

Medical Care Corporation Financial Conflict of Interest (FCOI) Policy

Revised: January 1, 2021

PURPOSE

Medical Care Corporation (“MCC”) conducts research and development activities which are often supported by small business grants from federal agencies. The purpose of this Financial Conflict of Interest (FCOI) policy is to document and define our standards and procedures for identifying and managing financial conflicts of interests to safeguard the integrity of research conducted by MCC and our subawardees and contractors.

This policy has been developed to comply with the following regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, [Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought](#).
- Title 45 Code of Federal Regulations (CFR), Part 94, [Responsible Prospective Contractors](#).

This policy will be publicly available on the MCC website at:

<http://mccare.com/innovation/randd.html>

SCOPE

This policy applies to investigators participating in, or planning to participate in, the design, conduct, or reporting of research and research proposals. This policy does not apply to research and development conducted under Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) awards.

For federally-supported research projects involving subawardees or contractors (collectively “subrecipients”), the subrecipient institutions are required to provide written assurance that a FCOI policy is in effect that is compliant with all applicable federal regulations, or that the subrecipient will conform to and abide by MCC FCOI policy and procedures.

TRAINING REQUIREMENTS

MCC and all participating subawardees and contractors are required to complete training related to FOCI. If any conflicts of interest are found or known, they are required to be disclosed. FCOI training must be updated no less than every three years or as designated based on specific grant requirements or project role.

MCC FCOI training is conducted through the [NIH Financial Conflict of Interest Tutorial](#) available through the National Institutes of Health (NIH), which was designed to provide education training on what constitutes financial conflict of interest. Upon completion of the training tutorial, a certificate completion is generated, which must be turned in to the Chief Financial Officer (CFO).

SIGNIFICANT FINANCIAL INTEREST (SFI)

Significant Financial Interest is defined by federal regulations as:

1. A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse and dependent children) that reasonable appears to be related to the Investigators institutional responsibilities:
 - a. 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 the 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 in stock, stock options or other ownership interest, as determined through reference to public prices and other reasonable measures of fair market value;
 - b. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remunerations from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interests (e.g. stock, stock options, or other ownership interest) or
 - c. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (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 their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is 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, medical center, or research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS-funded research.
3. The term significant financial interest does not include the following types of financial interests: salaries, royalties or other remuneration paid by the institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the investigator, if the Institution is a commercial or for profit organization; income from investment vehicles, such as mutual funds and retirements 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, 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.

FINANCIAL CONFLICT OF INTEREST (FCOI)

A Financial Conflict of Interest exists when MCC reasonably determines that a SFI (as defined above) could directly and significantly affect the design, conduct, or reporting of federally-funded research.

REPORTING PROCESS

It is the responsibility of the Principal Investigator (PI) of a research project to identify all participating Investigators who have a SFI which would require disclosure under this policy. It is also the responsibility of the PI to conduct an annual review to identify any new SFI or to update existing disclosures.

All Investigators with an identified SFI must prepare and submit a SFI Disclosure Form ("Disclosure") to MCC' designated FCOI official(s), who will review all disclosures and evaluate whether an applicable FCOI exists. If no FCOI is determined, the SFI Disclosure Form will be kept on file by the CFO. If a FCOI is identified prior to the start of the research project, an FCOI report will be submitted to the awarding agency prior to expending any funds. If any FCOI is subsequently identified during the course of the research project, MCC will submit an FCOI report to the awarding agency within 60 days of receiving the disclosure. If it is found that an investigator conducted or participated in research with an undisclosed FCOI, MCC is required to disclose the FCOI in all public presentations of the results of the research.

MANAGEMENT OF IDENTIFIED FCOI

When MCC' designated FCOI official(s) determines that a FCOI exists, steps will be taken to reduce or eliminate the FCOI to ensure that the design, conduct, and reporting of research will be free from bias to the maximum extent possible. A management plan may be required to establish terms, conditions, and restrictions to ensure compliance with this policy. A management plan may require one or more of the following actions:

- Public disclosure of significant financial interests;
- Review of research protocols by independent reviewers;
- Monitoring of research by independent reviewers;
- Modification of research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divestiture of significant financial interests;
- Severance of relationships that create actual or potential conflicts

All management plans are required to be signed by the Investigator and the CFO, and compliance to the management plan will be monitored by the CFO.

ENFORCEMENT OF FCOI POLICY

If an Investigator fails to comply with MCC' FCOI policy, the CFO will make recommendations to the Board of Directors regarding the imposition of sanctions, disciplinary proceedings, or termination of the Investigator. In addition, MCC will follow federal regulations regarding the notification of the awarding agency if an Investigator has been found to have violated this policy. The federal agency may take subsequent action as appropriate, including suspension of funding for the Investigator until FCOI compliance is resolved.

RECORD KEEPING

Investigator SFI disclosure, records of FCOI determinations, and FCOI management plans will be retained by the CFO for three (3) years from the date the final expenditures report is submitted to the awarding agency.

POINT OF CONTACT

If you have a conflict of interest to report or have a question regarding the FCOI policy, contact MCC' FCOI Official:

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