



Research Conflict of Interest for Individuals Policy

Responsible Executive:

Vice President for Research

Responsible Office:

Notre Dame Research – Research Security

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1. INTRODUCTION

Consistent with the research mission of the University of Notre Dame du Lac (Notre Dame or the University), faculty, staff, and students are encouraged to engage in appropriate outside activities and relationships with private industry and the nonprofit sector. Members of the University community are expected to avoid conflicts of interest (COI) that have the potential to directly and significantly affect the University's research interests, compromise objectivity in conducting research, or otherwise impair the integrity of research activities, unless such conflicts are disclosed, reviewed, and managed in accordance with this Policy and related University policies listed below.

As members of a scientific and intellectual community, individuals recognize that decisions of objectivity about one's own situation and credibility with others requires an external evaluation. This Policy and related standard operating procedures (SOPs) are written in the context of this paradigm.

2. SCOPE

This policy applies to all Covered Researchers, those responsible for the design, conduct, or reporting of research projects which are designed or conducted under University auspices. These projects can include sponsored research projects, any research grants and cooperative agreements, such as career development, center, and institutional training grants; individual fellowship, infrastructure, and research resources awards; and program projects.

As required by Sponsors, this policy may also apply to external individuals or subrecipients for specific research projects.

3. DEFINITIONS

The following definitions are applicable to the use of this Policy. Some definitions are and are not applicable for any other purpose:

Conflict of Interest (COI)	A Conflict of Interest arises in a situation where financial or other personal or professional considerations compromise, or have the potential to compromise, an individual's objectivity, professional judgment, professional integrity, and/or ability to perform his or her responsibilities to the University. These considerations may be those of the Covered Researcher or their Immediate Family.
Covered Researcher	Any University Member, regardless of title, role, or position, who is responsible for the design, conduct, and/or reporting of research. Individuals with such research responsibilities are generally senior/key personnel. The term does not apply to individuals who primarily provide technical assistance, administrative support, or who are purely advisory, such that these individuals



	have no influence over the research results or control over data collection, analysis or reporting. Covered Researchers may include retired faculty who are listed in applicable roles on sponsored research projects. Certain sponsors, including federal agencies, may extend this definition for COI oversight in regulations or via notices of funding opportunity or award terms to include co-investigators, subrecipient investigators, collaborators, consultants, students, trainees, or research coordinators or even all personnel paid from the project.
Financial Conflict of Interest (FCOI)	When a Covered Researcher's significant financial interest, domestic or foreign, is determined to be related to a research project and that interest could directly and significantly affect the design, conduct, or reporting of the research.
Financial Interest	A financial interest includes one or more of the following of a Covered Researcher, and their Immediate Family, related to the University Responsibilities, within the past twelve months, or anticipated in the upcoming twelve months after an approval for Outside Activity request, for any entity, domestic or foreign: • External Compensation: Salary, royalties, licensing fees, consulting fees, honoraria, or other payments from outside the University, including any money from non-U.S. entities. • Equity Interests: Ownership interests, stock, stock options, stock grants, or warrants in any publicly-traded or non-publicly traded entities. • Financial Roles – Director, Board Member • Intellectual Property (IP): Rights and interests, such as inventorship, authorship, or copyright ownership. Received royalties, user fees or any type of income paid in relation to IP.
Financial Interest Exclusions	Financial Interest does not include: • Internal Compensation: Salary, reimbursement or other remuneration through or from the University. Royalties related to IP rights paid through the University are excluded from financial interest consideration, as permitted by a Sponsor. • Teaching: Seminars, lectures, or teaching engagements sponsored by a U.S. Federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institution that is affiliated with a U.S. institution of higher education. • Review Panels: Service on advisory committees or review panels for a U.S. Federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institution that is affiliated with a U.S. institution of higher education. • Investment: Investment vehicles, such as mutual funds, retirement accounts or blind trusts, where a Covered Researcher or Immediate Family has no control or input over the selection of holdings.



Financial Interest: Travel	Any travel that is not paid directly through the University, which is related to the performance of University responsibilities or duties, and for which a Covered Researcher either receives direct reimbursement from, or is covered by, an external entity, either domestic or foreign. For the purposes of this Policy, reimbursed or sponsored Travel is only applicable for a Research COI review for Covered Researchers as required by a sponsor. Any travel reimbursed or covered by any international entity, including but not limited to foreign academic centers, hospitals or professional non-profit associations, is required for reporting. <i>Exclusion:</i> Reporting is not required when the travel is paid by or reimbursed from a U.S. Federal, state, or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institution that is affiliated with a U.S. institution of higher education.
Honoraria	A payment made to a person for services rendered in a volunteer capacity, or situations where the giver does not have legal obligations, or for services where fees are not traditionally negotiated or expected
Immediate Family	Covered Researcher's spouse and dependent children. As specified by federal funding agencies or other sponsors, immediate family may have a broader definition which is applied in those cases.
University Professional Responsibilities or Duties	Professional responsibilities to the University include research and scholarship, teaching and instruction, administrative service to the University, institutional committee membership and all other work and activities the University considers in its review of a faculty or staff member's performance as a University employee. For University students or trainees, this means adherence to the rules or guidelines in their School or Program. For subrecipient investigators, institutional responsibilities refer to the work being done for the University under the subaward.
University Member	All University employees (including full-time and part-time faculty and staff, visiting faculty, and postdoctoral scholars) who are in a position to influence or commit University resources are Members. Trainees (including undergraduates, graduate students, and postdoctoral fellows) who are in a position to influence or commit University resources are also Members.
Personal Interest	An external executive, board position, consulting, volunteer or advisory position related to an activity that involves, or is related to, a Covered Researcher's University Responsibilities. These activities may or may not be compensated.
Research Project	Any research, testing, evaluation, training, and/or instructional plan conducted in connection with and under the auspices of the University.
Research Relatedness	The extent to which a financial or personal financial interest is related to the sponsor, investigational drug/device, or overall research project.



Senior/Key Personnel	Lead Principal Investigator, Principal Investigator, Project Director and any other person identified as senior/key personnel by the University in a proposal, grant application, progress report, or any other report submitted to a Sponsor.
Significant Financial Interests (SFIs)	Financial interests which meet the following thresholds for Covered Researcher and their Immediate family combined: • External compensation from a single entity greater than \$5,000. • Equity interest in a publicly traded entity greater than \$5,000. • For the same entity, external income and public equity interest combined which is greater than \$5,000. • Equity interest in any private entity which is greater than 0 (zero) percent or dollars. • Intellectual Property interests where there are a) inventorship rights or royalties on IP external to the University; b) inventorship rights in licensed or optioned Notre Dame IP. Royalties paid through Notre Dame are excluded, unless required by a sponsor.
Sponsor	Any individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a research project.
Subrecipient	A legal entity that receives a subaward or subcontract from a pass-through entity (PTE) to carry out part of an award (scope of work).

All capitalized terms in this Policy which are not defined have the same definition as the University's Conflict of Interest Policy, except that the terms Project Director, Principal Investigator, Co-Principal Investigators, Teaching and Research Faculty, Research Faculty, Postdoctoral Scholars, Staff, Graduate Students, and Undergraduate Students will have their ordinary and customary meaning at the University.

4. POLICY STATEMENT

This Policy is to promote objectivity and minimize bias in sponsored research conducted in association with the University, and under its auspices. It establishes the framework for identifying, reviewing, and managing conflicts of interest that may arise from Covered Researcher's personal or financial interests. It also ensures the University's compliance with standards issued by sponsors, regulations from federal agencies and any applicable local, state or federal laws. This Policy incorporates by reference all sections in the SOPs and the University will utilize any sponsor specific requirements as applicable.

Three main principles guide the research conflict of interest process, review and determinations: transparency, honoring the student or trainee experience; and protecting the credibility of the individuals doing the work. All aspects of this Policy, including training, disclosure, evaluation, management, and sanctions, are written with these principles in mind.

4.1. Research COI Training

Covered Researchers must complete RCOI training before involvement in any federal project, or those projects from non-federal entities which require the University to follow federal COI standards, and which is funded through the University. Training is



required every four years thereafter, or as otherwise specified by the sponsor and noted in the SOPs.

4.2. University Disclosure

University members must disclose all financial and personal interests, as defined in the University's COI Policy, as well as those held by their immediate family and/or close relations, regardless of compensation, compensation level, or type.

For the purposes of this Policy, Covered Researchers only have to disclose for themselves and their immediate family. Covered Researchers may be required to disclose additional information if required by a Sponsor. An Annual COI disclosure must be submitted in the University's system at the time of proposal for external funding.

4.3. Research Project Specific Disclosure Process

The Research Project Specific disclosure process establishes the framework for identifying, reviewing, and managing conflicts of interest related to any University Research Project. The final authority of the determination as to whether any research COI exists, and how it will be managed, rests with the University.

As prompted by the disclosure system, a Covered Researcher will be notified of a requirement to submit a research project specific form, populated with information from their annual COI form for themselves and their immediate family for all interests domestic and foreign. The research project specific forms which are routed to the Research COI Program will be processed as specified in the SOPs.

4.4. Review

Research Project Specific COI disclosures shall be reviewed in keeping with definitions in this Policy and SOPs. The bias that such external activities, interests or relationships may impart can affect many University responsibilities related to research such as decisions about personnel; the purchase of equipment and other supplies; the collection, analysis and interpretation of data; the sharing of research results; the choice of research protocols; the use of statistical methods; and the mentoring and judgment of student work on the research project.

Conducted by the Research COI Program Director, or designee, the review will include an analysis of the Covered Researcher's Personal and Financial Interests, including those designated SFIs, in conjunction with their University Professional Responsibilities and relatedness with a research project. The determination of the review will depend upon the nature of the interests, their responsibilities, and the relatedness and nature of the research activities potentially affected by the interests.

The Research COI Program Director, Executive Director of Research Security or COI Program staff or any University Members involved in a Research COI review will recuse themselves from participation in case reviews where they have a financial interest or related relationship that could appear to create a preference or bias their judgement.

When the need for a Research COI analysis is indicated through the review processes of the Notre Dame Research offices, or any other University office, the related proposal or awarded Project may not proceed for funding until the Research COI Disclosure form has been evaluated, and approved or resolved, including any required reporting to a Sponsor. It is expected the Covered Researcher will not begin work on the project in any



capacity until the Research COI review has been completed and the Covered Researcher has been notified of a final RCOI determination.

4.5. Review Standards

While certain situations are subject to specific provisions regarding particular types of relationships or interests, the following standards are generally applicable for all project specific reviews:

- A. Where a Covered Researcher proposes to be engaged in the design, conduct or reporting of University research, their COI or FCOI may be allowed with University evaluation, approval and appropriate management.
- B. The training experience and academic progress of University students and trainees must not be subordinated to the Personal or Financial interest of a Covered Researcher nor the commercial interests of research sponsors.

4.6. Specific Situations

Particular situations arise in the research area which require additional parameters and criteria for review.

4.6.1. Gifts to the University for the Benefit of a Covered Researcher

For purposes of this Policy, gifts and donations that have been made to the University for the benefit of the professional activities of a Covered Researcher are considered to be a Financial Interest of the intended beneficiary, even though such gifts or donations are not the legal property of the beneficiary. Such gifts and donations as allowable under other applicable University policies and where they coincide with University research undertaken by the Covered Researcher which relates to the entity, or an individual making the gift or donation, shall be reviewed under this Policy in the same manner as for any other Financial Interest when the Covered Researcher completes an applicable Research COI form.

4.6.2. Intellectual Property (IP)

Actions related to the licensing or optioning of IP or copyrights as defined in the [IP Policy](#) can trigger a new personal or financial interest, related to possible inventorship or authorship, where this new interest may need Research COI review, management and/or reporting to an external sponsor. Accordingly, the Research COI Program will conduct a review of the intersection of research projects with a potential license action when a Covered Researcher is named on any type of intellectual property and when the Notre Dame office responsible for technology transfer activities, the IDEA Center, or a third party which has ownership rights, begins negotiations with an external company on either an option or license for IP rights.

4.6.3. Purchasing, Contracting, Subawards or Other Business Transaction on behalf of the University

A Covered Researcher generally may not participate in awarding, negotiating, reviewing, supervising, or approving a financial transaction (including but not limited to purchases, contracts, selection of independent contractors, and subcontracts) related to a research project involving the



University and an entity or person which the Covered Researcher has a Personal or Financial Interest without prior review and approval. Such review is in accordance with University policy, as allowable, or not, under Uniform Guidance procurement regulations and any sponsor-specific guidelines. In all cases, Covered Researchers will conduct University research or related business in keeping with any applicable codes of conduct.

For any research project, regardless of Sponsor, it's the University's standard that a Lead Principal Investigator (PI) may not review, negotiate, authorize, or supervise any outgoing transaction to an entity where they, or an immediate family member, have equity or a fiduciary relationship. Some examples of outgoing transactions to the entity would include a sub-award, contract, vendor selection, procurement activity or other business agreement. For grant proposals, an alternative structure, including a new Lead PI of greater or equal rank with applicable scientific expertise, may be considered on a case- by-case basis.

4.6.4. SBIR/STTR Research

Covered Researchers are prohibited from conducting research or administrative activities for both the University and the small business concern involved in Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) grants on the same research project. As permitted by sponsors, Covered Researchers may participate in the incoming subawards received from the small business concern even with a COI or FCOI determination. These types of grants are subject to additional requirements and review standards as delineated on the [Notre Dame Research website](#).

4.6.5. Joint Projects with Industry and Government

For funding mechanisms other than SBIR/STTR research, Covered Researchers may be permitted to conduct research at the University and provide administrative activities for an industry partner on the same project, as permitted by government sponsors. Particular care must be taken if Covered Researcher has any SFIs given at least the appearance of a COI in these situations. These types of grant proposals are subject to additional requirements and review standards as delineated in the SOPs, including review by a central COI committee. Covered Researchers should contact researchcoi@nd.edu at least six weeks prior to submission for initial discussion.

4.6.6. Use of University Resources, including Privileged Information

Confidential, non-public or privileged information created, developed or acquired by the University in research projects may not be used by a Covered Researcher for personal gain, nor may any Covered Researcher permit unauthorized access to such confidential, non-public or privileged information. Insider trading is just one form of impermissible use of privileged information for personal gain. Sharing the information or providing access can only be authorized by the applicable University Office.



4.6.7. Unspecified Situations

Periodically situations may arise in research which could meet the definition of a COI which do not fit into the prior sections. If such a situation is raised to the attention of the Research COI Program Director, in consultation with Notre Dame Research and any other applicable University office, a review will be conducted of such situations, including interviewing the Covered Researcher, maintaining the confidentiality as outlined in this Policy.

4.7. Management of Research COI

Through any review of an Annual COI, if relationships are identified with an entity and the University Member conducts research, a foundational Research Management Plan is established by their school or unit.

Through the Research Project Specific COI review, if any related interests are identified and determined to be manageable for a research project, the Research COI Program must develop a plan to appropriately manage the relevant conflicts for project specific reviews, taking into account the foundational plan, and may include additional parameters. The Program may include such management items as, modification of the research plan, monitoring, oversight of student efforts, divestiture of the financial interest, or recusal from research activities. Detailed examples are provided in the SOPs.

4.8. Appeals for COI Determinations

A Covered Researcher can appeal a Research COI determination from any review directly to the Vice President for Research (VPR) or their designee within five (5) University business days of receiving a Research COI determination, in accordance with the SOPs. The VPR, or designee, will make a final decision within ten (10) University business days from the receipt of the appeal. The final decision of the VPR, or designee, cannot be further appealed.

4.9. Compliance with External Sponsors

The University will be compliant regarding the collection of information, review, management and reporting, as required, under any related federal COI regulations, policies or standards in the terms of agreement as specified by external sponsors. Incorporated by reference into this Policy, variances which are more stringent for specific federal agencies are included in the SOPs.

4.10. Research COI Confidentiality and Record Retention

4.10.1. Confidentiality

The Research COI disclosure forms, review information and communications contain information that may have a direct bearing on a Covered Researcher's employment. They are considered confidential information that should be maintained in a secure and confidential file.

Access to information disclosed in the research COI review process, including project specific management plan additions, is limited to those individuals with a need to know. This information is available only to individuals duly charged with the responsibility for related reviews in Notre Dame Research, specific University administrative positions, and other



University offices with a related business purpose. The information may also be released only in accordance with and as required by federal regulation or lawful court order.

4.10.2. Record Retention

All records relating to the reporting of potential conflicts of interest, and to the actions taken with respect to those disclosures, reports or plans, shall be maintained for three years following the expiration of their relevance, or as required by applicable government regulations and policies, whichever is greater.

5. RESPONSIBILITIES

Policy Implementation

The Vice President for Research or their designee is responsible for overseeing the implementation of this Policy. Day-to-day responsibility for such implementation is delegated to the Research COI Program Director, or designee, who shall act as the University's designated official for Research COI, including review or any required reporting to a Sponsor.

The University will make this Policy and the SOPs for Research COI for Individuals available on its website.

Policy Breaches or Violations

The Vice President of Research, or delegate, will review all alleged breaches or violations of this Policy, including the provisions of the SOPs for Research COI for Individuals. Breaches or violations may include but are not limited to:

- A. failure to comply with the process (by failure to disclose timely Personal or Financial Interests as required, failure or refusal to respond to requests for additional information, providing incomplete or knowingly inaccurate information, or otherwise);
- B. failure to remedy conflicts; and
- C. failure to comply with prescribed management agreement or monitoring plan.

Such breaches or violations will be reviewed as specified in the SOPs, taking into account any requirements deemed by a particular Sponsor.

Possible sanctions for violation of this Policy, including furnishing false, misleading, or incomplete information, can lead to administrative intervention or disciplinary action up to termination of employment or of enrollment, all in accordance with applicable University policies.

6. PROCEDURES

For procedures and processes related to this policy, please reference the Research COI Policy for Individuals Standard Operating Procedures (SOPs).

7. POLICY ENFORCEMENT

Enforcement	The Research COI Program will investigate suspected violations, and report to the Vice President for Research or designee. The Vice President for Research, or designee, may consult with the Provost Office and may recommend disciplinary action in accordance with University codes of conduct, policies, or applicable laws. Sanctions may include one or more of the following:
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	• suspension or termination of access to research projects or related data; • disciplinary action up to and including termination of employment; • student discipline in accordance with applicable University policy; • civil or criminal penalties.
Reporting Violations	Any determined violations made by the University will be reported to a Sponsor of the research project as required by agreement, in combination with, or required by, federal regulations governing research.

8. RELATED DOCUMENTS

ND COI Policy	https://policy.nd.edu/assets/586594/conflict_of_interest.pdf
ND Conflict of Commitment Policy	https://policy.nd.edu/assets/185214/conflict_commitmentpolicy.pdf
ND Outside Activity Policy	https://policy.nd.edu/assets/586595/outside_activities_policy.pdf
ND Intellectual Property Policy	https://policy.nd.edu/assets/424679/ip_final_2021_v3.pdf
ND Charitable Contributions in Lieu of Compensation/Payment for Services	https://controller.nd.edu/assets/169856/charitable_contributions_in_lieu_of_comp.pdf
ND Charitable Contributions Directed	https://policy.nd.edu/assets/185205/charitable_contributions_made_by_nd_03_10.pdf
ND Ethical Conduct Policy	https://policy.nd.edu/assets/185231/ethicalconductpolicy.pdf
ND Non-Retaliation Policy	https://policy.nd.edu/assets/185253/non_retaliation_revision.pdf
ND Integrity Line	Phone: (1-800-688-9918)
Anonymous Online Reporting	https://secure.ethicspoint.com/domain/media/en/gui/80050/index.html

External Policies or Documents are maintained on the Research COI Program website.



9. CONTACTS

Subject	Office or Position	Telephone Number	Office Email or URL
Policy Clarification	Research COI Program Director	(574) 631-3659	researchcoi@nd.edu
Web Address for this Policy			