

Section 9: Conflict of Interest & Undue Influence

9.1. Investigator Conflict of Interest

Policy

The UIR follows federal regulations (Public Health Services, National Science Foundation, Food and Drug Administration) and institutional policies which require investigators to 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 UIR 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 (investigators) for expenditure.

The UIR 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 UIR 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 the conflicts of interest apply equally to all research whether the study is funded or non-funded.

Procedures

Definitions

Investigator

Any person responsible for the design, conduct, or reporting of the research. In accordance with UIR 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, staff member, fellow, student, 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 the PI, Chair or Department Head, or other University administrative officer responsible for the research activities. For purposes of this policy, “investigator” includes the investigator’s spouse and children.

Conflict of Interest (COI)

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.

Apparent Conflict of Interest

The possibility that a conflict might adversely affect the credibility of the research or the institution if the conflict were publicly exposed.

Significant Financial Interest

Anything of monetary value held by the investigator, his/her spouse, or children exceeding an aggregate threshold of \$5,000 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. Direct payment to the PI;
- E. 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;
- 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. Holding 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 \$5,000 in value as determined through reference to public prices or other reasonable measure of fair market value, or does not represent more than a 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 \$5,000.

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:

1. 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.
2. 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 subject's research.

3. Gifts to the university or university official from a company or other entity that has an interest in the outcome of human subject's research.

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.

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 University. [SEAM Form and guidance](#).

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 (i.e. Department Head, Conflict of Interest Officer, IRB, etc.).

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

Transactional Disclosures

IRB Application Form:

1. The PI 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 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 anytime 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 subject research protocol, RSS will notify the COI office in Chicago.
5. If the disclosure represents a significant financial conflict of interest, the COI office will contact the PI to develop a SEAM. The COI office will assist in the development of a SEAM for significant financial conflicts.
6. Once a SEAM is determined to be acceptable by either the COI-Human Subjects Research (HSR) subcommittee or the Conflict Review Committee (CRC) in Chicago, the COI Office will communicate the recommendation to RSS, including the SEAM for review by the UIR IRB.
7. RSS will upload the SEAM in the applicable IRBNet package. RSS 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 UIR IRB for its review.
8. The UIR IRB has final authority to approve the research, including the management mechanisms being implemented in the research protocol as described in the SEAM. The UIR 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.

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 (RNA). The RNA must be completed at least annually, and updated if activities change during the year. Department heads are responsible for reviewing the RNAs submitted by individuals within their department and for forwarding the RNAs with disclosed conflicts to the next administrative level (e.g., Dean, Vice Chancellor, and Provost) for additional review. RNA forms disclosing conflict 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 RNA 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 Institutional Official. The COI Office and the Institutional Official will 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 RSS.

Development of Management Plan (SEAM) and IRB Review

- A. When a potential conflict of interest involving human subject's 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.
 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.

9.2. IRB Member, Ad Hoc Consultant, and RSS Staff Conflicting Interest

Policy

- I. An IRB member with a conflicting interest will not be counted toward quorum.
- II. An IRB member, consultant, or RSS staff member is automatically considered to have a conflicting interest when the member/consultant or the member's or ad hoc consultant's immediate family has any of the following:
 - A. Involvement in the design, conduct, or reporting of the research.
 - B. Ownership interest (equity or stock options) or other financial interest related to the research unless it meets four tests:
 1. The value of the interest does not exceed \$5,000 when aggregated for the immediate family.
 2. The interest is publicly traded on a stock exchange.
 3. The value of the interest does not exceed 5% interest in any one single entity when aggregated for the immediate family.

4. No arrangement has been entered into where the value of ownership interests will be affected in the outcome of the research.
 - C. Compensation related to the research unless it meets two tests:
 1. The value of the compensation does not exceed \$5,000 in the past year when aggregated for the immediate family.
 2. No arrangement has been entered into where the amount of compensation will be affected by the outcome of the research.
 - D. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- III. “Financial Interest Related to the Research” does not include:
- A. Salary or other remuneration from the University;
 - B. Income from seminars, lectures, or other teaching engagements sponsored by the public or non-profit entities;
 - C. Income from service on advisory committees or review panels for public or non-profit entities; and/or
 - D. Holdings in mutual funds or pension accounts over which the IRB member or his/her immediate family does not exercise control.
- IV. “Other Interest” includes but is not limited to:
- A. Supervision of a project (i.e., an IRB member is the investigator’s Faculty Sponsor, or a situation exists in which any investigator must report to or is under the professional supervision of the IRB member);
 - B. Personal relationship with investigator (IRB member has an immediate family relationship or other close personal relationship with the investigator);
 - C. Other personal interests that may be conflicting interests, such as if (a) the IRB member has an interest that he/she believes conflicts with the member’s ability to review a project objectively; or (b) the IRB member is in direct competition with the investigator for limited resources, funding, sponsorship, or research subjects, (c) the IRB member is considered a personal or professional adversary of the investigators, or (d) the IRB member is a subordinate to the investigator. For (b), (c), and (d), the IRB member should disclose the circumstances to the IRB Chair or RSS Specialist for a determination of whether a conflicting interest exists; and/or
 - D. Any other reason for which the member or consultant believes that he or she cannot provide an independent review.

Procedures

- I. IRB Member Conflict of Interest
 - A. IRB members with a conflicting interest must recuse themselves from the meeting room for the review of research including the discussion and voting except to provide information requested by the IRB. IRB members are responsible for the

self-identification of their conflicting interests in advance of both convened IRB review and review using the expedited procedure.

- B. When an IRB member has a conflicting interest at a meeting the chair will ask the remaining IRB members whether they have any questions regarding the conflict of interest for the IRB member with a conflicting interest. Then the IRB chair will ask the IRB member with a conflicting interest to leave the room until the discussion and voting is complete.
- II. Ad Hoc Consultant Conflict of Interest
 - A. When the IRB uses an ad hoc consultant to aid in the review of a particular research protocol, the consultant must not have a real or perceived conflict of interest with the research. When an ad hoc consultant is identified, RSS staff informs them of this policy and determines whether the consultant has a conflicting interest. Ad hoc consultants with a conflicting interest may not serve as a consultant.
- III. RSS Staff Conflict of Interest
 - A. RSS staff is expected to self-identify when they have a conflicting interest with a protocol and to not be involved in any protocol in which they have a conflicting interest.

9.3. Undue Influence of IRB Members and RSS Staff

Policy

Undue influence with regards to the IRB refers to any attempt to interfere with the standard procedures of the IRB or to appropriately place pressure on an IRB member, IRB Chair or RSS staff member in order to obtain a specific outcome from the IRB or one of its members or staff. Any attempts to unduly influence any member of the IRB or RSS staff threatens the independence of the IRB and the integrity of the HSPP; and requires prompt reporting by individuals who experience or are aware of occurrences of undue influence.

Procedures

- I. Procedures for reporting allegations of undue influence for all research in which UIR is engaged are as follows:
 - A. IRB members should report this behavior to the IRB Chair.
 - B. IRB Chairs should report this behavior to the Institutional Official (IO).
 - C. RSS staff should report this to the IO.
 - D. If the IRB member believes the undue influence is coming from the IRB Chair it should be reported to the IO.
- II. Any allegations of undue influence are initially assessed for merit by the IRB Chair. Alternate individuals are assigned to fulfill these responsibilities in the event of a conflict of interest with the allegation of undue influence. In the event of a conflict of interest,

the individual responsible for review must recuse themselves from the review and the IO will investigate.

- III. Determinations resulting from the appropriate review of the allegations may include the following:
 - A. No response necessary, there was no intent for undue influence and there was no resultant influence on an IRB determination, RSS staff process, or within the HSPP program; or
 - B. Undue influence occurred; the investigator(s) will develop a corrective action plan, which may include possible sanctions.
- IV. The determinations are submitted to the IO in a written report prepared by the RSS Specialist.
- V. The written report is copied by the RSS Specialist to the IRB and the Institutional Official.
- VI. The IO determines whether more information from the investigator(s) is necessary and makes a final determination as to the report written by the investigator(s). If the IO has a conflict due to the perceived source or the nature of the undue influence, the behavior should be reported directly to the Associate Vice Chancellor for Research.
- VII. The IO at which the undue influence occurred is responsible for providing written notification to the person(s) who the investigation is directed against of the findings and the corrective action plan, if applicable, and ensuring the corrective action plan is carried out.
- VIII. The corrective action plan will be reviewed by the IRB. The IRB will evaluate whether the occurrence represents serious and/or continuing non-compliance.