

UNIVERSITY OF NOTRE DAME

Conflict of Interest Regulatory Compliance Guidelines

August 24, 2012

I. Overview

The University of Notre Dame's Conflict of Interest Policy (<http://conflictpolicy.nd.edu>) sets forth the standards and processes under which conflicts of interest at the University are identified and either managed or eliminated. These Conflict of Interest Regulatory Compliance Guidelines ("Compliance Guidelines") detail how the University Conflict of Interest Policy is implemented to facilitate compliance with the Public Health Service (PHS) regulations located at 42 C.F.R. Part 50 Subpart F and 45 C.F.R. Part 94 ("PHS Regulations"), including as made applicable by non-PHS entities. These Compliance Guidelines and the University Conflict of Interest Policy are not intended to and shall be not construed to require more extensive disclosures of financial interests than required by the PHS Regulations or to otherwise impose standards that are more stringent than those set forth in the PHS Regulations.

II. Applicability

These Compliance Guidelines apply to all Covered Researchers and Subrecipients planning to participate in or who are engaged in PHS-Funded Research.

III. Definitions

The definitions set forth for the following terms are applicable only to the use of the terms within these Compliance Guidelines and are not applicable for any other purpose:

- **Subrecipients:** Subrecipients, subgrantees, subawardees, subcontractors, and consortium members who carry out sponsored PHS-Funded Research on behalf of the University. University employees are not considered Subrecipients.
- **Covered Researchers:** The Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-Funded Research or would be responsible for such activities under proposed PHS-Funded Research, which may include collaborators or consultants. Those individuals considered "responsible" for the design, conduct, or reporting of research for the purposes of these Compliance Guidelines are those who have or would have independent responsibility for the substantive and material direction and execution of PHS-Funded Research, including but not limited to: the design, supervision, or direction of research methodologies; the evaluation and validation of research results; and the final reporting of research results and information. For the sake of clarity, individuals who are or may be engaged in PHS-Funded Research but whose activities are limited to acting at the direction of others are not considered "responsible" for the design, conduct, or reporting of research under these Compliance Guidelines. Ordinarily, in addition to a Project Director or Principal Investigator, all Co-Principal Investigators, Teaching and Research Faculty, and Research Faculty engaged in PHS-Funded Research or associated with a proposal for PHS-Funded Research will be Covered Researchers. On the other hand, while

Postdoctoral Scholars, Staff, Graduate Students, and Undergraduate Students may in certain circumstances be Covered Researchers based on their responsibilities with respect to certain active or proposed PHS-Funded Research, such individuals are generally not expected to have the requisite level of responsibility for PHS-Funded Research necessary to be Covered Researchers.

Ultimately, it is the responsibility of each Principal Investigator of active or proposed PHS-Funded Research to ensure at all times that Covered Researchers have been identified with respect to his or her PHS-Funded Research and that such Covered Researchers have fulfilled the requirements of these Compliance Guidelines.

If a Principal Investigator has any questions about whether an individual affiliated with his or her PHS-Funded Research is a Covered Researcher, the Principal Investigator should contact Notre Dame Research for assistance.

Subrecipients are responsible for identifying Covered Researchers within their own organizations, and the disclosures and Financial Conflicts of Interest of such Covered Researchers shall be determined in accordance with Section V herein.

- **PHS-Funded Research:** Research conducted under a grant, cooperative agreement, or contract by the University of Notre Dame with a PHS Agency, including a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional teaching grant, program project, or research resources award.
- **Funding Agency:** The PHS Agency that is funding the PHS-Funded Research.
- **PHS Agency:** Any one of the constituent agencies of the PHS, including the Centers for Disease Control and Prevention (“CDC”), Food and Drug Administration (“FDA”), the National Institutes of Health (“NIH”), and Substance Abuse and Mental Health Services Administration (“SAMHSA”). For a full list of PHS Agencies, see: <http://www.hhs.gov/about/orgchart/>.
- **Significant Financial Interest:** This term has the same definition as set forth for the term in the University Conflict of Interest Policy, except that—for the purposes of these Compliance Guidelines only—Significant Financial Interest also includes certain reimbursed or sponsored travel (i.e., that which is not paid on behalf of the Covered Researcher and not reimbursed to the Covered Researcher so that the exact monetary value may not be readily available) related to their institutional responsibilities. Specifically, a Significant Financial Interest exists for a Covered Researcher based on research or sponsored travel if: (1) the Covered Researcher and/or the Covered Researcher’s spouse and/or the Covered Researcher’s dependent children have engaged in reimbursed or sponsored travel related to the Covered Researcher’s institutional responsibilities during the prior twelve month period; and (2) the value of all such reimbursed and sponsored travel from any one entity exceeds \$5,000 when aggregated; provided, however, that travel that is reimbursed or sponsored by the University, by a Federal, state, or local government agency, by another non-profit institution of higher education accredited by a nationally recognized accrediting agency or institution, or by an academic teaching hospital, medical center, or research institute affiliated with such an institution of higher education does not constitute a Significant Financial Interest.
- **Financial Conflict of Interest:** A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-Funded Research.

All capitalized terms in these Compliance Guidelines that are not defined herein have the same definition as set forth for the term in the University 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.

IV. Covered Researcher Disclosure Requirements

A. Initial Disclosure

- Each Covered Researcher who is planning to participate in PHS-Funded Research must disclose to the University, no later than the time of application for the PHS-Funded Research, the Covered Researcher's Significant Financial Interests and those of his/her spouse and dependent children.

B. Ongoing Disclosures

- Each Covered Researcher who is participating in PHS-Funded Research must submit an updated disclosure of Significant Financial Interests in accordance with the University's annual Conflict of Interest disclosure process. The update must include any information not disclosed initially to the University or in a subsequent disclosure (e.g., any financial conflict of interest identified on a PHS-Funded Research project that was transferred from another Institution) and shall also include updated information on previously disclosed Significant Financial Interests (e.g., updated value of a previously disclosed equity interest).
- Each Covered Researcher who is participating in PHS-Funded Research must also submit an updated disclosure of Significant Financial Interests within 15 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

C. Method of Disclosures

- Except for the disclosure of reimbursed or sponsored travel constituting a Significant Financial Interest, as such travel is described in the definition of Significant Financial Interest in Section III, all disclosures of Significant Financial Interests that are required of Covered Researchers under these Compliance Guidelines shall be made through the University's online Conflict of Interest disclosure system (<http://conflictpolicy.nd.edu>).
- All disclosures of reimbursed or sponsored travel constituting a Significant Financial Interest that are required of Covered Researchers under these Compliance Guidelines shall be made by submitting the form available here: <http://or.nd.edu/forms>. The form shall include: the purpose of the travel, the identity of the sponsor and/or organizer of the travel, the destination(s) of the travel, and the duration of the travel. The University may request that the Covered Researcher also disclose additional information about the travel, such as the monetary value.

V. Subrecipient Disclosure Requirements

- Each Subrecipient shall be required to certify in a written agreement with the University that the Subrecipient has or is adopting as a condition of the written agreement a financial conflict of interest policy that complies with the PHS Regulations. The written agreement shall also specify the time periods for the Subrecipient to report to the University any financial conflicts of interest the Subrecipient identifies for its Covered Researchers, which time periods must enable the University to make timely reports to the Funding Agency of such financial conflicts of interest as required under Section VIII herein.

- If a Subrecipient cannot make the certification required under this Section V, the University will reevaluate the Subrecipient's involvement in the PHS-Funded Research, including whether the University Conflict of Interest Policy shall be made applicable to the Subrecipient in a written agreement as a condition of allowing the Subrecipient to participate in the PHS-Funded Research.

VI. Identification and Management of Financial Conflicts of Interest

All disclosures by Covered Researchers of Significant Financial Interests shall be reviewed by the relevant institutional officials designated in the University Conflict of Interest Policy and according to the procedures set forth in Section 7 of that policy.

A. Initial Identification

- With respect to each PHS-Funded Research project, the Significant Financial Interests of the Covered Researchers who are planning to participate in the PHS-Funded Research Project shall be reviewed by the designated University officials prior to the expenditure of funds on that project to determine whether any disclosed Significant Financial Interest relates to the PHS-Funded Research project. For any Significant Financial Interest determined to relate to the PHS-Funded Research project, the designated University officials shall also determine whether the Significant Financial Interest presents a Financial Conflict of Interest under these Compliance Guidelines.
- If a Financial Conflict of Interest exists, the Financial Conflict of Interest shall be eliminated or a management plan shall be developed according to the procedures set forth in Section 7 of the University Conflict of Interest Policy prior to expenditure of funds on the related PHS-Funded Research Project. A management plan shall specify the actions that have been, and shall be taken, to manage a Financial Conflict of Interest.
- In order to assist its designated officials in the identification of Financial Conflicts of Interest, the University has developed Identification Guidelines ("Identification Guidelines") consistent with the PHS Regulations describing how to determine whether a Covered Researcher's Significant Financial Interest is related to a PHS-Funded Research project and, if so, how to determine whether the Significant Financial Interest presents a Conflict of Interest under these Compliance Guidelines.
 - A Covered Researcher's Significant Financial Interest is related to a PHS-Funded Research Project if the designated University officials reasonably determine that the Significant Financial Interest could be affected by the PHS-Funded Research or is in an entity whose financial interest could be affected by the PHS-Funded Research. (The designated University officials may involve the Covered Researcher in the determination of whether such a relationship exists).
 - If this relationship exists, the designated University officials shall determine whether the Significant Financial Interest is a Financial Conflict of Interest. A Financial Conflict of Interest exists when the designated officials reasonably determine that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

B. Ongoing Identification

- During a PHS-Funded Research project, if a Covered Researcher new to the project discloses a Significant Financial Interest (such a Covered Researcher must disclose his or her Significant Financial Interests prior to participating in the PHS-Funded Research) or a Covered Researcher previously engaged in the PHS-Funded Research project discloses a new Significant Financial Interest, the designated University officials must conduct a review of the disclosure within 60 days according to the procedures set forth in Section 7 of the University Conflict of Interest Policy to determine whether a Financial Conflict of Interest exists under these Compliance Guidelines.
- If a Financial Conflict of Interest exists, the designated officials must implement—at least on an interim basis—a management plan that shall specify the actions that have been, and will be, taken to manage the Financial Conflict of Interest according to the procedures set forth in Section 7 of the University Conflict of Interest Policy.
 - Depending on the nature of the Significant Financial Interest disclosed, the University may also impose interim measures concerning the Covered Researcher’s participation in the PHS-Funded Research between the date of the disclosure of the Significant Financial Interest and the completion of the University’s review of whether the Significant Financial Interest presents a Financial Conflict of Interest.

C. Untimely Disclosures

- If the University identifies a Significant Financial Interest that was not disclosed in a timely manner by a Covered Researcher or was not previously reviewed by the designated University officials during an ongoing PHS-Funded Research project (e.g., was not timely reviewed or reported by a Subrecipient), the designated University officials shall conduct a review of the disclosure within 60 days to determine whether a Financial Conflict of Interest exists under these Compliance Guidelines.
- If a Financial Conflict of Interest exists in this circumstance, the designated officials shall implement, at least on an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the Financial Conflict of Interest according to the procedures set forth in Section 7 of the University Conflict of Interest Policy.

D. Retrospective Review of Untimely Compliance

- Whenever a Financial Conflict of Interest is not identified or managed in a timely manner—including (1) failure by the Covered Researcher to disclose a Significant Financial Interest that is determined by the University to constitute a Financial Conflict of Interest; (2) failure by the University to review or manage such a Financial Conflict of Interest; or (3) failure by the Covered Researcher to comply with a Financial Conflict of Interest management plan—the University Conflicts Committee (“UCC”) established by the University Conflict of Interest Policy shall complete within 120 days of the determination of noncompliance a retrospective review of the Covered Researcher’s activities and the PHS-Funded Research project to determine whether the PHS-Funded Research project conducted during the time period of the noncompliance, or any portion thereof, was biased in its design, conduct, or reporting.
- Depending on the nature of the Financial Conflict of Interest, the UCC may determine additional interim measures are necessary with regard to the Covered Researcher’s participation in the PHS-

Funded Research project between the date that either the occurrence of noncompliance or existence of the Financial Conflict of Interest is determined, and the completion of the retrospective review.

- The retrospective review shall be documented by the UCC and shall contain the following:
 - Project number
 - Project title
 - PD/PI, or the contact PD/PI if there are multiple PD/PIs listed
 - Name of Covered Researcher with the Financial Conflict of Interest
 - Name of the entity with which Covered Researcher has the Financial Conflict of Interest
 - The reasons for the retrospective review
 - Detailed methodology of the retrospective review
 - Findings of the review
 - Conclusions of the review
- If appropriate based on the retrospective review, the UCC shall update the Financial Conflict of Interest report previously submitted to the Funding Agency, specifying the actions that will be taken to manage the Financial Conflict of Interest moving forward.
- If the retrospective review finds that the Financial Conflict of Interest biased the design, conduct, or reporting of the PHS-Funded Research, the UCC shall notify the Funding Agency promptly and shall submit a mitigation report to the Funding Agency. The mitigation report shall contain the following:
 - The elements required in the retrospective review documentation
 - Description of the impact of the bias on the research
 - University's plan of action or actions taken to mitigate or eliminate the effect of the bias

E. Compliance with Management Plan

- Whenever the University institutes a management plan, the University shall monitor Covered Researcher compliance with the management plan under Sections 6 and 7 of the University's Conflict of Interest Policy on an ongoing basis until the completion of the relevant PHS-Funded Research Project.

VII. Public Accessibility

- Prior to the University's expenditure of any funds under a PHS-Funded Research project, the University shall, in response to written requests, make available certain information concerning Significant Financial Interests that have been disclosed to the University and that meet all of the following criteria:
 - The Significant Financial Interest was disclosed and is still held by senior/key personnel. "Senior/key personnel" means the PD/PI and any other person identified as senior/key personnel by the University in the grant application, progress report, or any other conflict of interest report submitted to the PHS by the University.
 - The Significant Financial Interest is related to the PHS-Funded Research project.
 - The Significant Financial Interest is a Financial Conflict of Interest.

- The information concerning Significant Financial Interests that the University shall make available in response to a written request is as follows, and shall be sent by the University in writing within 5 business days of the written request:
 - The Covered Researcher's name
 - The Covered Researcher's title and role with respect to the PHS-Funded Research project
 - The name of the entity in which the Significant Financial Interest is held
 - The nature of the Significant Financial Interest
 - The approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- The University shall note in its written response that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of the University's identification of a new Financial Conflict of Interest, which updated information must be requested subsequently by the requestor.
- Information subject to disclosure under this Section VII will remain available for at least 3 years from the date that the information was most recently updated.
- The Director of Research Contracts in Notre Dame Research Administration shall be responsible for tracking written requests for information and issuing written responses under this Section VII.

VIII. Reporting

A. Initial Report

- Prior to the University's expenditure of any funds under a PHS-Funded Research project, the University shall provide the Funding Agency with a Financial Conflict of Interest report regarding any Covered Researcher's Significant Financial Interest found by the University to constitute a Financial Conflict of Interest and shall ensure that the University has implemented an appropriate management plan. If the University identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of funds under the PHS-Funded Research project, no such report is required.
- For any Significant Financial Interest that the University identifies as a Financial Conflict of Interest during an ongoing PHS-Funded Research project (e.g., participation of a Covered Researcher new to the project), the University shall provide a Financial Conflict of Interest report to the Funding Agency within 60 days and shall ensure that the University has implemented an appropriate management plan. If the report involves a Significant Financial Interest that was not disclosed in a timely manner by a Covered Researcher or was not previously reviewed or managed by the University (e.g., was not timely reviewed or reported by a Subrecipient), the University shall conduct a retrospective review under Section VI.D of these Compliance Guidelines.

- All Financial Conflict of Interest reports that are submitted to a Funding Agency shall include the following:
 - Project number
 - PD/PI, or the contact PD/PI if there are multiple PD/PIs listed
 - Name of Covered Researcher with the Financial Conflict of Interest
 - Name of the entity in which the Covered Researcher has a Financial Conflict of Interest
 - Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
 - Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
 - Description of how the Significant Financial Interest relates to the PHS-Funded Research project and the basis for the University's determination that a Financial Conflict of Interest exists
 - Description of the key elements of the University's management plan, including:
 - Role and principal duties of the conflicted Covered Researcher in the PHS-Funded 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 relevant information

B. Annual Report

- For all Financial Conflicts of Interest previously reported by the University with regard to an ongoing PHS-Funded Research project, the University shall provide to the Funding Agency an annual Financial Conflict of Interest report that:
 - addresses the status of the Financial Conflict of Interest (whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists)
 - if the Financial Conflict of Interest is still being managed, any changes to the management plan
- The annual reports must be provided to the Funding Agency for the duration of the PHS-Funded Research project (including extensions with or without funds) in the time and manner specified by the Funding Agency.

IX. Recordkeeping

- The University shall maintain records relating to all Covered Researcher disclosures of Significant Financial Interests and the University's review of and response to such disclosures

(regardless of whether there was a Financial Conflict of Interest finding) and all actions under these Compliance Guidelines or a related retrospective review for at least 3 years from the date the final expenditures report is submitted to the Funding Agency or, where applicable, from other dates specified in 45 C.F.R. 74.53(b) and 92.42(b) for different situations. The University's Policy Specialist shall maintain individual-level records, including records regarding Significant Financial Interest disclosures, review of Significant Financial Interest disclosures, identification of Financial Conflicts of Interest, and development and implementation of management plans. Notre Dame Research shall maintain records by PHS-Funded Research project, including confirmation that Covered Researcher Significant Financial Interests have been disclosed prior to application for PHS-Funded Research, identity of Covered Researchers on each PHS-Funded Research project, and training records.

X. Training

- The University shall inform each Covered Researcher of: (1) the University's Conflict of Interest Policy and of these Compliance Guidelines; (2) the Covered Researcher's responsibilities regarding disclosure of Significant Financial Interests; and (3) any applicable regulations.
- The University shall require each Covered Researcher to complete training on the University's Conflict of Interest Policy, these Compliance Guidelines, the Significant Financial Interest disclosure requirements, and applicable regulations in the following situations:
 - Prior to engaging in research related to any PHS-Funded Research grant; and
 - At least every four years thereafter; and
 - Immediately after:
 - The University revises its University Conflict of Interest Policy or these Compliance Guidelines in any manner that affects the requirements of Covered Researchers
 - The University hires a Covered Researcher engaged in PHS-Funded Research
 - The University finds that a Covered Researcher is not in compliance with the University Conflict of Interest Policy, these Compliance Guidelines, or an applicable management plan.

XI. Certification

- Notre Dame Research shall certify, as required by applicable regulations, in each application for PHS-Funded Research funding that the University:
 - Has in effect an up-to-date written and enforced administrative process to identify and manage Financial Conflicts of Interest with respect to all research projects for which funding is sought or received by a Funding Agency
 - Shall promote and enforce Covered Researcher compliance with applicable regulations, including those pertaining to the disclosure of Significant Financial Interests
 - Shall manage Financial Conflicts of Interest and provide initial and ongoing Financial Conflicts of Interest reports to the Funding Entity as required by applicable regulations

- Agrees to make information available, promptly on request, to the U.S. Department of Health and Human Services (“HHS”) relating to any Covered Researcher disclosure of financial interests and the University’s review of and response to such disclosure
- Shall fully comply with the requirements of any applicable regulations

XII. Violations and Remedies

- If the failure of a Covered Researcher to comply with the University’s Financial Conflicts of Interest Policy, these Compliance Guidelines, or a management plan appears to have biased the design, conduct, or reporting of the PHS-Funded Research, the University shall promptly notify the Funding Agency of the corrective action taken or to be taken. The Funding Agency will consider the situation and take appropriate action, or refer the matter to the University for further action (which may include directions to the University on how to maintain appropriate objectivity in the PHS-Funded Research project).
- The Funding Agency and/or the HHS may inquire at any time before, during, or after award into any Covered Researcher disclosure of financial interests and the University’s review (including retrospective review) of and response to such disclosures. The University is required to submit or permit on site review of all relevant records. On the basis of the review, the Funding Agency may decide that a particular Financial Conflict of Interest will bias the objectivity of the PHS-Funded Research to such an extent that further corrective action is needed or that the Financial Conflict of Interest has not been adequately managed by the University. The Funding Agency may impose special award conditions (under 45 C.F.R. 75.14 and 92.12), suspend funding, or undertake another enforcement action (under 45 C.F.R. 74.62 and 92.43).
- In any case where the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a Covered Researcher with a Financial Conflict of Interest that was not managed or reported by the University, the University shall require the Covered Researcher to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.