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**Conflict of Interest Committee:**

**Procedures**

Originally published 2020

Revised: April 2022, November 2023

***Conflict of Interest Committee (COIC)***

COI Office

Research and Creative Activity

Research, Integrity and Compliance

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***1 Introduction***

A Conflict of Interest is a divergence between an individual’s private interests and their professional obligations to the University such that an independent observer might reasonably question whether the individual’s professional actions or decisions are determined by considerations of personal gain, financial or otherwise. For example, conflicts of interests occur in situations in which personal considerations may compromise or appear to compromise a researcher’s professional judgment in conducting or reporting research.

The University Conflict of Interest Committee (COIC) is responsible for (a) reviewing conflict of interest disclosures related to one’s research, and (b) developing, approving, and monitoring plans to manage or eliminate conflicts of interest.

***1.1 Types of Conflicts of Interest***

1. Commitment – Conflicts of commitment arise when university employees’ involvements in outside activities substantially interfere with their primary commitments to the university: to teach, to conduct research and to meet related institutional obligations.
2. Financial – Financial conflicts of interest arise when university employees' involvements in outside business activities substantially interfere with their primary commitments to the university: to teach, to conduct research and to meet related institutional obligations.
3. Personal – Personal conflicts of interest arise when university employees' involvements in personal activities or relationships may impair their ability to act impartially and substantially interfere with their primary commitments to the university: to teach, to conduct research and to meet related institutional obligations. These relationships may include spouses, siblings, relatives, friends or any other close personal relationships.

***1.2 Scope***

The *NDSU Conflict of Interest Procedures* apply to all University Members, including employees and students in their various University roles.

Sub-awardees and their personnel, and collaborators at other institutions (collectively ‘Sub-Awardees’) must either comply with this policy or document that their institutions or organizations are in compliance with US DHHS PHS rules. If they cannot so certify, they will be subject to North Dakota State University’s COI policy.

***1.3 Regulatory Authority***

The Conflict of Interest Guidelines are based on several federal funding requirements, as well as nationally recognized consensus standards and guidelines. The following federal regulations and guidelines are the basis for the NDSU conflict of interest program. This list is not all-inclusive. In cases where federal, state, and local regulations differ, NDSU follows the most stringent regulations.

Public Health Services FCOI Funding Guidelines - [Federal Reg 42CFR50 Subpart F](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F)

[National Institutes of Health FCOI Funding Guidelines](https://grants.nih.gov/grants/policy/coi/index.htm) - 4.1.10 Financial Conflict of Interest

[National Science Foundation FCOI Funding Guidelines](https://www.nsf.gov/pubs/2002/nsf02151/gpm5.jsp) - 510 CONFLICT OF INTEREST POLICIES

Department of Energy Interim Conflict of Interest Policy

[Conflict of Interest Policy for Recipients of NASA Financial Assistance Awards](https://www.federalregister.gov/documents/2023/08/31/2023-18802/conflict-of-interest-policy-for-recipients-of-nasa-financial-assistance-awards#:~:text=In%20summary%2C%20the%20policy%20requires,official%20prior%20to%20application%20submission.)

***1.4 Violations***

Violations of regulatory requirements regardless of the specific funding source can jeopardize funding from the National Institutes of Health (NIH), National Science Foundation (NSF), and other granting agencies for the entire NDSU campus.

Violations to any of the NDSU policies listed below are subject to procedures outlined in *Section 3 Non-compliance and Corrective Actions*. Examples may include failure to report conflicts to the committee or not completing training requirements.

***NDSU Policy 823*** - FINANCIAL CONFLICT OF INTEREST – PUBLIC HEALTH SERVICE, NATIONAL SCIENCE FOUNDATION OR OTHER APPLICABLE SPONSORED RESEARCH

***NDSU Policy 151.1*** - EXTERNAL ACTIVITIES AND CONFLICTS OF INTEREST

***NDSU Policy 308.4*** – CONFLICT OF INTEREST

## 2 Guideline Elements

The COI Committee reviews information submitted for the existence of conflicts related to significant financial interests, conflicts of commitment with research, teaching and other university responsibilities, and outside interests, and requires management of such conflicts when appropriate.

## Federal Funding Requirements

* Any investigator\* that receives federal funding from NIH, NSF, the Department of Energy, NASA (after 12/1/2023) or another PHS-sponsored agency is required to submit a Annual Disclosure Form each year, or within 30 days of a change in status.

[Agencies that have adopted the PHS FCOI Guidelines](https://www.ndsu.edu/research/for_researchers/research_integrity_and_compliance/research_conflict_of_interest/coi_resources/) can be found on the COIC website.

* Upon receipt of an applicable award, any investigator who has disclosed a significant financial interest (SFI), relationship, or other potential conflict, must complete a Project Specific Disclosure to indicate whether the interest, activity or relationship is related to the awarded project.
* Completion of the Conflict of Interest training in the CITI program is also required. Training must be renewed every four (4) years.

\*Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

## 2.1.1 Conflict of Interest Disclosure Form

The Annual COI Disclosure is required for all investigators listed on any proposal or award from a federal funding agency. It is required to be updated annually or within 30 days of discovery or acquisition (e.g., through purchase, marriage, or inheritance) of a new significant financial interest (SFI).

Disclosure of the following Significant Financial interests are required:

* Salary or other payments for services from a publicly traded company: (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works) when the aggregated value received 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.
* Salary or other payments for services from a Non-publicly traded company, when the aggregated value received from during the 12-month period preceding the disclosure exceeds $5,000.
* Equity interests in publicly traded entity (e.g., stocks, stock options, or other ownership interests) in a company exceeding $5,000 during the 12-month period preceding or as of the date of disclosure.
* Equity interests in a Non-publicly traded entity (e.g., stocks, stock options, or other ownership interests) in a company in any amount during the 12-month period preceding or as of the date of disclosure.
* Income related to intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights) not reimbursed through NDSU; and
* 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:**

* Salary, royalties, or other remuneration from NDSU.
* income from the authorship of academic or scholarly works.
* 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, or medical centers.
* 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.

***2.1.2 CITI Training - Conflict of Interest Course***

Conflict of Interest training is required for investigators funded by applicable agencies. Training must be renewed every 4 years

* Training is provided through the [CITI program website](https://www.citiprogram.org/members/index.cfm?pageID=585&instID=907&action=AllMembers).
* Required for the release of funds from an award from one of the listed agencies in *Section 2.1*.

***2.1.3 Disclosure of other potential conflicts***

University members must disclose for themselves, and for their family any significant personal, financial, commitment, or research conflict of interest. University members may also choose to disclose other financial or related interests that could present, or be perceived to present, a conflict of interest. These potential conflicts are disclosed through the Annual COI Disclosure.

***2.2 New Potential Conflicts of Interest, Approval and/or Oversight***

***2.2.1 Committee Determination of Conflict***

If a University employee encounters a commitment-related, financial, or personal conflict of interest, the University employee completes the Annual COI Disclosure in Novelution. The COI Administrator conducts an initial review of the disclosure and determines whether secondary review by the committee is needed.

* If the COI Administrator refers a disclosure for secondary review, the chair of the COI may either assign the item for review at a convened meeting or via expedited review procedures.
* Expedited review procedures – Review materials are provided to all primary and alternate members for review. At least two-thirds of primary members must agree to approve. Items failing to receive two-thirds support will be moved to the next available COIC agenda.
* Convened review procedures – A quorum is defined one more than 50% of the committee members. A two-thirds majority vote of present members at the meeting is required when reviewing disclosures and/or management plans. The COIC administrator/designee notifies the university employee of the review outcome and any actions required.
* The committee may determine that:
  + There is no conflict - No management plan needed
  + Conflict/management plan needed
  + Conflict/unmanageable.

***2.2.2 Examples of management strategies***

Management plans may include conditions or restrictions on the employee’s activities, including but not limited to:

* public disclosure of significant interests, including but not limited to notifying students, staff, or other relevant university employees or colleagues
* monitoring of the funded activities by independent reviewers
* modification of the planned activities (which may be subject to sponsor approval)
* disqualification from participation in all or a portion of the activity
* divestiture of significant financial interests
* severance of external relationships that create conflicts
* appointment of an alternate PI or supervisor
* appointment of an individual to provide independent technical or financial oversight
* review of the plan when new funding is acquired

***2.2.3 Familial Conflict of Interest Guidelines***

Conflicts include activities in which you may receive financial interest or advantage for yourself, your immediate family, your close associates, or a business over which you or your family has a direct or indirect financial interest. When family members are in a work situation in which one individual has supervisory or fiscal authority over the other (directly or indirectly), a conflict of interest exists as defined by state law. To maintain transparency, ensure proper oversight, and to comply with all NDSU and state policies, a COI management plan is required.

* It is the responsibility of the University employee(s) and/or the supervisor to notify the COIC of the presence of the conflict of interest.
* The COIC develops a management plan including, but not limited to, the listed provisions:
* No individual shall initiate or participate in institutional decisions involving a direct benefit or penalty (employment, retention, promotion, tenure, salary, leave of absence, etc.) to a person with whom that person is related.
* For grant funded research, oversight of financial reimbursements as well as time and effort reporting must be established.
  + The university employee shall notify all applicable personnel that a management plan is in place, and provide contact information for the COI administrator/Department head/chair/supervisor for reporting concerns.
* Management plans will remain in place as long as the working relationship exists. The plan may be modified if/when circumstances of the personal or professional relationship changes.

***2.2.4 Guidelines for Conflicts related to financial or business interests***

A university employee with ownership, controlling interest or significant financial interest in a company related to their professional, institutional duties may have a perceived or actual conflict of interest. The financial interests of a parent, sibling, independent child, unmarried domestic partner, or a close associate may be perceived as a conflict of interest, and should be reported, if known. Similarly, the promise of future gifts, or the offer of a loan on advantageous terms not available to the general public, might represent a significant financial interest that should be disclosed.

* It is the responsibility of the University employee(s) and/or their supervisor to notify the COIC of the presence of the conflict.
* The COIC develops a management plan including, but not limited to, the listed provisions:
* The amount of University time used is consistent with University policy.
* Use of university facilities or services by the company must be in compliance with all relevant university policies pertaining to use by external parties.
* If the company wishes to sell products or services to any North Dakota University System institution, it must first apply for and obtain approval as a Conflict of Interest vendor through the NDSU Director of Purchasing. (Policy 151)
* Publications and Intellectual property guidelines set within Policy 151.1.
* Notification to all NDSU students of employee involvement with company.
* Management plans will remain in place as long as the employee remains involved with the outside interest. The plan may be modified when the circumstances of the employee’s involvement with the company changes.

***2.3 Annual Updates to Disclosures***

A University employee who has completed an annual disclosure within Novelution will be prompted to update their disclosure annually.

* The updated disclosure is reviewed per the procedures described in Section 2.2.1.
* Management plans may require updates based on changes in relationships, outside activities, or financial interests.

Changes to existing conflict of interest management plans may also be initiated by the University employee. Requested modifications will be reviewed by the COIC per procedures in 2.2.1.

## Allegations of Noncompliance

If the Conflict of Interest committee receives an allegation or evidence that a University employee may have violated a management plan of any type, the COIC may request additional information from relevant parties. The initial data gathering process and all communications are documented in writing.

* The COIC may determine that there is no basis for complaint and that the allegation is unsubstantiated.
* If the allegation is substantiated, the conflict of interest committee may convene as a whole, or may establish a subcommittee to review relevant documentation.
* If the committee determines that there has been noncompliance with university policy and/or the established management plan, a letter will be sent to the University employee and copied to their department chair/head/supervisor, dean, and provost as applicable.
  + If the COIC determines that corrective actions are warranted, the employee is notified in writing of such actions as well as the timeframe for completion.
* The University employee may appeal a determination of the COIC if evidence is provided that the COIC has come to its conclusions in error, failed to follow their own written procedures, or has incorrectly applied federal regulations or policy, state law, NDSU policy.
  + The appellant provides the appeal in writing to the COIC and the VPR addressing the basis for the appeal and any evidence to support the claims.
  + The VPR makes an initial assessment, and may forward the appeal to the COIC for consideration at the next convened meeting.
  + The COIC serves to hear appeals of decisions in conflict of interest issues, and may meet with the appellant at the next scheduled meeting.
  + If a member of the COIC has any personal or working relationship with the appellant, that member should recuse him or herself and may be replaced by another member.
  + The COIC’s determination is considered final, and communicated in writing to the appellant, the VPR and the appellant’s direct supervisor as applicable.

## Roles and Responsibilities

* 1. ***COI Administrator Oversight***

The NDSU Vice President for Research and Creative activity (VPR) appoints COI members based on recommendation from Deans, Chairs, faculty and staff.

The COI office is responsible for:

* Submitting annual Office of Research Integrity report (ORI)
* Communicating with COI Chair, VPR as necessary, regarding significant problems or violations of policy.
* Recording and maintaining meeting minutes.
* Maintaining accurate records of disclosures and management plans
  1. ***Conflict of Interest Committee***

***4.2.1 Membership***

The VPR appoints committee members to a three (3) year terms with the possibility reappointment. The Chair is appointed by the VPR annually. The members are vested with voting rights. However, they must recuse from voting if they have a personal or professional conflict in an agenda item before the committee for consideration.

The COIC must be comprised of at least 8 NDSU members and 1 non-affiliated members

* At least one representative from each college at the University
  + [College of Agriculture, Food Systems and Natural Resources](https://bulletin.ndsu.edu/colleges/agriculture-food-systems-natural-resources/)
  + [College of Arts and Sciences](https://bulletin.ndsu.edu/colleges/arts-humanities-social-sciences/)
  + [College of Business](https://bulletin.ndsu.edu/colleges/business/)
  + [College of Engineering](https://bulletin.ndsu.edu/colleges/engineering/)
  + [College of Health and](https://bulletin.ndsu.edu/colleges/health-professions/) Human Sciences
  + The chair of the Research and Consulting Committee
  + Research and Creative Activity
  + Vice President of Finance and Administration or Technology Transfer
* At least one non-affiliated member with a financial background preferred.
* Alternates members are appointed when possible.

***4.2.2 Responsibilities***

COI members and alternates are expected to:

* maintain a working knowledge of issues pertaining to COIs by completing training on the CITI website ([www.citiprogram.org](http://www.citiprogram.org)),
* perform timely reviews of disclosures, management plans and other committee business,
* disclose any conflicts of interest with respect to agenda items,
* attend meetings or notify COI administrator of known absences,
* actively participate in meeting discussion and deliberation,
* maintain a signed confidentiality agreement on file with COI administrator.

***4.2.3 Quorum and voting***

A quorum consists of at least 50% of the total membership of the committee. A vote of approval requires at least a two-thirds majority of present members. The Chair or designee must be present to facilitate meeting discussion.