs are exempt (42 CFR 50.603) from the disclosure requirements:

- i. salary, royalties or other remunerations paid by the University of Illinois; including intellectual property rights assigned to the University of Illinois and agreements to share royalties related to such rights;
 - ii. income from investment vehicles (mutual funds or retirement account that are not managed directly by the individual);
 - iii. income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined by 20 U.S.C. 1001(a); an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
 - iv. income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined by 20 U.S.C. 1001(a). (e.g., NIH review panel)
- V. **INSTITUTIONAL CONFLICT OF INTEREST:** The possibility that financial interests of the university or a university official acting within his or her authority on behalf of the institution might affect or reasonably appear to affect institutional processes for the design, conduct, reporting, review, or oversight of human subjects research. Examples of institutional conflict of interest include but are not limited to:
 - A. The university has an equity interest in a company or the university holds a patent, license, or some type of intellectual property interest related to the product that is the subject of the research.

- B. A university official acting within his or her authority on behalf of the institution has equity interest, serves on an advisory or other Board, or serves in a fiduciary role in an entity that has an interest in the outcome of human subjects research.
 - C. Gifts to the university or university official from a company or other entity that has an interest in the outcome of human subjects research.
- VI. **REBUTTABLE PRESUMPTION:** An assumption that an investigator with a FCOI may not be involved in research that uses human subjects. The rule is not intended to be absolute; an investigator with a FCOI may rebut the presumption by demonstrating facts that constitute compelling circumstances, in the opinion of the reviewing body. If compelling circumstances are found, the individual is allowed to design, conduct, report, or manage the research under conditions specified in an approved management plan and in accordance with regulatory and ethical requirements. An investigator with a FCOI must provide both a sufficient reason detailing his/her unique contribution to the research and a reasonable plan that will protect human subjects, the research data, and the integrity of the HSPP.

PROCEDURE:

At UICOM-P, conflicts of interest are reported through transactional processes. The transactional disclosures are linked to specific research protocols.

I. Transactional Disclosures—Unpaid University Faculty or Non-University

A. Unfunded/Non-Sponsored Research

1. Non-Sponsored Significant Financial Conflict of Interest Disclosure Form (NSCIODF)
 - a. The Principal Investigator is responsible for identifying SFIs that may exist for all investigators associated with a research protocol. In addition, other real or apparent conflicts of interest that may affect human subject protections or the integrity of the HSPP, including institutional conflicts of interest, must be disclosed by the PI.
 - b. SFIs must be disclosed at the initial review of a project or at the time of continuing review. The PI is also required to promptly disclose all real or apparent SFIs developing after the initial approval of the research, or any time the PI realizes that an existing interest has not been fully disclosed. New key personnel being added to any studies require an updated Significant Financial Conflict of Interest Disclosure Form completed by the PI. New disclosures must be made using the Change in Research form. The PI is required to sign electronically in IRBNet.
2. SFI disclosures are required whether the research is eligible for exempt or expedited review (greater than minimal risk studies; i.e. full board studies, will require completion of the Part I: Significant Financial Interest Disclosure Form (SFIDF) for each investigator (**please see section B1.**)
3. If the Part I: SFIDF indicates a SFI for the investigators associated with a research protocol, the OHRO will contact the Principal Investigator for clarification and instructions to complete Part II (**please see section B2.**)

B. Funded/Sponsored Research

1. Part I: Significant Financial Interest Disclosure Form (Part I: SFIDF)

- a. All Investigators involved in the research (see Definition I) must disclose all real, apparent, or potential SFIs to the IRB; including institutional conflicts of interest.
- b. All Investigators will be required to answer 5 questions on the Part I Disclosure Form including:
 - Declarant Information
 - Remuneration for salary or payments for service
 - Interest in Publicly Traded Entity
 - Interest in Non-Publicly Traded Entity
 - Intellectual Property Interest
 - Reimbursed Travel/Sponsored Travel
 - Relation of SFI to the research
 - Timeframe of relationship
- c. All investigators involved in the research are required to physically sign the Part I Form before uploading into IRBNet.
- d. The IRB will review all SFI disclosures by Investigators via Part I and determine whether the disclosure is related to a research protocol and whether a FCOI exists. NOTE: A SFI disclosure on this form will prompt a request for the submission of the Part II: SFIDF, which requires a proposed management plan.

2. Part II: Significant Financial Interest Disclosure Form

- a. Upon determination by the IRB that the SFI disclosure in Part I represents a FCOI or if the Investigator self-identifies that the SFI may present a potential FCOI with the proposed IRB protocol, then the Investigator must complete Part II of the SFIDF form.
- b. All Investigators presenting a FCOI or an Investigator who self-identifies that the SFI may represent a potential FCOI is required to answer 5 questions on the Part II Disclosure Form including:
 - Declarant Information
 - Role of conflicted Investigator
 - Description of SFI
 - Relation of SFI to the research
 - Function of conflicted Investigator in the research
 - Justification for conflicted Investigator's involvement in the research
- c. Part II presents the management techniques that will be put in place to manage the conflict.
- d. All conflicted Investigators involved in the research are required to physically sign the Part II Form before uploading into IRBNet.
- e. The IRB has final authority to approve the research, including the management mechanisms being implemented to manage or eliminate the conflict (as described in the Part II Form.) The IRB will make a determination regarding the level of disclosure required in the consent process, if any, as well as other measures to manage or eliminate the potential conflict. If the IRB determines additional

disclosure or measures to protect subjects are necessary, revisions will be requested to the research protocol, protocol application, and/or consent document/process as part of the review.

- f. All FCOIs must be managed or eliminated prior to expenditure of funding.

II. Transactional Disclosures—Paid University Faculty ONLY

A. Unfunded/Non-Sponsored Research

1. Non-Sponsored Significant Financial Conflict of Interest Disclosure Form (NSCIODF)

Same procedures described in I.A.1-3.

B. Funded/Sponsored Research

1. University Proposal Approval Form (PAF)

- a. The PAF includes a COI Certification section which must be completed as follows:
 - FOR ALL SPONSORED RESEACH the University requires that all Investigators must indicate on the PAF COI Certification when a SFI is reasonably related to the sponsored research in the proposal or the investigator's University responsibilities.
 - FOR PHS SPONSORED RESEACH the University also requires senior/key research personnel to indicate on the PAF COI Certification when a SFI is reasonably related to the PHS-sponsored research proposal or their University responsibilities.
 - FOR PHS SPONSORED RESEACH the University requires that all PHS investigators and senior/key research personnel must complete Part I of the SFI-DMP annually, regardless of whether they have any SFIs to disclose; Part II must be completed when a SFI is determined by designated University officials to represent a FCOI with the proposed research. Annually or at the time of continuing review of the grant, Part I must be updated for all PHS funded investigators and senior/key research personnel while Part II may require updating if a change to the SFI disclosure is determined by University designated officials to require additional management or elimination of the FCOI.
 - FOR NON-PHS SPONSORED RESEARCH the University requires that when an Investigator indicates on the PAF COI Certification that there is a SFI reasonably related to the sponsored research or the Investigator's University responsibilities, then the Investigator must complete Part I of the SFI-DMP form; Part II must be completed when a SFI is determined by designated University officials to represent a FCOI with the proposed research.

The PI submits the PAF to ORS Grants and Contracts Pre-Awards. ORS forwards all PAF forms with disclosed SFIs to the campus COI Office for review.

- b. The COI Office contacts the Investigator to obtain the SFI-DMP: Part I. A Part II of the SFI-DMP is subsequently requested if the SFI disclosed in Part I is determined by University designated officials to represent a Financial Conflict of Interest (FCOI) with the research.
- c. When a PAF with a FCOI determination indicates that the research involves human subjects, the campus COI Office will notify the OHRO of the existence of a potential conflict of interest.
- d. The OHRO will match the sponsored research project identified by the campus COI Office with the applicable research protocol. The OHRO will ensure that initial IRB approval is not granted until the COI Office has communicated the recommendation for a management plan, the SFI-DMP, to the IRB for its review and approval.

2. Development of Management Plan (SFI-DMP) and IRB Review

- a. The SFI creating the FCOI need not always be eliminated; however, the FCOI must be managed in order to reduce the potential for the conflict to adversely affect the conduct of the research, including the protection of human subjects or the integrity of the research data. A research protocol with an identified FCOI will not receive approval from the IRB until a recommendation for a management plan (SFI-DMP) is received from the COI Office. The SFI-DMP is composed of two parts, Part I represents disclosure of SFI and management when disclosure is sufficient; Part II represents additional management mechanisms when disclosure alone is not sufficient to manage a FCOI.
- b. The main elements of the SFI-DMP: Part I include:
 - Description of the financial relationship with the non-University entity.
 - Description of how the financial interest is or may be related to the Investigator's research or University responsibilities.
- c. The four main elements of the SFI-DMP: Part II include:
 - Description of the nature of the conflict.
 - Description of conflicted investigator's role and function in the research.
 - Justification for the inclusion of the conflicted investigator/conflict in the research which must address the principle of rebuttable presumption.
 - Description of the proposed management techniques/mechanisms.
- d. The SFI-DMP may include one or more specific techniques or strategies including, but not limited to, the following:
 - Disclosure of the conflict in writing or orally, as is appropriate, to the public, the sponsor, the IRB, researchers and other participants, publishers, or conference organizers and attendees;
 - Disclosure of the conflict to potential research subjects through the informed consent process;
 - Monitoring and/or auditing of the conduct of the research by independent overseers or a panel (e.g., data safety monitoring board) who have no professional ties to the research or direct reporting relationships to the investigators;
 - Modification of the research plan, methodology, or performance to add additional protections or to minimize the role of the conflicted individual;
 - Disqualification from participation in the conduct of the research or restriction of a researcher's role in all or a portion of the research (e.g.,

- cannot conduct data analysis, restricted from recruiting human subjects, and/or conducting the informed consent process);
- Requirement that a monitor or research subject's ombudsperson be present during recruitment and/or the informed consent process;
 - Divestiture or restructuring of the significant financial interest;
 - Modification of the significant financial interest or severance of relationships that create actual or perceived potential conflicts of interest.
- e. Following the acceptance of the SFI-DMP by either the COI-HSR subcommittee or the CRC, the recommendation for a management plan will be forwarded to PIRB. The submission (either initial review or an amendment related to the conflict of interest) will not be considered for final approval until a SFI-DMP is forwarded by the COI Office. Continuing Review submissions may be considered for final PIRB approval if a lapse in the approval period would increase harm to subjects or affect the integrity of the research. SFI-DMPs that are not finalized when the Continuing Review submissions are reviewed may be addressed through the submission of a separate amendment. PIRB has the authority to put into place restrictions of research activities to prevent harm to subjects until the FCOI has been adequately managed.
- f. PIRB will evaluate the SFI-DMP in the context of the research protocol. PIRB may approve the research with the SFI-DMP, or PIRB may modify the SFI-DMP by requiring additional measures to manage or eliminate a potential FCOI. Any revisions of the SFI-DMP initiated by PIRB will be communicated by the OHRO staff to the PI and the COI Office.
- g. PIRB has final authority to approve the research, including the management mechanisms being implemented in the research protocol as described in the SFI-DMP. PIRB will make a determination regarding the level of COI disclosure required in the consent process. PIRB may require other measures to manage or eliminate the potential FCOI. If PIRB determines additional disclosure or measures to protect subjects are necessary, revisions will be requested to the research protocol, protocol application, and/or consent document/process. Any revisions of the SFI-DMP initiated by PIRB will be communicated by the OHRO staff to PI and the COI Office.

3. Annual Disclosure

- a. Illinois Law and University statutes and regulations require each salaried member of the academic staff complete a Report of Non-University Activities (RNA). The RNA must be completed at least annually, and updated if activities change during the year. The RNA serves as the University management plan for the academic staff member's non-University income producing activities in most cases.
- b. The disclosure of potential conflicts through the RNA process represents the sum total of an individual's external activities over a 12-month academic year rather than a SFI with a specific research protocol. On an as-needed basis, the campus COI Office will communicate with the OHRO. The UICOM-P and UIC offices work together to ensure that potential FCOIs relating to human subjects research are reported to PIRB and any information that is pertinent to the PIRB's review of the research is made available to OHRO.

