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Financial Conflict of Interest

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I. REASON FOR THIS POLICY

The following sections detail the policy and procedures for the Conflict of Interest declaration (upon hire and annually) and the policy on Financial Conflict of Interest at The University of South Dakota. This policy applies to employees who have direct control over the design, conduct or reporting of research which includes externally funded projects with primarily educational or service activities. It also applies to institutional officials who have decision-making authority over university assets and procedures, such as negotiation of licenses and purchases or who may be perceived as having reason for influencing the conduct of research.

The basic principle guiding this Policy is the obligation of the university to conduct its administrative, research and related academic activities in an ethical manner. Therefore, situations in which the general public may reasonably expect the possibility of conflict of interest shall be disclosed and managed so as to reduce or dispel any perception of lack of objectivity on the part of an investigator or administrator. At a time when university research activities are becoming more complex and collaborative and relationships with the private sector are strongly encouraged, investigators and administrators face additional challenges in maintaining objectivity and the appearance of objectivity in research and daily administrative activities. Therefore, the primary purpose of this process is to protect investigators and staff, and preserve the credibility of The University of South Dakota through a transparent procedure for conflict disclosure and resolution. Investigators and employees are expected, for their own

protection and that of the university, to disclose potential conflicts of interest that may appear to bias any research or decision-making under their influence.

This policy is also guided by Code of Federal Regulations (Title 42 CFR Part 50, Subpart F) that promotes “objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS (Public Health Service) grants or cooperative agreements will be biased by any conflicting financial interest of an investigator.” Separate definitions labeled “PHS” are included for researchers and key personnel of research funded under PHS grants.

II. STATEMENT OF POLICY

Investigators, administrators, and other relevant university staff will disclose to the designated university official any financial interests that the informed-general public may reasonably perceive to bias administrative decision-making and/or the design, conduct, or reporting of research or other externally sponsored projects.

Human Resources will initiate the Conflict of Interest forms during the initial hire process and annually during contract renewals and the Office of Research and Sponsored Programs will prepare disclosures upon submission of proposals for external funding or of protocols to the Institutional Review Board. Changes in financial holdings will require new disclosures when the changes occur.

III. DEFINITIONS

INSTITUTIONAL CONFLICT OF INTEREST occurs when university officials with responsibility for purchasing, contracts, hiring, promotion, salary, and other control of university assets, have financial or business relationships that may benefit from certain research and/or administrative decisions. This includes benefit to the *institution's* financial assets as well. Examples include: 1) dean who owns significant stock in a drug company and has faculty who are researching the effects of this drug; 2) university purchasing official who anticipates purchase of major research equipment from a company upon whose Board of Directors he or she sits; and 3) university

development foundation that holds equity in a company for which university investigators are doing research.

INVESTIGATOR is a principal investigator and any other person who is responsible for the design, conduct, or reporting of research. It includes subgrantee/contractor/collaborating investigators but to date excludes Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

SENIOR/KEY PERSONNEL means the Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other reports.

RESEARCH means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.

NON PHS RESEARCH - SIGNIFICANT FINANCIAL INTEREST means anything of monetary value, including but not limited to, salary or other payment for services (e.g., consulting fees or honoraria); equity interests, whether or not those interests can be readily determined through reference to public prices (e.g., stocks, stock options or ownership interests); and proprietary interest including intellectual property rights (e.g., trademarks, patents, copyrights and royalties from such rights in license agreements) whose value would be affected by the study outcome, or serving on the Board or executive relationship related to the research, regardless of compensation. The term does not include:

1. Salary, royalties, or other remuneration from The University of South Dakota;
2. Any ownership interests in The University of South Dakota, if the institution is an applicant under the SBIR Program;
3. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
4. Income from service on advisory committees or review panels for public or nonprofit entities;
5. Any financial interest that when aggregated for the investigator (as defined above), meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than 5% ownership interest in any single entity;
6. Salary, royalties or other payments that when aggregated for the investigator (as defined above) over the next 12 months, are not expected to exceed \$10,000.

PHS IS PUBLIC HEALTH SERVICE, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

PHS AWARDING COMPONENT means the organizational unit of the PHS that funds the research that is subject to 42CFR 50, Subpart F.

PHS - SIGNIFICANT FINANCIAL INTEREST means a financial interest consisting of one or more of the following interests of the investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) 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 salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-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, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also 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.

(3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements 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; or income from service on advisory committees or review panels for 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."

SBIR MEANS SMALL BUSINESS INNOVATION RESEARCH PROGRAM, the extramural research program for small business established by PHS Awarding Components under Pub. L. 97-219; and for the purpose of this policy includes the Small Business Technology Transfer (STTR) program under Pub. L. 102-564.

IV. PROCEDURES

INSTITUTIONAL AND INVESTIGATOR RESPONSIBILITIES:

The following procedures will be used to comply with the expectations of 42 CFR 50, Subpart F, and the South Dakota Board of Regents Policy 4:35 (Conflict of Interest).

1. *Initial Hire.* All faculty and Non-Faculty Exempt employees are required to complete a Conflict of Interest disclosure statement. This disclosure statement will be sent to new employees via a program called Formsite. Employees are prompted to answer specific questions. If no significant financial interests exist, then no further action is necessary unless a change in situation occurs. If a significant financial interest does exist, appropriate administrative level staff will review and determine if the conflict is allowed or if the employee must sever ties to retain USD employment.
2. *Routine annual disclosure.* All faculty, Non-Faculty Exempt, and specific CSA employees are required to complete a Conflict of Interest form annually to comply with Board Policy No. 4:32 (Investigator Financial Disclosure) and Board Policy 4:35. Human Resources will distribute Conflict of Interest disclosure forms annually using a program called Formsite. Employees are prompted to answer specific questions. Steps outlines in paragraph 1 above then proceed.
3. *Disclosure upon submission of proposal for external funding.* When submitting a proposal for external funding, investigators are required to disclose significant financial interests that may reasonably be thought to influence objectivity in the proposed research. The USD Proposal Routing & Authorization Form checklist asks for conflicts of interest, and if “Yes” is checked and a valid form is not already on file, the investigator will be asked to complete the Conflict of Interest disclosure statement.
4. *Disclosure upon submission of proposal for Institutional Review Board (IRB) approval.* When submitting a proposal for IRB approval, investigators are required to disclose significant financial interests that may be affected by the conduct or the outcome of the proposed research. The IRB application asks for conflicts of interest, and if “Yes” is checked the investigator will be asked to complete a Conflict of Interest disclosure form. The IRB will then follow the University of South Dakota Institutional Review Boards Standard Operating Procedures set out in 801-SOP Conflict of Interest (Investigator).
5. *Disclosure upon change in financial interests.* If an investigator’s or employee’s financial status changes so as to create a new or potential conflict of interest, the individual will be asked to complete a Conflict of Interest disclosure statement
6. *Review of disclosures.* The vice president for research (or designee) will review disclosure statements in which a financial conflict of interest is reported

Checklists on Proposal Routing & Authorization Forms will be reviewed by the vice president for research or designee for conflicts of interest. For those situations in which there is unlikely to

be a conflict, disclosures are filed in the Office of Research and Sponsored Programs. For those cases in which there is a real or perceived conflict, the vice president for research will ask the researcher to complete a Conflict of Interest disclosure statement.

7. *Management of conflicting interests.*

- a. *Committee.* The committee on Intellectual Property and Financial Conflicts of Interest is a standing committee of the University Senate whose membership is elected at the May meeting of the University Senate. The Committee will have eight (8) members. One member will be elected by the University Senate from each of the following faculties: Business, Education, Fine Arts, Health Sciences, Law, Library, Medicine, and Arts and Sciences. The Vice President for Research or designee will be a non-voting *ex officio* member. Elected members will serve 3-year terms (a maximum of two terms), with two or three terms expiring in each of the first 2 years and three terms expiring in the third year. The chair of the committee will be selected by its membership by October 15 each year; in the absence of a chair, the Vice President for Research or designee will convene the committee.
- b. *Committee responsibilities.* The responsibilities of the Committee, relative to financial conflicts of interest, will be to receive disclosures with real or perceived conflicts of interest. The vice president for research, in consultation with the Committee chair or the University General Counsel, may triage those disclosures that an informed general public would not reasonably expect to constitute a conflict. Disclosures with real or perceived conflict of interest will be sent to the Committee for review in a face-to-face meeting of a quorum of the Committee within 30 days of receiving the disclosure. By written or electronic memo, the Committee chair will inform the President, Vice President for Research, and cognate dean or supervisor of the Committee's opinion as to whether there is reasonable expectation that a significant financial interest will influence conduct of research. The memo will include recommendations on management, reduction or elimination of the conflict of interest. The President will accept or modify the recommendations and communicate the decision and any required actions in writing to the investigator, or may sign an Authorization of Waiver under BOR Policy 4.35.

The Institutional Review Board will be consulted if reasonable evidence exists that a research project involves human subject research. The evaluation criteria do not vary by funding or regulatory oversight.

- c. *Recommendations for management, reduction or elimination of the conflict of interest.*

Recommendations of the Committee may include but are not limited to:

- i. Public disclosure of significant financial interests;
- ii. Monitoring of research by independent reviewers;
- iii. Modification of the research plan;

- iv. Disqualification from participation in all or a portion of the research;
 - v. Divestiture of significant financial interests;
 - vi. Severance of relationship that create actual or potential conflicts.
 - vii. Recommendation of Authorization of Waiver by USD President.
- d. Appeal of resolution decisions and final authority.* Investigators and administrators may appeal the resolution in writing to the President within 10 days of receiving written notice of the President's decision. The appeal is confined to presenting new information about the conflicting interest or a viable resolution procedure that was not previously discussed. The President shall meet with the Committee chair, other Committee members as appropriate, and vice president for research and either accept or decline the appeal in writing to the investigator or administrator within 10 days. If the appeal is accepted, a revised strategy for conflict management, reduction or elimination will be provided to the investigator or administrator in writing. A declined appeal is final.
- e. Continuing review.* Strategies for managing conflicts of interest will include: specified periods for continuing review, identifying the person(s) responsible for conducting and reporting on reviews, and establishing the authority to enforce management mechanisms and sanctions.
8. *PHS Reporting conflicts of interest.* Prior to the institution's expenditure of any funds under an award, the institution (vice president for research or designee) will report to the funding agency the existence (but not nature or details) of a conflict of interest found and assure that the conflict has been managed, reduced, or eliminated (in accordance with 42 CFR 50 Subpart F). Any conflict of interest identified subsequently will be reported and managed, reduced, or eliminated within 60 days of the identification. To the extent required by law, the institution will make available to the appropriate governmental agencies, upon request, information regarding all identified conflicts of interest and their management, reduction, or elimination. If the investigator has biased the research, the university will promptly notify the funding agency (in case of PHS, the PHS awarding component) of the corrective action taken or to be taken.
9. *Drugs, medical devices, and treatments.* If a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by 42 CFR 50 Subpart F, the university will require that the Investigator(s) involved disclose the conflicting interest in each public presentation of this results of the research.
10. *Recordkeeping.* Records will be kept in the Office of Research and Sponsored Programs for 3 years following the date of submission of the final expenditures report to the external funding agency. (Records for personnel of the Office of Research and Sponsored Programs are kept in the Office of the President with copies in the Office of Research and Sponsored Programs.)

11. PHS Public Accessibility. The University will make information available concerning identified FCOIs held by senior/key personnel by a written response to any requestor within five business days of a request, and update such information as needed. This information will include at a minimum the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI, of a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Questions about this policy should be directed to the Vice President for Research in the USD Office of Research and Sponsored Programs (orsp@usd.edu).

V. RELATED DOCUMENTS, FORMS AND TOOLS

This university policy is guided by the following federal and state regulations and reports:

42 CFR 50, Subpart F: Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

South Dakota Board of Regents Policy 4:35: Conflict of Interest

South Dakota Board of Regents Policy 4:32: Investigator Financial Disclosure

NIH OER: http://grants.nih.gov/grants/policy/coi/nih_review.htm

NOT-OD-05-013: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-013.html>