

SDSU Procedures for Investigator Conflict of Financial Interest Disclosure for PHS, NSF, and Other Sponsored Projects

South Dakota Board of Regents Policy No. 4:35, Appendix S of the COHE agreement requires that all employees avoid private endeavors for profit that may interfere with their performance of university responsibilities. SDSU regards this requirement as particularly relevant to the conduct of research.

The South Dakota State University (SDSU) procedures regarding conflicts of interest in relation to sponsored projects are meant to implement *South Dakota Board of Regents Policy No. 4:32, Appendix Q* of the collective bargaining agreement between the Board and the Council on Higher Education and to satisfy the *Public Health Service Final Rule on Objectivity in Research* as published in the July 11, 1995, Federal Register (corrected on July 31, 1995) and the *NSF Investigator Financial Disclosure Policy* (with changes and clarifications) as published in the July 11, 1995, Federal Register (corrected on July 31, 1995). The Public Health Service (PHS) and the National Science Foundation (NSF) requirements are effective for all applications submitted on October 1, 1995 and thereafter.

Background

PHS and the Office of the Secretary of Health and Human Services promulgated regulations establishing standards and procedures to be followed by institutions that apply for research funding from PHS to ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements, or contracts will not be biased by any conflicting financial interest of those investigators responsible for the research. In the same issue of the Federal Register (July 11, 1995 and corrected on July 31, 1995) NSF made technical changes and clarifications to its Investigator Financial Disclosure Policy that makes its policy more consistent with the PHS provisions.

Under these rules, investigators are required to disclose to an official(s) designated by the awardee Institution any *significant financial interests* (and those of their spouse and dependent children) that reasonably appear to be affected by the research proposed for funding by PHS or NSF. The Institution's official(s) will review the disclosures and determine whether any of the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research. When a potential or real conflict of interest is found, the Institution must act to protect the research from bias. **SDSU has a responsibility to manage, reduce, or eliminate any actual or potential research conflict of interest posed by a related financial interest of an investigator.**

On applications for funding from PHS, NSF, and other sponsors SDSU certifies (or implies) that it has a conflict of interest policy and that SDSU is in compliance with the federal policy. For PHS-funded projects, prior to expenditure of awarded funds, SDSU must report the existence of conflicting interests to the PHS awarding component and it must assure that the conflict of interest has been managed, reduced, or eliminated. For NSF-funded projects, no reporting is required if the conflict of interest issues are resolved to the satisfaction of SDSU. However, the NSF Office of the General Counsel must be informed if SDSU finds that it is unable to manage a conflict satisfactorily.

Terminology (For legal definitions refer to Board of Regents policy.)

Conflict of interest A significant financial interest of a research investigator that could directly and significantly affect the design, conduct, or reporting of the sponsored research.

Investigator The principal investigator, project director, co-investigators, or any other person who is responsible for the design, conduct, or reporting of research funded or proposed for funding. The term “investigator” *includes* the person’s spouse and dependent children.

Significant financial interest Anything currently held of monetary value, including but not limited to:

- Salary and other payments for services (e.g., consulting fees and honoraria)
- Equity interests (e.g., stocks, stock options, or other ownership interests)
- Gifts from related entities
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights)

Not included are:

- Salary, royalties, or other remuneration from the applicant or primary employing Institution
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
- Income from service on advisory committees for review panels for public or nonprofit entities
- An equity interest that, when aggregated for the Investigator and the Investigator’s spouse and dependent children, meets both of the following tests: (1) it *does not exceed \$10,000 in value* as determined through reference to public prices or other reasonable measures of fair

market value, and (2) *does not represent more than a five percent (5%) ownership interest* in any single entity

- Salary, royalties or other payments that, when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve (12) months, are *not expected to exceed \$10,000*.

Management of Conflicting Interests

1. Investigators applying for external funding disclose potential conflicts of interest as part of the application routing process and, *when appropriate*, complete a **confidential SDSU Financial Interests Disclosure Form** with supporting documentation and submit it with the research proposal to SDSU's Office of Research & Sponsored Programs for evaluation. Each investigator on the research project (key personnel) should disclose any significant financial interest.
2. Significant financial interests must be disclosed *prior* to submitting a research proposal to the sponsor.
3. The Associate Dean of Research & Sponsored Programs at SDSU shall review all Financial Interest Disclosures. If this initial review finds a potential or real conflict of interest, the following actions will be taken:
 - a. The Associate Dean of Research & Sponsored Programs will advise the investigator that a potential or real conflict of interest exists.
 - b. The investigator shall prepare, in cooperation with the Department/Unit Head, a **Conflict of Interest Resolution Plan** that details proposed steps that will be taken to manage, reduce, or eliminate any conflict of interest.
 - c. The Conflict of Interest Resolution Plan and the Financial Interest Disclosure materials will be reviewed by the Associate Dean of Research & Sponsored Programs, who will accept the Plan or consult with the investigator and Department/Unit Head to clarify or modify the Plan.
 - d. The Associate Dean of Research & Sponsored Programs shall provide all documentation and make a recommendation to the President of SDSU. The President of SDSU will make the final determination about conflict of interest and any conditions or restrictions to be imposed.

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- e. When approved by the President of SDSU, the Conflict of Interest Resolution Plan will be incorporated into an **Investigator Agreement** between SDSU and the investigator that details the conditions and restrictions imposed on the investigator in the conduct of the research. This Agreement will be signed by the investigator, Department/Unit Head, and the Associate Dean of Research & Sponsored Programs.
- f. The Office of Research & Sponsored Programs will retain all records related to financial disclosures and conflict of interest resolution. For SDSU employees a copy of all relevant documents will be included in their personnel file.
- g. SDSU shall follow the Federal regulations regarding the notification of PHS or NSF if an investigator fails to comply with the policy or abide by an Investigator Agreement.

Subgrantees, Contractors, or Collaborators

Subgrantees, contractors, or collaborators from other academic or not-for-profit institutions must either certify that they comply with SDSU's procedures or that their institution is in compliance with the Federal regulations and that their part of the project is in compliance with their institutional policy. Subcontractors from commercial firms must provide such certification when PHS is the funding source.

The PHS regulations *do not* apply to Small Business Innovation Research (**SBIR**) and Small Business Technology Transfer (**STTR**) Phase I grant applications. The Phase II grants are not exempted. NSF exempts applicant organizations employing 50 persons or less.

These Procedures are Effective as of 11/14/2000