

Policy Title: Conflicts of Interest in Research
Policy Owner: Office of Compliance
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SCOPE:

This policy was developed for SIU Medicine (SIU). SIU Medicine collectively applies to the SIU School of Medicine (SIU SOM), including the Federally Qualified Health Center (FQHC), and SIU HealthCare (SIU HC). These entities are collectively referred to as SIU in this policy.

This policy applies to SIU staff, faculty, trainees, agents, officers, directors, interns, volunteers, contractors, and any other individual or entity engaged in providing teaching, research and health care items and services at SIU. These individuals are collectively referred to as SIU personnel in this policy.

PURPOSE:

SIU is committed to ensuring that research conducted within the organization is conducted with integrity and that the rights of research subjects are protected. The purpose of this policy is to establish guidelines for identifying and managing potential and perceived conflicts of investigators and others involved in the conduct and administration of research.

POLICY:

Any individual engaged in the conduct of research at SIU must complete a financial disclosure at least annually that covers the prior twelve months through the designated system used by SIU, whether or not he or she has financial interests to report. Any individual required to complete a disclosure under this policy must submit an updated disclosure within thirty (30) days of acquiring a new financial interest or within thirty (30) days of any change to a previously reported financial interest. SIU requires individuals to submit a disclosure prior to the application for Public Health Service (PHS) funds and/or prior to submitting a research proposal to one of the SIU review boards (Institutional Review Board, Institutional Animal Care and Use Committee) or to an external review board that SIU is relying upon for the regulatory review of that research.

DEFINITIONS:

Equity interest: means stock, stock options, warrants, partnership or other ownership interests. Excluded from this definition are equity interests in publicly traded mutual funds or retirement accounts so long as the investigator does not directly control the investment decision made in these vehicles.

Family: means any member of the individual's immediate family including spouse or domestic partner, household members, and dependents, including step-children and children by adoption.

Financial interest: means anything of monetary value or potential monetary value, whether or not the value is ascertainable.

Non-compliance: means any failure to adhere to the requirements of this policy, related policies or applicable federal, state, and local regulations. Non-compliance also means failure to adhere to the requirements of a management plan imposed by the Office of Compliance.

Remuneration: means all salary and wages, consulting fees, honoraria, paid authorship, travel reimbursement, gifts, licensing revenue, and royalties for books, publications or equity interest. Excluded from this definition is salary paid to the individual by SIU.

Significant Financial Interest: means a financial interest consisting of one or more of the following interest of an individual or their family member that reasonable appears to be related to the individual's institutional responsibility:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest as of the date of disclosure, when aggregated, exceeds \$5,000.
2. With regard to a non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity during the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the individual or their family member holds any equity interest in the entity.
3. A significant financial interest includes any intellectual property rights and interests (i.e. patents, copyrights), upon receipt of income related to such rights and interests.

Excluded from the definition of significant financial interest:

1. Salaries, royalties or other remuneration paid by SIU if the individual is employed or otherwise appointed by the institution;
2. Income from seminars, lectures, or teaching engagement sponsored by or from advisory committees or review panels for a Federal, state or local government agency, a domestic institution of higher education, academic teaching hospitals and medical centers;
3. Income from the authorship of academic or scholarly works;
4. Equity interests or income from investment vehicles so long as the individual does not directly control the investment decisions made in these vehicles.

Travel: means any travel that is reimbursed or paid for on behalf of the individual and related to the investigator's institutional responsibilities. Excluded from the disclosure requirement is travel that is reimbursed or sponsored by Federal, state, or local governmental agencies, institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals and medical centers.

PROCEDURES:

Disclosure

Any individual who is required to complete a disclosure will do so through the designated disclosure system. Individuals who are required to complete a disclosure for participation in research must comply with the SIU *Conflict of Interest and Conflict of Commitment* policy.

Once disclosures are submitted in the designated disclosure system, the Office of Compliance will review them. If the administrative review of the disclosure reveals that the disclosed financial interests or relationships do not represent a Significant Financial Interest, that determination shall be recorded and no further action will be required. If the disclosure represents a Significant Financial Interest and a real or perceived financial conflict of interest appears to exist, the Office of Compliance will draft a management plan for the disclosed interest which includes management's terms related to the individual's role in research at SIU.

The Office of Compliance will develop and implement a management plan that shall specify the actions that will be implemented to manage the real or perceived conflict of interest as it relates to the research being conducted at SIU. Examples of conditions or restrictions that might be imposed to manage real or perceived conflicts of interest in research include, but are not limited to:

- Public disclosure of financial interests during presentations, publications, or other dissemination, whether oral or written;
- Disclosure of financial interest to prospective subjects and to the research sponsor, whether governmental or private;
- Monitoring of the research by independent reviewers;
- Modification of the research plan, research staff roles, or changes in location of certain research activities to address potential bias from interests;
- Disqualification from participation in all or a portion of the research;
- Required periodic reports regarding implementation of the management plan and its progress to oversee and monitor the entire project;
- Reduction or elimination of the financial interest; or
- Severance of the relationships that create financial conflicts.

The Office of Compliance will be responsible for communicating applicable management plans to the individual, the grants office, and to the reviewing regulatory boards. Any real or perceived conflict of interest with regard to the individual's current or proposed research must be reviewed by the Office of Compliance prior to final review by the regulatory review board or the expenditure of PHS funds. The regulatory review board may impose additional management actions than those that are imposed by the management plan. The regulatory review board may not alter the terms of the management plan or impose less stringent management actions for any research study than those imposed in the management plan by the Office of Compliance.

Non-compliance

If the Office of Compliance becomes aware of any real or perceived conflict of interest that was not disclosed or identified in a timely manner while research is ongoing, the Office of Compliance will within sixty (60) days of discovery of the financial interest, require disclosure from the individual through the designated system, review it, determine whether a conflict of interest exists and if so, implement a management plan that shall specify the actions that have been, and will be taken to manage such a conflict of interest going forward.

In the case of PHS funded research, if a conflict of interest was not identified or managed in a timely manner due to failure by the individual to disclose the interest, failure by the institution to review or manage the interest, or failure by the individual to comply with the imposed management plan, the following steps will be taken:

- Within 120 days of discovery of the noncompliance, the Office of Compliance will ensure that a retrospective review of the individual's activities and of the research project is completed to determine if any of the research conducted during the period of noncompliance was biased in design, conduct, or reporting of such research.
- Based on the results of the retrospective review, if appropriate, SIU will update the previously submitted conflict of interest report specifying the actions that will be taken to manage the conflict going forward.
- If bias is found, SIU will notify the PHS Awarding component and submit a mitigation report.

If the Office of Compliance receives a report of or discovers (1) a failure to adhere to a management plan or (2) failure of the individual to disclose any interest or relationship, the individual may be subject to sanctions, up to and including termination of employment and/or suspension of the privilege to conduct research at SIU.

Training

SIU shall inform individuals who participate in PHS funded research about applicable federal regulations, this policy, and the disclosure process. All individuals must complete conflict of interest training prior to engaging in PHS funded research and at least every three years afterward. Training will also be completed when any of the following occur: the Research Conflict of Interest policy changes, an individual covered by the policy is new to SIU, or an individual is found to be noncompliant with the policy or his/her approved management plan.

Public Accessibility

Prior to the expenditure of PHS funds, SIU will publish on its publicly accessible website a notification that the institution will respond to any requestor within five business days of a request, information concerning any significant financial interest that has been identified as a conflict of interest and is related to PHS funded research. The response will include the individual's name, title and role in the research, the nature of the significant financial interest and the approximate dollar value reported in a range. The information concerning financial conflicts of interests in response to written requests will remain available for at least three years from the date that the information was most recently updated.

SIU will also publish the Research Conflict of Interest policy on the publicly accessible website.

Reporting to PHS

In the case of PHS funded research, SIU will report financial conflicts of interest or noncompliance to PHS in accordance with PHS regulations. If funding for research is made available from a prime PHS-awardee, such reports shall be made by the prime awardee prior to the expenditure of any funds and within sixty (60) days of any subsequently identified financial conflict of interest so that the prime awardee may fulfill their reporting obligations to PHS.

Prior to the expenditure of any PHS funds, SIU will report to the PHS Awarding Component the existence of a conflict of interest in accordance with PHS financial conflict of interest instructions and assure that the conflict of interest has been managed, reduced, or eliminated in accordance with 42 CFR 50.605.

Record Retention

In the case of PHS funded research, SIU will retain all disclosure forms, conflict management plans and related documents for a period of three years from the date the final expenditure report is submitted to PHS or the prime PHS awardee.

PERIODIC REVIEW OF POLICIES AND PROCEDURES

SIU shall review its policy and procedure for Conflict of Interest in Research at least once every two (2) years.



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