Statement on Research and Evaluation Independence and Integrity

6WRFNWRQ 8QLYHUVLW\ Procedure 6350: Managing Conflicts of Interest (Authority: N.J.S.A. 18A:64-8; Effective Date: July 29, 2021; Policy I-50: Code of Ethics; Procedure File Number: 6350)

state laws regarding ethics and integrity, the University requires that all employees submit annual questionnaires (https://stockton.edu/diversity-inclusion/ethics.html#ethics-forms) regarding outside employment and activities; the disclosure of personal and business relationships; and supervisory conflicts of interest forms (when applicable). The University also ensures that all employees undergo annual trainings to engender awareness of policies governing charitable activities, gifts and favors, political activity, contracts with state agencies and nepotism, as well as other possible conflicts of interest.

Additionally, all of Stockton's research activities are subject to evaluation by an internal Institutional Review Board (IRB) for the Protection of Human Subjects specifically for the purpose of protecting the health, welfare, safety, rights, privileges and best interests of all human subjects participating in research. Stockton gives assurance that it will comply with the Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects (45 CFR 46) better known as the ´&RPPRQ 5XOH µ ,Q GRLQJ VR WKH HWKLFDO LQYHVWLJDWLRQ RI SURSRVHG ZKLFK experimental research will be reviewed by the Institutional Review Board (IRB) at intervals appropriate to the degree of risk but not less than annually. The IRB must review all applications that: a) will be conducted by or under the supervision of staff or faculty, or b) involve Stockton University staff, faculty or students, or c) will be performed on the campus or involve University equipment or facilities. Stockton University · V Ser-96 Tf RJ 0.0 (subjectsy)Tj18 or (45 perform Codo

Should you have any further questions or concerns regarding evaluative independence, ethics, and integrity, please do not hesitate to contact the Office of Research and Sponsored Programs.

Sincerely,

Jennifer Kosakowski, Executive Director
Office of Research and Sponsored Programs
101 Vera King Farris Drive, Suite E2
Galloway, NJ 08205
T: (609

Department of Health and Human Services. 45 CFR: Title 42, Chapter I, Subchapter D, Part 50, Subpart F: Promoting Objectivity in Research.

National Science Foundation. Proposal and Award Policies & Procedures Guide and Code of Federal Regulations: Title 2, Subtitle A, Chapter II, Part 200, Subpart B, 200.112.

V. PROCEDURE

1.

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 ¶ 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. Intellectual property rights (e.g., pending patent applications, patents, licenses, material transfer agreements, copyrights and royalties of any amount from such rights, including those royalties distributed by the University);

    iii. With regard to any publicly traded entity, a significant financial interest 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 compensation, royalties, consulting fees, honoraria, gifts or other emoluments, bonuses, enrollment incentives or milestone payments, and "in kind" compensation or entitlement to same made directly or indirectly to the investigator by a financially interested company (or entitlement to the same), whether for consulting, lecturing, travel (including reimbursed travel or sponsored travel), service on an

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 eitthpany 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 sudieet refo rerecipient's Invebrecip (

disclosure of 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 to manage the conflict of interest. Depending on the nature of the significant financial interest, the Executive Director of the Office of Research and Sponsored Programs may determine that interim measures are necessary with regard to the Investigator's participation in the research project between the date of disclosure and the

7. severance of relationships that create conflicts of interest or the appearance of such conflicts.

iii. Whether significant interests constitute a conflict or appearance of conflict and cannot be managed, reduced or eliminated. In these cases, the research cannot proceed.

c. In making these determinations, the COIC may:

i. Ask the investigator to appear before it to provide additional information to assist in the Committee's deliberations. In the event the Committee determines that the investigator has a conflict of interest or an appearance of such conflic

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.

Awarding Component. The mitigation report mu

STOCKTON UNIVERSITY

PROCEDURE

General Assurances Statement: Protection of Human Rights in Experiments

Procedure Administrator: Provost
Authority: Code of Federal Regulations Part 46
Effective Date: May 17, 1978; May 31, 1978; November 9, 2009
Index Cross-References: Policy I-52.5: Committee on the Protection of Human Subjects
Procedure File Number: 1035
Approved By: Dr. Herman J. Saatkamp, Jr., President

II. PROCEDURE:

A. The University will follow a review process for all proposals involving the use of human subjects, regardless of whether or not the project has received funding support. This will apply to internal activities as well as those seeking external or governmental support. Individuals seeking approval will complete an application package available on the University website which includes the information outlined in Part B which follows which then should be sent to the IRB for review and approval. Students seeking approval must have the signature of a supervising faculty member in the appropriate discipline. Individuals responsible for the research activity must wait for approval from the IRB before beginning the project.

1. Applications that require a review by the full committee shall be submitted to the IRB two weeks prior to the review/meeting date of the IRB. Governmental proposals often must be reviewed before submission to the agency. Applications that request an exempt or expedited review may be submitted at any time. The review category is defined by the federal government and is based on the level of risk involved for the human participants.

2. During a full committee review, the IRB members will examine and discuss the application and make a written recommendation to the project director as to whether or not the application should be approved. The IRB may suggest modifications and/or request additional information before a final determination. Once approved, the application is signed by the Chair, date stamped and filed. Approvals are valid for one year. If a project continues beyond this anniversary date, the researcher must formally apply for a renewal.

3. Projects involving applications for outside funding must be routed through the normal internal approval procedure for proposals and ultimately approved by the President.

B. The application form is available on the University website and should be thoroughly completed and signed before submitting to the IRB for review. While the application requires more information than outlined below, its basic details include: A general description of the project, including beginning date and duration of the project, and location.

1. The names and titles of the investigator(s).

2. Identification of the target study group, especially noting any vulnerable populations. A description of the background and purpose of the proposed study, including a literature review of relevant research.

This process requires each subject to acknowledge consent to participate by signing a form, checking a box for online participation or by other verifiable means which indicates one's willingness to participate.

III. COMMITTEE STRUCTURE

A. The IRB shall consist of at least five faculty members who have expertise in research involving human subjects and who have been nominated by their Dean to the IRB. As required by federal regulations, the IRB must also include at least one male and one female member, at least one scientist and one non-science member, and at least one member of the community who is unaffiliated with the University. This member shall be invited by the Provost to participate onen nomiipav