POLICY STATEMENT

1. INTRODUCTION

It is the policy of The University of North Dakota to ensure its human subject research is conducted with integrity and is free from any actual or apparent institutional conflict of interest. This policy establishes the principles and procedures that enable the University to identify and avoid institutional conflicts of interest of a financial nature that present a significant risk to the perceived or actual objectivity of such research.

This policy is distinct from the University of North Dakota Conflict of Interest Policy, which provides for the management of conflicts of interest that are personal to the individual.

REASON FOR POLICY

2. ETHICAL STANDARDS

2.1. Institutional Conflict of Interest (ICOI): Can occur whenever the external financial interests or business relationships of the University or of one of its officials are such that their actions could affect, or could reasonably appear to affect, the conduct, review or oversight of the University’s human subject research. The potential for institutional conflict of interest that could compromise the integrity of the University’s research mission generally arises in one of the three situations described below:

2.1.1. When the University, as an institution, has taken an equity interest in a business enterprise in which University employees conduct, or propose to conduct, research that could affect the value of the equity interest in that enterprise;

2.1.2. When the University holds a patent, license, or right to royalties on a process, technique, or production that it licenses to external companies, which in turn use University employees to conduct research on that process, technique or product; or

2.1.3. When a University official, with the authority to act on behalf of the University and to make decisions that have institution-wide implications, or whose decisions could reasonably be seen as affecting the conduct, review, or oversight of human subject research, holds a significant
financial interest in, consults for, serves on the board of, or is otherwise expected to act for the benefit of an entity that has a financial, consulting, or other interest in University sponsored human subject research, or gives permission for research by University personnel.

SCOPE OF POLICY

This policy applies to all members of the University Community and should be read by:

✔ President ✔ Faculty
✔ Vice Presidents ✔ Staff
✔ Deans, Directors & Department Chairs ✔ Students

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RELATED INFORMATION

| UND Conflict of Interest Policy | University of North Dakota Conflict of Interest Policy |

CONTACTS

General questions about this policy should be directed to your department’s administrative office. Specific questions should be directed to the following:

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<tr>
<th>Subject</th>
<th>Contact</th>
<th>Telephone</th>
<th>E-Mail / Web Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy and Procedure Content Clarification</td>
<td>Research Development &amp; Compliance</td>
<td>777-4278</td>
<td><a href="http://und.edu/research/resources/index/">http://und.edu/research/resources/index/</a></td>
</tr>
</tbody>
</table>

DEFINITIONS

**Integrity Officer**

Integrity Officer: person responsible to ensure compliance with this policy.

**Human Subject**

Human Subject: a living individual about whom an investigator conducting research obtains: 1) data through intervention or interaction with the individual; or 2) identifiable private information.

**Outside Entity**

Outside Entity: any organization (including for-profit or not-for-profit and whether incorporated or otherwise) that is not owned or controlled by the University, or any individual that is not employed or otherwise affiliated with the University.

**Research**

Research: a systematic investigation designed to develop or contribute to generalizable knowledge, including biomedical, behavioral, and social sciences research or other scholarly activity.

**VPRED**

VPRED: the Vice President for Research and Economic Development (VPRED) or a designee.
The following provisions are procedures amendable by the Office of Record or the Conflict of Interest/Scientific Misconduct Committee as appropriate. Amendments to procedures do not require University Senate approval. However, the Office of Record shall inform the Conflict of Interest/Scientific Misconduct Committee of changes needed or made; and the Conflict of Interest/Scientific Misconduct Committee shall inform the University Senate of amendments to these procedures in a timely fashion.

PROCEDURES

1. PROCEDURES FOR DISCLOSURE, REVIEW, AND RESPONSE TO INFORMATION REFLECTING INSTITUTIONAL CONFLICT OF INTEREST

1.1. Responsibility

The Vice President for Research & Economic Development (VPRE&D) has the responsibility for overseeing the process for reviewing, resolving, and monitoring institutional conflict of interest that may arise from the business relationships of either the University or its officials with outside entities. Disclosures that may identify actual or potential institutional conflict of interest shall be handled as provided in Section 1.4 below.

1.2. Disclosures

1.2.1. Disclosure of University Financial or Business Relationships

1.2.1.1. The University's Office of Intellectual Property Commercialization & Economic Development, which serves as a bridge between University-sponsored research and commercialization partners, shall provide the VPRE&D with quarterly reports that disclose the entities in which the University holds equity positions or from which it has the right to receive royalty payments.

1.2.2. Disclosure of Officials' Financial or Business Relationships

1.2.2.1. University officials must furnish written conflict of interest disclosures as may be required by state or federal authorities or by North Dakota University System or institutional policies. This disclosure will be made at least annually and within thirty (30) days of a change in the individual's financial or business relationship that would require disclosure under such laws or policies.

1.3. Review of Disclosure Information

1.3.1. The Office of Research Development & Compliance (RD&C) assists, supports, and reviews all proposed human subject research and administers the Institutional Conflict of Interest (ICOI) program. The VPRE&D shall provide the Integrity Officer with copies of financial disclosures that are related to human subject research and meet the definition of “Significant Financial Interest in a Business Entity,” and with the quarterly reports received from the Office of Intellectual Property Commercialization & Economic Development. The Integrity Officer shall review all proposed human subject research proposals it receives with the disclosure information provided by the VPRE&D to identify any actual or potential institutional conflict of interest present in the proposals. The Integrity Officer must refer any research proposals for which an actual or potential ICOI has been identified to the VPRE&D for a response pursuant to Section 2.2.4. below. Once the ICOI is resolved,
the affected proposal shall be returned to RD&C for review by the University's Institutional Review Board.

1.4. Responding to Information Reflecting Potential Institutional Conflict of Interest

1.4.1. Actual or Apparent Conflict of Interest of the President or Vice President

If the President or Vice President is found to have an actual or apparent institutional conflict of interest, he or she shall either:

1.4.1.1. Totally divest him or herself of the financial interest; and

1.4.1.2. Resign from the board or other position with the external entity that has a financial interest in University-sponsored human subject research. Proposed research cannot be approved or continued until such action is taken by the affected official.

1.4.2. All Other Institutional Conflicts of Interest

1.4.2.1. The VPR shall appoint an Institutional Conflict of Interest Committee (ICOIC), which must consult with the VPR where other actual or apparent institutional conflicts of interest are identified to determine whether to:

1.4.2.1.1. In cases involving a business entity, require the Office of Intellectual Property Commercialization & Economic Development to divest the University's current equity holdings and its right to royalties in that business entity, as well as its right to acquire equity holdings in the future;

1.4.2.1.2. Propose modifications to the proposed human subject research that would remove the possibility that the University, or any of its units or officials, would benefit financially from the results of the proposed research;

1.4.2.1.3. Prohibit the proposed human subject research when in the best interests of the public or the University, upon recommendation from the Institutional Review Board

1.4.2.1.4. Direct that the University official who holds a significant financial interest divest him- or herself of that interest, or remove him- or herself from the decision process involving such research; or

1.4.2.1.5. If feasible, develop an institutional conflict of interest management plan.

1.5. Monitoring the Institutional Conflict of Interest Process

1.5.1. The Institutional Conflict of Interest Committee (ICOIC) shall monitor the ICOI process. It shall meet as required but not less than annually to:
1.5.1. Ensure that University officials are in compliance with the disclosure obligations of this policy;

1.5.2. Review and propose to the VPR ED modifications to the plans for managing institutional conflict of interest.

1.5.3. Any member of the ICOIC who has a financial interest in or serves as a paid consultant for an entity that is involved in a research proposal shall not participate in the review under this policy.

RESPONSIBILITIES

<table>
<thead>
<tr>
<th>Vice President for Research and Economic Development</th>
<th>The Vice President for Research &amp; Economic Development is responsible for articulating and enforcing the institutional conflict of interest policy (ICOI) at the University of North Dakota.</th>
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<tr>
<td>Associate Vice President for Research &amp; Economic Development</td>
<td>The Associate Vice President for Research &amp; Economic Development is responsible for administering ICOI matters.</td>
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<tr>
<td>Institutional Review Board</td>
<td>The IRB Chairperson, IRB Vice Chairperson, and IRB Members are responsible for reviewing human subject research and considering any ICOI involved with research protocols.</td>
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SOURCES


2. The University of Texas at Austin Institutional Conflict of Interest Policy

REVISION RECORD

| 05/13/2015- Policy Implementation | Signed by President Robert O. Kelley |