Conflict of Interest Committee: Procedures

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Institutional Conflict of Interest Committee (COIC)

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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 significant conflict of interest disclosures, and (b) developing, approving, and monitoring plans to manage or eliminate conflicts of interest.

1.1 Types of Conflicts of Interest

1. Commitment – Commitment conflicts of interest 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 USDHHS 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 federal regulations and guidelines that follow 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 will follow the most stringent regulations.

- National Institutes of Health FCOI Funding Guideline - 4.1.10 Financial Conflict of Interest
- National Science Foundation FCOI Funding Guideline - 510 CONFLICT OF INTEREST POLICIES
- Public Health Services FCOI Funding Guidelines - Federal Reg 42cfr50

### 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 either of the NDSU policies listed below are subject to procedures outlined in Section 3 Non-compliance and Corrective Actions, and may result in disciplinary action up to and including termination. 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 significant financial interests, conflicts in commitment with research, teaching and other university responsibilities and outside interests, and makes a motion and majority vote for management when appropriate.

2.1 Federal Funding Requirements

- Any *investigator that receives federal funding from NIH, NSF or another PHS sponsored agency is require to submit a Significant Conflict of Interest Disclosure Form annually, or within 30 days of a change in status. Agencies that follow the PHS FCOI Guidelines

- Completion of the Conflict of Interest training in CITI program is also required.

*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 Significant Financial Interest Disclosure Form

The SFI form is required for all investigators listed on any proposal or award from a federal funding agency. It is required to be updated annually or if a conflict arises.

Disclosure of the following is 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

Federal agencies require Conflict of Interest training every 4 years

• Training is provided through the CITI program website and must be completed every 4 years.
• Required for the release of funds from an award from one of the listed agencies in Section 2.1.
• 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.
2.1.3 COI Disclosure and Administrative Review Form

If there is a conflict that is reported either through the SFI form or volunteered by the employee, then a COI Disclosure and Administrative Review Form is required. The form is sent to the COI Committee for determination. If a conflict is found, a management plan will be put in place.

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 will complete the Conflict of Interest Disclosure-Administrative Review form and submit it to both the Research Integrity Office and their supervisor. The Research Integrity Office will send the disclosure form to all COIC committee members for an initial classification review via email. The COIC will then classify the potential conflict as:

1. No management plan needed
2. Conflict, management plan needed
3. Conflict unmanageable

- A 2/3rds majority of email voting members of the COIC is necessary for classification. If this majority is not reached, the potential conflict of interest will be scheduled for discussion at the next COIC meeting.
- A 2/3rds majority vote of present members at the meeting will also be required for classification. Research Integrity will notify the university employee of the review’s outcome and any actions required.
- All plans will be approved for a 3 year period
2.2.2 *Examples of conflicts requiring a management plan*

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 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 *Spousal/Family Relationships 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, a conflict of interest exists as defined by state law. To maintain transparency, to ensure proper oversight of the COI, 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 will develop a management plan including, but not limited to, the listed provisions:
  - independent reporting to the department chair/employee’s supervisor
  - oversight of financial reimbursements as well as time and effort reporting
  - yearly performance evaluations and salary related decisions
  - any grant budget revisions that impact the other family member
  - notification by University employee to all personnel that the plan is in place and providing contact to COI administration/Department head/chair/supervisor for reporting concerns.
- New plans expire 3 years from approval date. New submission required after 3 years.
2.2.4 Business Conflict Guidelines

Business ownership, controlling interest or arrangements which might result in conflicts of interest for University Employees. The financial interests of a parent, sibling, independent child, unmarried domestic partner, or a close associate may be perceived as grounds for the same kind of 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 the supervisor to notify the COIC of the presence of the conflict of interest.
- The COIC will develop 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.
- New plans expire 3 years from accepted management plan. Updated submission required at this time.

2.3 Annual Updates to Managements Plans

The University employee is required to submit an update for their existing management plan annually. The COIC will send a yearly reminder and review for any changes.

- If no changes, COIC Chair’s approval will be given.
- Revised plans with changes – Management plan will be evaluated by the COIC. If approved by 2/3 email vote of committee members, COI administrator will inform the University employee.
- If the plan is not acceptable to the COIC, it will be sent back for revisions. If all corrections are made, the COIC Chair’s approval will be given and notification of
approval will be sent to the University employee. If not, the plan will go to full committee meeting for discussion.

• All plans expire 3 years from the approval date. A new plan will need to be approved after 3 years.

Changes to existing conflict of interest management plans may also be initiated by the University employee. The procedure outlined above will be followed in that scenario.

3 Noncompliance and Corrective Actions

When a University employee has potentially violated a management plan of any type, the COIC will request clarification.

• If a violation remains after clarification, a letter will be sent to the department chair/head/supervisor, dean, and provost and copied to the University employee.
• If the employee’s research or conduct is determined to be subject to restrictions or conditions due to COI, the University employee may appeal the decision to the Faculty Senate President, as described in Policy 151.1.
• The COIC serves to hear appeals of decisions in conflict of interest issues, and shall meet with the appellant member within 15 working days of receipt of the appeal.
• If a member of the COIC has any personal or working relationship with the appellant investigator, that member should recuse him or herself and be replaced by another member.
• More than one meeting may be scheduled to decide the case, if necessary.

The recommendation to either uphold or change the original decision shall be sent to the appropriate Dean, VP, or Provost.

• If the COIC finds that the original decision should be upheld, then a final appeal may be made to the NDSU President.
• If the recommendation is to change the original decision, the Dean, VP, or Provost shall take appropriate action as he or she deems fit.
• A copy of the final recommendations shall be provided to the University employee.
4 Roles and Responsibilities

4.1 COI Administrator Oversight

The NDSU Vice President for Research and Creative activity (VPR) will appoint 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 problem or violations of policy.
- Recording and maintaining meeting minutes.
- Maintaining files of management plans, SFI forms and disclosures.
- Sending annual updates for management plans.

4.2 Conflict of Interest Committee

4.2.1 Membership

The VPR appoints committee members to a three (3) year term with the possibility of serving longer. The Chair is also appointed by the VPR. The members are vested with voting rights. However, they must abstain from voting if they are engaged or have a vested interest in a management plan before the committee for consideration.

The COIC must be comprised of 9 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
  - College of Arts, Humanities, and Social Sciences
  - College of Business
  - College of Engineering
  - College of Health Professions
  - College of Human Sciences and Education
- College of Science and Mathematics
- Research and Creative Activity
- Purchasing

- At least one non-affiliated member, financial background preferred.
- Alternates members will be appointed when possible

### 4.2.2 Responsibilities

COI members and alternates are expected to:

- maintain a working knowledge of issues pertaining to the COI by completing training on the CITI website [www.citiprogram.org](http://www.citiprogram.org)
- perform timely reviews of plans
- disclose any conflict of interest with respect to submitted plans
- 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

A quorum consists of at least 50% of the total membership of the committee and a vote of approval requires at least a 2/3 majority of present members. The Chair or designee must be present.