Standard Operating Procedures for 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

In conjunction with the Research Conflict of Interest (COI) for Individuals Policy (Policy), these Standard Operating Procedures (SOPs) detail the framework at the University for identifying, reviewing, and managing COIs that may arise from Covered Researcher's personal or financial interests and ensuring the University's compliance with standards issued by sponsors, including regulations and policies from federal agencies and any applicable local, state or federal laws.

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

The SOPs are maintained and executed, except as noted, by the Research COI Program, its Director, and any affiliated staff. In the absence of the Research COI Program Director, the Executive Director of Research Security shall designate a person to fulfill such functions. These SOPs are subject to change.

2. SCOPE

These SOPs document all processes and standards in accordance with the Research COI for Individuals Policy as implemented by the Research COI Program.

3. DEFINITIONS

The definitions specified in the Research COI for Individuals Policy are applicable to these SOPs.

All capitalized terms in these SOPs 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, Postdoctoral Scholars, Staff, Graduate Students, and Undergraduate Students will have their ordinary and customary meaning at the University.

4. PROCEDURES

The following list of procedures are in support of the Policy. The procedures may be expanded or adjusted in accordance with a sponsor's requirements.

4.1. Research COI Training

All Covered Researchers are required to complete research COI training prior to involvement in a federally funded research project or for any research funded by non-federal entities which require the University to follow federal conflict of interest regulations.

Staff in administrative offices which support the research enterprise are also encouraged to take this training. The University has established training in the CITI Program taken on-line via the CITI

system. The training covers the University's Policy, a Covered Researcher's disclosure responsibilities of all foreign and domestic significant financial interests (SFI) for research as well as the federal regulations.

Except as detailed elsewhere in these SOPs, completion of training is valid for four years. Training status for a Covered Researcher will be reflected in any appropriate electronic administration research system. Researchers new to the University are required to take Notre Dame specific COI training upon employment.

In accordance with federal regulations, the Research COI Program within NDR may immediately require more frequent training if there is a substantive change in the Research Individual COI policy such as University revises its COI policies or procedures in a manner that affects the Covered Researcher's responsibilities or to address specific instances of noncompliance.

A Lead Principal Investigator (PI) may propose alternative training options for certain project-specific situations. Any Lead PI who wishes to use alternative training for a particular research project should use the PHS guidance on COI training for crafting a proposed training plan. Requests for use of alternative training should be submitted via email to researchcoi@nd.edu and attach a proposed plan for the alternative training. The request will be reviewed by the Research COI Program Director.

4.2. University Disclosure

For University members, disclosure should occur in accordance with the University COI Policy and related Procedures. As specified in the University's COI Policy, Covered Researchers as University Members, must disclose in the following situations:

4.2.1. Annual

Each University Member is required to annually submit a disclosure.

4.2.2. New Employees

Covered Researchers who are new employees at the University are required to submit within 30 days of their starting date.

4.2.3. New Interest

Within **15 calendar days** of discovering or acquiring a new personal or financial interest, receiving an increase for previously reported financial interest, or eliminating a previously reported financial interest.

Any foundational Research Management Plan determined through the Annual COI review process will be used as part of the Research Project Specific review process.

4.3. Research COI Project Specific Disclosure

The University requires that all Covered Researchers involved in a Project submitted through Notre Dame Research submit a project specific Research COI disclosure form, for themselves and their immediate family, generally sent at the time of project award; and annually thereafter, if sponsor required.

Certain sponsors require project specific Research COI review at the time of proposal. Covered Researchers will be notified at the applicable time.

Independent contractors or consultants who have been determined to be "Covered Researchers", and if required by a sponsor, would be subject to all of the procedures specific to their sponsored research project.

The requirement to complete a project specific Research COI disclosure form is communicated through an email notification to the Covered Researcher. The email provides a link to access the form. For Covered Researchers, these forms are always available for access through the University's disclosure system. The Research COI form includes information for activities, interests and relationships, domestic and foreign, from their annual disclosure form.

4.4. Research Project Specific Disclosure Process and Review

Once the Covered Researcher has submitted their Research COI form, the online system assesses the form to determine any indicators for a potential COI. If a potential COI or related interests are not indicated, the disclosure is finalized in the Research COI system and an email is sent to inform the Covered Researcher. Related electronic research systems are updated automatically indicating the review status of the particular disclosure as complete and may include a "no conflict" designation.

If a potential COI, or related activities, interests or relationships, are identified by the Covered Researcher on the form or otherwise in the system, the Research COI form is triaged for review by the Research COI Program. A Covered Researcher may be contacted to gather additional or supplemental information necessary to evaluate the form. The Research COI Program may also consult other offices or departments on campus, access systems or gather information from external sources. Specifically, information on potential COIs may be shared with the appropriate Dean or Unit Head, to gather further information to assist in the review.

If the Research COI Program staff determines that a potential COI exists, the Research COI Program Director or designee will review the disclosure and make a determination regarding whether the case can be handled via expedited review through the Program or whether the case should be assigned to an agenda for committee review as applicable.

4.5. Review

The Research COI Program Director or staff will review the submitted RCOI form along with any related information, to determine whether a Covered Researcher's significant financial interest(s) for research, activities or relationships are related to the research project. They are considered related if it is reasonably determined that interest(s) or relationships could be a) affected by the research; or b) is in an entity whose financial interest could be affected by the research. The interests are then reviewed to determine if they can significantly and directly affect the design, conduct or reporting of the research, which would result in a FCOI determination. Interests can be determined to be COIs, but may be determined to be not both significant and directly affecting the research project.

4.5.1. University Conflicts Committee

Periodically a situation is identified with a high level of COI interest (such as equity along with multiple interests or relationships) and where any one, or more, of the following exist:

- An atypical structure, including those not consistent with normal business practice;
- Where standard management strategies may need to be significantly expanded; and/or
- Where there is an element of higher risk to the University (financial, academic, or reputational).

In such cases, the Research COI Program Director will conduct due diligence and consult with the Executive Director of Research Security, the Associate VP for Research and the Senior Associate General Counsel. After such consultation, the case may be referred for review by the Vice President for Research for their approval or referral to the University Conflicts Committee (UCC) for its review, in accordance with the University's COI Policy and procedures. The Research COI Program Director will convey the determination of the

UCC to a Covered Researcher, including any terms or project revisions which would make the project manageable if applicable.

4.6. Research Project Review Determinations

The Research COI Program Director shall confirm in the RCOI system one of the following determinations and convey the decision to the Covered Researcher, copying any related individuals or offices as needed:

Determination	Description
No evaluation, Declined/Withdrawn	If the application is withdrawn or the individual removed from the project after submission.
No conflict	No conflict was reported or determined.
Transparency	Request for disclosure in any public dissemination, not limited to publications and presentations. No management determined.
COI with Administrative Considerations	A COI is determined with minimal need for ongoing oversight. Requires disclosure in any public dissemination, not limited to publications and presentations. Additional management requirements are sometimes included within the context of the project and the disclosed relationships.
FCOI Management	Interests which meet the FCOI definition with the need for ongoing management and monitoring. Disclosure required in any public dissemination, not limited to publications and presentations. Change in Roles may be possible.
Not Manageable	Relationships have been determined to be a COI or FCOI and further determined no management is sufficient to effectively counter the actual or potential bias created.
Deferral	A status where a COI or FCOI exists which cannot be managed as presented. Changes to the project, such as scope, roles, structure, and budget are required in order to proceed.
Not Funded	Status indicated if review was initiated or determined but funding did not occur.

The Research COI finalization email will contain a determination, an acknowledgement of existing foundational Research Management Plan as sufficient, or language indicating the need for additional management parameters to manage the conflict(s) to promote objectivity and minimize bias. Any management terms included in the letter are immediately applicable upon transmission to the Covered Researcher. Copies of these finalization email letters may be obtained upon request by a Covered Researcher with an email to the Research COI Program researchcoi@nd.edu.

4.7. Management of Research COI

The Research COI Program Director is responsible for confirming appropriate management mechanisms for COI activities which have been determined to be capable of being managed. Building upon the foundational Research Management Plan, the Research COI Program will work with Department Chairs or Schools on determining the management plan and tools. The Research COI Program Director may seek advice from individuals outside as well as within the University in confirming such mechanisms, maintaining appropriate confidentiality.

As stated in the Policy, the University maintains three principles for COI management:

- Transparency
- Honoring the student/trainee experience
- Protecting the credibility of the individuals doing the work

With transparency being the foundation of COI management, public disclosure of personal or financial relationships, if related to a research project, is generally required in any publication, presentation, abstract, poster, website or other public dissemination as applicable. Notification of such requirements will be included as a reminder in the Research COI finalization letter; samples of such disclosure text are available on the Research COI Program website. If the research involves a human subjects project, the reviewing Institutional Review Board will determine if disclosure to participants is needed and provide further guidance.

In addition to public disclosure, possible additional measures to be taken in managing a research COI include, but are not limited to, any of the following:

- Modification or reformulation of the work plan
- Close monitoring of the research project including an independent monitor or review committee
- Change of roles on the research project
- Substituting supervisors and/or any other personnel
- Divestiture of Financial Interests
- Disqualification or reduction of involvement in the research project
- Termination of inappropriate student involvement in Project
- Severance of relationships that create the conflict(s)

Other management measures may be determined upon review of the specific project.

4.8. Appeals for Research COI Determinations

Appeals for any Research COI determination and project specific management terms must be made as specified in the Policy. The appeal request should be a justification for the appeal, the inclusion of additional information if available, and alternative project specific management terms, if applicable.

4.9. External Sponsors

Given the variance of sponsor requirements, the University will apply any sponsor-specific requirement regarding the collection of information, review, management and reporting, as required. The guidance may be in related federal COI regulations, policies or standards in the proposal documents or terms of agreement as specified by external sponsors. Policy requirements and processes required by federal regulation for some specific sponsors are included.

4.9.1. Subrecipients

For subrecipients, compliance will generally include the flowing down of the COI terms or requirements to subrecipients through proposal forms or as detailed in any sponsored agreements.

Certain federal sponsors may have different requirements. As required by PHS, NSF, NASA, DOE and other agencies, whether the subrecipient will follow its own compliant COI policy or where the University will be providing Research COI policy coverage might be stated at the time of proposal or include such language in the subrecipient agreement. The statement

of which entity is providing such compliance coverage, as well as supporting details, will be specified at the applicable time point as required by the Sponsor, including any deadlines by which the subrecipient should report back to the University as the prime recipient to ensure appropriate reporting to the Sponsor. The Research COI Program maintains responsibility, through policy delegation, for reporting any required COI/FCOI to sponsors, or the prime recipient, as applicable.

4.9.2. Independent Contractors, Contractors, Collaborators or Consultants

Sponsors, either federal or private, may require independent contractors, collaborators or consultants to be responsive to the Sponsor's COI standards and requirements. The University will provide coverage or flow down the terms through contracts or forms as detailed in any sponsored agreements.

If required by the sponsor, any individuals required to be covered by the University for Research COI purposes will be required to complete the Research COI training module and submit a related Research COI disclosure form for the project.

4.9.3. PHS / HHS Regulation 42 CFR Part 50 and Part 94

In addition to the general definitions and processes set forth in the Policy and SOPs, the following sections are applicable to any Covered Researcher included on a PHS or HHS proposal or funded project, regardless of whether the University is the prime recipient or subrecipient. In accordance with NIH NOT-OD-22-210, the most recent version of the Policy and the related SOPs is maintained by the University's Authorized Official at Notre Dame Research in the eRA Commons Institutional Profile Module.

4.9.3.1. Additional Disclosure Requirement - Travel

Covered Researchers who apply for or receive PHS research funding must disclose travel related to their University Responsibilities, as included in the definition of financial interests, in their Annual COI disclosure. Such information will be included in the project specific review.

4.9.3.2. Reporting of FCOI for PHS-Funded Covered Researchers

FCOI Reports shall be submitted prior to the University's expenditure of funds for PHS-funded Projects and annually thereafter. In addition, the University must submit an FCOI Report within sixty (60) days of the identification of any new FCOIs (e.g., upon the participation of a Covered Researcher who is new to the research).

As required by PHS regulations, the University shall report the following information regarding FCOIs related to PHS-funded research to the funding agency through the eRA Commons:

- Project Number
- PD/PI or Contact PD/PI if multiple PD/PI model is used
- Name of the Covered Researcher with the FCOI
- Name of the entity with which the Covered Researcher has the FCOI
- Nature of the Financial Interest (e.g. equity, consulting fee, travel reimbursement, honorarium)
- Value of the Financial Interest, or a statement that the interest is one for which value cannot be readily determined through reference to public prices or other reasonable measure of fair market value

- A description of how the Financial Interest relates to the PHS-funded research and the basis for the University's determination that the Financial Interest conflicts with such research
- A description of key elements of the University's Management Plan including:
    - Role and principal duties of the conflicted Covered Researcher in the research Project Conditions of the Management Plan
    - How the Management Plan is designed to safeguard objectivity in the research Project
    - Confirmation of the Covered Researcher's agreement to the Management Plan
    - How the Management Plan will be monitored to ensure Covered Researcher compliance
    - Other information as needed or requested by the funding agency

For any previously reported FCOI Report, the University shall provide to the PHS awarding component an Annual FCOI Report that addresses the status of the FCOI and any changes to the management plan. Such Annual Reports shall be provided for the duration of the PHS-funded research Project and in the manner specified by the PHS awarding component (e.g., at the time of the annual progress report or, at time of extension, etc.).

If the University is the prime awardee of PHS funds, the University will report any initial or annual FCOIs from subrecipients to PHS, as specified in the subaward agreements.

4.9.3.3. FCOI Noncompliance in PHS-Funded Research

When the University identifies a Significant Financial Interest for Research which was not disclosed in a timely fashion, not identified, or not reviewed, the Research COI Program will take the following actions within 60 calendar days:

1. Review the Significant Financial Interest for Research
2. Determine if the SFI is related to the Covered Researcher's PHS-funded research
3. Determine if an FCOI exists related to the research project

If a FCOI is determined to exist, a FCOI report will be submitted to the PHS awarding component and the Research COI Program will then conduct a Retrospective Review.

4.9.3.4. PHS Retrospective Review and Mitigation Report

For PHS-funded studies, or as otherwise required by the applicable sponsor, the University and Covered Researchers are subject to the following procedures when an FCOI is not identified or managed in a timely manner including failure by the Covered Researcher to disclose a Significant Financial Interest for Research that is determined by the University to constitute an FCOI; failure by the University to review or manage such an FCOI; or failure by the Covered Researcher to comply with an FCOI Management Plan.

1. The University must implement, on at least an interim basis, a Management Plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward;
2. Within 120 days of the University's determination of noncompliance, the University must complete a retrospective review of the Covered Researcher's activities and the PHS-funded research Project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
3. The University must document the retrospective review and include, at minimum, the following information:
    a. Project number
    b. Project title
    c. PD/PI or contact PD/PI if a multiple PD/PI model is used
    d. Name of the Covered Researcher with the FCOI
    e. Name of the entity with which the Covered Researcher has an FCOI
    f. Reason(s) for the retrospective review
    g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the reviewer(s) or panel, documents reviewed)
    h. Findings of the review
    i. Conclusions of the review

    Based on the results of the retrospective review, if appropriate, the University shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

    If the retrospective reviewer(s) find bias, the University is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research Project and the University's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research Project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research Project is salvageable).

    Thereafter, the University will submit to the PHS Awarding Component FCOI reports annually. Depending on the nature of the FCOI, the University may determine that additional interim measures are necessary with regard to the Covered Researcher's participation in the PHS-funded research Project between the date of the Covered Researcher's noncompliance and the completion of the retrospective review.

4.9.3.5. PHS Remedies

PHS has the authority to inquire about any Covered Researcher's reporting of financial interests and the University review and response to the financial interests at any time. PHS may impose special award conditions, suspend funding, or impose other mechanisms if PHS decides that a particular FCOI will bias the objectivity of the research.

If the Department of Health and Human Services determines that a PHS-funded clinical research project, aimed at evaluating the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by a Covered Researcher with an FCOI that was not managed or reported, the Covered Researcher must disclose the FCOI in all public presentations of the research results and request an addendum to previously published presentations.

The University will be responsive to any inquiries from or requirements by the PHS awarding agency regarding FCOI management, in order to maintain the objectivity of the research. Despite the University's management of a conflict, the PHS Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the University has not managed the financial Conflict of Interest in accordance with the PHS FCOI Regulation. The PHS Awarding Component may determine that imposition of specific award conditions under 45 CFR 75.207, or suspension of funding or other enforcement action under 45 CFR 75.371, is necessary until the matter is resolved.

4.9.3.6. PHS Public Accessibility

In accordance with the federal regulations, the University will make certain information available to the public regarding FCOIs for those Covered Researchers in conjunction with a specific PHS-funded research project. Requests must be submitted in writing to the Research COI Program, Research Security, University of Notre Dame, 940 Grace Hall, Notre Dame, IN 46556, Attention: FCOI Public Request, or via email to researchcoi@nd.edu.

Requests will be answered within five business days (when the University is open for business) from the date of receipt by the Research COI Program. The request must identify the specific PHS project number and Covered Researcher name for which the information is being requested and must include a named individual as recipient. If the request is in writing, a return address with a physical street address must be included; P.O. Boxes are not acceptable.

The University will note in its written response that the information is current as of the date of the correspondence, and is subject to updates at least annually or within 60 days of the University's identification of a new FCOI, which must be requested under separate cover by the requestor. This information will remain available for request for three years from the date the information was most recently updated.

In accordance with PHS regulations, the following information will be provided:

1. Project Number
2. Name of the Covered Researcher with a conflicted interest;
3. Covered Researcher's title and role with respect to the PHS research Project;
4. Nature of the Financial Interest (e.g. equity, consulting fee, travel reimbursement, honorarium); and Value of the Financial Interest (in ranges), or a statement that the interest is one for which value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

Information concerning FCOIs for Covered Researchers as set forth in this section shall remain available for at least three years from the date that the information is most recently updated.

4.9.4. Department of Energy (DOE) 2 CFR Part 910, Subpart C

In addition to the general definitions and processes set forth in the Policy and SOPs, the following sections are applicable to any Covered Researcher included on a DOE proposal or funded project, regardless of whether the University is the prime recipient or subrecipient. The University will maintain the Policy and SOPs in a publicly available website location or provide it within five (5) business days following any request.

Definitions

For any DOE project, the following expanded or specific definitions will be applied:

- The University will include actual, apparent and potential conflicts of interests, both foreign and domestic, in its collection of information, review and determination processes.
- Covered Researcher is any covered individual who contributes substantively to a project funded or proposed for funding by the DOE. The designation applies regardless of title or position whenever an individual role is explicitly named as such by the DOE. It includes anyone serving as a Principal Investigator, Co- PI, Project Director, Co-PD, or Project Manager, or any other research personnel as determined by the University.
- Covered Researchers who apply for or receive DOE research funding must disclose travel related to their University Responsibilities, as included in the definition of financial interests, in their annual COI disclosure. Such information will be included in the project specific review.

4.9.4.1. Training

The DOE requires training on COI disclosure requirements every two years. The agency has indicated this training can be satisfied by the Research Security Training (RST) module. For the University and, for Research COI purposes, the RST module would be complementary to the required Research COI Training. Additionally, the DOE requires that COI re-training must be completed within 30 days if any of the following circumstances occur:

- The institution revises its COI policies or procedures in a manner that affects the Covered Researcher's responsibilities.
- A Covered Researcher is newly appointed or transferred to the institution.
- The University determines a Covered Researchers is out of compliance with the Policy or an active research management plan.

4.9.4.2. Mandatory Certification Statement

Any Research COI disclosures, including updates or annuals, related to a DOE project will include the exact text of the Disclosure Certification Statement specified in Appendix A of 2 CFR Part 910, Subpart C.

4.9.4.3. Reporting to the DOE Awarding Component

Reports on foreign COIs or FCOIs for those Covered Researchers with DOE proposals shall be submitted to the DOE awarding component. For domestic COI

or FCOIs, such reports will only be submitted if the University determines they are not manageable at time of proposal or thereafter, and there is an intent to include the Covered Researcher in the research project. In all cases, COI or FCOI Reports, if required, shall be submitted with the University's proposal, or if newly determined during the course of the project, and annually thereafter for the duration of the research project period. Any annual report will address the status of the COI or FCOI, if it is still under management and any changes, if applicable, to the management plan. If the COI or FCOI no longer exists, an explanation will be provided.

If the University is the prime awardee of DOE funds, the University will report any initial, new or annual COIs or FCOIs, foreign or domestic, as specified in the regulation, from subrecipients to DOE, as specified in the subaward agreements.

4.9.4.4. Noncompliance in DOE Funded Research

If the University becomes aware that a Covered Researcher has failed to disclose an SFI, COI, or has failed to adhere to the research management plan, the University will immediately initiate an internal Research COI review. The University will promptly notify the DOE in writing of the non-compliance and any related corrective actions. The DOE requires a formal report must be submitted to the DOE within 15 days of discovering the failure to comply, and the report may include proposed or ongoing mitigation plans.

4.9.4.5. DOE Remedies

The DOE, or its awarding units or agencies, has the authority to inquire about any Covered Researcher's reporting of financial interests and the University's review and response to the financial interests at any time before, during or after a Federal financial assistance award, including obtaining copies of Research COI disclosures, review information, and supporting information or conducting an on-site review of such information.

Under federal regulations § 910.270 and 2 CFR 200.339, when conflicts are undisclosed or mismanaged in relation to a research project, the DOE can deploy financial and administrative remedies against non-compliant entities, including permanently disallowing any costs or procurement transactions connected to an unmitigated conflict. DOE also reserves the right to temporarily suspend or completely terminate a financial assistance award. Finally, active applications for funding may be summarily rejected if an unmanageable conflict is identified during the initial review phase.

Additionally, the DOE can impose long-term administrative restrictions on both individuals and institutions. The DOE may officially disqualify specific covered individuals or entire organizations from participating in future federal awards. It can also enforce highly restrictive, specific award conditions under 2 CFR 200.208, which can include mandatory on-site reviews of all financial and research records. Furthermore, non-compliance can be formally recorded in the Federal Awardee Performance and Integrity Information System to alert other federal agencies. This tracking significantly compromises the entity's ability to secure future federal funding opportunities across the government.

4.10. Investigation and Resolution of Policy Violations

Any time the Research COI Program staff becomes aware of a potential violation of the Policy or of any other situation that could indicate that University research, education and training may have been affected inappropriately by a Research COI, a preliminary investigation shall be conducted to determine whether the concerns appear to be warranted.

On receipt of such a report, the Research COI Program Director shall notify the Vice President for Research, the Associate Vice President for Research and the Executive Director for Research Security. In consultation with those persons, the Research COI Program Director may:

1. Investigate the matter and make a written memorandum of their conclusions;
2. Request that the person or committee assigned to monitor the activity conduct an investigation and file a written report of the results of that investigation; or
3. Appoint another faculty member or a committee of faculty members to conduct an investigation and file a written report of the results of that investigation.

Any such investigation should, at a minimum, include a personal interview with the person bringing forth the allegations or concerns, if known, and a personal interview with the Covered Researcher, who should be informed with specificity of the allegations or concerns that have arisen. The Covered Researcher will be informed that the University's Ethical Conduct Policy and Non-Retaliation Policy prohibits retaliation against any person making such allegations.

Upon determination that a violation of this Policy has occurred or of the existence of a situation that could indicate that University research or other performance may have been affected inappropriately by a Research COI, the Research COI Program Director will consult on the steps necessary to correct the situation, including and up to disapproval of the Research COI being managed.

The Research COI Program Director, in conjunction with Vice President for Research, the AVP for Research and the Executive Director of Research Security, shall have the authority to direct that the research activities of the Covered Researcher affected by the Research COI be suspended pending conclusion of an investigation or, on conclusion of an investigation, that they be suspended pending amelioration of the Policy violation. In addition, where appropriate, the Research COI Program Director must consider recommending to the relevant officials the imposition of disciplinary or other action under other appropriate University policies. Such possible actions or sanctions could include a letter of reprimand, increased monitoring of the conflict or other appropriate actions which would be determined by the office with applicable oversight.

Upon a determination that no violation of the Policy has occurred, or otherwise at the conclusion of any investigation conducted under this Policy, all materials generated in the course of such investigation should be placed with the Covered Researcher's personnel file or, if a student, with the Office of the Vice President for Student Affairs, marked as "confidential" and stored in a secure manner, in order to ensure the confidentiality of these records.

5. POLICY & SOPs ENFORCEMENT

Enforcement	The Research COI Program is responsible for the day-to-day implementation of these SOPs. Any suspected violations of the Policy and or the SOPs will be initially conducted by the Research COI Program Director and staff, and reported to the Vice President for Research or their designee. The Vice President for Research will consult with the Provost's Office and recommend disciplinary action in accordance with University's codes of conduct, policies, or applicable laws to the appropriate University Office. Sanctions may include one or more of the following: ● 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 as required by the Sponsor of the research project, as included in any agreements and in combination with federal regulations governing research.

6. RELATED DOCUMENTS

University of Notre Dame Policies are included in the Main Policy.

Federal Agencies Policies or Regulations are listed on the Research COI Program website.

7. 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 SOP		policy.nd.edu	