

Financial Conflict of Interest Policy

Dascena is committed to protecting the integrity and objectivity of its research-related activities. The identification and responsible management of financial conflicts of interest (FCOI) are important for safeguarding objectivity and for compliance with federal regulations and Dascena policies.

Purpose

Dascena seeks to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. The procedures described in this policy (the "Policy") were created and designed primarily to comply with the federal PHS requirements for institutions that seek funding. This Policy was developed to be in conformance with Federal regulation 42 CFR Part 50 Subpart F (Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought) and 45 CFR Part 94 (Responsible Prospective Contractors) and to fulfil Dascena's obligation under the FCOI regulations to maintain up-to-date, written, enforced policy and processes on Investigator conflicts of interest.

Application of Policy

This Policy applies to all Investigators, including subrecipient investigators (sub-grantees, subcontractors, collaborators, contractors, or consultants) and applicable research staff and contractors who are planning to participate in or are participating in PHS funded research. Compliance with this Policy is a condition of employment and/or relationship with Dascena. All Investigators planning to or participating in PHS-funded research are required to disclose to Dascena, Inc. his/her known significant financial interests (and those of his/her spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities.

Definitions

For purposes of this Policy, the following definitions shall apply:

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Investigator means the project director or principal investigator and any other person, including senior/key personnel, who are responsible for the design, conduct, or reporting of the research or proposed research, which may include, for example, collaborators, consultants or other Investigators.

Research means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). For PHS-Funded Research, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.

Significant Financial Interest (SFI) means a financial interest consisting of one or more of the following interests of the Investigator's - or other employee's immediate family (i.e. spouse and dependent children) which reasonably appear to be related to the Investigator's Dascena project responsibilities, including:

- Publicly Traded Entities - With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock options, or other ownership interests as determined through reference to public prices or other reasonable measures of fair market value.
- Privately Held Entities - With regard to any non-publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure, in which the value when aggregated exceeds \$5,000, or when the Investigator or his/her immediate family holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual Property - Intellectual property rights and interests (e.g., patents, copyrights), must be disclosed upon receipt of income (e.g., royalties) related to such rights and interests.
- Travel expenses - Investigators must also disclose the occurrence of reimbursed or sponsored travel (which is paid on behalf of the Investigator and is not reimbursed such that the exact monetary value is not readily available) unless the sponsored travel is paid for 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, or a research institute that is affiliated with an institution of higher education. Disclosures relating to travel expenses must specify at a minimum the purpose and duration of the trip, the identity of the sponsor/organizer and the destination.

Significant financial interest does not include the following:

- Salary, royalties, or other remuneration paid by Dascena (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by Dascena, including that paid for intellectual property rights assigned or licensed to Dascena and agreements to share in royalties related to such rights;
- Any ownership interest in Dascena (or a subrecipient as applicable) held by the Investigator (e.g., Employee Stock Ownership Plan);

- 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;
- Income from seminars, lectures, or teaching engagements 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; or a research institute that is affiliated with an institution of higher education; or
- Income from service on advisory committees or review panels for 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; or a research institute that is affiliated with an institution of higher education.

Investigator Training Requirements

Investigators receive training to promote objectivity in research and must be informed about (i) this Dascena FCOI Policy, (ii) the Investigator's responsibilities regarding disclosure of significant financial interests relating to the Investigator's institutional responsibilities and (iii) the FCOI Regulations. PHS-funded Investigators must undergo training regarding items (i) - (iii) as follows:

- Immediately upon being hired by Dascena
- Prior to engaging in any PHS-funded Research and at least every four years
- Immediately when this Policy changes in a manner that affects PHS-funded Investigator disclosure or compliance requirements;
- If Dascena determines that a PHS-funded Investigator is not compliant with the FCOI Policy or an FCOI Management Plan;

The training module and other resources developed by NIH will be updated as appropriate and can be accessed through the [NIH Website](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html). (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)

Disclosure, Review and Monitoring Requirements

Disclosure Requirements

Investigators who are planning to or are currently participating in research activities that are either partially or wholly supported by PHS funds must disclose their SFI (and those of the investigator's spouse and dependent children) in a timely fashion to the Designated Dascena Official; no later than at the time of application for PHS-funded Research, at least annually during the period of the award, and within 30 days of discovering or acquiring a new SFI. The annual update will typically be done in conjunction with completion of the annual training. Such disclosures shall include any information that was not previously disclosed; any change in information regarding any previously disclosed significant financial interest; or, within 30 days of discovery or acquisition of any new significant financial interest (e.g., an interest acquired through purchase, marriage, or inheritance).

Review of Disclosures and Monitoring and Reporting Requirements

The Designated Official shall:

- Inform Dascena Investigators of their obligations under this Policy and any related regulations;
- Solicit and review SFI disclosures from Investigators and make the requisite determinations if they constitute FCOIs and take any necessary subsequent action;
 - An FCOI exists when the Institution reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research.
- Develop and implement management plans and adequate enforcement mechanisms, as needed, to manage FCOIs and take subsequent action;
- Take reasonable steps to ensure that Investigators for subrecipients (e.g., subgrantees, subcontractors, or collaborators) fully comply with this Policy or provide Dascena with sufficient assurances to enable Dascena's compliance with all applicable laws or regulations;
- Maintain records relating to all Investigator disclosures of financial interests and the Dascena's review of, and response to, such disclosures;
- Provide FCOI reports to the PHS Awarding Component regarding all FCOI of all subrecipient Investigators prior to the expenditure of funds or, with respect to an ongoing PHS-funded project, within 60 days of the disclosure or discovery of a significant financial interest;
- Based on the FCOI management plan, the Designated Official will submit initial, annual (i.e., ongoing) and revised FCOI reports to the PHS Awarding Component; and

Management of Financial Conflicts of Interest

The management plan will include appropriate steps to manage, reduce, or eliminate the conflict of interest to ensure, to the extent possible, that the design, conduct and reporting of Research will be free from bias.

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

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the Research);
- For Research involving human subjects, disclosure of financial conflicts to research participants;
- Monitoring of the research by independent reviewers;
- Modification of the research plan;
- Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the Research;
- Reduction or elimination of the financial interest; and/or
- Severance of relationships that create such conflicts.

Noncompliance and Remedies and Enforcement Mechanisms

If an Investigator has failed to comply with a management plan or, for whatever reason, an FCOI was not identified, reviewed or managed in a timely manner, the Designated Official shall, within 120 days of the determination of noncompliance, conduct a retrospective review. The retrospective review will determine whether there was bias in the design, conduct, or reporting of the PHS-funded research, or portion thereof, conducted prior to the identification and management of the conflict. The review shall be documented consistent with the FCOI Regulations [§60.605(a)(3)(ii)(B)]. If bias is found, Dascena will promptly notify the PHS Awarding Component and submit a mitigation report consistent with the FCOI Regulations [§60.605(a)(3)(iii)]. If appropriate, the Designated Official will update the previously submitted FCOI report. In any event, the Designated Official shall submit FCOI reports annually thereafter.

If the Department of Health and Human Services (HHS) determines that a clinical PHS-funded research project 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 neither disclosed nor managed, Dascena shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

Enforcement Mechanisms

All researchers to whom this Policy applies are expected to fully and promptly comply with it. The Designated Official may impose sanctions for noncompliance which may include, but is not limited to, the following: failure to make timely, full or accurate disclosures; failure to provide information requested; failure to update a disclosure form as necessary; or failure to comply with a management plan.

For Dascena employees, sanctions may include suspension or dismissal, denial of eligibility to engage in the research at issue or other appropriate penalties. Such sanctions may require giving notice of relevant information to funding agencies, professional bodies or journals, or the public. The Designated Official will determine what sanctions, if any, are to be applied.

Public Accessibility Requirements

Prior to expending any funds under a PHS-funded grant or cooperative agreement, Dascena shall ensure public accessibility by posting this Policy on a publicly available website or providing a written response to any written request as required under the FCOI Regulations [§50.605(a)(5)(ii), (iii), (iv)].

Maintenance of Records

The Designated Official shall maintain all disclosure forms and related records of determinations made and actions taken for a period of three years from the date of submission of the final expenditures report to the PHS (or, where applicable, from other dates specified in 45 C.F.R. 75.361 (see FAQ A.11) for different situations).

Confidentiality

Dascena will, to the extent possible, protect the confidentiality of disclosures. In every instance, Dascena will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and manage conflicts of interest. Disclosures will be available to Dascena staff only on a need-to-know basis and will not be disclosed outside of Dascena unless necessary to comply with contractual, legal, or regulatory requirements.