STOCKTON UNIVERSITY

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Statement on Research and Evaluation Independence and Integrity

Stockton University's *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**) ensures the integrity of the University's research; protects the rights and welfare of human subjects; maintains the intellectual freedom of faculty, students, postdoctoral appointees and other University employees; and safeguards the freedom to publish, communicate and discuss research results. At the direction of the University President, the Chief Officer for Diversity and Inclusion implements and ensures compliance with this procedure at Stockton University, with input from the Office of Research and Sponsored Programs. This procedure applies to all Stockton University faculty, non-faculty employees, students and other individuals who, in the course of their association with the University: 1) apply for or receive funds for any research, service or training purpose, by grant or subgrant, or by contract or subcontract, or by cooperative agreement (individually and collectively referred to herein as "Funding Agreement(s)"); or 2) wish to conduct unsponsored research. Procedure 6350 and its relevant appendices are attached to this letter.

Stockton University reviews the disclosures of Financial Conflicts of Interest (FCOI) for each Principal Investigator, Co-Investigator, and/or subrecipient involved in projects in order to identify any research integrity issues. To the best of Stockton University's knowledge, the design, conduct and/or reporting of research and evaluation funded by grants – and any subsequent agreements and/or contracts – is free from any personal or FCOI on the part of project staff, consultants and/or subrecipients who are responsible for a project's research and evaluative work. This assurance is ascertained through a thorough vetting of Stockton University employees who will contribute to the project, as well as a review of prospective contractors and consultants.

In cases where there could be a potential conflict(s) of interest (COI), all contributors/partners are asked to provide detail related to any perceived or actual COI(s) and to provide a specific mitigation plan to address any noted COI(s). Stockton University is committed to conducting scientific research on social and economic issues to foster sound public policy and effective governance. Consistent with Stockton University's independence and non-partisan reputation, this research project will embrace the following principles and procedures to protect research independence and integrity.

First, all proposed research will be guided by a group of experts who will not only provide technical guidance, but who will also ensure the soundness of the project's research methods and policy recommendations. Research and analysis will be conducted and assessed fairly and objectively, using rigorous and discipline-specific best practices methodologies. Findings from any proposed research will also be peer reviewed before dissemination to a wider audience.

Second, Stockton University enforces stringent policies concerning the ethical behavior of employees and the avoidance of conflicts of interest. These policies govern the manner in which proposals are developed and submitted, as well as the procedures and practices under which research is performed. To adhere to

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 University's research is subject to meticulous 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 "Common Rule." In doing so, the ethical principles which guide projects involving individuals in studies or 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) will involve Stockton University staff, faculty or students, or c) will be performed on the campus or involve University equipment or facilities. Stockton University's *Procedure 1035: Protection of Human Rights in Experiments* (**Authority: Code of Federal Regulations Part 46; Effective Date: May 17, 1978/May 18, 1978/November 9, 2009; Policy I-52.5: Committee on the Protection of Human Subjects; Procedure File Number: 1035**) references the University's commitment to the pursuit of excellence in teaching, research and service. Following these protocols, all research projects are conducted in the most responsible and competent manners possible. Procedure 1035 is attached to this letter.

Third, Stockton University is a public university within the State of New Jersey, and as such, is a non-profit entity as recognized in the U.S. Internal Revenue Code (26 U.S.C. 501(c)) and seeks no financial profits from this or any research project. The University adheres to the New Jersey Conflicts of Interest Law (**52:13D-12; https://www.nj.gov/ethics/statutes/conflicts/**) as a state institution of higher education. Additionally, the Uniform Ethics Code (**N.J.S.A. 52:13D-23; N.J.A.C. 19:61-2.2(a)(1); https://www.nj.gov/ethics/ethics/state/**) is the primary code of ethics for state agencies to govern and guide the conduct of state officers and state employees. Employees are expected to conduct themselves in an ethical manner, including: 1) adherence to all applicable laws; 2) avoidance of real or potential conflicts of interest; 3) strict observance of all sponsor regulations and award provisions; and 4) accurate charging of allowable time and other expenses to project awards.

Finally, Stockton University staff, consultants and/or subrecipients must not use their positions for personal gain or to benefit relatives, friends or any individuals with whom they have financial ties. Stockton University staff, consultants, and/or subrecipients must also not participate knowingly in the actions of any business or other entity in which they have a financial interest or to which they have a significant relationship. Some relationships, such as the employment of a spouse or other relative in a firm with which the University does business, may constitute a conflict of interest. Additionally, holding a substantial portion of the shares of a public corporation with which the University has a business relationship is recognized as a conflict of interest. In order to comply with requirements of the IRS Form 990, the University requires corporate officers to annually submit a statement of no conflict of interest with companies doing more than $10,000 of business with the University. This process is managed by the Office of the President, which serves as the custodian of these statements.

Any violations of the Stockton University code of conduct and standards of ethics and integrity will result in disciplinary action, up to and including termination of employment.

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

Sincerely,

Jennifer Kosakowski

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References

New Jersey Conflict of Interest Law (N.J.S.A. 52:13D-12, seq.): Establishes specific standards of conduct for State employees and officers. This procedure supplements State law.

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.

STOCKTON UNIVERSITY

PROCEDURE

Managing Conflicts of Interest

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 shall implement this procedure at Stockton University, with input from the Office of Research and Sponsored Programs, and ensure compliance with this procedure.

III. APPLICABILITY

This procedure shall apply to all Stockton University faculty, non-faculty employees, students and other individuals who, in the course of their association with the University:

1. Apply for or receive funds for any research, service, or training purpose, by grant or subgrant, or by contract or subcontract, or by cooperative agreement (individually and collectively referred to herein as "Funding Agreement(s)"); or
2. Wish to conduct unsponsored research.

Funded sponsors include but are not limited to Federal, State, and Local governments, non-profit institutions, industry and for-profit entities or businesses, or any individual, organization, or foundation that has funding available or will provide funding for sponsored research conducted by or on behalf of Stockton University.

IV. REFERENCES

New Jersey Conflict of Interest Law (N.J.S.A. 52:13D-12, seq.): Establishes specific standards of conduct for State employees and officers. This procedure supplements State law.

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. Stockton University recognizes the importance and potential benefits of transferring to the private sector knowledge developed through University research and scholarship. It also recognizes the risks inherent when researchers have financial or other personal interests in their research or training activities, and the need to avoid arrangements that might compromise, or appear to compromise, the intellectual principles, independence and responsibility to the public that underlie the ethical conduct of research. Therefore, while welcoming industry sponsorship, collaboration and licensing of its technology, the University recognizes the need for procedures to identify and manage actual or perceived conflicts of interest that may arise in research. Such procedures help to ensure the integrity, objectivity and freedom of inquiry of Stockton's investigators and the safety and welfare of University human research subjects.

    a. Of critical importance is 76 Fed. Reg. 53,256: On Aug. 25, 2011, the U.S. Department of Health and Human Services (HHS) published its final rule on financial conflicts of interest (FCOI). The regulations are a significant update on initial rules published in 1995, and they demand greater transparency and accountability for research institutions that receive Public Health Service (PHS) funds from the National Institutes of Health (NIH). Though this rule has many similarities with regulations promulgated in 1995, the new modifications have greater impact on the conflict of interest for institutions that receive HHS funds.

    b. Thus, procedures described below are intended to implement the HHS final rule published in August 2011 for applicants for promoting Objectivity in Research for which PHS funding is sought (42 CFR Part 50, Subpart F) and Responsible Prospective Contractors (45 CFR part 94) and to provide the reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from Investigator financial conflicts of interest.

    c. Thus, procedures described below are not intended for sponsored research whose sponsor is not DHHS, a DHHS agency, or the National Science Foundation, but upon identification of a conflict by an investigator, reporting of any significant financial interest that is a conflict can follow the procedures below.

2. Relationship Between the Conflict-of-Interest Committee (COIC) and Stockton's Institutional Review Board (IRB)

    a. In cases of human subjects research, the COIC will inform the Stockton University IRB of its decision and reasons. The Stockton University IRB may either accept the decisions of the COIC, or impose additional requirements or restrictions, and shall convey its final decision in writing to the investigator, the relevant Dean, the Executive Director of the Office of

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. Contracts with research sponsors may not include provisions that prevent the investigator from independently accessing, examining, analyzing and interpreting the research data, or that restrict publication or other public communications of the methods, data and results of the research. Sponsors may be given up to thirty (30) days in which to review a manuscript, presentation or abstract that originates from the sponsored research prior to submission for publication or otherwise publicly communicated. Such review shall be limited to protection of confidential information furnished by the sponsor to the investigator, if any, or for the purpose of protection of patent or other intellectual property rights covered under the contract. The sponsor does not have the right to approve or consent to the publication or other communication of the research results.

b. In the event that the proposed publication or other communication contains patentable subject matter or confidential information, the University will, upon written request from the sponsor within the thirty (30)-day review period, delay the publication or other communication for a maximum of an additional sixty (60) days to allow the sponsor to file a patent application, or to modify the proposed publication or communication to delete sponsor-provided confidential information and/or to present the results in a manner that will not compromise such confidential information.

c. Publications should conform to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals with regard to conflicts of interest.

d. 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 University's COI policy.

6. Enforcement and sanctions

    a. Non-compliance with any provision of these procedures shall be subject to sanctions up to and including dismissal or termination for cause. Non-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 project, or from the conclusion of unsponsored research, or until the resolution of any governmental or legal actions involving these records, whichever is longer.

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 determine if these constitute a conflict of interest and, if so, to decide how such conflicts will be managed, reduced or eliminated.
    a. The committee is appointed on an Ad hoc basis by the Provost. Representation will include the Executive Director of the Office of Research and Sponsored Programs, and will include faculty members and others, when necessary. The committee may have additional ad hoc members in order to appropriately assess the presence of a conflict based on individual disclosures.
4. ***Conflict of Interest Training*** is required of all "investigators" (defined below) prior to engaging in sponsored or unsponsored research and every four years thereafter, and immediately under designated circumstances.
5. ***Financial Conflict of Interest*** *(FCOI) Report* means an Institution's report of a financial conflict of interest to a Public Health Service (PHS) Awarding Component.
6. ***Financially Interested Company*** means a commercial entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the research, or any entity acting as the agent of or with an equity interest in such an entity. This term includes companies that sponsor the research, are competitors of the sponsor, are the manufacturers or licensees of an investigational product, or the investment industry (individual stockbrokers and analysts, investment bankers, venture capital firms and investment firms).
7. ***Human Subjects Research*** includes all "research" performed with "human subjects" as these terms are defined in the federal Common Rule (45 C.F.R. Part 46 and 21 C.F.R. Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation.
8. ***Immediate Family*** means spouse (by marriage or civil union), domestic partner,

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 advisory board, or for any purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement between the sponsor and the University), as determined through reference to public prices or other reasonable measures of fair market value, either in the year prior to the grant application or initiation of unsponsored research and submission of the accompanying Disclosure Form, or in the twelve months following the grant application or initiation of unsponsored research;

   iv. Greater than 1% of the ownership of stock, assets or profits of a company which has, or seeks to have an agreement with the University, where the agreement is for the development of scientific or technological discoveries or innovations in which the University has or will have a property right;

   v. Equity interests, including stock options, of any amount in a non-publicly traded financially interested company (or entitlement to the same);

   vi. Equity interests (or entitlement to the same) that in aggregate exceed $5,000 in a publicly- traded financially interested company;

b. Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or 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. 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 affiliated with an Institution of higher education;
    iii. 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; A significant interest does not necessarily constitute a conflict of interest or the appearance of a conflict of interest as defined above.

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 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 investigator has an equity interest of any amount, all investigators must complete and submit to the Office of Research and Sponsored Programs the Investigator Financial and Other Personal Interests Disclosure Form, (hereinafter "Disclosure Form") for themselves and/or members of their immediate family. If the investigator has no such interest, the investigator must check the box indicating that no such interest exists.
    c. Each investigator named on the project must complete a Disclosure Form. If one or more such investigators have not been named at the time of proposal submission, a Disclosure Form or Forms must be completed subsequently by such investigator(s) and submitted to the Office of Research and Sponsored Programs as soon as such investigators are assigned to the project.
    d. In the event the research involves human subjects, all investigators must also attach the completed Disclosure Form to the protocol submitted for IRB review.
    e. All Disclosure Forms must be completed in full and in detail, with sufficient information to determine if the interests meet the definition of "significant interest," and must be signed by the investigator and the relevant Dean. If the investigator is a Dean, the form must be signed by the Provost. Sponsored or unsponsored research for which there are disclosed interests from any investigator on the research project may not commence until the disclosures are reviewed to determine whether the disclosure(s) poses a real or perceived COI and, if needed, a plan developed to manage any and all disclosures determined to represent a COI.
    f. On an annual basis during the duration of the research, or within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) new interests with respect to potential conflict of interest which otherwise changes since the original disclosure, each investigator must complete a new Disclosure Form and submitting it to the Office of Research and Sponsored Programs and, when human subjects are involved, to the IRB. The Executive Director of the Office of Research and Sponsored Programs shall review

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 and Sponsored Programs and, when human subjects are involved, to the IRB.

b. The Executive Director of the Office of Research and Sponsored Programs shall review the Disclosure Form and determine which interests, if any, are significant interests as defined in Section IV.O.

c. Disclosure Forms that reveal no significant interests shall remain on file in the Office of Research and Sponsored Programs.

d. Whenever significant interests are disclosed, either on initial Disclosure Forms or on annual or revised Disclosure Forms, the Executive Director of the Office of Research and Sponsored Programs shall forward the Disclosure Form to the COIC with notice to the investigator, the relevant Dean, and, when human subjects are involved, to the IRB.

e. If an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Executive Director of the Office of Research and Sponsored Programs, the COIC shall, within sixty days: review the

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 completion of the COIC's review.

3. Assessment of Significant Interests by the COIC

    a. It is the responsibility of each member of the COIC to divulge potential conflicts of interest. In the event that any member of the COIC has any real or apparent personal or professional conflicts of interest or bias with respect to the disclosure being considered, that member shall be recused. Such conflicts include, but are not limited to, involvement with the research in question, competition with the investigator, and a previous or ongoing close professional or academic relationship with the investigator, the sponsor, or competitor of the sponsor

    b. The COIC will review all Disclosure Forms forwarded by the Executive Director of the Office of Research and Sponsored Programs and make the following determinations:

        i. Whether the significant interests disclosed are relevant to the proposed research and whether they constitute or appear to constitute a conflict of interest. A conflict of interest shall be deemed to exist when the COIC reasonably decides that the significant interest could directly and significantly affect the objectivity of the research through the design, conduct or reporting of the research or training activities, or have the appearance of doing so. Not all significant interests constitute or appear to constitute a conflict of interest.

        ii. Which conditions or restrictions, if any, should be imposed upon the investigator prior to the expenditure of any funds under the Funding Agreement or the initiation of unsponsored research or training activities in order to manage, reduce or eliminate such conflicts of interest or appearances of conflicts of interest. The COIC may impose conditions or restrictions to manage, reduce or eliminate conflicts of interest including but not limited to:

            1. public disclosure of significant interests
            2. monitoring plan with independent reviewers, such as data safety monitoring board, routine on-site study review, and/or consent process with independent subject advocate/representative
            3. audits of the informed consent and subject enrollment process
            4. modification of the conduct of the research plan or educational activity
            5. disqualification of those with significant interests from participation in all or a portion of the research or training activity
            6. reduction or divestiture of significant interests

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 conflict, the investigator must present compelling circumstances that the research can go forward as proposed, or with modifications imposed by the Committee.

ii. Consult with individuals such as other faculty, scientists, financial experts, patents and licensing experts, IRB representatives, the relevant Dean or other University officials, and others from inside or outside the University.

d. COIC Decisions:

i. When no conflicts of interest exist or appear to exist, the Committee will inform in writing the investigator, the relevant Dean, and the Executive Director of the Office of Research and Sponsored Programs that the research can proceed as proposed. If the research involves human subjects, the Committee will also notify the appropriate IRB.

ii. When conflicts exist or appear to exist, the Committee may decide that the research may not proceed, or may impose measures to reduce, manage or eliminate the conflicts as a condition of the research going forward.

iii. When conflicts exist or appear to exist and the Committee decides that the research can proceed as proposed or with measures to reduce, manage or eliminate the conflict or the appearance of a conflict, the Committee shall require the following disclosures:

1. those investigator interests which constitute conflicts of interest in human research subjects be included in the consent forms associated with the research, and

2. those investigator interests which constitute conflicts of interest be disclosed to research sponsors, journal editors, co-investigators, other relevant IRBs, and in oral presentations of the research.

e. Outcome of the COIC's decisions:

i. The COIC will report its decision, including an explanation of its decision and a description of conditions or restrictions, if any, in writing to the investigator(s), the investigator's Chair, the Executive Director of the Office of Research and Sponsored Programs, and the relevant Dean. If the research involves human subjects, the Committee will also notify the appropriate IRB. In the case of PHS funded research, the Research Dean will notify the PHS funding agency within 60 days of the existence of the conflict of interest prior to any expenditure of any funds under the

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 human subjects are involved, the IRB, prior to the expenditure of any funds under the Funding Agreement or the commencement of unsponsored research.

iv. If the final decision is that a conflict of interest exists but can go forward under conditions specified, the Executive Director of the Office of Research and Sponsored Programs shall note this interest in an initial report to the PHS funding agency or sponsor of the identification of the conflict of interest prior to the expenditure of any funds under the Funding Agreement. If the final decision includes conditions or restrictions to manage, reduce or eliminate the conflict, the Executive

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. Reason(s) for the retrospective review
    7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)
    8. Findings of the review; an
    9. Conclusions of the review

vii. Based on the results of the retrospective review, if appropriate, the Executive Director of the Office of Research and Sponsored Programs shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS

Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS- funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

viii. Compliance with the conditions for managing the conflict of interest will be monitored annually. If the investigator fails to comply with the management plan and it is determined by the COIC that this noncompliance has biased the design, conduct, or reporting of the research, this shall be promptly reported to the relevant Dean, the Executive Director of the Office of Research and Sponsored Programs, and the funding agency or sponsor along with a corrective action plan taken or to be taken to maintain appropriate objectivity of the research.

Review History:

	Date
Procedure Administrator	07/21/2021
Divisional Executive	07/21/2021
General Counsel	07/21/2021
Cabinet	07/29/2021
President	07/29/2021

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 18, 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

I. PURPOSE:

Stockton University is committed to the pursuit of excellence in teaching, research, and service. In an effort to maintain these pursuits and permit progress of research activity, Stockton has established an Institutional Review Board for the Protection of Human Subjects (IRB) specifically for the purpose of protecting the health, welfare, safety, rights, privileges and the 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 "Common Rule." In doing so, the ethical principles which guide projects involving individuals in studies or 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) will involve Stockton staff, faculty or students, or c) will be performed on the campus or involve Stockton equipment or facilities.

All researchers submitting IRB applications are required to demonstrate proficiency in knowledge about how to protect human subjects by completing the online training and submitting certificates of that training with the application. Online training is available through the Stockton website.

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.

3. A full and detailed explanation of procedures and methods to be followed involving human subjects, including any procedures which are experimental.

4. Detail of anticipated physical, mental or emotional risk to the subjects of the research or a statement explaining why there are no risks anticipated.

5. Description of measures to be taken to protect confidentiality of the data and the subject's rights to privacy.

6. Informing human subjects about their rights and privileges and the activities of the study is a continuous process that should be regularly communicated throughout the project period. In addition to this open-ended process, the mechanism to fully inform participants at the beginning of a project should include a written and sometimes verbal message. This informed consent form must consist of the following:

    a. A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental.

    b. A description of any attendant discomforts and risks reasonably to be expected.

    c. A description of any risks that might result from participation. And if risks are anticipated, contact information for appropriate assistance.

    d. A description of any benefits reasonably to be expected.

    e. Acknowledgement of compensation participants might receive or costs they may incur as a result of the study.

    f. A disclosure of any appropriate alternative procedures that might be advantageous for the subject.

    g. An offer to answer any inquiries concerning the procedures, and a phone number and email of the researcher or faculty sponsor given to participants to take away, in case there are questions later.

    h. An instruction that participation is voluntary and the person is free to withdraw his/her consent and to discontinue participation in the project or activity at any time without prejudice to the subject.

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 on the IRB. The chair of the IRB shall be a member of the IRB and serve at the invitation of the Provost. All members must receive training and become certified in the protection of human subjects.

B. The IRB will meet monthly or as necessary and a quorum will be defined as a simple majority of the total membership (3). No IRB member shall be involved in the review of a proposal in which he/she has a conflicting interest, except to supply requested information.

C. The IRB shall continually review its activities, procedures and competence and will promptly act to supplement or replace any of its members with competent personnel when and if such action is found necessary. Outside expertise may be called upon at any time.

D. Records of all IRB actions will be maintained in the Grants Office for compliance and inquiry.

IV. COMMITTEE RESPONSIBILITIES

Upon receipt of an application package, the application will be distributed depending on the level of review requested - exempt, expedited or full committee. Regardless of the review category, all categories require fulfillment of research protocols, including the need for the consent of participants where applicable. IRB members will individually review the materials, and record their findings on a review form. If an application correctly requests an exempt review, the application will be read by the IRB chair who may request another member also review. If approved, the chair will sign the application, and this decision will be recorded and communicated in writing to the applicant. If the application correctly requests an expedited review, it will be reviewed by at least two IRB members who will recommend to the Chair that it be approved or not; their decision will be recorded and communicated to the applicant in writing. If the application requires review by the full committee, the IRB members each read the application and meet together for discussions. Regardless of the level of the review category, the review process is to determine:

1. That the safety, health, privileges, rights and welfare of the subjects are maintained.

2. Whether or not there is risk for the subjects involved.

3. That, if risk to the subject is involved, (a) the risks are outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained; (b) the risk is not extreme.

4. That legally effective informed consent will be obtained by adequate and appropriate methods.

In case of a negative decision, or request for modification or more information by the IRB, a written explanation will be communicated to the applicant. The IRB may also call upon professionals both inside and outside of the University for opinions concerning possible harm to human subjects when warranted.

(Please note: Special guidelines apply to research involving drugs, pregnant women, fetuses, possible impregnation or prisoners. Refer to Code of Federal Regulations 45 CFR 46.)

Approval History:

	Date
President	11/09/09