

**CREARE
CORPORATE POLICY & PROCEDURE**

CPP-009
November 24, 2020

TO: RJK
FROM: HGARDNER, DDUCHARME
CC: PJM
SUBJECT: **CREARE POLICY ON FINANCIAL CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE-FUNDED RESEARCH**

1 STATEMENT OF PURPOSE AND MANAGEMENT COMMITMENT

Creare management is strongly committed to promoting objectivity in research. This policy (“Policy”) implements federal disclosure requirements pertaining to objectivity in research promulgated by the U.S. Public Health Service (“PHS”) in 42 CFR Part 50 and 45 CFR Part 94. These federal regulations require Creare to maintain an appropriate written policy on financial conflict of interest (“FCOI”) disclosure as a condition to receiving PHS-funded grants and contracts.

This Policy is enacted to:

- Establish standards that provide a reasonable expectation that research projects are designed, conducted, and reported objectively by managing financial conflicts of interest that may occur between an investigator’s personal financial interests and Creare’s research interests under PHS grants and contracts.
- Establish a Creare Financial Conflict of Interest (FCOI) Board responsible for enforcing the Policy.
- Establish a process of disclosure and independent review when an investigator has Significant Financial Interest(s). When Creare, through its FCOI Board, determines that such an interest might reasonably appear to affect the research directly and significantly, Creare will take steps to manage the conflict.
- Inform investigators of their responsibilities under the Policy.
- Facilitate financial conflict of interest training for all affected investigators.

2 APPLICABILITY

This Policy applies to research projects for which Creare submits a proposal to, or receives research funding from, PHS (either as a prime applicant or subrecipient). This Policy sets forth requirements that each investigator who participates in such research must follow, provided,

however, that this Policy does not apply to SBIR/STTR Program Phase I applications.¹

3 DISCLOSURE OF FINANCIAL INTERESTS

When an investigator applies for research for potential funding by the PHS, the investigator must complete a Creare Significant Financial Interest (“SFI”) disclosure form. If the investigator has an SFI (as defined below) the SFI must be disclosed on the disclosure form, detailing the interest, as required. When an investigator does not have an SFI, the investigator must still complete the disclosure form upon submission of an application for PHS-funded research, but can check the box stating that no SFI exists.

During the period of the PHS-funded research project, each investigator who previously disclosed an SFI must update their financial disclosures by completing a new disclosure form annually; if an investigator acquires any new SFIs that have not been previously disclosed, the investigator must submit an updated disclosure form within 30 days.

4 DEFINITIONS

4.1 FCOI BOARD

A Board consisting of the Creare President (the Chair), Vice President, and Contracts Manager that is responsible for overseeing investigator and subrecipient compliance with this Policy, establishing a management plan for FCOIs, and ensuring that reporting obligations are fulfilled.

4.2 FINANCIAL CONFLICT OF INTEREST (FCOI)

A Financial Conflict of Interest (FCOI) is an SFI that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

4.3 INVESTIGATOR

An investigator is any individual responsible for the design, conduct, or reporting of research funded by the PHS. This includes the Principal Investigator, co-investigators, and any other individual, regardless of title or position, who is responsible for designing, conducting, or reporting of this research.

4.4 INVESTIGATOR’S PROFESSIONAL RESPONSIBILITIES

For Creare-employed investigators, the investigator’s professional responsibilities on behalf of Creare include the conduct of research (including hardware/software design, prototype construction, experimental testing, modeling/simulation, and project management), business development, and corporate services/management.

¹ This Policy applies to all Creare-employed investigators. If Creare conducts PHS-funded research through a subrecipient (e.g., subcontractor or consortium member), Creare requires that the subrecipient certify that it has a financial conflict of interest policy compliant with 42 CFR Part 50 and 45 CFR Part 94. If the subrecipient cannot certify that it has a PHS-compliant financial conflict of interest policy, the subrecipient shall be required to follow this Policy in its entirety.

For subrecipients, the investigator's professional responsibilities on behalf of the employing entity, as so defined by that entity.

4.5 RESEARCH

Research means a systematic investigation, study, or other research and development work designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research (e.g., engineering analyses, a technical published article or progress report), and product development (e.g., prototype and technology development).

4.6 SIGNIFICANT FINANCIAL INTEREST (SFI)

Creare applies the definition of an SFI as promulgated by the U.S. Public Health Service (PHS) in 42 CFR Part 50 and 45 CFR Part 94. See Section 5 below for more details.

5 INVESTIGATOR'S RESPONSIBILITY—DISCLOSURE REQUIREMENT

5.1 GENERAL RESPONSIBILITY

Each investigator has the responsibility of reporting an SFI to the Creare FCOI Board. Unless an exemption applies, as defined below in Section 6, an SFI means any interest of the investigator (including the investigator's spouse and dependent children), with respect to:

- Publicly traded entities.
- Non-publicly traded entities.
- Intellectual property rights and interests.
- Reimbursed travel, which reasonably appears to be related to the investigator's professional responsibilities.

5.1.1 Publicly Traded Entities

An SFI exists if the value of any remuneration received by the investigator from the entity in the 12 months preceding the disclosure to the FCOI Board and the value of any equity interest in the entity, as of the date of disclosure, when aggregated, exceeds \$5,000.²

5.1.2 Non-Publicly Traded Entities

An SFI exists if the value of any remuneration received by the investigator from the entity in the 12 months preceding the disclosure to the FCOI Board, when aggregated, exceeds \$5,000, or when the investigator holds any equity interest (e.g., stock, stock option, or other ownership interest).³

² For purposes of this section, 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 option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

³ *Ibid.*

5.1.3 Intellectual Property Rights and Interests

An SFI exists in intellectual property rights and interests (e.g., patents, copyrights), upon the investigator's receipt of income related to such rights and interests. For Intellectual Property Rights and Interests that are not exempt from disclosure requirements (see Section 6 Exemptions, below) there is no *de minimis* value initiating the disclosure requirement.

5.1.4 Reimbursed or Sponsored Travel

Investigators must disclose to the FCOI Board the occurrence of any reimbursed or sponsored travel expenses related to their investigator's professional responsibilities, other than travel reimbursed by Creare. For reimbursed or sponsored travel that is not reimbursed by Creare, or otherwise exempt from disclosure requirements (see Section 6 Exemptions, below), there is no *de minimis* value initiating the disclosure requirement.

5.2 THE DISCLOSURE REQUIREMENT

Each investigator planning to participate in PHS-funded research is required to disclose to the Creare FCOI Board the investigator's SFIs (and those of the investigator's spouse and dependent children) no later than at the time of application for PHS-funded research. Each investigator must do so by completing the Creare SFI disclosure form.

During the period of the PHS-funded research project, each investigator who previously disclosed an SFI must update his or her financial disclosures by completing a new disclosure form annually. If an investigator discovers or acquires any new SFIs that have not been previously disclosed, the investigator must submit an updated disclosure form within 30 days of the discovery or acquisition.

The FCOI Board is responsible to ensure that procedures are in place to require each sub-recipient (i.e., consultant, consortium member) to certify that it has an FCOI Policy that complies with 42 CFR Part 50 and 45 CFR Part 94 and to notify Creare whether it has identified any FCOIs with respect to the PHS-funded research at the time of application and then either annually within the period of the award, or within 30 days of discovering or acquiring a new FCOI that was not originally reported to Creare.

If a subrecipient does not have its own FCOI Policy, the investigator will disclose identified SFIs to Creare, at the appropriate times as prescribed under 42 CFR Part 50 and 45 CFR Part 94, from filing of the application through the period of the PHS-funded research project. See Section 7.5.

6 SIGNIFICANT FINANCIAL INTEREST (SFI) EXEMPTIONS

The term SFI does not include the following types of financial interests. These interests do not need to be reported by the investigator to the FCOI Board as SFIs:

- A. Salary, royalties, travel expenses, bonuses, or other remuneration paid by Creare to the investigator if the investigator is currently employed by Creare.

- B. Intellectual Property rights assigned by the investigator to Creare, as per the Creare Confidentiality, Innovation, and Professional Conduct Agreement.
- C. Income from investment vehicles, such as mutual funds (including the Creare-sponsored 401(k) retirement plan), where the investigator (or spouse/dependent children) does not directly control the investment decisions made in these vehicles.
- D. Income related to serving on a university, industry, or trade advisory committee or review panel.
- E. Travel reimbursed by the Government, a university, or industry group sponsoring the investigator's participation in an event that is unrelated to the investigator's professional responsibilities under this Policy.
- F. Any ownership interest in Creare held by the investigator.

7 RESPONSIBILITIES OF THE FCOI BOARD

7.1 INFORMING INVESTIGATORS OF FCOI POLICY

Prior to Creare's submission of an application for PHS-funded research, and for each new investigator added to the project, the Creare FCOI Board will ensure that procedures are in place to provide each investigator:

- A copy of Creare's FCOI Policy.
- An SFI disclosure form and ensure that each investigator completes the form.

7.2 REVIEW OF DISCLOSURES OF SFIS AND MANAGEMENT OF FCOIS

7.2.1 Review and Management

Prior to Creare's expenditure of any funds under a PHS-funded research project, the Creare FCOI Board Chair will:

- Review all investigators' SFI disclosure forms.
- Determine whether any SFI relates to PHS-funded research.
- Determine whether an FCOI exists.
- In conjunction with other Board members, develop and implement a management plan that specifies the actions that have been and will be taken to manage such an FCOI, should an FCOI be found.

The FCOI Chair and Board will, within 60 days, perform the same above steps whenever in the course of an ongoing PHS-funded research project an investigator who is new to participating in the research project discloses an SFI; an existing investigator discloses a new SFI; or the Creare FCOI Board identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Creare FCOI Board. In the case of an SFI that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed by the Creare FCOI Board, and the FCOI Board determines that the SFI is an FCOI, the Board will, within 120 days of the determination of noncompliance, complete and document a

retrospective review of the investigator'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. If bias is found, the FCOI Board will promptly notify the PHS Awarding Component as specified below and submit a mitigation report.

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

- Public disclosure of the FCOI;
- Oversight of the FCOI Board, or its duly appointed agent, including taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Replacement of an investigator with an FCOI, or revision of the investigator's responsibilities involved with the research; disqualification of the investigator from participation in all or a portion of the research; or other removal of the FCOI.

7.3 RECORD KEEPING RESPONSIBILITIES

On behalf of the FCOI Board, the Contracts Department will retain records regarding each investigator's SFI disclosure, the FCOI Board's official determinations, and actions regarding management of an FCOI for a minimum of three (3) years beyond the date of the final expenditure report submitted to PHS under an award.

7.4 PUBLIC ACCESSIBILITY

The FCOI Board will ensure accessibility of Creare's Policy by making it available to the public on the Creare website.

In those instances where the FCOI Board has determined there to be an FCOI, prior to the expenditure of funds under the affected PHS-funded project, the FCOI Board will ensure that the information required to be publicly disclosed by the U.S. Public Health Service (PHS) in 42 CFR Part 50 and 45 CFR Part 94 has been made available to the public on the Creare website. The information regarding FCOIs will be maintained and updated on the Creare website as required by the PHS in 42 CFR Part 50 and 45 CFR Part 94.

7.5 COMPLIANCE OF SUBRECIPIENT

The Creare FCOI Board has established internal procedures to ensure that a subrecipient (i.e., consultant or consortium member) that participates in PHS-funded research projects follow its official FCOI Policy pertaining to PHS-funded research. If the subrecipient does not have an official FCOI Policy, the subrecipient is subject to all aspects of this Policy beyond certification and reporting of FCOIs.

7.6 FCOI REPORTING RESPONSIBILITIES

7.6.1 Initial FCOI Report

Prior to Creare's expenditure of any funds under a PHS-funded research project, Creare will provide to the PHS awarding component an FCOI report regarding any investigator's SFI found by the Creare FCOI Board Chair to be an FCOI, and ensure that Creare has implemented a management plan to adequately manage the conflict.

In cases where the Creare FCOI Board has identified an FCOI and eliminated it prior to the expenditure of PHS-awarded funds, Creare does not need to submit an FCOI report to the PHS awarding component.

7.6.2 Subsequent FCOI Reports and Updates

For any SFI that the Creare FCOI Board identifies as an FCOI after the FCOI Board's initial FCOI report has been filed with the PHS awarding component during an ongoing PHS-funded research project, Creare will provide to the PHS awarding component an additional FCOI report regarding the newly identified FCOI within 60 days of the FCOI Board's finding. Based on the results of a retrospective review, Creare will provide to the PHS, if appropriate, an updated version of a previously submitted report within 120 days of the FCOI Board's determination of noncompliance.

During the period of performance of the PHS-funded research project, updated FCOI reports will be submitted annually to the PHS awarding component to report the status of the FCOI and any changes made by the FCOI Board with respect to management of the FCOI.

7.6.3 Contents of FCOI Report

Any FCOI report required will include sufficient information to enable the PHS awarding component to understand the nature and extent of the financial conflict, and to assess the appropriateness of Creare's management plan. Specific elements of the Creare FCOI report filed will comply with the requirements of 42 CFR Part 50 and 45 CFR Part 94.

7.6.4 Notification of Bias and Submission of Mitigation Report

If a retrospective review is required for the reasons set forth in Section 7.2.1 and bias is found, the FCOI Board shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

7.6.5 Internal Procedures

The FCOI Board has established internal procedures to ensure that the certification requirements of 42 CFR Part 50 and 45 CFR Part 94 will be provided to the PHS awarding component prior to award of PHS-funded research.

The FCOI Board has established internal procedures to ensure that the reporting of FCOIs for all investigators and subrecipients to the PHS awarding component will follow the requirements of 42 CFR Part 50 and 45 CFR Part 94.

7.7 INVESTIGATOR FCOI TRAINING

The FCOI Board requires that each investigator complete FCOI training.

FCOI training is required:

- Prior to engaging in PHS-funded research.
- At least every four years from the initial training.
- Within 30 days after Creare's FCOI Policy has been revised in a manner that affects investigator requirements, or upon a finding by the Creare FCOI Board that the investigator has been noncompliant with respect to Creare's FCOI Policy.

8 ENFORCEMENT OF THIS POLICY

Failure to comply with this Policy, including failure of an investigator to file a complete or timely SFI disclosure form to the Creare FCOI Board, or to update or to comply with any conditions or restrictions imposed on the conduct of PHS-funded research under this Policy (including a management plan) will be grounds for discipline up to and including termination.

If the failure of an investigator to comply with this Policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, Creare will promptly notify the PHS awarding component of the corrective action taken or to be taken. PHS awarding components may impose special award conditions or may suspend or terminate an award, or take other actions, should noncompliance with this Policy be found.

10CONTR.00.003/kwhite