Conflicts of Interest in Research - Interim Policy

POLICY STATEMENT

University of North Dakota (UND) encourages its faculty, staff, and students to participate in research activities and to do so with the highest ethical standards. While the potential for conflicts of interest to arise in research is understandable due to the innovative and entrepreneurial pursuits of the research community, employees must identify and manage situations in which financial or other personal interests could bias or compromise – or have the appearance of biasing or compromising – objectivity or judgment relative to research.

Employees who are involved in outside consulting or business activities must clearly separate their UND and outside obligations in order to avoid concerns as to their appropriate use of UND resources and contributions by other UND personnel. Employees must be open about their involvement with and obligations to outside parties and should provide students, staff and colleagues with information about the funding that supports their research.

REASON FOR POLICY

UND encourages its faculty, staff, and students, as appropriate, to seek research funding from internal and external sponsors. As external sponsors establish their own policies regarding conflict of interest, UND is expected to administer and oversee compliance with these requirements. This policy, along with UND’s Disclosure of Non-Research Related Conflicts of Interest and Conflicts of Commitment, promotes objectivity in research and establishes the University’s conflict of interest compliance framework.

SCOPE OF POLICY

This policy applies to all members of the UND community and should be read by:

- President
- Vice Presidents
- Deans, Directors & Department Heads
- Managers & Supervisors
- Faculty
- Staff

RELATED INFORMATION

Collaborative Institutional Training: [https://about.citiprogram.org/en/homepage/](https://about.citiprogram.org/en/homepage/)
<table>
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<tbody>
<tr>
<td>National Science Foundation financial conflict of interest</td>
<td><a href="https://www.federalregister.gov/agencies/public-health-service">https://www.federalregister.gov/agencies/public-health-service</a></td>
</tr>
<tr>
<td>Public Health Service</td>
<td><a href="http://grants.nih.gov/grants/policy/coi/">http://grants.nih.gov/grants/policy/coi/</a></td>
</tr>
<tr>
<td>SBHE Policy 308.4 – Conflict of Interest</td>
<td><a href="https://ndusbpos.sharepoint.com/:w:/s/NDUSPoliciesandProcedures/EF2NWancQ9VPvnm-paQEIkB8PbslU_-JZVokGzsW8dg?rtime=wulja48t2Eg">https://ndusbpos.sharepoint.com/:w:/s/NDUSPoliciesandProcedures/EF2NWancQ9VPvnm-paQEIkB8PbslU_-JZVokGzsW8dg?rtime=wulja48t2Eg</a></td>
</tr>
<tr>
<td>UND Faculty Handbook Section II: Personnel Information, Part V</td>
<td><a href="https://UND.policystat.com/policy/5300700/latest/#autoid-de8mn">https://UND.policystat.com/policy/5300700/latest/#autoid-de8mn</a></td>
</tr>
<tr>
<td>UND Staff Handbook Conflict of Interest</td>
<td><a href="https://UND.policystat.com/policy/7636073/latest/#autoid-wm6ep">https://UND.policystat.com/policy/7636073/latest/#autoid-wm6ep</a></td>
</tr>
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**CONTACTS**

Specific questions should be directed to the following:

<table>
<thead>
<tr>
<th>Subject</th>
<th>Contact</th>
<th>Telephone</th>
<th>Department Email / Web Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Content and Clarification</td>
<td>Research &amp; Sponsored Program Development</td>
<td>701.777.4152</td>
<td><a href="mailto:UND.rspd@UND.edu">UND.rspd@UND.edu</a></td>
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<td></td>
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<td><a href="https://UND.edu/research/">https://UND.edu/research/</a></td>
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<td>resources/conflict-of-interest.html</td>
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**DEFINITIONS**

All definitions used in UND’s policy on disclosure of non-research related conflicts of interest and conflicts of commitment also apply to this policy, along with those listed below, which specifically apply to this policy on conflict of interest in research:

- **Conflict of Interest Management Plan**: Strategies designed to mitigate the potential for an investigator's significant financial interests to impact or bias research objectivity and/or the safety or welfare of human research participants.

- **Entity**: An external business, company, or other such organization, and includes (but is not limited to) any partnership, corporation, limited liability corporation, sole proprietorship, unincorporated association, or other institution or organization, whether for-profit, academic, or professional.

- **Financial Conflict of Interest**: A financial conflict of interest exists when UND, through its designated official(s), reasonably determines that an investigator's significant financial interest is related to a funded research project and could directly and significantly affect the design, conduct or reporting of the funded research, or present the appearance thereof.
<table>
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<tr>
<th><strong>Immediate Family Member</strong></th>
<th>Includes an investigator's spouse, domestic or civil union partner, and children.</th>
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<tbody>
<tr>
<td><strong>Institutional Responsibilities</strong></td>
<td>Professional activities that relate to an investigator's responsibilities on behalf of UND, such as research, teaching, institutional committee memberships, professional practice, and administrative activities and responsibilities for UND.</td>
</tr>
<tr>
<td><strong>Investigator</strong></td>
<td>Anyone responsible for the design, conduct, or reporting of research, regardless of title or position, and their immediate family members. This may include key personnel, based on their proposed role in the project.</td>
</tr>
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</table>
| **Significant Financial Interest** | An external financial interest consisting of one or more of the following interests of an investigator (and those of the investigator's immediate family members) related to their institutional responsibilities, when combined for the 12 months preceding the disclosure date, from a single entity:  
  - Remuneration, compensation, and/or other payments for services (e.g., consulting, speaking) that exceeds $5,000  
  - Equity interests in a publicly-traded entity that exceeds $5,000  
  - All equity interests in a non-publicly-traded entity (e.g., a start-up company)  
  - Intellectual property rights and interests that exceeds $5,000  
  - Sponsored or reimbursed travel that exceeds $5,000 (applies to Public Health Service funded researchers only)  
  - Significant financial interests do NOT include:  
    ◦ Salary, royalties or other remuneration paid by UND to the investigator if the investigator is currently employed or otherwise appointed by the University;  
    ◦ Intellectual property rights assigned to UND and agreements to share in royalties related to such rights;  
    ◦ Equity interests through investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles;  
    ◦ Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education;  
    ◦ Income from service on advisory committees or review panels for a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education; or  
    ◦ Sponsored or reimbursed travel paid by a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a qualifying institution of higher education. |
| **Subrecipient** | A legal entity that receives a subcontract from a pass-through entity to carry out a portion of a sponsored program. A subrecipient has responsibility for programmatic decision making; has its performance measured in relation to whether objectives of a programmatic scope of work were met; and is responsible for adherence to applicable sponsored program requirements specified in the sponsored award, as opposed to providing routine goods or services for the benefit of the pass-through... |
The U.S. Public Health Service (PHS) was structured under the Public Health Service Act of 1944 as the primary division of the Department of Health, Education and Welfare (HEW) which was later renamed the United States Department of Health and Human Services (HHS). The PHS comprises all agency divisions of Health and Human Services including:

- Administration for Children and Families (ACF)
- Administration on Aging (AoA)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Federal Occupational Health (FOH)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian health Service (HIS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Public Health Service Commissioned Corps

The central mission of the PHS is to protect the health of the country’s population.

### PRINCIPLES

#### Overview

UND encourages its faculty, staff, and students, as appropriate, to seek research funding from internal and external sponsors. As external sponsors establish their own policies regarding conflict of interest, UND is expected to administer and oversee compliance with these requirements. This policy, along with UND’s Disclosure of Non-Research Related Conflicts of Interest and Conflicts of Commitment, promotes objectivity in research and establishes UND’s comprehensive conflict of interest compliance framework.

#### Guiding Principles

UND, and external research sponsors, seek to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from financial interests.

#### Applicability

This policy applies to UND employees who engage in research in the course of their employment at UND. Investigators funded by Public Health Service (PHS) and/or other agencies that abide by PHS FCOI...
regulations are subject to additional requirements as specified in this policy. Faculty and staff must also comply with UND's policy on Conflicts of Interest and Conflicts of Commitment.

PROCEDURES

Public Health Service Financial Conflict of Interest Training

Investigators involved in research funded by Public Health Service (PHS) must complete the required Collaborative Institutional Training Initiative (CITI) Program financial conflict of interest training before engaging in research and every four years thereafter. UND may require training more frequently than every four years if there is a substantive conflict of interest policy change or specific instances of noncompliance. CITI Program financial conflict of interest training is only required of those investigators who are applying for funding from a PHS agency.

Disclosure

1. **What Must Be Disclosed?** Investigators are required to disclose any significant financial interests (as defined herein) that reasonably appear to be related to the investigator's institutional responsibilities.

2. **Who Must Disclose?** Any individual responsible for the design, conduct, or reporting of research covered under this policy, regardless of title or position, is an investigator and must satisfy the requirements of this policy. For purposes of this policy, individuals meeting the definition of investigator may include faculty, staff, postdoctoral and clinical fellows, graduate students, and/or others who assume independent responsibility for the design, conduct, or reporting of research covered under this policy. The principal investigator is responsible for designating which individuals involved in specific research activities meet the definition of investigator.

3. **When is Disclosure Required?** Investigators must disclose significant financial interests prior to engaging in research, within 30 days of discovery or acquisition of a new significant financial interest, and at least annually during the annual conflict of interest disclosure process. Investigators must perform initial and ongoing disclosures of significant financial interests in UND's conflict of interest disclosure system.

4. **Where to Disclose?** Investigators must perform initial and ongoing disclosures of significant financial interests in UND's conflict of interest disclosure system.

Review

Significant financial interests are reviewed by UND's Office of Research & Sponsored Program Development (RSPD) in conjunction with applicable executive head of a unit and/or conflict of interest committees, in the context of each research project on which an individual is an investigator. Conflict of interest reviews take into account the nature and extent of an investigator's role on a project, the nature and extent of an investigator's significant financial interest(s), and the nature of the research activity under review. These reviews are conducted to assess whether or not significant financial interests of an investigator relate to and could directly and significantly affect the design, conduct, or reporting of research, thus presenting a financial conflict of interest relative to the research, or an appearance thereof. RSPD performs an initial review of all investigator disclosures of significant financial interests relative to all applicable research projects. RSPD may make determinations, on a research project by research project basis, that an investigator's significant financial interests do not relate to nor have the ability to directly and significantly affect the design, conduct, or reporting
of the research, or RSPD may refer reviews to the vice president, CEO or college in which the investigator holds a primary appointment for further evaluation and disposition.

Any significant financial interests that have the potential to present a financial conflict of interest for any research project are referred by RSPD to the applicable college/unit for review and disposition. Designated individuals in each college/unit then review the significant financial interest(s) to determine whether or not the significant financial interest presents a financial conflict of interest for the related research activity. The determination of whether or not a significant financial interest represents a financial conflict of interest may occur by designated individuals in the college/unit.

Reviews and determinations must occur prior to expenditure of funds for new projects and within 60 days of newly-disclosed significant financial interests. Additionally, reviews and determinations must occur within 60 days of the addition of new investigators to projects during the life of a project.

Management

If a financial conflict of interest determination is made, VP/colleges/units and RSPD will work with investigators and others as needed) will develop a conflict of interest management plan to manage, reduce, or eliminate the financial conflict of interest. Conflict of interest management plans may include disclosure of the financial conflict of interest (to study teams, collaborators, the Institutional Review Board, human research participants, and in presentations and publications), a reduced role in the research, and/or independent review of research data and results. Additional conflict of interest management strategies may be employed depending on the nature of the financial conflict of interest and the nature of the research activity. In extreme cases, an investigator may be prohibited from participating in research due to the level and extent of significant financial interests deemed to present a financial conflict of interest relative to specific research activity. Investigators must acknowledge agreement to conflict of interest management plans in order to engage in research for which financial conflict of interest determinations are made.

Financial conflict of interest determinations are made, and conflict of interest management plans implemented, by designated applicable institutional conflict of interest officials/parties. However, it is in the purview of UND's Institutional Review Board (IRB) to review the conflict of interest management strategies associated with IRB protocols and determine whether or not the conflict of interest management is sufficient with respect to the rights and welfare of human research participants, or whether the IRB determines that additional conflict of interest management is necessary to protect the rights and welfare of human research participants. The IRB is notified of financial conflict of interest determinations made, and conflict of interest management strategies implemented, relative to research involving human research participants. The conditions of and compliance with investigator conflict of interest management plans are reviewed on at least an annual basis by colleges/unit and RSPD. On an ad hoc basis, colleges/unit also conduct independent monitoring and verification to ensure that the conditions of conflict of interest management plans are being met.

Appeals

When an investigator disputes any action or decision related to a potential conflict of interest or conflict of commitment, existing University policies for disputes of faculty and staff will be used. Disputes with decisions or actions taken by an established conflict of interest committee for those projects for which the committee is responsible must be through the processes established by the applicable committee.

External Reporting

RSPD administers and oversees all research related, external conflict of interest reporting for UND in
Subrecipients

Public Health Service Financial Conflict of Interest Training

Investigators involved in research funded by Public Health Service (PHS) must complete the required Collaborative Institutional Training Initiative (CITI) Program financial conflict of interest training before engaging in research and every four years thereafter. UND may require training more frequently than every four years if there is a substantive conflict of interest policy change or specific instances of noncompliance. CITI Program financial conflict of interest training is only required of those investigators who are applying for funding from a PHS agency.

For proposals that contain subrecipient, the principle investigator (PI) must submit documentation indicating whether the investigators working on the subaward/subcontract will be following this UND Conflicts of Interest in Research policy or the investigators institution's policy. In the former case, the PI will need appropriate documentation from all key personnel. In the latter case, the PI will need to supply documentation signed by an authorized representative of the subcontractor's institution indicating that the institution has an acceptable conflict of interest policy which is followed by the institution. Principal investigators must also assure that all key personnel listed in a proposal or potential contract have filed appropriate documentation (see Procedures: Disclosure). Principal investigators must provide evidence of completion of these requirements.

Noncompliance

The following are examples of noncompliance with this policy:

1. Failure to submit a timely disclosure;
2. Submission of an incomplete, erroneous or misleading initial, updated or annual disclosure;
3. Failure to disclose information as required by this policy; or
4. Failure to comply with prescribed management plans.

Any instances of investigator noncompliance may require that the investigator repeat UND's required conflict of interest training module. Additional disciplinary action for noncompliance with this policy will be decided in accordance with applicable UND disciplinary policies and procedures as outlined in the Faculty Handbook, the Staff Handbook, and other relevant UND and SBHE policies. Ramifications for noncompliance could include restrictions relative to proposing and engaging in UND research and/or an internal review of the research, as well as other disciplinary action up to and including termination.
# RESPONSIBILITIES

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
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<tbody>
<tr>
<td>Individual</td>
<td>• Complete conflict of interest forms annually or as needed.</td>
</tr>
<tr>
<td>Executive Head of a Unit Head</td>
<td>• Review and approve conflict of interest forms.</td>
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<td>• Participate in review of potential conflicts and management plans.</td>
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<tr>
<td>Research &amp; Sponsored Program</td>
<td>• Collect, advise, and monitor compliance.</td>
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<td>Development</td>
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## FORMS

| Conflict of Interest Form 3         | [https://coi.UND.edu/](https://coi.UND.edu/) |

## Attachments

No Attachments

## Approval Signatures

<table>
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<tr>
<th>Approver</th>
<th>Date</th>
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<tbody>
<tr>
<td>Jennifer Rogers: Policy Office</td>
<td>pending</td>
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<tr>
<td>Jennifer Rogers: Policy Office</td>
<td>08/2021</td>
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<tr>
<td>Jennifer Rogers: Policy Office</td>
<td>08/2021</td>
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<tr>
<td>Michael Sadler: Export Control &amp; Contract Ofcr</td>
<td>08/2021</td>
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