

Title: Financial Conflicts of Interest Policy for PHS-Funded Research**Policy Reference: Conflicts of Interest Policy****Background:**

Benedictine University (the "University") and its Investigators are required to comply with the requirements of [42 CFR 50, Subpart F, Promoting Objectivity in Research](#) (FCOI Regulation), as implemented in the 2011 [Final Rule](#) for grants and cooperative agreements. Regulations identified in this document are implemented for the timely disclosure of financial interests, reporting and management of identified conflicts.

Policy Statement:

It is the policy of Benedictine University to assure that research conducted under the University will be free from bias by any conflicting financial interest of an Investigator, defined as the PI/PD and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by U.S. Department of Health and Human Services, Public Health Service, or proposed for such funding, which may include, for example, collaborators or consultants.

This policy applies to all Investigators at Benedictine University who are involved with PHS-funded research. Each Investigator doing PHS-funded research must complete the FCOI training. The Chief Institutional Compliance and Risk Management Officer is responsible for ensuring implementation of this policy and may suspend all relevant activities until a Financial Conflict of Interest ("FCOI") is resolved or other action deemed appropriate. Violation of any part of this policy may also constitute cause for disciplinary or other administrative action.

Definitions:

Designated Official: An institutional official designated to solicit and review disclosures of Significant Financial Interests from Investigators. The Designated Official at Benedictine University is the Chief Institutional Compliance and Risk Management Officer.

Financial Conflict of Interest ("FCOI"): A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS-Funded Research.

Investigator: The Principal Investigator or Project Director and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-Funded Research.

PHS-Funded Research: Research funded by or proposed to be funded by PHS, including without limitation NIH awards. The term includes any research for which funding is available from a PHS awarding component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

Significant Financial Interest ("SFI"): A financial interest consisting of one or more of the following interests of an Investigator, or the Investigator's spouse or dependent children that reasonably appears to be related to the Investigator's institutional responsibilities:

- **Publicly traded entity:** A SFI exists if the value of any remuneration from the entity in the 12 months preceding the disclosure of the SFI and/or the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5000. Remuneration includes any payment for services not otherwise identified as University-paid salary (e.g., consulting fees, honoraria, paid authorship fees). Equity interest includes any stock, stock option or other ownership interest,

as determined through reference to public prices or other reasonable measures of fair market value.

- **Nonpublicly traded entity:** A SFI exists if the value of any remuneration, as described above, received from the entity in the 12 months preceding the disclosure of the SFI, when aggregated, exceeds \$5000 or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interests).
- **Intellectual property:** Rights and interests (e.g. patents, copyrights) upon receipt of royalties or other income related to such rights and interests that exceed \$5000 not compensated through the University.
- **Reimbursed or sponsored travel:** Sponsored travel being that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available, as related to an Investigator's institutional responsibilities.

Significant Financial Interest does not include:

- Salary, royalties, or other remuneration paid by Benedictine University to the Investigator, if the Investigator is currently employed or otherwise currently holding an appointment at such institution;
- Intellectual property rights assigned to Benedictine University and agreements to share in royalties related to such rights;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; and
- Income from seminars, lectures, teaching engagements, service on advisory committees or review panels, or travel expenses that are reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, a research institute affiliated with an institution of higher education.

Training:

The Chief Institutional Compliance and Risk Management Officer will inform each Investigator of the FCOI policy, disclosure requirements and Federal regulations and training located at:

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html.

Investigators will complete training on Investigator responsibilities at the following times:

- Prior to engaging in PHS-Funded Research and at least once every four (4) years thereafter;
- Immediately after policy and procedures are revised that affects the requirements and responsibilities of Investigators; is new to Benedictine University; is not in compliance with University policy and procedures or a FCOI Management Plan, as determined by the Designated Official.

Procedures:

The Chief Institutional Compliance and Risk Management Officer will perform the following actions prior to expenditure of any funds for a PHS-Funded Research project:

- Solicit and review Investigator Significant Financial Interest ("SFI") Disclosures Forms and any other information deemed relevant. The SFI will be requested at time of application, at least

annually during the period of the award, and within thirty days of discovering or acquiring a new SFI.

- Determine whether an Investigator's SFI is related to PHS-Funded Research, and if it is, is the SFI a FCOI.
- Determine actions necessary to manage the FCOI, including development and implementation of a FCOI Management Plan.

Determine If FCOI Exists:

An FCOI exists when the Designated Official, reasonably determines that the Investigator's SFI could directly and significantly affect the design, conduct, or reporting of the PHS-Funded Research.

Determination of FCOIs is completed after a thorough examination by the Designated Official. The Designated Official will prepare a report for the Provost detailing a recommended FCOI Management Plan which includes any proposed conditions or restrictions to manage the FCOI. The Provost will make a final determination in writing and specify the conditions or restrictions, if any, that should be imposed to manage the FCOI.

The Chief Institutional Compliance and Risk Management Officer will provide copies of the final decision to the Investigator and the appropriate senior managers.

FCOI Management Plans:

FCOI Management Plans shall specify the actions and conditions that have been and will be taken to manage the FCOI.

Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

- Public disclosure of the FCOI;
- Modification of the research plan;
- Change personnel participating in all or a portion of the PHS-Funded Research;
- Reduction or elimination of a financial interest; or
- Elimination of relationships that create the FCOI.

The Chief Institutional Compliance and Risk Management Officer will monitor Investigator compliance with the FCOI Management Plan on an ongoing basis until the completion of the PHS-Funded Research.

Reporting of New SFIs during Ongoing PHS-Funded Research:

During the course of ongoing PHS-Funded Research, a newly participating Investigator discloses a SFI or an existing Investigator discloses a new SFI, the Designated Official will perform the following, within sixty (60) days:

- Review the Significant Financial Interest;
- Determine whether it is related to PHS-Funded Research; and
- Determine whether a FCOI exists;
- If an FCOI exists, the Designated Official will create a FCOI Management Plan that shall specify the actions that will be taken to manage the identified FCOI.

Ongoing PHS-Funded Research: Review of Existing SFIs and Retrospective Review of FCOIs:

When Benedictine University identifies an existing SFI that was not disclosed timely by an Investigator or was not previously reviewed during ongoing PHS-Funded Research, the Designated Official will, within sixty (60) days, undertake the same review, determinations and FCOI Management Plan implementation set forth in the section above.

Retrospective Review:

When an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI that is determined by Benedictine University to constitute an FCOI, failure by Benedictine University to review or manage such an FCOI, or failure by the Investigator to comply with an FCOI Management Plan, the Designated Official will, within 120 days of the University's determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS- Funded Research to determine whether any PHS-Funded Research, or portion thereof, conducted during the time period of the non-compliance, was biased in design, conduct, or reporting of such research.

The **Office of Institutional Compliance and Risk Management** will document the retrospective review in accordance with federal requirements set in 42 CFR, Part 50, Subpart F, §50.605(a)(3)(ii)(B)(1-9), for PHS-funded research grants or cooperative agreements, or 45 CFR Part 94, §94.5(a)(3)(ii)(B)(1-9), for PHS-funded research contracts, and if appropriate, will update the previously submitted FCOI report, describing the new FCOI Management Plan.

Reporting FCOIs to the PHS-Awarding Component:

Prior to the University's expenditure of any funds under PHS-Funded Research, the Designated Official shall provide to PHS, as required, an FCOI report regarding any Investigator's FCOI (unless eliminated) and ensure that a FCOI Management Plan has been implemented. The FCOI report to PHS will contain all information required under federal regulations at 42 CFR, Part 50, Subpart F, § 50.605(b)(3) and 45 CFR, Part 94, § 94.5(b)(3), as applicable.

Newly acquired FCOIs during ongoing PHS-Funded Research, the Designated Official shall provide to the PHS awarding component, within sixty (60) days, a FCOI Report ensuring that the University has implemented a FCOI Management Plan.

FCOIs that were not previously disclosed, reviewed or managed during ongoing PHS-Funded Research, the Designated Official shall, if the retrospective review results in a finding of bias in the design, conduct or reporting of the PHS-Funded Research, promptly submit its mitigation report to the PHS awarding component. In accordance with 42 CFR, Part 50, Subpart F, § 50.605(a)(3)(iii) and 45 CFR, Part 94, § 94.5a)(3)(iii).

After the submission of any initial FCOI Report with regard to ongoing PHS-Funded Research, the Designated Official shall provide the PHS awarding component with annual FCOI Reports that address the status of the FCOI and any changes to the FCOI Management Plan for the duration of the PHS-Funded Research in the time and manner specified by the PHS awarding component.

The **Office of Institutional Compliance and Risk Management** on behalf of Benedictine University shall, upon request of the PHS awarding component, make information available to PHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI.

Notification and Mitigation Report:

If the Designated Official finds bias in the design, conduct, or reporting of PHS-Funded Research, they will notify the PHS awarding component promptly and submit a mitigation report, as required by and including all key elements specified in 42 CFR, Part 50, Subpart F, § 50.605(a)(3)(iii) and 45 CFR, Part 94, § 94.5(a)(3)(iii).

Non-Compliance:

Benedictine University may impose sanctions for non-compliance including suspension, denial of eligibility to engage in research, or other appropriate sanctions. Such sanctions may require giving notice to the public, professional bodies and/or journals.

If an Investigator fails to comply with Benedictine University's FCOI policy and procedures or a FCOI Management Plan in a way that could have biased the design, conduct, or reporting of PHS-Funded Research, Benedictine University will promptly notify the PHS awarding component of the corrective action taken or to be taken.

Subrecipients:

If Benedictine University is the awardee and conducts PHS-Funded Research through a subrecipient, the Designated Official will take reasonable steps to ensure that subrecipient Investigators are in compliance with Benedictine University's policy and procedures.

Benedictine University's written agreement with the subrecipient will establish whether the University's policy and procedures or the subrecipient's FCOI policy will apply to the subrecipient's Investigators. The written agreement will state either:

- The subrecipient certifies that its FCOI policy complies with the applicable federal regulations, and that the subrecipient's Investigators will comply with the subrecipient's policy, or
- If the subrecipient cannot provide such certification, that subrecipient Investigators are subject to Benedictine University policy and procedures.
- If the subrecipient's policy applies, the written agreement will specify the time period(s) for the subrecipient to report all identified FCOIs initially and annually thereafter to Benedictine University. The time period(s) will allow Benedictine University to provide FCOI reports to PHS prior to the expenditure of funds and within 60 days of finding any additional FCOI.

If Benedictine University's policy, as awardee, applies, the subrecipient Investigators will disclose all SFIs that are directly related to the subrecipient's work for Benedictine University. The written agreement with the subrecipient will specify the time period in which to comply, sufficiently allowing Benedictine University enough time to comply timely with its review, management and reporting obligations. These reporting obligations are to provide FCOI reports to PHS prior to the expenditure of funds, within 60 days of finding any additional FCOI and annually thereafter.

Maintenance of Records:

The Office of Institutional Compliance and Risk Management will maintain records relating to all Investigator SFI disclosures, including the review of and response to such disclosures for at least three (3) years from the date the final expenditures report is submitted to PHS or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

Public Accessibility

This document and related forms shall be made publicly available on Benedictine University's website. Upon written request to Benedictine University's Office of Institutional Compliance and Risk Management, information will be provided including as specified in 42. CFR, Part 50, Subpart F, §50.605(a)(5)(ii) and 45 CFR, Part 94, § 94.5(a)(5)(ii), concerning a specific SFI disclosed to Benedictine University and meeting the following criteria:

- The SFI was disclosed and is still held;
- Determined that the SFI is related to the PHS-Funded Research; and
- Determined that the SFI is an FCOI.

Information concerning the SFIs of Senior Management shall remain available for responses to written requests for at least three (3) years from the date that the information was most recently updated.

When the PHS-Funded Research is conducted by a subrecipient Investigator, and under their written agreement, the subrecipient is required to comply with the subrecipient's FCOI policy, the subrecipient will have the responsibility of making such information publicly accessible.

Responses will be returned within five (5) business days from the written request by Benedictine University's Chief Institutional Compliance and Risk Management Officer.

Contacts:

- Chief Institutional Compliance and Risk Management Officer (630) 829-6404
- Provost and Chief Academic Officer (630) 829-6240

Additional Resources:

- *Conflicts of Interest Policy*
- *Faculty Handbook*
- *Employee Handbook*

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Department Responsible: Office of Institutional Compliance and Risk Management