

# STOCKTON UNIVERSITY

## PROCEDURE

<b>Managing Conflicts of Interest</b>
Procedure Administrator: Chief Officer for Diversity and Inclusion Authority: N.J.S.A. 18A:64-8 Effective Date: July 29, 2021 Index Cross-References: Policy I-50: Code of Ethics Procedure File Number: 6350 Approved By: Dr. Harvey Kesselman, President

### **I. PURPOSE**

The purpose of this procedure is to ensure the integrity of the University's research, protecting the rights and welfare of human subjects, maintaining the intellectual freedom of faculty, students, postdoctoral appointees and other University employees, and safeguarding the freedom to publish, communicate and discuss research results.

### **II. ACCOUNTABILITY**

At the direction of the President, the Chief Officer for Diversity and Inclusion







## Attachment 1

### Definitions

1. **Compelling Circumstances** are facts that convince the Conflict-of-Interest Committee (see definition below) that an individual with a conflict of interest that is relevant to the proposed research project should be permitted to conduct the proposed research under requirements established by the Committee. These facts may include but are not limited to: the nature of the research, the magnitude of the financial or other personal interest, the degree to which these interests are related to the research, the extent to which these interests could be affected by the research and in the case of human subjects research, the degree of risk to the human research subjects.
2. **Conflict of Interest** is a divergence between an investigator's financial or other personal interests and the obligation to abide by principles of the ethical conduct of research, especially the obligation to protect the rights and welfare of human subjects, such that considerations of personal gain, financial or otherwise, may influence or create the perception of influencing that investigator and compromise the objectivity or appropriate design, conduct or reporting of the research.
3. **Conflict-of-Interest Committee (COIC)** is a Stockton University committee whose role is to review disclosures of significant interests (see definition below) and

children, parents, or siblings who reside in the same household.

9. **Institutional responsibilities** mean an Investigator's professional responsibilities on behalf of the University including: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
10. **Institutional Review Board (IRB)** is a committee established in accord with federal Common Rule at 45 C.F.R. Part 46 and FDA regulations at 21 CFR Part 50 and 56 with the authority to approve, require modifications in, or disapprove all University research activities involving human subjects.
11. **Interest** is a financial or other personal involvement of the investigator, or his or her immediate family that are related to the individual's institutional responsibilities. Financial interest means anything of monetary value, whether or not the value is readily ascertainable. Interests include, but are not limited to: income; honoraria or other payment for services; equity such as stock, stock options or other ownership rights (except interests of any amount in publicly traded, diversified mutual funds, pension funds, or other institutional investment funds over which the faculty member does not exercise control); patents and copyrights; contracts, licensing and other agreements; royalties (including those royalties distributed by the University); employment; reimbursed travel or sponsored travel; and services, relationships or positions, even if uncompensated.
  - a. Excluded from the disclosure requirement are income from seminars, lectures, or teaching engagements, reimbursed travel or sponsored travel, and service on advisory or review panels sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 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.
12. **Investigator** means the Principal Investigator, co-principal investigator, co-investigators and any other University personnel (including faculty, non-faculty employees, residents, postdoctoral trainees and students) who, in the course of their association with the University are or will be responsible for the design, conduct, administration, collaboration, analysis and/or reporting of either research or training activities, funded or proposed for funding by any sponsor, or of unsponsored research or training activities. As used herein, the term "investigator" also covers collaborators, grantors or contractors.
13. **Manage** means taking action to address a real or apparent financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
14. **Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). For the purposes of this policy, research shall include training activities.
15. **Significant Interest means:**

- a. Financial or other personal interests of the investigator, his or her spouse, domestic partner, children, parent or siblings that reasonably appears to be related to the Investigator's institutional responsibilities:
  - i. Service as an officer, director or in any other fiduciary role for a financially interested company, whether or not remuneration is received for such service;
  - ii. In

with an Institution of Higher Education. This disclosure must include the



## **Attachment 2**

### **Conduct of Research**

1. Disclosure of Interests and Conflicts:
  - a. Prior to the submission of applications to sponsors for funded research (whose sponsor is not DHHS, DHHS agency, or the National Science Foundation), or prior to the commencement of unsponsored research, or prior to the execution of a licensing agreement with a publicly-traded company in which the investigator has eithpany in which the

annual and revised Disclosure Forms as in [Section VI. A.2.b-e], below.

- g. For projects involving contracts, subcontracts or collaborations with outside institutions or groups, the Office of Research and Sponsored Programs will take steps to ensure that any subrecipient Investigator complies with the Public Health Service, pursuant to 42 CFR Part 50, Subpart F by incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of Stockton University for disclosing significant financial interests that are directly related to the subrecipient's work for Stockton University. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable Stockton University to provide timely COI reports, as necessary, to PHS as required by this subpart. If the outside entity is an agency of the State of New Jersey, its policy must meet the requirements of New Jersey Law, Conflicts of Interest Law, N.J.S.A. 52:13D-19.1, and of the Public Health Service pursuant to 42 CFR Part 50, Subpart F. In the event the outside entity has no investigator conflict-of-interest policy, the written agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to Stockton University. Such time period(s) shall be sufficient to enable Stockton University to comply timely with its review, management, and reporting obligations under this subpart

## 2. Processing of Disclosure Forms

- a. All completed original and updated Disclosure Forms must be submitted by the investigator to the Office of Research



7.

Funding Agreement in an Initial FCOI Report which will include the following elements:

1. the name of the entity with which the investigator has a COI; the nature of the COI e.g., equity, consulting fees, travel reimbursement, honoraria, etc.; the value of the financial interest in increments of \$5000, \$10,000, \$20,000 or \$50,000 or a statement to the effect that the value cannot be readily determined;
2. a description of how the financial interest relates to the funded research and the basis for the institution's determination that the financial interest conflicts with such research;
3. key elements of the Institution's management plan, including:
  - a. Role and principal 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.

Following an Initial Report, the Institution will submit an Annual Report to the PHS Funding Agency to provide the information on the status of the financial conflict of interest and any changes to the management plan.

- ii. If the COIC's decision is that the research cannot proceed, the investigator(s), the investigator's Chair, and the relevant Dean will be notified of this decision. The funding agency or sponsor will be notified of the existence of the conflict of interest prior to any expenditure of any funds under the Funding Agreement and in the case of a PHS award, with an Initial Report as described above.
- iii. If the final decision includes conditions or restrictions to manage, reduce or eliminate a conflict of interest, the investigator shall document his or her compliance with such conditions or restrictions in writing to the investigator's Chair, the relevant Dean, the COIC and, in cases where

Director of the Office of Research and Sponsored Programs shall provide within the initial report to the funding agency or sponsor details of how the conflict of interest has been eliminated or acceptably managed or reduced.

- v. Whenever an Investigator discloses a significant financial interest that was not previously disclosed or, for whatever reason, was not previously reviewed by the COIC during an ongoing research project (or was not timely reviewed or reported by a subrecipient), the COIC shall, within sixty days: review the significant financial interest; determine whether it is related to the research; determine whether a financial 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 financial conflict of interest going forward
- vi. For any interest that the COIC identifies as a conflict of interest subsequent to the COIC's initial report under the Funding Agreement, and after the expenditure of funds, the Institution will conduct a retrospective review of these cases of non-compliance to determine the impact of the bias on the research project. In instances where bias of the research has been found to exist, the Executive Director of the Office of Research and Sponsored Programs will file a report to sponsor indicating what was found and what actions the Institution has taken, or will take, to eliminate or mitigate the effect of the bias within 120 days of that identification. In case of PHS-funded research, the Executive Director of the Office of Research and Sponsored Programs will document the retrospective review to the agency. Such documentation shall include, but not necessarily be limited to, all of the following key elements:
  - 1. Project number
  - 2. Project title
  - 3. PD/PI or contact PD/PI if a multiple PD/PI model is used
  - 4. Name of the Investigator with the COI
  - 5. Name of the entity with which the Investigator has a financial conflict of interest
  - 6.

