

# **MFI Financial Conflict of Interest Policy**

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## 1.0 Introduction

### 1.1. SCOPE:

MFI's financial conflict of interest (FCOI) policy covers all projects conducted with government funds in MFI and is applicable to all employees, sub recipients, consultants, or any other covered organizations or persons involved in governmental awards.

### 1.2. PURPOSE:

Under this policy, MFI strives to ensure that all work performed under Government Awards meets the highest standard of integrity and is free of any real or perceived conflicts of interest that could harm patients, the reputation of MFI, the governmental agency providing the funding, and/or external partners. As MFI must comply with government regulations when making expenditures with Government Awards, this policy governs the disclosure of individual financial interests and the management and reporting of individual financial conflicts of interest in Governmental Awards. It is intended to comply with the requirements of federal regulations, including , but not limited to, the conflict of interest regulations of the U.S. Department of Health and Human Services Public Health Service ("the PHS FCOI Rules") as found in 42 CFR Part 50 Part F (titled Promoting Objectivity in Research) and 45 CFR Part 94 (titled Responsible Prospective Contractors) and the Federal Acquisition Regulation FAR 52.203-16 (collectively referred to as the "Financial Conflict of Interest Rules").

### 1.3. DEFINITIONS:

**Conflict Management Plan (CMP):** the document specifying the actions to be taken to manage a Financial Conflict of Interest.

**Conflict of Interest Official:** the MFI official responsible for managing conflicts of interest. The conflict of interest official is typically the MFI Signing Official for Government Awards; however, another MFI official may be appointed as acting conflict of interest official to manage conflicts involving the SO.

**External Partner:** a consultant, subcontractor, or sub-recipient performing work under a Government Award who is not employed by MFI

**Government Award:** government grants and cost reimbursement contracts including research grants or contracts, and other types of government financial assistance (e.g., cooperative agreements, loans, loan guarantees, property, donated supplies, and direct appropriations) that MFI receives directly from government agencies or indirectly from pass through entities. (At MFI, Government Awards are commonly referred to as "Sponsored Projects.") Government Awards do not include procurement contracts, payments for health care services provided under government health care programs (e.g., Medicare, Medicaid) or Medical Education and Research Costs (MERC)).

**Financial Conflict of Interest (FCOI):** a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of a research study or other government funded project.

**Immediate Family Member:** a spouse, domestic partner, child or step-child, parent or step-parent, or sibling or step-sibling.

**Investigator:**

(1) For PHS-funded research: the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

(2) For other Government Awards: project staff directly involved in management of the project or who hold key responsibilities on the Government Award. Typically, these would be individuals specifically named to a Government Award or whose participation is key to the success of the project.

**Institutional Responsibilities:** An Investigator's professional responsibilities on behalf of MFI, which may include, but is not limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**Public Health Service (PHS):** a division of the Department of Health and Human Services, consisting of the following agencies: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA).

**Research:** 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.

**Remuneration:** salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorships).

**Significant Financial Interest:**

(1) A financial interest consisting of one or more of the following interests of the Investigator or their Immediate Family Member that reasonably appears to be related to the Investigator's Institutional Responsibilities:

(i) the value of any remuneration received from a public 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; or

(ii) the value of any remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or their immediate family) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators must disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities. The disclosure will include, at a minimum, the following details: (i) the purpose of the trip; (ii) the identity of the sponsor/organizer; (iii) the destination; and (iv) the trip duration. (This disclosure requirement does not apply to travel that is reimbursed or sponsored by MFI itself, or by a federal, state, or local government agency, an

institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.)

(3) A significant financial interest does not include the following:

- Salary, royalties, or other remuneration paid by MFI to the Investigator if the Investigator is currently employed or otherwise appointed by MFI;
- Intellectual property rights assigned to MFI 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;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined in 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; and
- Income from service on advisory committees or review panels for a federal, state, or local government agency, or 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.

**Signing Official (SO):** The signing official is the official at MFI that has signature authority on applications for government awards and other research-related agreements with external organizations. The SO is the conflict of interest official at MFI.

## **2.0 POLICY:**

It is the policy of MFI to comply with the Financial Conflict of Interest Rules (FCOI Rules) to ensure that the work performed under Government Awards is carried out in a manner that is free from any bias which may result from financial conflicts of interest. All Investigators for Government Awards must disclose any Significant Financial Interests (SFI) to MFI.

Investigators must complete or update a disclosure survey at least annually during the period of the award and must disclose any new SFI's within thirty days of discovering or acquiring the SFI. Investigators also must ensure that the disclosure survey is completed or updated no later than the time of application for a Government Award.

If MFI determines that a SFI constitutes a Financial Conflict of Interest (FCOI), MFI will establish and monitor a Conflict Management Plan (CMP) to manage or eliminate the conflict of interest. The MFI signing official (SO) for Government Awards will be the conflict of interest official responsible for managing the FCOI process for Government Awards. No Government Award funds may be expended unless the conflict of interest official has determined either that no FCOI exists or that any FCOI is manageable in accordance with the terms of a CMP that has been adopted and implemented in accordance with the procedures set forth in this policy.

### **2.1. Duty to Cooperate**

If the conflict of interest official requests additional information from an Investigator to assess whether a SFI constitutes a Financial Conflict of Interest, (including but not limited to documents relating to the SFI), the Investigator must cooperate with the request. If a CMP is implemented in connection with a SFI, the Investigator must comply with the CMP. Compliance with the requirements of this policy is a condition of employment with MFI for employed Investigators and a condition of participating in Government Award projects as an External Partner. Failure to comply may result in appropriate sanctions.

### **2.2. Education**

Investigators must complete training regarding this policy and the applicable regulations at the following times:

- (i) upon becoming an Investigator for MFI;
- (ii) before performing work under a Government Award;
- (iii) when this policy is revised to alter the responsibilities of an Investigator; and
- (iv) at least every four years.

### **2.3. Public Posting of Policy**

This policy will be posted on a publicly accessible Internet site for MFI.

### **2.4. Reporting of Financial Conflicts of Interest for PHS-Funded Projects**

Before the expenditure of any funds under a PHS-funded project and within sixty days of subsequently identifying a Financial Conflict of Interest, the conflict of interest official will report all Financial Conflicts of Interest that have not been eliminated to the PHS awarding component and will ensure that an appropriate Conflict Management Plan has been implemented. The report will include the elements required under the PHS FCOI Rules. For subsequently identified FCOI's, the conflict of interest official will conduct a retrospective review to determine whether the PHS-funded project was affected by the financial conflict of interest, and if bias is

found, will submit a mitigation report to the PHS awarding component. The conflict of interest official also will provide an annual FCOI report that addresses the status of any previously reported FCOI's and CMP's related to an ongoing PHS-funded project.

## **2.5. External Partners**

Any individual or organization acting as a consultant, subcontractor, or subrecipient ("External Partner") to MFI on a PHS-funded award must either:

- (1) have a FCOI policy that meets the requirements of the PHS FCOI Rules; or
- (2) follow this policy.

### **2.5.1. External Partners With Their Own Policy**

Organizations with their own policy will certify that the policy meets the requirements of the PHS FCOI Rules by registering with the FDP Clearinghouse <https://fdpclearinghouse.org/> before submission of the Government Award. The conflict of interest official will verify registration with the FDP Clearinghouse before submission.

- The contractual agreement with MFI shall contain language requiring compliance with the partner organization's FCOI Policy.

### **2.5.2. External Partners *Without* Their Own Policy**

Individuals and organizations without their own FCOI policy are required to follow MFI's FCOI policy.

- The contractual agreement with MFI shall contain language requiring compliance with MFI's FCOI Policy.

### **3.0 MFI's FCOI Procedure**

This procedure is for use by MFI officers, employees, and External Partners that do not have their own FCOI policy.

#### **3.1.1. Training**

Before the expenditure of funds under a Government Award, Investigators must complete the training on MFI's Government Awards FCOI Policy. All external investigators must complete FCOI training required under the policy. Training shall be completed using the NIH FCOI tutorial found at:

<https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

#### **3.1.2. Training Certification**

Training must be documented by submitting the Government Award FCOI Training Certification form to the MFI conflict of interest official. The required training is valid for four years; however, Investigators are required to certify annually that they understand and have complied with their responsibilities under MFI's Government Awards FCOI Policy.

#### **3.1.3. FCOI Disclosure**

After the training is completed, the Investigator will complete the FCOI Disclosure (section 6.0). This survey must be completed no later than the time of application for a Government Award and before any funds are expended. It also must be updated as required by the policy.

#### **3.1.4. Government Award Approval Form**

The principal investigator/project director will complete the Government Award Approval Form (section 5.0), which requires verification that those meeting the definition of Investigator and External Partners have been informed of the requirement to comply with this policy.

#### **3.1.5. Sponsored Travel**

The Investigator must report and update their Government Award FCOI Questionnaire when he/she is a recipient of sponsored travel. The Investigator will disclose: the purpose of the trip; the name of the entity that paid for the travel; the travel destination; the duration of the trip; the dates of the travel; and if known, the approximate value of the Sponsored Travel.

#### **3.1.6. Conflict Management Plan (CMP)**

If the conflict of interest official determines a FCOI exists, he/she will create a draft CMP. The draft CMP will be presented to the Research Compliance Oversight Committee (RCOC) for consideration and approval. The RCOC is comprised of MFI officers and will act as the Conflict of Interest Committee for purposes of Government Awards.

### **3.1.7. CMP Oversight**

The actions taken by the RCOC will be documented in the RCOC meeting minutes. The conflict of interest official will ensure that CMP's are properly implemented and will monitor compliance with CMP's on an ongoing basis. The RCOC will review the status of established CMP's at intervals determined by the RCOC and indicated in the CMP, and will have oversight responsibility for the enforcement of CMPs and compliance with this policy.

### **3.1.8. Compliance**

Each Investigator under a CMP must comply fully and promptly with the CMP, and each person identified in the CMP as having responsibility for monitoring compliance with the CMP must carefully and fully monitor that compliance.

### **3.1.9. Disclosure to PHS Awarding Component**

For PHS-funded projects, the conflict of interest official will disclose the FCOI and CMP to the PHS awarding component before the expenditure of any federal funds.

### **3.1.10. Available Upon Request**

For PHS-funded projects, MFI will make FCOI information available to those who submit a request by sending an email to [service@MFIimage.com](mailto:service@MFIimage.com). Responses will be sent within five business days.

### **3.1.11. Retention of Records**

MFI will keep records related to FCOI and the related CMP for the longer of at least three years after:

- the date of creation;
- the date of termination or completion of the Government Award and submission of the final expenditure report for the Government Award identified in the disclosure statement;
- the date of final resolution of any investigation, audit, or similar action involving the records; or
- the date required to be in compliance with MFI's Record Retention policies.

### **3.1.12. Policy Review**

RCOC will regularly evaluate compliance with this policy and will review the effectiveness of the SO's conflict of interest management program, including a review of the implementation and effectiveness of these procedures.

## **4.0 Procedure for External Partners with their own PHS Rule policy**

### **4.1. Notification of FCOI Requirements**

The principal investigator/project director will complete the Government Award Approval form, which requires them to inform any External Partner if they need to comply with FCOI Rules.

### **4.2. Confirmation of External Partner FCOI Policy**

Prior to any application submitted by MFI for a Government Award, the conflict of interest official must receive confirmation the External Partner has a FCOI policy that meets the PHS FCOI Rules.

The External Partner will have two options to verify they have a FCOI:

- 1) Register with the FDP Clearinghouse, <https://fdpclearinghouse.org/>. At this time, this website is acting as a central registration location for many colleges. MFI will accept this method of verification. Registration is free and you may contact the conflict of interest official if you have questions.; or
- 2) Submit the External Partner Financial Conflict of Interest Disclosure.

**5.0 Government Award Approval Form**

The principal investigator/project director for all Government Awards shall complete the form below and submit it to the MFI conflict of interest official before any funds are received for a Government Award. This serves to verify that all individuals meeting the definition of Investigator or External Partners have been informed of the requirement to comply with the MFI FCOI Policy, and that they have submitted the required disclosure.

Government Award Title: \_\_\_\_\_

Identifier / Award Number: \_\_\_\_\_

List all Investigators and External Partners, and mark either Disclosure Received or FDP Clearinghouse once verified:

Name: \_\_\_\_\_  Disclosure Received -OR-  FDP Clearinghouse Verified

(Attach additional pages as needed.)

Once FCOI compliance by all Investigators and External Partners have been verified as listed above, sign and return this form to the MFI conflict of interest official.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

(Note: PDF copy with digital signature is acceptable.)

MultiFunctional Imaging LLC

## 6.0 **FCOI Disclosure**

- Review the MFI Financial Conflict of Interest Policy
- All investigators for a Government Award must complete FCOI training at:  
<https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>,  
before working on a Government Award, and at least every 4 years thereafter.
- Disclose all potential conflicts of interest, including Significant Financial Interests, below
- Disclose any Sponsored Travel, including: the purpose of the trip; the identity of the sponsor/organizer; the destination; and the trip duration.

### **Financial Conflict of Interest (FCOI) Disclosure**

By signing this form and initialing below, I certify that the following statements are true and accurate to the best of my knowledge:

- \_\_\_\_\_ I have completed the tutorial at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.  
My certificate of completion has been submitted to the MFI conflict of interest official.
- \_\_\_\_\_ I have read and understand the MFI Financial Conflicts of Interest Policy, and I agree to abide by the policies and carry out my responsibilities outlined therein, and in the supporting federal regulations.
- \_\_\_\_\_ I will notify the MFI conflict of interest official within 30 days of any change or discovery that requires modification of the statements below, and reaffirm this disclosure annually.

### **Initial either statement below:**

- \_\_\_\_\_ I have no Significant Financial Interests pertaining to my research or other institutional responsibilities, as defined in the MFI FCOI policy; -OR-
- \_\_\_\_\_ I have the following relationships, affiliations, activities or interests (financial or otherwise), which constitute potential conflicts of interest according to MFI FCOI policy:  
(List all such relationships, including sponsored travel; attach additional pages if necessary):

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Annual Affirmation of No Changes (Initials/Date): \_\_\_\_\_

(Note: PDF copy with digital signature is acceptable.)