

Procedure Administrator: Chief Officer for Diversity and Inclusion

Authority: N.J.S.A. 18A:64-8

Effective Date: July 29, 2021; March 30, 2023

Index Cross-References: Policy I-50: Code of Ethics

Procedure File Number: 6350

Approved By: Dr. Harvey Kesselmh:

freedom of faculty, students, postdoctoral appointees and other Univer
and safeguarding the freedom to publish, communicate and discuss

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At the direction of the President, the Chief Officer for Diversity and Inclusion shall implement this procedure at Stockton University, with input from the Office of Research and Sponsored Programs, and ensure compliance with this procedure.

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Research and Sponsored Programs, and the Provost.

- b. Where the proposed research involves human subjects and the investigator's interests are beneath the threshold of a significant interest, the IRB may request a review and recommendation from the COIC, both as to whether or not to permit the investigator to conduct the proposed research and, if the research is permitted, under what terms and conditions.
3. Publication and Other Communications of Research Results
 - a. Publications and research shall conform to the locally negotiated agreement on Intellectual Property and Scholarly Works. Publications should conform to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals with regard to conflicts of interest.
 - b. In the case of multi-site clinical trials, the contract should state: how the results will be published; how authorship will be decided; how each investigator will have access to all data from all sites (and not simply to summary tables) in order to be able to analyze the full data independently if there is no multi-site publication within one year of the termination of the study; and that such one-year delay in publication or presentation of data results by the investigator can be waived if the investigator has a good faith belief that publication or presentation should not be delayed for reasons of public health, safety or public welfare.
4. Protection of students, postdoctoral appointees and other University employees.

Contracts with research sponsors may not include restrictions on the activities of students, postdoctoral appointees or other University employees, and may not include non-disclosure provisions regarding such individuals beyond those specified above (Sections VI.B.1 and 2). Exceptions must be approved by the COIC and must be fully disclosed to all students, postdoctoral appointees and other University employees prior to their involvement in the research. However, students, postdoctoral appointees and other University employees may not, under any circumstances, be permitted to participate in research if such participation would prevent them from meeting pertinent University degree requirements.
5. Investigator conflict of interest training
 - a. The Office of Research and Sponsored Programs will create training content and be responsible for the implementation of a University-wide web-based training module.
 - b. Each investigator must complete the COI training prior to engaging in sponsored or unsponsored research and at least every four years, or immediately if the University's conflict of interest policy changes in a manner that affects investigator requirements, an investigator is new to the University, or the University finds an investigator noncompliant with the [(a)-2 (f)10 (fe)-2 (c)2 (ts)]TJ0 Tc 2(t)2 (h)10 'ns

compliance shall be reported by any knowledgeable individual to the COIC, and the University IRB if human subjects are involved. These bodies shall investigate the allegation, reach a conclusion, and recommend sanctions or dismissal of the charges to the Provost, who shall have the final decision. Recommendations will also involve the notification of the sponsor and/or journal editors if non-compliance may have resulted in compromise of the integrity of the research and/or resulting publications or other communications.

- b. Appeal of the committee's decision may be made to the President of Stockton University. After the President, or designee, has made a final decision, the committee will inform the Investigator.
- c. Standards set by governmental agencies will be monitored and considered in the University's routine review of this procedure.

7. Reports and record keeping

Stockton's Office of Research and Sponsored Programs shall maintain records of all disclosures of financial and other personal interests, COIC determinations and recommendations, final decisions, actions taken to resolve conflicts of interest and the outcomes thereof for at least three (3) years from the date of submission of the final expenditure report of the project0 (f)2 (l)6anditurea(m)-3 ()JT(e of)-let0 (nda)10 (t)2

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1. *Compelling Circumstances*

- 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:
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with an Institution of Higher Education. This disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration

- c. The term “significant interest” does NOT include:
 - i. Salary or other remuneration from the University unrelated to the investigator's Institutional responsibilities;
 - ii. Reimbursement and/or income from seminars, lectures, or teaching engagements sponsored by, reimbursed travel or sponsored travel, and service on advisory or review panels for 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

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 either an equity interest or other association that is a conflict, investigators must identify if a conflict exists, the nature of the conflict, any significant financial interests to the conflict, and any conflicts of commitment.

b. Upon the submission of applications to sponsors for funds, 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 either an equity interest that exceeds \$5,000 or a greater than one percent (1%) ownership interest, whichever is less, or prior to the execution of a licensing agreement with a non-publicly traded company in which the

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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

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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 (own) (c) (1) 0.0010.002080.002 Tw 0.25 0 Td[(c)-2 (o)

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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 notwa008 Tc an

