

Financial Conflict of Interest Policy (FCOI)

November 2024

PURPOSE

The Federal Department of Health and Human Services has developed regulations ([42 CFR Part 50 Subpart F and 45 CFR Part 94](#)) on Promoting Objectivity in Research. The regulations were first developed in 1995, and in 2011, the regulations were revised. These regulations describe the actions an individual and an organization must take to promote objectivity in PHS-funded research. The regulations apply to all Public Health Service (PHS) (e.g., National Institutes of Health [NIH]) funded grants, cooperative agreements, and research contracts. The regulations do not apply to Phase 1 Small Business Innovation Research or Small Business Technology Transfer applications and/or awards. This policy implements the regulatory requirements provided in 42 CFR Part 50 Subpart F for Dominican University (Institution).

DEFINITIONS

For these policies and procedures, the following definitions apply.

1. **Financial Conflict of Interest (FCOI):** a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
2. **Financial Interest:** Anything of monetary value, whether or not the value is readily ascertainable.
3. **Institutional Responsibilities:** The professional activities an Investigator performs on behalf of Dominican University (e.g., administration, research, or consulting).
4. **Designated Official:** Ms. Doris Dumas, Associate Vice President, Finance & Controller, Business Office, has been designated by Dominican University to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests and identify FCOIs per the regulatory criteria provided in 42 CFR 50.604(f) and as stated within the policy below.
5. **Investigator:** The Project Director (PD) or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by award or proposed for such funding, which may include, for example, collaborators or consultants. Dominican University's Principal Investigator/Project Director,

7. **PHS:** The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
8. **NIH:** National Institutes of Health, the biomedical research agency of the PHS.
9. **Senior/Key Personnel:** Generally speaking, the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other

- medical center, or a research institute that is affiliated with a U.S. Institution of higher education or;
- iv. Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States (U.S.), a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.
3. Investigators must disclose the occurrence of any foreign or domestic reimbursed or sponsored travel that exceeds \$5,000 (i.e., 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) related to the Investigator's institutional responsibilities. The initial disclosure of reimbursed or sponsored travel should include income received over the previous twelve months. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- a federal, state, or local government agency located in the United States,
- a United States institution of higher education,
- an academic teaching hospital,
- a medical center, or
- a research institute affiliated with a United States Institution of Higher Education.

11. **Foreign Financial Interests** – Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure which is \$0.

DISCLOSURE REQUIREMENTS

At the time of application, the Principal Investigator and all other individuals who meet the definition of "Investigator" must disclose their SFIs to Dominican University's designated official. Any new Investigator who, after applying to NIH for funding from NIH or during the research project, plans to participate in the project must similarly disclose their SFI(s) to the designated official promptly and before participation in the project.

Each Investigator who is participating in research under an NIH award must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to Dominican University according to this Policy or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on an NIH-funded project directly as an NIH Grantee and/or indirectly through a sub-award that was transferred from another Institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator participating in PHS/NIH-funded research must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). In addition, Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

[Disclosures should be made via the Dominican FOCI and SFI Disclosure Form](#)

REVIEW OF SFI DISCLOSURES BY DOMINICAN UNIVERSITY’S DESIGNATED OFFICIAL

The designated official will conduct reviews of SFI disclosures. The designated official will review any SFI that has been identified in a disclosure; these interests will be compared to each PHS/NIH research application and/or award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the PHS/NIH-funded research and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award. The designated official at Dominican University is the Associate Vice President, Finance & Controller, Business Office, Doris Dumas.

GUIDELINES FOR DETERMINING “RELATEDNESS” OF SFI TO PHS/NIH-FUNDED RESEARCH AND A FINANCIAL CONFLICT OF INTEREST

Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board, etc.);
For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document;
Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
Modification of the research plan;
Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
Reduction or elimination of the financial interest (e.g., sale of an equity interest);
Severance of relationships that create financial conflicts .

If the designated official determines that a conflict exists, it will communicate its determination and the means it has developed for managing the FCOI in writing to the individual, to the relevant Principal Investigator/Project Director, and to the appropriate direct supervisor.

No expenditures on an NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the designated official necessary to manage the Financial Conflict of Interest. The designf1 0 0 1 4(c)-13(i)7(a)7(l)7(n)-20(e)7(c)7(e)7(s)-6(s)-6(a)7(ry t)7(o)-20(m)-13(a)713(81.775 43165 555.4

- E. The approximate dollar value of the Significant Financial Interest in the following ranges: \$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.

If Dominican University uses a publicly accessible website to comply with the public disclosure requirements of the NIH regulations, the information posted will be updated at least annually and within sixty days of receipt or identification of information concerning any additional Significant Financial Interest of the senior/key personnel for the NIH-funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the NIH-funded research project, if it is determined by the designated official that the Significant Financial Interest is related to the research and is a financial conflict of interest.

Information concerning an individual's SFI, as limited by this Policy, will remain available for responses to written requests or for posting via Dominican University's publicly accessible web site for at least three years from the date that the information was most recently updated.

REPORTING OF FINANCIAL CONFLICTS OF INTEREST

Before the expenditure of any funds under an award funded by NIH, Dominican University will provide NIH a FCOI report compliant with NIH regulations regarding any Investigator's Significant Financial Interest found to be conflicting, and will ensure that the Investigator has agreed to and implemented the corresponding management plan.

Dominican University will assign an institutional official to serve as the FCOI SO within the eRA Commons FCOI Module. The FCOI SO has the authority to submit FCOI reports to the NIH. The FCOI Module User Guide is available at Financial Conflict of Interest User Guide (nih.gov).

While the award is ongoing (including any extensions with or without funds), Dominican University will provide NIH with an annual v8-6(i)7(t)7(h or w)-7(i)7(t)7(hout)7(funds)-6(), D)-6(om)7(i)7(ni)7

Additional information on FCOI reporting can be found under this reference: Types of FCOI Reports Summary Chart for NIH and is available at required FCOI reports through era commons.

TRAINING REQUIREMENTS

- o Dominican University's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, Dominican University shall submit FCOI reports annually to NIH in accordance with the regulations and terms and conditions of the award agreement. Depending on the nature of the Financial Conflict of Interest, Dominican University may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of Dominican University's independent retrospective review. If bias is not found, no further action is required.

CLINICAL RESEARCH REQUIREMENTS

If HHS determines that one of its funded clinical research projects whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by Dominican University, Dominican University shall require the Investigator involved 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.

SUBRECIPIENT REQUIREMENTS

A subrecipient relationship is established when federal funds flow down from or through Dominican University to another individual or entity, and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to Dominican University for programmatic outcomes and compliance matters. Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees, are subject to Dominican University's terms and conditions, and as such, Dominican University will take reasonable steps to ensure that any subrecipient Investigator complies with the federal FCOI regulation at 42 CFR Part 50 Subpart F.

Dominican University will incorporate, as part of a written agreement with the subrecipient, terms that establish whether Dominican University's FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator(s). See the NIH Grants Policy Statement Section 15.2.1 Written Agreement at 15.2 Administrative and Other Requirements (nih.gov). If the subrecipient's FCOI policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with Dominican University that its policy complies with the federal FCOI regulation. In this situation, the agreement shall specify the period for the subrecipient to report all identified FCOIs to Dominican University in sufficient time to enable Dominican University to provide timely FCOI reports, as necessary, to the PHS/NIH as required by the regulation (i.e., before the subrecipient's expenditure of funds and within 60 days of the subrecipient's identification of an FCOI during the period of an award). Therefore, the written agreement may establish a reporting requirement of FCOIs identified during the period of an award to be submitted to Dominican University within 50 or 55 days of the subrecipient's identification of an FCOI to allow Dominican University to report the FCOI within the 60 days. The Dominican University assigned FCOI SO will submit the FCOI report (subrecipient report) to the NIH via the eRA Commons FCOI Module.

