

**Investigator Conflict of Interest
Disclosure Policy for Human
Subjects Research**

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INTRODUCTION:

Investigators must monitor whether new conflicts arise on a continuous basis until a final report is approved by the IRB. Investigators must disclose conflicts at initial review or whenever a new conflict arises, the Principal Investigator must disclose the conflict via an amendment. Previously-reported and new conflicts must be disclosed at the time of continuing review.

DEFINITIONS:

I. **INVESTIGATOR:** any person responsible for the design, conduct, or reporting of the research. In accordance with UIC HSPP policy, this includes, but is not limited to, the Principal Investigator, 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 [engages](#) the University in research involving human subjects pursuant to the review and approval of the IRB; or is otherwise identified as involved in research by a Principal Investigator, Chair or Department Head, or other University administrative officer responsible for research activities.

For purposes of this policy, "Investigator" includes the investigator's spouse and children.

- II. **CONFLICT OF INTEREST:** The possibility that an investigator's interests might compromise or be perceived to affect the design, conduct or reporting of the research, including the protection of the human research subjects.
- III. **APPARENT CONFLICT OF INTEREST** (also called perceived conflict of interest or appearance of conflict of interest): The possibility that a conflict might adversely affect the credibility of the research or the HSPP if the conflict were publicly exposed.
- IV. **SIGNIFICANT FINANCIAL INTEREST:** Anything of monetary value held by the investigator, his/her spouse, or children exceeding an aggregate threshold of \$10,000 in a 12-month period or 5% ownership regardless of value. Categories of financial interest include but are not limited to:

- A. Salary or other payments for services (e.g., consulting fees or honoraria);
- B. Equity interests (e.g., stocks, stock options or other ownership interests);
- C. Intellectual property rights (e.g., patents, trademarks, copyrights, licensing agreements, and royalties from such rights).
- D. Any other relationships that might present a financial conflict of interest, such as fiduciary interests (e.g., the investigator or investigator's spouse or children holding paid or unpaid positions as director, officer or other management positions 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, may be affected by the outcome of the research.

Significant financial interest does not include:

- A. Salary or other remuneration from the University or the JBVAMC;
 - B. Income from seminars, lectures, or other teaching engagements sponsored by public or non-profit entities;
 - C. Income from service on advisory committees or review panels for public or non-profit entities (Note: service on boards of directors for non-profit entities sponsoring or related to the research should be disclosed);
 - D. Holdings in mutual funds or pension accounts over which the investigator or his/her immediate family does not exercise control;
 - E. An equity interest that when aggregated for the investigator and the investigator's spouse and children meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, or does not represent more than a five percent (5%) ownership interest, regardless of value, in any single entity; or,
 - F. Salary, royalties or other payments that when aggregated for the investigator and the investigator's spouse and children over the next 12 months are not expected to exceed \$10,000.
- 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. An 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. **MANAGEMENT PLAN:** A written plan describing the mechanisms and techniques by which known or apparent conflict of interest related to the research

may be managed, reduced, or eliminated. Depending on the nature of the conflict and the management plan, reviewing bodies of the management techniques may include the Department Head, Dean, COI Office, Conflict Review Committee (CRC), the Conflict of Interest in Human Subjects Research (COI-HSR) subcommittee, and/or other institutional officials as relevant. The COI is described and the management plan is operationalized through the development of the Statement of Explanation and Management (SEAM) form. The COI office provides a recommendation for a management plan found to be acceptable by either the CRC or the COI-HSR subcommittee. The IRB has final authority to approve the research, including the management mechanisms being implemented in the research protocol as described in the SEAM.

VII. STATEMENT OF EXPLANATION AND MANAGEMENT (SEAM): The form utilized to describe the conflict of interest and present a plan for managing the conflict in order to minimize the effect on the design, conduct, or reporting of the research and/or the integrity of the human subject protection program. The form and guidance can be found at http://uic.edu/depts/ovcr/research/conflict/COI_statements.shtml. The COI Office assists the investigator in the SEAM's development. Once a SEAM is determined to be acceptable by either the COI-HSR subcommittee or the CRC, the COI Office will communicate the recommendation to OPRS for review by the IRB.

VIII. REBUTTABLE PRESUMPTION: An assumption that an investigator with a significant financial interest may not be involved in research that uses human subjects. The rule is not intended to be absolute; an investigator with a significant financial interest may rebut the presumption by demonstrating facts that constitute compelling circumstances, in the opinion of the reviewing bodies (Department Head, Conflict of Interest Officer, CRC, COI-HSR subcommittee, and IRB). 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 (SEAM) and in accordance with regulatory and ethical requirements. An investigator with a significant financial stake in the outcome of the research will need to 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.

POLICY:

I. Federal regulations (Public Health Service, National Science Foundation, Food and Drug Administration, Veterans Health Administration) and University policies require that investigators disclose significant financial interests related to the research 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 real or potential conflicts and for the development of a management plan that manages, eliminates, or reduces the potential conflict. The disclosure and management of the conflict must occur before any funds are released to the grantee institution and contractors (investigator) 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 HSPP. For the HSPP and the IRB, the disclosure of conflicts goes beyond financial conflicts, and includes institutional conflicts of interest and other potential conflicts, 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.

PROCEDURE:

At UIC, conflicts of interest are reported through transactional and annual disclosure processes. The transactional disclosures are linked to specific funding proposals and research protocols.

- I. Transactional disclosures.
 - A. Proposal Approval Form (PAF).
 1. In this transactional disclosure mechanism, investigators are required to disclose financial conflicts of interest on each PAF submitted to ORS Grants and Contracts Pre-Awards. All applications for research funding and support are processed using the PAF mechanism. ORS forwards all PAF forms with disclosed conflicts of interest to the campus COI Office for review.
 2. The COI Office contacts the Principal Investigator and assists him/her or her designee in the development of a SEAM. A SEAM is required for all PAFs disclosing a conflict of interest.
 3. When a PAF discloses a conflict of interest and indicates that the research involves human subjects, the campus COI Office will notify the OPRS of the existence of a potential conflict of interest in accordance with the COI/OPRS Coordinating SOP.
 4. The OPRS will match the conflict disclosure identified by the campus COI Office with the applicable research protocol. The OPRS will ensure that initial IRB approval is not granted until the COI Office has communicated the recommendation for a management plan, the SEAM, to the IRB for its review.
 - B. OPRS/IRB Application Form.
 1. The Principal Investigator is responsible for identifying significant financial conflicts of interest 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.
 2. Conflicts of interest must be disclosed on the initial review, amendment, and continuing review OPRS application forms, whether the research is eligible for exempt, expedited, or full review.
 3. The PI must disclose conflicts of interest on the initial review application. The PI is also required to promptly disclose all real or apparent conflicts of interest developing after the initial approval of the research, or any time the PI realizes that an existing conflict has not been fully disclosed. This disclosure must be

made using the amendment form promptly when the conflict arises or is discovered.

4. When the application form discloses a financial conflict of interest on a human subjects research protocol, the OPRS will notify the COI Office in accordance with the COI/OPRS Coordinating SOP.
5. If the disclosure represents a significant financial conflict of interest, the COI Office will contact the Principal Investigator to develop a SEAM. The COI office will assist in the development of a SEAM for significant financial conflicts, and, if requested by OPRS, for institutional conflicts of interest.
6. Once a SEAM is determined to be acceptable by either the COI-HSR subcommittee or the CRC, the COI Office will communicate the recommendation to OPRS, including the SEAM, for review by the IRB.
7. The OPRS will match the SEAM with the applicable research protocol. The OPRS will ensure that initial IRB approval is not granted until the COI Office has communicated its recommendation for a management plan, the SEAM, to the IRB for its review.
8. The IRB has final authority to approve the research, including the management mechanisms being implemented in the research protocol as described in the SEAM. The IRB will make a determination regarding the level of disclosure required in the consent process, as well as other measures to reduce 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.

II. Annual Disclosure.

The annual disclosure is reported through the Report of Non-University Activities process.

- A. Illinois Law and University statutes and regulations require each salaried member of the academic staff complete a Report of Non-University Activities (RNUA). The RNUA must be completed at least annually, and updated if activities change during the year. Department heads are responsible for reviewing the RNUAs submitted by individuals within their department and for forwarding the RNUAs with disclosed conflicts to the next administrative level (e.g., Dean, Vice Chancellor, Provost) for additional review. RNUA forms disclosing conflicts of interest are then forwarded to the campus COI Office. If it is determined to be necessary, the individual will complete a written Conflict Management Plan (CMP; OVCR Form 0703) that is reviewed and approved by the CRC and approved by the Vice Chancellor for Research.
- B. The disclosure of potential conflicts through the RNUA process represents the sum total of an individual's external activities over a 12-month period rather than a conflict with a specific research protocol. On an as-needed basis, the campus COI Office will communicate with the OPRS. In accordance with the COI/OPRS Coordinating SOP, the offices work together to ensure that potential conflicts of interest relating to human subjects research are reported to the IRB and any information that is pertinent to the IRB's review of the research is made available to OPRS.

III. Development of Management Plan (SEAM) and IRB Review.

- A. When a potential conflict of interest involving human subjects research is disclosed, the investigator must respond to the rebuttable presumption in the SEAM. Conflicts of interest need not always be eliminated; however, they need to 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 potential conflict of interest will not receive initial approval from the IRB until a recommendation for a management plan (SEAM) is received from the COI Office.
- B. The four main elements of the SEAM include:
 - 1. Description of the nature of the conflict.
 - 2. Description of conflicted investigator's role and function in the research.
 - 3. Justification for the inclusion of the conflicted investigator/conflict in the research.
 - 4. Description of the proposed management techniques/mechanisms.
- C. The SEAM may include one or more specific techniques or strategies including, but not limited to, the following:
 - 1. 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;
 - 2. Disclosure of the conflict to potential research subjects through the informed consent process (sample disclosure language for the consent document is available from the SEAM web page referenced in the definitions section, above).
 - 3. 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;
 - 4. Modification of the research plan, methodology, or performance to add additional protections or to minimize the role of the conflicted individual;
 - 5. 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);
 - 6. Requirement that a monitor or research subject's ombudsperson be present during recruitment and/or the informed consent process;
 - 7. Divestiture or restructuring of the significant financial interest;
 - 8. Modification of the significant financial interest or severance of relationships that create actual or perceived potential conflicts of interest.
- D. Following the acceptance of the SEAM by either the COI-HSR subcommittee or the CRC, the recommendation for a management plan will be forwarded to the IRB. The submission (either initial review or an Amendment related to the conflict of interest) will not be considered for final approval until a SEAM is forwarded by the COI Office. Continuing Review submissions may be considered for final IRB approval if a lapse in the approval period would increase harm to subjects or affect the integrity of the research. SEAMs that are not finalized when the Continuing Review submissions are reviewed may be addressed through the submission of a separate Amendment. The IRB has the authority to put into

place restrictions of research activities to prevent harm to subjects until the COI plan has been adequately managed.

- E. The IRB will evaluate the SEAM in the context of the research protocol. The IRB may approve the research with the management plan as presented in the SEAM, or the IRB may modify the management plan, including the requirement of additional measures to manage, reduce or eliminate a potential conflict in the research.
- F. The IRB has final authority to approve the research, including the management mechanisms being implemented in the research protocol as described in the SEAM. The IRB will make a determination regarding the level of disclosure required in the consent process. The IRB may require other measures to manage, reduce 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.

IV. Research at the JBVAMC.

- A. Research involving human subjects engaging the JBVAMC will be reviewed by the Collaborative JBVAMC/NU/UIC IRB (UIC IRB#4). Conflicts of interest will be handled in accordance with the UIC HSPP policy *Investigator Conflict of Interest Disclosure Policy for Human Subjects Research*. NU and UIC will manage financial and institutional conflicts of interest for research involving their respective faculty in accordance with their own policies.
- B. The disclosure of the conflict will occur on the respective NU or UIC IRB application form until the Collaborative IRB application form is operational. In addition, the VA form [Research Financial Conflict of Interest Statement](#) must be submitted as part of the R&D application and be reviewed by the Collaborative IRB.
- C. For investigators having a UIC appointment or a JBVAMC-only appointment, when a potential conflict of interest is disclosed, the UIC COI Office will work with the investigators to develop a management plan (SEAM) for financial conflicts of interest, which will be processed in accordance with the COI/OPRS Coordinating SOP.
- D. For investigators with a NU-only or a NU/JBVAMC-only (no UIC appointment) appointment disclosing a potential conflict of interest, NU will be responsible for the evaluation and provision of a conflict management plan, as appropriate, to the Collaborative IRB.
- E. Institutional conflicts of interest for JBVAMC are reported to the ACOS for R&D by UIC and NU and evaluated by the ACOS for R&D or designee at the time of the IRB pre-review by the JBVAMC R&D office. If an institutional conflict of interest is found, the Medical Center Director consults with the ACOS for R&D and regional counsel to develop a management plan.
- F. The IRB has the final authority to decide whether the conflict of interest and management plan are acceptable and to allow the research to be approved.
- G. The IRB has final authority to approve the research methods and the management mechanisms being implemented in the protocol, including, but not limited to, the means and level of disclosure to subjects.

- H. The protocol is not forwarded to the JBVAMC R&D Committee until after IRB approval of the research, including any conflict of interest management plan. The IRB will inform the JBVAMC R&D Committee of the conflict of interest management plan by means of the correspondence to PI, the approved consent document(s), and/or the IRB meeting minutes.

REFERENCES:

[Public Health Service 42 CFR 50 Subpart F](#)
[National Science Foundation Grants Policy Manual Section 510](#)
[21 CFR 54](#)
[Department of Health and Human Services Final Guidance Document, *Financial Relationships and Interest in Research Involving Human Subjects: Guidance for Human Subjects Protection*](#)
[110 Illinois Compiled Statutes \(ILCS\) 100/1](#)
[University of Illinois *Policy on Conflicts of Commitment and Interest* adopted in March 1996 and a clarification adopted in March 1998](#)
[VHA Handbook 1200.05 \(7\)](#) - in proposed revision 1200.05 (9)

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 3/06/09	1.0, 4/17/07	Revised definitions, inclusion of definition of institutional COI, addition of SEAM form and review process, references to COI/OPRS Coordinating SOP, clarification of the recommendation provided by the SEAM, inclusion of the VA Research Financial Conflict of Interest Statement, and update of JBVAMC section to ensure consistency with the Operating and Coordinating Policy of the Collaborative IRB.
1.2, 6/11/09	1.1, 3/06/09	Pages 5, 6, 7 change the word 'final' to 'initial.' Page 6, Section III A: added "unless concerns for the protection of human subjects warrants otherwise." Clarification of the IRB's process for approving a protocol in relation to the SEAM.
1.3, 5/09/2011	1.2, 6/11/09	Update definition of institutional conflict of interest