

Financial Conflicts of Interest Policy for Externally Funded Projects



**NORTH CENTRAL
COLLEGE 1861**

The purpose of this policy is to uphold the integrity and public trust of North Central College's research activities. This policy is intended to supplement the College's general conflict of interest policy and to meet the requirements of Federal regulations (42 CFR Part 50 Subpart F for grants and cooperative and 45 CFR Part 94 for contracts). North Central College (the "College") has a responsibility to identify, manage, and reduce or eliminate financial conflicts of interest that may arise because of the financial interests of an Investigator. Investigator means the principal investigator and any other person who, regardless of title, is independently responsible for the design, conduct, or reporting of research funded by the Federal sources, or proposed for such funding, which may include, for example, collaborators and consultants.

- I. **Personnel authorized to monitor disclosure of significant financial interests.** The Office of Sponsored Research and Programs will manage the administration of the financial interest disclosure forms and will monitor training of investigators required by this policy. The Vice President of Finance will evaluate all disclosures by investigators made under this policy; determine whether a financial conflict of interest exists; develop and implement a management plan for financial conflicts of interest subject to this policy; makes, as required by federal regulation, information on investigator financial conflicts of interest publicly available; and reports, as required by federal regulation, on College determination of the existence of a financial conflict of interest, implementation of management plan for a financial conflict of interest, determination of noncompliance, and the results of any retrospective review.

- II. **Personnel responsible for disclosure of significant financial interests.** Any person who, regardless of title, is independently responsible for the design, conduct, or reporting of research funded by the Federal sources, or proposed for such funding, (each, an "Investigator") are required to disclose to the College all significant financial interests of the Investigator and/or the Investigator's spouse, partner, and dependent children. The College responsible for determining all project personnel who meet the above definition of Investigator and therefore who must be trained, must disclose financial interests to the College, and must report when the status of any financial interest changes or when new interests are acquired.

- III. **Definition of significant financial interests.** Significant financial interest (SFI) means one or more of the following interests of the Investigator (or the Investigator's spouse, partner, or dependent children), if it reasonably appears to be related to the Investigator's institutional responsibilities, including all research, teaching and/or service to the College:
 - a. With regard to any *publicly traded entity*, an SFI 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 the disclosure, when aggregated, exceeds \$5,000. Remuneration includes any salary and any payment for services not otherwise identified as salary (e.g., consulting fees, paid authorship, honoraria); 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.
 - b. With regard to any *non-publicly traded entity*, an SFI 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, partner, or dependent children) owns *any* equity interest, regardless of dollar value.

- c. With regard to *intellectual property rights and interests* (e.g., patents and copyrights) an SFI exists upon receipt of income exceeding \$5,000 related to such rights and interests.
- d. Any occurrence of *reimbursed or sponsored travel* related to the Investigator's institutional responsibilities exceeding \$5,000 must also be disclosed, with the exception of any travel reimbursed or sponsored by a federal, state, or local government agency located in the U.S., a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education. The Investigator must disclose the purpose of the trip, the identity of the sponsor and/or organizer, the destination and its duration. Additional information, including the estimated cost of travel, may be required.

IV. Exclusions of significant financial interests. An SFI does not include the following types of financial interests:

- a. salary, royalties, or other remuneration from the College;
- b. income from investment vehicles such as mutual funds or retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- c. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an U.S. institution of higher education (20 U.S.C. 1000(a)), an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education; or
- d. income from service on advisory committees or review panels for a federal, state, or local government agency, an U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education.

Note on Foreign Interests: *Disclosure of foreign financial interests differs from disclosure of domestic financial interests as it relates to the exclusions described above. References to institution of higher education refer to U.S. institutions, and references to federal, state, and local governments refer to agencies within the U.S. Therefore, Investigators must disclose all financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from a foreign institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).*

V. Training requirements for a Federal sponsor (Exception: For training requirements specific to the National Institutes of Health [NIH] – refer to section IV below)

- a. The College will notify each proposed Investigator seeking Federal funding of this policy, the Investigator's disclosure responsibilities, and the Federal regulation.
- b. Investigators must complete FCOI training prior to engaging in research related to any Federally-funded grant or contract and at least every four years, and immediately under the designated circumstances:
 - i. College FCOI policies change in a manner that affects Investigator requirements;
 - ii. an Investigator is new to the College; or
 - iii. the College finds an Investigator noncompliant with College's FCOI policy or management plan.

- c. To meet the training requirement, Investigators must review this policy and complete successfully the Conflict of Interest mini-course, a web-based curriculum provided by the Collaborative Institutional Training Initiative ([CITI](#)).

VI. Training requirements specific to NIH

- a. See section V.a and V.b. above
- b. To meet the NIH training requirement, Investigators must review this policy and complete successfully the [NIH FCOI Training Module](#).

VII. Disclosure of significant financial interests.

- a. Investigators must complete the financial disclosure form:
 - i. Prior to submission of a proposal to a Federal funding agency.
 - ii. Annually for Federally-funded grants: In January of each year, Investigators will complete an updated SFI Disclosure Form.
 - iii. Within 30 days of discovering or acquiring a new SFI.
 - iv. As a new Investigator joining the College who is conducting research sponsored by Federal funding agencies to which this policy applies will provide all necessary disclosures within 30 days.
- b. Using the College's SFI Disclosure Form, each Investigator will certify that he/she has read and understood the College Policy on Financial Conflicts of Interest for Federally-funded Research and disclose their foreign and domestic SFIs (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities.
- c. Disclosures of travel must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value.

- VIII. Review of financial disclosures.** The following process shall apply to financial disclosures submitted by Investigators. The Office of Sponsored Research and Programs (OSRP) will collect all SFI Disclosure Forms. If a SFI is disclosed, OSRP will send the form to the Vice President for Finance who will review the SFI Disclosure Form and determine whether a financial conflict of interest exists. An FCOI exists when the College reasonably determines that an Investigator's SFI is related to a Federally-funded research project based on the criteria below:
- a. the SFI could be affected by the research or
 - b. the SFI in an entity whose financial interest could be affected by the research and
 - c. the SFI could directly and significantly affect the design, conduct, or reporting of the Federally-funded research.

The Vice President for Finance may, depending on the scope of the potential conflict, request that additional staff or faculty serve on an *ad hoc* review committee to assist in this review, and they or the Vice President for Finance may request additional information from the Investigator who disclosed the SFI.

- IX. Management of financial conflicts of interest.** If the Vice President for Finance determines a SFI constitutes a financial conflict of interest, the Vice President for Finance, in consultation with the Provost/Vice President for Academic Affairs and the affected Investigator, shall determine what conditions or restrictions should be imposed as part of a formal management plan to

manage, reduce, or eliminate such conflict of interest. Management plans may contain one or more elements, including:

- a. public disclosure of FCOIs (e.g., when presenting or publishing the research; to staff members working on the project; to the College's Institutional Review Board, Institutional Animal Care and Use Committee, etc.);
- b. for research projects involving human subjects research, disclosure of FCOIs directly to participants;
- c. monitoring of the sponsored program by independent reviewers;
- d. modifications of the research plan;
- e. appointment of an oversight panel or person to review research;
- f. limitations on the Investigator's involvement in all or a portion of the funded research;
- g. divestiture of SFIs;
- h. severance of relationships that create actual or potential conflicts; and/or
- i. other arrangements that manage, reduce, or eliminate a potential FCOI.

The management strategies will be incorporated into a Memorandum of Understanding (MOU) between the College and the Investigator, which will detail the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the business entity. The Management Plan MOU will be signed by the Investigator and the Vice President for Finance and filed with the Office of Sponsored Research and Programs. OSRP will certify that FCOIs will be satisfactorily managed, reduced, or eliminated in accordance with these guidelines prior expending any funds from the applicable Federal award, or they will be disclosed to the sponsoring agency in writing for action.

X. Reporting requirements to a Federal sponsors (*Exception: For reporting requirements specific to NIH – refer to section XI. below*)

The review of disclosures and development of any necessary management strategies shall be conducted prior to the College's expenditure of funds, and within the required compliance timelines of the sponsoring Federal agency for Investigators newly assigned to an existing project or for newly identified FCOIs for existing Investigators.

If any identified conflict or noncompliance requires reporting to the sponsoring Federal agency, OSRP will provide such a report in accordance with applicable regulations. Review, determination of whether a conflict exists, the creation and implementation of the management plan, and any required reports to the Federal sponsor will occur within 60 days of submission of the SFI Disclosure Form.

XI. Reporting requirements specific to NIH

- a. OSRP shall send initial, annual, and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for the College and its subrecipients, if applicable, as required by the regulations in 42 CFR 50.604(h) and/or 42 CFR 50.605(b). This shall be performed:
 - i. Prior to the expenditure of funds
Within 60 days of identification for an Investigator who is newly participating in the project
 - ii. Within 60 days for new, or newly identified, FCOIs for existing Investigators

- iii. At least annually (at the same time as when the College is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
 - iv. Following a retrospective review (for details, see sections VI.B.2. and VI.B.3. below) to update a previously submitted report, if new information is discovered following completion of the review. 42 CFR 50.605(a)(3)(iii)
- b. All original FCOI reports must include sufficient information to enable the NIH to understand the nature and extent of the FCOI and to assess the appropriateness of the College's management plan. The original FCOI report to NIH, which must be submitted through NIH's eRA Commons FCOI Module by OSRP, must include the following key elements (but are not necessarily limited to the following):
 - i. Project number;
 - ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
 - iii. Name of the Investigator with the FCOI;
 - iv. Name of the entity with which the Investigator has an FCOI;
 - v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - vi. Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or 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);
 - vii. A description of how the financial interest relates to the NIH-funded research and why the College determined that the financial interest conflicts with such research;
 - viii. A description of the key elements of the College's management plan, including
 - 1. Role and principal duties of the conflicted Investigator in the research project;
 - 2. Conditions of the management plan;
 - 3. How the management plan is designed to safeguard objectivity in the research project;
 - 4. Confirmation of the Investigator's agreement to the management plan;
 - 5. How the management plan will be monitored to ensure Investigator compliance; and other information as needed.
- c. Based on the results of a retrospective review (again, for details, see sections VI.B.2. and VI.B.3. below), OSRP shall notify NIH promptly if bias is found with the design, conduct, or reporting of NIH-funded research and submit the required Mitigation Report. The Mitigation Report must include, at a minimum, the key elements of the retrospective review (see section VI.B.3. below) and a description of the impact of the bias on the research project and the College'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). 42 CFR 50.605(a)(3)(iii)

- d. OSRP shall notify NIH promptly if an Investigator (or subrecipient Investigator) fails to comply with this policy or if an FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research. 42 CFR 50.606(a). a. This policy confirms the College's requirement to notify NIH promptly and take corrective action for noncompliance with this policy or any management plan that has been developed.

XII. Violations of FCOI in research policy

- a. Investigator Noncompliance: Whenever an Investigator has violated this policy or the terms of any resolution plan required by the Vice President of Finance (including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms), the Provost/Vice President of Academic Affairs, will impose sanctions or institute disciplinary proceedings against the Investigator in accordance with the Faculty Handbook. In addition, OSRP shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.
- b. Enforcement Mechanisms and Remedies and Noncompliance Specific to NIH
 - i. See Investigator Noncompliance (section XII.a.) above.
 - ii. The Vice President for Finance shall complete and document retrospective reviews within 120 days of the College's determination of noncompliance for SFIs when they are:
 - 1. not disclosed in a timely manner or
 - 2. not previously reviewed or
 - 3. whenever an FCOI is not identified or managed in a timely manner, including:
 - a. Failure by the Investigator to disclose an SFI that is determined by the College to constitute an FCOI;
 - b. Failure by the College to review or manage such an FCOI
 - c. Failure by the Investigator to comply with the FCOI management plan.
 - iii. The retrospective review shall include, at a minimum, the following key elements:
 - 1. Project Number;
 - 2. Project Title;
 - 3. PD/PI or contact PD/PI if multiple PD/PI model is used;
 - 4. Name of the Investigator with the FCOI;
 - 5. Name of the entity with which the Investigator has an FCOI;
 - 6. Reasons for the retrospective review;
 - 7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed);
 - 8. Findings of the review; and

9. Conclusions of the review

- iv. The Vice President for Finance shall ensure that in any case in which the Department of Health and Human Services determines that a PHS or NIH-funded research 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 an FCOI that was not managed or reported by the College as required by the regulation, the College shall require the Investigator involved to:
 1. Disclose the FCOI in each public presentation of the results of the research, and
 2. Request an addendum to previously published presentations.

XIII. Maintaining records of financial disclosure. OSRP shall maintain all FCOI-related records pertaining to all Investigator disclosures of SFIs and the College's review of, and response to, such disclosures (whether or not a disclosure resulted in the College's determination of an FCOI) and all actions under the College's policy or retrospective review, if applicable, shall be retained for at least three years from the date the final expenditure report is submitted, or, where applicable, from other dates specified in 45 CFR 75.361.

XIV. Collaborative Projects/Subrecipient Requirements (*Exception: For collaborative projects/subrecipient requirements specific to NIH – refer to section XV. below*)
Collaborators/subrecipients from other organizations must either comply with this policy or provide a certification or written agreement that their organizations are in compliance with Federal policies regarding Investigator SFI disclosure and that their portion of the project is in compliance with their institutional policies.

XV. Collaborative Projects/Subrecipient Requirements Specific to NIH
The awardee institution is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified FCOIs for subrecipient Investigators to the NIH. Awardee institutions must incorporate as part of a written agreement with a subrecipient terms that establish whether the FCOI policy of the awardee institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements.

Subrecipient institutions who rely on their FCOI policy must report identified FCOIs to the awardee institution in sufficient time to allow the awardee institution to report the FCOI to the NIH to meet its reporting obligations.

Subrecipient institutions that must comply with the College's policy must submit all Investigator disclosures of SFIs that are directly related to the subrecipient's work for the College. The submission of disclosures to the College must be in sufficient time to allow the College to review, manage, and report identified FCOIs to the NIH.

The College is responsible for monitoring subrecipient's compliance with the FCOI regulation, management plans, and for reporting all identified FCOIs to the NIH.

XVI. Public accessibility requirements

- a. The College will make this FCOI policy publicly accessible on its website.
- b. The College will make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation), publicly accessible within five business days. The information will:
 - i. Include the minimum elements as provided in the regulation
 - ii. Be posted on a public website or made available within five business days of a written request
 - iii. Be updated, at least annually (website only but any response to a written request should include the updated information)
 - iv. Be updated, within 60 days of a newly identified FCOI (website only but any response to a written request should include the updated information)
 - v. Remain available for three years from the date the information was most recently updated.

Policy adopted from the financial conflict of interest policies of Bates College, Linfield University, Kalamazoo College, and Dickinson College.