OFFICE OF THE VICE CHANCELLOR FOR RESEARCH

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Institutional Review Board
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Investigator Conflict of Interest Disclosure Policy for Human Subjects Research

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Director of OPRS,
and Executive IRB Chair
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INTRODUCTION:

The University of Illinois Policy on Conflict of Commitment and Interest and the campus processes comply with the Public Health Services (PHS) Regulations, Department of Health and Human Services 42 CFR Part 50 and 45 CFR Part 94, on Financial Conflicts of Interest (FCOI). In addition, the processes are in compliance with the FDA regulation 21 CFR 54.2 regarding Financial Disclosure by Clinical Investigators. The policy and processes ensure accountability, transparency, regulatory compliance and effective Institutional management of Investigators' financial conflicts of interest. 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 financial conflicts of interest. In accordance with the Human Subjects Protection Program (HSPP) Policy, the *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 (Public Health Service, National Science Foundation, Food and Drug Administration) and University policies require that investigators disclose significant financial interests (SFIs) that are reasonably related to the research or to an investigator's University 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 Financial Conflict of Interest (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 by the University 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 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. 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, Unit Executive Officers, or other University 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 Significant Financial Interest (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): Consists of one or more of the following interests of the Investigator (and those of the Investigator's family) that appear to be reasonably related to the sponsored research or to the Investigator's University responsibilities:
   A. With regard to any **publicly traded entity**, a significant financial interest (SFI) exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds **$5,000**.
      - For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measure of fair market value;
   B. With regard to any **non-publicly traded entity**, a significant financial interest (SFI) exists if the value of any remuneration received from the entity in the twelve

months preceding the disclosure, when aggregated, exceeds **$5,000**, or when the Investigator or Investigator's family holds ***any*** equity interest (e.g., stock, stock options, or other ownership interest); or

C. Intellectual property rights and interests (e.g., patents, trademarks, copyrights, licensing agreements, and royalties from such rights), upon receipt of income related to such rights and interests.

D. HHS/PHS Investigators must also disclose the occurrence of reimbursed or sponsored travel. There is a $5,000 de minimis for reporting sponsored or reimbursed travel. University designated officials must assess the travel disclosure and determine whether the sponsored or reimbursed travel presents financial conflicts of interest.

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 and sponsored or reimbursed travel 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. DESIGNATED UNIVERSITY OFFICIALS FOR REVIEW OF SFI-DMP: Include the Unit Executive Officer(s), COI Officer, Conflict Review Committee (CRC), the Conflict of Interest in Human Subjects Research (COI-HSR) subcommittee, IRB, and/or other institutional officials as relevant.

VII. SIGNIFICANT FINANCIAL INTEREST – DISCLOSURE AND MANAGEMENT PLAN (SFI-DMP): The SFI-DMP has two parts (disclosure and management plan). University investigators complete the SFI-DMP by using an online questionnaire in the START myDisclosures application. https://myresearch.uillinois.edu/myDisclosures/ A questionnaire is utilized to disclose the Significant Financial Interest (SFI) and determine if a SFI represents a Financial Conflict of Interest (FCOI) with an Investigator's research. START myDisclosures also includes a project specific management plan tool that is utilized to present a plan specific to the research project for managing the Investigator's FCOI. The SFI-DMP serves to minimize the effect of FCOIs on the design, conduct, or reporting of the research and/or the integrity of the human subject protection program. The questionnaire is available at START myDislcosures: https://myresearch.uillinois.edu/myDisclosures/. Guidance can be found at https://research.uic.edu/compliance/conflict-of-commitment-interest-coi/ under the section "Managing Conflicts." The COI Office assists the investigator in the SFI-DMP's development. Once a SFI-DMP 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. The IRB has final authority to approve the research, including the management mechanisms being implemented in the research protocol as described in the SFI-DMP.

VIII. REBUTTABLE PRESUMPTION: An assumption that an investigator with a Financial Conflict of Interest (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 bodies (Unit Executive Officers, 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 (SFI-DMP) 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.

IX. INSTITUTIONAL RESPONSIBILITIES (e.g., University Responsibilities) means an Investigator's professional responsibilities on behalf of the University, which includes but is not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service

on panels such as Institutional Review Boards and Data Safety Monitoring Boards.

X. REIMBURSED OR SPONSORED TRAVEL: For investigators and senior/key research personnel on PHS sponsored researcher, or as required by the sponsor, there is a $5,000 de minimis for disclosing reimbursed or sponsored travel (42 CFR 50.603). Sponsored or reimbursed travel includes expenses such as airfare, gas, car rental, hotel room, meals, stipends, etc. Travel must be reported from any entity unless the travel is reimbursed or 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. Disclosures of sponsored or reimbursed travel must specify the purpose of the trip, the identity of the sponsor or organizer, the destination, the duration, and the aggregate value of the travel expenses paid by any one external entity. The University, through its designated officials, must determine if the travel represents a Financial Conflict of Interest (FCOI).

PROCEDURE:

At UIC, Significant Financial Interests (SFIs) are reported through transactional and annual disclosure processes. The transactional disclosures identify the related funding proposals and research protocols.

RECORDS MANAGEMENT: The University maintains records relating to all Investigator disclosures of financial interests and the University's review of, or response to, such disclosures (whether or not a disclosure resulted in the University's determination of a FCOI), and all actions under the University's policy or retrospective review, if applicable, for at least three years from the date of the final expenditures report is submitted to the NIH or, where applicable, from other dates specified in 45 CFR 74.53(b) and 94.42(b) for different situations.

I. Transactional disclosures.
   A. Proposal Approval Form (PAF).
      1. The PAF includes a COI Certification section which must be completed as follows:
         a) 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.
         b) 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.
         c) FOR PHS SPONSORED RESEACH the University requires that all PHS investigators and senior/key research personnel must complete disclosure of the SFI-DMP annually, regardless of whether they have

any SFIs to disclose; a management plan 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, disclosures must be updated for all PHS funded investigators and senior/key research personnel while the management plan 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.

d) 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 a disclosure; the management plan 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 a report of all PAF forms with disclosed SFIs to the campus COI Office for review.

2. The COI Office contacts the Investigator to obtain the disclosure. A management plan is subsequently requested if the SFI disclosed is determined by University designated officials to represent a Financial Conflict of Interest (FCOI) with the research.
3. When a PAF with a FCOI determination 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 sponsored research project 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 SFI-DMP, to the IRB for its review and approval.

B. OPRS/IRB Application Form.
1. The Principal Investigator is responsible for identifying significant financial interests (SFIs) that may exist for all investigators associated with a research protocol. In addition, institutional conflicts of interest that may affect human subject protections or the integrity of the HSPP must be disclosed by the PI.
2. SFIs 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 SFIs on the initial review application. The PI is also required to promptly disclose all real or apparent SFIs discovered or acquired after the initial approval of the research within 30 days of acquiring or discovering the SFI or when an existing SFI has not been fully disclosed.
4. When the application form discloses a SFI on a human subjects research protocol, the OPRS will notify the COI Office in accordance with the

COI/OPRS Coordinating SOP. The COI Office will ask the PI to complete a disclosure.

5. If the disclosure is determined by University designated officials to represent a Financial Conflict of Interest (FCOI), then the COI Office will contact the Principal Investigator (and conflicted investigator) to complete a management plan. The COI Office will assist in the development of a SFI-DMP for FCOIs, and, if requested by OPRS, a management plan for institutional conflicts of interest.
6. Once a SFI-DMP 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 SFI-DMP, to be reviewed by the IRB.
7. The OPRS will match the SFI-DMP 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 SFI-DMP, to the IRB for its review and approval.
8. The IRB has final authority to approve the research, including the management mechanisms being implemented in the research protocol as described in the SFI-DMP. The IRB will make a determination regarding the level of disclosure required in the consent process, 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.

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. The Unit Executive Officer is responsible for reviewing the RNUAs submitted by academic staff 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. The campus COI Office has read only access to view all RNUA disclosures in START myDisclosures. The RNUA serves as the University management plan for the academic staff member's non-University income producing activities in most cases. The START myDisclosures application identifies when a disclosure meets certain conditions defined by the University COCI Policy that require the academic staff member to follow the standard RNUA Terms & Conditions. Upon certification of the RNUA, the academic staff member confirms he/she will follow the RNUA Terms & Conditions.

RNUA Terms & Conditions:
https://www.vpaa.uillinois.edu/cms/one.aspx?portalId=420456&pageId=469536

In cases when a faculty start-up company will license University intellectual property, then a more detailed RNUA for the faculty start-up company 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 academic year. 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 FCOIs 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 (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, disclosure of the SFI; disclosure of the SFI may be determined to be sufficient to manage the conflict; and a management plan, which implements additional management mechanisms, when disclosure alone is not sufficient to manage a FCOI.

B. The main elements of the disclosure include:
1. Description of the financial relationship with the non-University entity.
2. 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 management plan 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 which must address the principle of rebuttable presumption.
4. 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:
1. Implementing an impartial review prior to the submission of a manuscript;
2. Disclosure of the conflict in writing or orally, as is appropriate, to the public, the sponsor, the IRB, researchers and other participants, PI of other study sites, publishers, or conference organizers and attendees;
3. Disclosure of the conflict to potential research subjects through the informed consent process (sample disclosure language for the consent document is available from the COI web page referenced in the definitions section, above).
4. 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;
5. Modification of the research plan, methodology, or performance to add additional protections or to minimize the role of the conflicted individual;
6. 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);
7. Requirement that a monitor or research subject's ombudsperson be present during recruitment and/or the informed consent process;
8. Divestiture or restructuring of the significant financial interest;
9. 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 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 SFI-DMP 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. SFI-DMPs 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 FCOI has been adequately managed.

F. The IRB will evaluate the SFI-DMP in the context of the research protocol. The IRB may approve the research with the SFI-DMP, or the IRB may modify the SFI-DMP by requiring additional measures to manage or eliminate a potential FCOI. Any revisions of the SFI-DMP initiated by the IRB will be communicated by the OPRS staff to the PI and the COI Office.

G. The IRB has final authority to approve the research, including the management mechanisms being implemented in the research protocol as described in the SFI-DMP. The IRB will make a determination regarding the level of COI disclosure required in the consent process. The IRB may require other measures to manage or eliminate the potential FCOI. 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. Any revisions of the SFI-DMP initiated by the IRB will be communicated by the OPRS staff to PI and the COI Office.

H. MONITORING: Appropriate monitoring of the activities and the management plan is required by the *University Policy on Conflict of Commitment and Interest*. The Unit Executive Officer is responsible for monitoring the implementation of management plans to ensure compliance with and evaluate the effectiveness of the conflict management mechanisms. Monitoring includes the submission and review of the annual disclosure. Other forms of monitoring may also be implemented, such as Unit Executive Officer oversight to evaluate the effectiveness of and ensure compliance with the mechanisms specified in a management plan.

I. SANCTIONS: The *University Policy on Conflicts of Commitment and Interest* states that sanctions are warranted for failure to report potential conflicts or to abide by a management plan. The University has the right to impose sanctions consistent with the rights of academic staff members under the university *Statutes* and other applicable policies and practices. Severity of sanctions depends on the extent of the violations of the Policy. Inadvertent, unintentional,

and minor breaches require lesser sanctions, whereas knowing, deliberate, and major violations demand the severest sanctions. Nothing in this Policy is intended to diminish or replace the procedural rights of academic staff, including the procedures for revocation of tenure contained in the *Statutes*. In situations that require the review of the Vice Chancellor for Research (VCR), the VCR will be advised by the Conflict Review Committee.

For HHS/PHS sponsored research: If an Investigator fails to comply with the University's COCI policy or a FCOI management plan, the University shall complete within 120 days of determining noncompliance a retrospective review of the Investigator's activities and the NIH-funded research project, document the University's methodology of reviewing the SFI(s), and document the University's determination as to whether any NIH-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research.

If bias is found, the University shall submit a mitigation report to the NIH, in accordance with 42 CFR 50.605(b)(3), that shall address the impact of the bias on the research project and the actions the University has taken to mitigate the bias.

The regulation further requires that if the NIH determines that one of its funded clinical research projects whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with an FCOI that was not managed or reported by the University, the University shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

IV. Education & Training

A. Annually, University academic staff must complete the Report of Non-University Activities (RNUA) and certify that he/she has read the *University Policy on Conflict of Commitment and Interest*.

B. For HHS/PHS sponsored research: Investigators and senior/key research personnel must complete a University-approved FCOI training prior to engaging in NIH-funded research and thereafter, every four years and immediately when any of the following circumstances apply:

1. The University revises the *Policy of Conflict of Commitment and Interest* and procedures in any manner that affects the requirements of the Investigator to comply with the PHS regulation;
2. An Investigator is new to the University of Illinois;
3. The University finds that an Investigator is not in compliance with the University's *Policy on Conflicts of Commitment and Interest* or with the University-approved management plan.

V. Reporting to Funding Agencies

A. Reporting to HHS/PHS Funding Agencies, the University has implemented the following procedures:
   1. At the time of application, the University provides a certification that it:
      a. Has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOIs with respect to all research projects for which funding is sought or received from the NIH;
      b. Shall promote and enforce Investigator compliance with the regulatory requirements including those pertaining to disclosure of SFIs;
      c. Shall manage any FCOI and provide initial and annual (e.g., ongoing) FCOI reports to the NIH consistent with the regulation;
      d. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the University's review of, or response to, such disclosure, whether or not the disclosure resulted in the University's determination of an FCOI; and
      e. Shall fully comply with the requirements of the regulation.

   2. Prior to spending any funds under an NIH award: The University must submit an FCOI report to the NIH for any identified FCOI of each Investigator and manage the FCOI. If the FCOI is eliminated prior to submission of the initial report, no FCOI report is required. In addition, the University shall submit an FCOI report for any FCOI(s) identified for subrecipient investigator, if applicable.
   3. Within sixty (60) days (FCOI identified during ongoing NIH-funded project): The University must submit an FCOI report to the NIH within sixty (60) days for any SFI that the University identifies as an FCOI subsequent to the University's initial FCOI report during an on-going (e.g., FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new SFI to the University during the period of the award). The University shall within sixty (60) days: review the disclosure of the SFI; determine whether it is related to the research; and if so, implement a management plan that shall specify the actions that have been and will be taken to manage such FCOI; and submit the FCOI report to the NIH.
   4. Within sixty (60) days of the Investigator's disclosure of an SFI that was not disclosed in a timely manner by the Investigator or if the University fails to review a previously existing SFI during an ongoing NIH-funded project, the University designated official(s) shall: Review the SFI; determine whether it is related to the NIH-funded research; and determine whether an FCOI exists. If an FCOI exists, the University must implement a management plan that shall specify the actions that have been or will be taken to manage such FCOI going forward and submit an FCOI report to the NIH. In addition to the FCOI report, the University must, within 120 days of the University's determination of noncompliance, complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the period of noncompliance, was biased in the design, conduct, or reporting of such research. Based on the results of the retrospective review, if appropriate, the

University shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

5. Promptly notify NIH when bias is found in the design, conduct or reporting of NIH-funded research: The University must promptly notify NIH and submit a mitigation report if bias is found during a retrospective review. The mitigation report must include the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the University's plan of action taken to eliminate or mitigate the effects of the bias. Thereafter, the University must submit FCOI reports annually.
6. Annually for any FCOI previously reported by the University with regard to an ongoing NIH-funded research project: For any FCOI previously reported, the University shall provide an annual FCOI report that addresses the status of the FCOI and any changes to the management plan. The University shall provide annual FCOI reports to the NIH for the duration of the project period (including extensions with or without funds) at the same time when the University is required to submit the annual progress report or at the time of project extension.

7. FCOI reports and mitigation reports submitted to the HHS/PHS Funding Agencies: For grants and cooperative agreement, all FCOI reports, including revised FCOI reports and mitigation reports will be submitted through the Office of Vice Chancellor for Research, Conflict of Interest Office. The University's FCOI Report will include, at minimum:
    a. Project number;
    b. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
    c. Name of the Investigator with the FCOI;
    d. Name of the entity with which the Investigator has an FCOI;
    e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
    f. Value of the financial interests (per specified ranges in the regulation) or a statement that the dollar value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
    g. A description of how the financial interest relates to the NIH-funded research and basis for the University's determination that the financial interest conflicts with such research;
8. A description of the key elements of the University's management plan, including:
    a. Role and principle duties of the conflicted Investigator in the research project;
    b. Conditions of the management plan;
    c. How the management plan is designed to safeguard objectivity in the research project;
    d. Confirmation of the Investigator's agreement to the management plan;
    e. How the management plan will be monitored to ensure Investigator compliance; and
    f. Other information as needed.

B. REPORTING TO OTHER FUNDING AGENCIES: The University will comply with the requirements of the funding agency.

VI. Research reviewed by the National Cancer Institute Central IRB (NCI CIRB) Initiative

A. Human subjects research involved in the NCI CIRB initiative are under the purview of the NCI CIRB. However, the UIC IRB is responsible for local context and oversight. UIC conflicts of interest will be handled in accordance with this policy. Rush University Medical Center and John H. Stroger, Jr. Hospital of Cook County 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 UIC CIRB application form.
C. For investigators with a UIC appointment, when a potential conflict of interest is disclosed, the UIC COI Office will work with the investigators to develop a management plan (SFI-DMP) for financial conflicts of interest, which will be processed in accordance with the COI/OPRS Coordinating SOP.
D. For investigators with a Rush University Medical Center or John H. Stroger, Jr. Hospital of Cook County appointment disclosing a potential conflict of interest, the respective institution will be responsible for the evaluation and provision of a conflict management plan, as appropriate, to the UIC IRB.
E. The UIC 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.
F. The UIC IRB has final authority to approve the management mechanisms being implemented, including, but not limited to, the means and level of disclosure to subjects.

VII. Research reviewed by Western IRB (WIRB)

A. Human subjects research eligible for review by the Western IRB (WIRB) are under the purview of WIRB. Investigators submit the UIC for *Registration for Protocol Review by Western IRB (WIRB)* and applicable documents to OPRS for an administrative review.
B. The disclosure of the conflict will occur on the WIRB application; however, the UIC form *Registration for Protocol Review by Western IRB (WIRB)* includes instructions that if a Financial Interest has been declared that exceeds $5000, then the investigator must complete a Significant Financial Interest – Disclosure and Management Plan (SFI-DMP).
C. During the OPRS administrative review, if it is noted that a financial conflict of interest was disclosed on the WIRB application, the investigator will be instructed to attach the WIRB application and financial disclosure form to the UIC application.
D. After the OPRS administrative review has been completed, an acknowledgement letter will be sent to the investigator who will then submit the letter to WIRB. The letter will include a statement as to whether there was or was not an identifiable conflict of interest. If there is an identifiable conflict of interest, the conflict must be identified on the acknowledgement letter along with any additional language to include in the informed consent document. WIRB will incorporate the specified

additional language into the informed consent document during the processing of the submission.

E. In the instance where the WIRB application identifies a conflict that is not identified during the OPRS administrative review, and, therefore, is not identified on the acknowledgement letter; WIRB will notify OPRS of the discrepancy, will send OPRS the WIRB application and financial disclosure form, and will hold the submission until a revised acknowledgement letter has been received.
F. Financial conflicts of interest will be managed by WIRB in accordance with their own policies; however, WIRB has agreed to abide by the UIC monetary limitations.
G. A copy of the acknowledgement letter identifying a conflict of interest will be sent to the UIC COI Office to allow the linking of the conflict to the contract or grant. Copies of the WIRB application, financial disclosure form, and meeting minutes associated with the conflict will be made available to the UIC COI Office upon request.

VIII. Research reviewed by the Chicago Area Institutional Review Board (CHAIRb)
A. The conflict of interest procedures are described in the *CHAIRb Operations SOP*.

REFERENCES:

Public Health Service 42 CFR 50 Subpart F and 45 CFR Part 94 revised August 2011
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*

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, 5/06/2011	1.2, 6/11/09	Update definition of institutional conflict of interest
2.0, 7/24/12	1.3, 5/06/11	Revised the policy to incorporate the 2011 PHS regulations; updated the thresholds for financial disclosures and definition of significant financial interest; replaced "SEAM" with Significant Financial Interest – Disclosure and Management Plan (SFI-DMP); included procedures for WIRB and CIRB.
2.1, 7/24/15	2.0, 7/24/12	Removal of references to the Collaborative JBVAMC/NU/UIC IRB (IRB #4). Inclusion of reference to CHAIRb Operations SOP. Revisions to the WIRB section due to form changes.
2.2, 10/21/16	2.1, 7/24/15	Removal of references to Mercy Hospital and Medical Center from the section regarding the NCI CIRB Initiative. Correction to the SFI-DMP submission language.