

Dakota State University

Policy Manual

SECTION 823

FINANCIAL CONFLICT OF INTEREST – PUBLIC HEALTH SERVICE, NATIONAL SCIENCE FOUNDATION OR OTHER APPLICABLE SPONSORED RESEARCH

SOURCE: SBHE Policy Manual, Section 611.4
NDSU President

1. INTRODUCTION

- 1.1. The US Public Health Service (PHS), National Science Foundation (NSF) and other applicable 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.
- 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 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 PHS 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. **Administrative Head:** a Department Chair or Head, Dean, Director, Vice President, President or equivalent officer who has the primary authority for administering an administrative unit, and is responsible for solicitation and review of disclosures of Investigator's Significant Financial Interests (SFI) related to their institutional responsibilities, including interests of an Investigator's family members. When a conflict exists for an Administrative Head, refer the matter to the next level of administrative authority in the normal reporting lines. (See also in [Policy 151.1](#).)
- 2.2. **Conflict of Interest Advisory Committee (CIAC):** a committee comprised of five members recommended by the Faculty Senate Executive Committee and appointed by the President of the Faculty Senate. The CIAC shall serve as an advisory body to the University administration on conflict of interest issues, and shall also hear appeals of decisions in conflict of interest cases. (See also in [Policy 151.1](#).)
- 2.3. **Family:** any member of the Investigator's immediate family, including spouse, domestic partner, parents, siblings, and children.
- 2.4. **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.

- 2.5. **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.
- 2.6. **Investigator:** the project director/principal investigator, 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) or research or educational activities(NSF) funded by the PHS, NSF or other sponsors, or proposed for such funding, which may include collaborators or consultants.
- 2.7. **Management:** taking action to address a Financial Conflict of Interest (FCOI), which includes a documented plan to reduce or eliminate the FCOI to ensure, to the extent possible, that the design, conduct or reporting of the project will be free from bias.
- 2.8. **Public Health Service (PHS):** the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.
- 2.9. **Research:** a systematic investigation, study, or experiment designed to 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).
- 2.10. **Retrospective Review:** a review of a financial interest that was either not disclosed, or not reviewed and managed by the University in a timely manner. The review is conducted to determine whether any PHS research conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting.
- 2.11. **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:
 - 2.11.1. 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
 - 2.11.2. 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
 - 2.11.3. 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

- 2.11.4. Income related to intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights) not reimbursed through NDSU; and
- 2.11.5. 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:

- 2.11.6. Salary, royalties, or other remuneration from NDSU;
- 2.11.7. Income from the authorship of academic or scholarly works;
- 2.11.8. 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
- 2.11.9. 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. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

- 3.1. Investigators must disclose all SFI related to their Institutional Responsibilities (or certify no SFI) by completing the [SFI Disclosure Form](#) and submit it to their Administrative Head and Dean for initial review.
 - 3.1.1. PHS, NSF or other sponsors proposal submission. Investigators must have a current (within the last 12 months) *SFI Disclosure Form* on file with the University prior to submitting a Research proposal to PHS, NSF or other sponsors as a principal or subrecipient Investigator. A copy of the *SFI Disclosure Form* is routed with the Proposal Transmittal Form to Sponsored Programs Administration (SPA). (The disclosure does not require review by the Administrative Head and Dean until funding has been awarded, unless otherwise required under Policy 151.1.)
 - 3.1.2. Annual disclosure. Investigators participating in PHS, NSF or other sponsor funded Research are required to submit to their Administrative Head and Dean an updated disclosure at least annually by submission of the *SFI Disclosure Form*. New investigators must disclose within 30 days of their initial appointment or employment. The disclosure must be reviewed, managed, and reported to PHS, NSF or other sponsor when necessary, within 60 days of employment.
 - 3.1.3. New SFI. Investigators participating in, or applying for PHS, NSF or other sponsor funded Research are required to submit an updated 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 PHS, NSF or other sponsor when necessary, within 60 days of identification.

3.1.4. Travel. Investigators participating in, or applying for PHS, NSF or other sponsor-funded Research are also required to disclose any reimbursed or sponsored travel related to their Institutional Responsibilities as defined under 2.11.5 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 SFI DISCLOSURE

- 4.1. Prior to expenditure of funds, the review and management of any FCOI must be complete, and a copy of the documentation forwarded to SPA. SPA will report any identified FCOI to the PHS, NSF or other applicable agency. If the proposal does not result in an award, FCOI disclosures will be returned to the Administrative Head and Dean for further action if required under Policy 151.1.
- 4.2. If the Investigator has certified that he/she has no SFI to disclose, the Administrative Head and Dean, if they are in agreement with the Investigator's disclosure, sign the *SFI Disclosure Form*, acknowledging receipt and agreement, and sending a copy to SPA.
- 4.3. When the Investigator has disclosed SFI, the Administrative Head and Dean must review the *SFI Disclosure Form(s)* before the expenditure of funds. This review is to determine whether:
 - 4.3.1. The SFI reasonably appears to be related to the funded Research (e.g., if the SFI could be affected by the Research, or is in an entity whose financial interests could be affected by the Research); and
 - 4.3.2. The interest constitutes a FCOI (e.g., a SFI that may directly and significantly affect the design, conduct, or reporting of PHS, NSF or other sponsor-supported Research).
- 4.4. If the SFI is either found to not be related to the funded Research, or does not involve a potential FCOI, the Administrative Head and Dean sign the *SFI Disclosure Form*, forwarding a copy to SPA; no further action is needed.
- 4.5. If the SFI is determined to constitute an actual or apparent FCOI, the Administrative Head and Dean sign the determination, forwarding the *SFI Disclosure Form* to the respective VP, Provost, or the CIAC for additional review and Management, as set forth in Section 5.
 - 4.5.1. Should the VP, Provost, or CIAC review result in a determination that no actual or apparent FCOI exists, the final determination is documented on the *SFI Disclosure Form*, a copy is forwarded to SPA, and no further action is required.
 - 4.5.2. In the event the Dean, VP, Provost, or CIAC determines that the FCOI cannot be satisfactorily managed, NDSU will refuse the award. The final determination is documented on the *SFI Disclosure Form*, a copy is forwarded to SPA, and no further action is required.

5. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

- 5.1. Prior to expenditure of funds, the VP, Provost, or CIAC are responsible for development of a Management plan including conditions or restrictions to eliminate, reduce, or manage the FCOI. The Investigator, Administrative Head, and Dean may also be involved in drafting the plan, including conditions such as:

- 5.1.1. Public disclosure of the conflict when publishing or presenting Research;
 - 5.1.2. For human Research projects, disclosure of the conflict directly to participants;
 - 5.1.3. Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the Research against bias resulting from the conflict;
 - 5.1.4. Modification of the Research plan;
 - 5.1.5. Change of personnel or their responsibilities, or disqualification from participating in all or a portion of the Research;
 - 5.1.6. Reduce or eliminate the SFI; or
 - 5.1.7. Sever relationships that pose a FCOI.
- 5.2. Upon review and consideration, the Management plan is documented in writing, including:
- 5.2.1. Role and principal duties of the conflicted Investigator;
 - 5.2.2. Conditions of the Management plan;
 - 5.2.3. How the plan is designed to safeguard objectivity in the Research;
 - 5.2.4. Confirmation of the Investigator's agreement to the Management plan;
 - 5.2.5. How the plan will be monitored to ensure Investigator compliance; and
 - 5.2.6. Any other information relevant to the management of FCOI.
- 5.3. The Dean and the VP or Provost signs the Management plan, and appoints an individual to monitor the project until completion of the funded Research. SPA receives a copy of the approved Management plan, and reports all instances of FCOI to PHS, NSF or other sponsor, or the primary awardee institution, including applicable Management plans.
- 5.4. Where the Research involves human subjects, the Investigator provides a copy of the approved Management plan to the IRB for review with the IRB protocol. The IRB may impose additional, specific conditions or restrictions, where necessary, to ensure protection of the rights and welfare of research participants, but may not alter the Management plan finalized by the VP or Provost.

6. TRAINING

- 6.1. Investigator training on FCOI, this policy, and their responsibilities regarding disclosure of SFI is:
- 6.1.1. Recommended prior to submitting a Research proposal to the PHS, NSF or other sponsors;
 - 6.1.2. Required prior to expenditure of PHS , NSF or other sponsored funds;
 - 6.1.3. Required every 4 years during the period of award;

- 6.1.4. Required immediately when the FCOI policy is revised, an Investigator is new to a PHS, NSF or other sponsor project, or an Investigator is not in compliance with the policy or Management plan.
- 6.2. Online training modules shall be completed via www.citiprogram.org. The principal Investigator of each PHS, NSF or other sponsor funded project ensures that all applicable individuals involved in the design, conduct or reporting of their Research complete training.

7. SUBRECIPIENT REQUIREMENTS

- 7.1. PHS, NSF and other sponsors requires the awardee institution take reasonable steps to ensure that any subrecipient complies with FCOI requirements.
 - 7.1.1. Subrecipient awards must specify whether the FCOI policy of NDSU, or that of the subrecipient will apply to the subrecipient's Investigators.
 - 7.1.2. 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 PHS, NSF or other sponsors 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.
 - 7.1.3. 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 PHS, NSF or other sponsors 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.

8. APPEALS

- 8.1. If Research is determined to be subject to restrictions or conditions due to FCOI, the Investigator may appeal the decision to the Faculty Senate President, as described in [Policy 151.1](#). The CIAC serves to hear appeals of decisions in conflict of interest issues, and shall meet with the appellant Investigator within 15 working days of receipt of the appeal. If a member of the CIAC has any personal or working relationship with the appellant Investigator, that member should recuse him or herself and be replaced by another member appointed by the President of the Faculty Senate. More than one meeting may be scheduled to decide the case, if necessary.
- 8.2. The appellant Investigator has the right to call any witnesses and produce any evidence that could bear on a recommendation to allow the activity, as well as to have an advisor accompany him/her to any CIAC deliberations. The CIAC, however, will come to its conclusions and write its final recommendations in private. The recommendation to either uphold or change the original decision shall be sent to the appropriate Dean, VP, or Provost. If the CIAC finds that the original decision should be upheld, then a final appeal may be made to the President of the University. If the recommendation is to change the original decision, the Dean, VP, or Provost shall take appropriate action as he or she deems fit. All records of the proceedings shall be maintained on file in the office of the appropriate Dean, VP, or Provost for three (3) years. A copy of the final recommendations shall be provided to the appellant Investigator.

9. COMPLIANCE AND SANCTIONS

- 9.1. In the event an Investigator fails to disclose SFI, or the Institution fails to review the disclosure in a timely fashion, PHS, NSF and other sponsors requires the Institution to conduct a review within 60 days of knowledge of the failure. If the SFI is found to involve FCOI, an interim Management plan is required, as well as a report to the sponsor by SPA.
- 9.2. In the event a FCOI is not identified or managed in a timely fashion, or the Investigator fails to comply with terms of a Management plan, PHS, NSF and other sponsors requires that the Institution conduct a Retrospective Review. Within 120 days of identification of the noncompliance, the Dean, VP, Provost, or CIAC performs the review to determine whether the Research conducted during the period of noncompliance was biased in its design, conduct or reporting. The process and findings of the review are documented, and reported promptly to the sponsor by SPA.
- 9.3. If bias is found, the Institution is required to notify PHS, NSF or other sponsors promptly, and submit a mitigation report. The report is prepared with the assistance of the Investigator, Administrative Head, and Dean, and shall include a description of the impact of the bias on the Research project and the plan of action to eliminate or mitigate the effect of the bias.
- 9.4. Violations of this policy shall be subject to disciplinary procedures, including sanctions up to and including suspension and termination of employment at NDSU. In addition, any NDSU employee who has received financial benefit from transactions in violation of this policy shall be liable for repayment (to the appropriate entity) of all financial benefits resulting from such violation. Compliance with this policy may also be enforced through the exercise of administrative oversight of funded Research and management of NDSU facilities and other property. Such enforcement measures may include, but are not limited to:
 - 9.4.1. Freezing Research funds or accounts;
 - 9.4.2. Rescinding contracts entered in violation of this policy or state law; or
 - 9.4.3. Bringing legal action for restitution to the appropriate entity or entities of the amount of financial benefit received by the NDSU employee as a result of the employee's violation of this policy.

10. REPORTING

- 10.1. Prior to expenditure of funds, SPA shall report all findings of FCOI to PHS, NSF or other applicable sponsor. The report shall include sufficient information to allow the agency to understand the nature of the conflict and appropriateness of the Management plan. It shall include:
 - 10.1.1. Project number; project director or principal Investigator;
 - 10.1.2. Name of Investigator with the conflict, and the entity involved;
 - 10.1.3. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium, etc.);
 - 10.1.4. Value of the financial interest (dollar ranges are acceptable), or a statement that value is not readily determined;

10.1.5. Description of how the SFI relates to the funded Research and the basis for determining that the SFI conflicts with the Research;

10.1.6. Description of the key elements of the Management plan, as described above.

10.2. On an annual basis, SPA reports to PHS, NSF or other sponsor the status of any previously identified FCOI, and any changes to the Management plan.

10.3. SPA submits Retrospective Review and mitigation reports promptly to PHS, NSF or other sponsors as necessary.

11. RECORDS AND CONFIDENTIALITY

11.1. Records of all disclosures of SFI and of all actions taken to review and manage conflicts will be maintained by the respective Department or College until at least three (3) years after the later of the termination or completion of the award to which they relate, or the resolution of any governmental action involving these records.

11.2. The disclosure and supporting documents filed in compliance with this policy will be maintained as confidential to the extent possible under applicable state and federal requirements and the North Dakota Open Records Act. Whenever requests for such information are requested by any external entity, the individual will be notified.

12. PUBLIC ACCESSIBILITY

12.1. PHS, NSF and other sponsors requires NDSU to ensure public accessibility of SFI information related to PHS, NSF and other sponsored Research, including an obligation to respond to any requestor within five business days, with information concerning any SFI that meets all the following criteria:

12.1.1. The SFI was disclosed and is still held by the senior/key personnel;

12.1.2. A determination has been made that the SFI is related to the funded Research; and

12.1.3. A determination has been made that the SFI constitutes an FCOI.

12.2. The information to be made available shall include the Investigator name, title and role in Research, name of entity involved with the FCOI, nature of the interest, approximate dollar amount of interest, or statement that the value is not readily determined.

12.3. The information must be made available for a period of three (3) years from the date that it was most recently updated.

HISTORY:

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