

North Dakota State University

Policy Manual

SECTION 823

FINANCIAL CONFLICT OF INTEREST – PUBLIC HEALTH SERVICE, NATIONAL SCIENCE FOUNDATION, DEPARTMENT OF ENERGY, NATIONAL AERONAUTICS AND SPACE ADMINISTRATION, OR OTHER APPLICABLE SPONSORED RESEARCH

SOURCE: SBHE Policy Manual, Section 308.4
NDSU President

1. INTRODUCTION

- 1.1. Several Federal and non-federal sponsors require institutions to establish standards that promote the objectivity of research by ensuring that the design, conduct, and reporting of such research is free from any potential for bias resulting from Investigator financial conflicts of interest. Investigators should conduct their affairs as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. Applicable sponsors include: The US Public Health Service (PHS), National Science Foundation, (NSF), Department of Energy (DoE), the National Aeronautics and space Administration (NASA) (for new and amended awards starting December 1, 2023), and several other [agencies which have adopted the PHS Guidelines](#).
- 1.2. This policy governing financial conflict of interest applies to all Investigators funded by, or submitting proposals for funding to, any agency of the PHS, except for Small Business Innovation Research (SBIR) Program Phase I applications. This SBIR exclusion does not apply to investigators submitting proposals to NSF. Investigators are required to disclose any external financial interests related to their NDSU responsibilities for review, and any required management, to ensure the design, conduct or reporting of the research is not biased by a financial conflict of interest. Investigators of sponsored projects funded by any other external agency are referred to [NDSU Policy 151.1, External Activities and Conflicts of Interest](#) to address conflicts of interest, including financial.

2. DEFINITIONS

- 2.1. **Family member:** includes the investigator's spouse/partner or dependent children.
- 2.2. **Financial Conflict of Interest (FCOI):** a Significant Financial Interest (SFI) that the University reasonably determines could directly and significantly affect the design, conduct or reporting of NDSU research.
- 2.3. **Investigator's Institutional Responsibilities:** the Investigator's responsibilities associated with his or her institutional appointment or position, such as research, teaching, clinical activities, professional practice, institutional committee memberships and service on panels, such as an Institutional Review Board.
- 2.4. **Investigator:** the project director (PD)/principal investigator (PI), co-PD/co-PI and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research (PHS/DoE) or research or educational activities (NSF) funded by the PHS, NSF or other applicable sponsors, or proposed for such funding, which may include collaborators or consultants.

- 2.5. **Significant Financial Interest (SFI):** anything of monetary value received or held by an Investigator or a Family member, whether or not the value is readily ascertainable, that reasonably appears to be related to the Investigator's Institutional Responsibilities. (Note: this exceeds the definition of SFI in [Policy 151.1](#)). SFI includes:
- 2.5.1. Salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works) when the aggregated value received from a *publicly traded* entity during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
 - 2.5.2. Salary or other payments for services, when the aggregated value received from a *non-publicly traded* entity during the 12 month period preceding the disclosure exceeds \$5,000; or
 - 2.5.3. Equity interests (e.g., stocks, stock options, or other ownership interests) in a non-publicly-traded company of any value during the 12 month period preceding or as of the date of disclosure; or
 - 2.5.4. Income related to intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights) not reimbursed through NDSU; and
 - 2.5.5. Reimbursed or sponsored travel that is related to Investigator's Institutional Responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state, or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

SFI does NOT include:

- 2.5.6. Salary, royalties, or other remuneration from NDSU;
- 2.5.7. Income from the authorship of academic or scholarly works;
- 2.5.8. Income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- 2.5.9. Equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

3. INVESTIGATOR REQUIREMENTS

- 3.1. Investigators must disclose all Significant Financial Interests (SFI) related to their Institutional Responsibilities (or certify no SFI) by completing the Annual COI Disclosure in Novelution.
 - 3.1.1. Prior to submitting a proposal to an applicable agency, Investigators must have a current (within the last 12 months) *COI Disclosure in Novelution*.

- 3.1.2. Annual disclosure. Investigators participating in research funded by an applicable sponsor are required to submit an updated disclosure at least annually by submission of the *COI Disclosure Form*. New investigators must disclose within 30 days of their initial appointment or employment. The disclosure must be reviewed, managed, and reported to the funding agency by Research and Creative Activity (RCA) when necessary, within 60 days of employment.
- 3.1.3. Updating SFI Disclosures. Investigators participating in, or applying to an applicable agency are required to update their Annual COI disclosure within 30 days of discovery or acquisition (e.g., through purchase, marriage, or inheritance) of a new SFI. The disclosure must be reviewed, managed, and reported to the sponsor by RCA when necessary, within 60 days of identification.
- 3.1.4. Travel. Investigators participating in, or applying for PHS, NSF or other applicable sponsor-funded research are also required to disclose any reimbursed or sponsored travel related to their Institutional Responsibilities as defined under 2.3 above. Such disclosures must include, at a minimum: the purpose of the trip, identity of the sponsor/organizer, destination, duration, and monetary value, if known. The administrative head determines if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a FCOI with the Investigator's Research.

4. REVIEW OF COI DISCLOSURE

- 4.1 The University Conflict of Interest Committee (COIC) shall be responsible for (a) reviewing significant financial interests as well as other relationships/activities related to the discloser's professional responsibilities and (b) developing, approving, and monitoring plans to manage or eliminate FCOI. The COIC's Procedures are available on the [NDSU COI website](#).

5. TRAINING

- 5.1. Investigator training on FCOI, this policy, and their responsibilities regarding disclosure of SFI is:
 - 5.1.1. recommended prior to submitting a research proposal to an applicable sponsor;
 - 5.1.2. required prior to expenditure of funds from an applicable sponsor; and
 - 5.1.3. required every 4 years during the period of award;
 - 5.1.4. Online training modules shall be completed via the CITI program (www.citiprogram.org).

6. SUBRECIPIENT REQUIREMENTS

- 6.1. Applicable sponsors require the awardee institution take reasonable steps to ensure that any subrecipient complies with FCOI requirements.
 - 6.1.1. Subrecipient awards must specify whether the FCOI policy of NDSU, or that of the subrecipient will apply to the subrecipient's Investigators.
 - 6.1.2. When the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient award will certify that the subrecipient's policy complies with the applicable sponsor's regulations, and specify the time period to report all identified FCOI to NDSU, in

sufficient time to allow NDSU to report any FCOI to PHS, NSF or other sponsors prior to expenditure of funds by subrecipient.

- 6.1.3. When the subrecipient's Investigators must comply with NDSU FCOI policy, the subrecipient award will specify the time period to report all SFI disclosures to NDSU, in sufficient time for review, management and reporting of any FCOI to the sponsor prior to expenditure of funds by subrecipient. In such a case, the subrecipient disclosure and review will follow the same process required by NDSU Investigators in Section 3 and 4.

7. RECORD KEEPING

- 7.1. Research Integrity & Compliance is responsible for maintaining records related to all disclosures, associated reviews and actions (whether or not a disclosure resulted in a determination of a financial conflict of interest), reporting/updating information, etc.

HISTORY:

New	June 1995
Amended	October 1997
Amended	August 2007
Revised	August 23, 2012
Amended	May 3, 2017
Amended	February 13, 2019
Housekeeping	February 15, 2022
Amended	May 13, 2022
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