

**UNITED MSD FOUNDATION  
FINANCIAL CONFLICT OF INTEREST POLICY  
FOR PROMOTING OBJECTIVITY IN RESEARCH**

**Introduction**

The United MSD Foundation, Inc. (“UMSDF”) seeks excellence in the discovery of the treatment for Multiple Sulfatase Deficiency. It is the responsibility of all individuals engaged in Research at UMSDF to discharge their duties in a manner that promotes and preserves public trust, proper stewardship, and confidence in the integrity of UMSDF. The purpose of this Financial Conflict of Interest Policy for Promoting Objectivity in Research (this “Policy”) is to assure the objectivity with which Research projects are designed by identifying and managing, through a process of disclosure and review, conflicts of interest between an Investigator’s Research responsibilities and his/her personal financial interests.

This Policy is written to conform to the Public Health Service regulations regarding Financial Conflicts of Interest, 42 Code of Federal Regulations Part 50, Subpart F. These regulations require that all individuals who participate in the design, conduct, or reporting of Research funded by the Public Health Service (“PHS”) complete training on financial conflicts and disclose personal financial interests that could give rise to an actual conflict of interest or the appearance of a conflict. A copy of the full text of the regulations and the final rule implementing the regulations published in the Federal Register can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>.

**Applicability**

This Policy is applicable to each Investigators (as defined below) who is planning to participate in, or is participating in PHS research funding by means of a grant or cooperative agreement through UMSDF. Any procedures contained in this Policy that are specific to PHS supported Research shall apply to PHS funded grants or cooperative agreement with an issue date of the Notice of Award that is subsequent to May 1, 2021 and to solicitations issued and contracts awarded subsequent to May 1, 2021.

**I. DEFINITIONS**

*Disclosure of significant financial interests* means an Investigator's disclosure of significant financial interests to an Institution.

*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.

*HHS* means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

*Institution* means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

*Institutional responsibilities* means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

*Investigator* means 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.

*Manage* means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

*PD/PI* means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

*PHS* means 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).

*PHS Awarding Component* means the organizational unit of the PHS that funds the research that is subject to this subpart.

*Public Health Service Act* or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

*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). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

*Senior/key personnel* means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

*Significant financial interest* means:

(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 reasonably appears to be related to the Investigator's institutional responsibilities:

(i) 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 option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-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, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) 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 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, a medical center, or a 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 an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, 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 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.

## II. OVERVIEW

All Investigators covered by this Policy are required to disclose Financial Interests that could affect or be affected by Research on which they are working or proposing to work for or on

behalf of UMSDF. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this Policy and must undergo regular training as described herein. Any Investigator with questions regarding financial conflicts of interest or this Policy should contact UMSDF for assistance.

UMSDF will review and manage, minimize, or eliminate Significant Financial Interests to ensure that Research will be free from bias resulting from Investigator financial interests. In determining an appropriate FCOI Management Plan, UMSDF will work to achieve the following goals:

- Safeguard the integrity of UMSDF Research programs.
- Ensure that the Research project is objective and without bias in the design, conduct or reporting of the Research.
- Ensure that Research sponsors' access to UMSDF equipment, supplies and intellectual property rights is appropriate and consistent with applicable law, UMSDF policy, and UMSDF financial and reputational interests.
- Address unique circumstances and conditions that may be presented by individual cases.

As required by Federal regulations, UMSDF will report to the funding agency Financial Conflicts of Interest for PHS supported projects and provide information to the public when a written request is received. UMSDF will also take reasonable steps to ensure that any Investigators for Sub-recipients of Research comply with this Policy and any applicable Federal regulations regarding Financial Conflicts of Interest.

### III. DISCLOSURE PROCEDURES

**A. Annual Disclosure Requirements** All Investigators must report any Significant Financial Interest that reasonably appears related to the Investigator's Institutional Responsibilities on an annual basis utilizing a Significant Financial Interest Disclosure Form (the "SFI Disclosure Form").

**B. Ad Hoc and Continuing Disclosure Requirements** In addition to the annual disclosure requirements, certain situations require ad hoc disclosure. Investigators new to UMSDF must complete and submit a SFI Disclosure Form to UMSDF, within thirty (30) days of their initial employment or appointment.

All Investigators also have an ongoing obligation to update disclosures to reflect changes in or additions of Significant Financial Interests. Investigators must disclose within thirty (30) days after a new Significant Financial Interest is acquired or discovered (e.g. through purchase, marriage, or inheritance). These ongoing disclosure obligations apply to any reimbursed or sponsored travel expenses which constitute a Significant Financial Interest under this Policy. Travel expenses paid by a third party through a grant to, or a contract with UMSDF do not need to be reported.

#### C. Sponsored Research Disclosure Requirements

Prior to entering into or submitting a letter of intent, proposal or application for a sponsored Research project, Investigators or their designees are responsible for accurately completing a Proposal Disclosure Form, which details information about the study and lists UMDSF and external Investigators and Sub-recipients on the study. The Investigators will then be prompted to complete an SFI Disclosure Form.

Each year of a sponsored grant or contract, an Investigator must update his/her SFI Disclosure Form. The form must be updated at the time of the annual progress report, twelve (12) months after the notice of award, or the initiation of Research, whichever date is earliest.

#### IV. REVIEW, MANAGEMENT AND REPORTING PROCEDURES

##### A. Institutional Official Review and Responsibilities

The Institutional Official, or his/her designee, will review all SFI Disclosure Forms and will conduct a preliminary inquiry regarding any SFI Disclosure Form that identifies a Significant Financial Interest. Prior to the initiation of any inquiry, the Institutional Official will consult with the FCOI Committee and follow directions from them and other legal counsel regarding appropriate procedures to afford the maximum confidentiality and privilege protection for the investigation.

The Institutional Official will forward all SFI Disclosure Forms revealing a Significant Financial Interest to the Financial Conflict of Interest Committee (the "FCOI Committee") for review, along with the Institutional Official's recommendations as to which Significant Financial Interests warrant further inquiry to determine whether a Financial Conflict of Interest exists.

It is also the responsibility of the Institutional Official to perform the following tasks, as more fully described in this Policy:

- Conduct a preliminary investigation of any other reports of Significant Financial Interests and forward such reports to the attention of the FCOI Committee along with a recommendation as to whether the Significant Financial Interest warrants further investigation;
- Implement and manage the training of Investigators in accordance with this Policy;
- Maintain an up-to-date version of this Policy on UMDSF's publicly available Website;
- Oversee initial and ongoing reporting to PHS and other sponsors, as required;
- With respect to PHS funded projects, respond to requests from the public regarding Financial Conflicts of Interest;
- With respect to Research funded by a sponsor other than PHS, determine all requirements related to Financial Conflicts of Interest contained in the funding agreement, including sponsor reporting and Sub-recipient monitoring.
- Implement and monitor compliance with FCOI Management Plans;
- Coordinate with the FCOI Committee and the Executive Director to impose disciplinary sanctions for violations of this Policy or any FCOI Management Policy;
  - Oversee the retrospective review and related procedures if a Financial Conflict of Interest is not identified or managed in a timely manner; and
- Maintain records relating to training, disclosures, review and response under this Policy.

B. Financial Conflict of Interest Review Committee The FCOI Committee is responsible for investigating Significant Financial Interests as necessary and determining whether a Financial Conflict of Interest exists. A Financial Conflict of Interest will exist if the FCOI Committee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the Research. Per Federal regulations and this Policy, Investigators cannot make the decision about whether a Significant Financial Interest must be managed or whether it is a Financial Conflict of Interest; this determination is made through the review process. The FCOI committee will decide on the appropriate action to manage, reduce or eliminate any Financial Conflict of Interest and, with support from the Institutional Official, will develop a FCOI Management Plan if needed, as more fully described below.

It is also the responsibility of the FCOI Committee to perform the following tasks, as more fully described in this Policy:

- Review any reports made regarding Significant Financial Interests, whether made on pertinent forms or otherwise brought to the attention of the FCOI Committee;
- Request and review any additional materials needed to fully evaluate the relationship of the Financial Interest to the Research;
- Recommend whether the Significant Financial Interest requires a FCOI Management Plan to manage, reduce, or eliminate the Financial Interest and to develop such a plan with support from the Institutional Officer;
- Identify what particular Research project a Significant Financial Interest is related to and determine whether the Significant Financial Interest is a Financial Conflict of Interest that must be reported to the PHS funding agency or other sponsor, as applicable;
- With respect to Research involving human subjects, evaluate Significant Financial Interest and recommend appropriate management measures and reporting to IRB panels;
- Investigate allegations of noncompliance with this Policy or any FCOI Management Plan and work with the Executive Director, to determine corrective actions, disciplinary sanctions, and sponsor reporting, as appropriate.

### **C. FCOI Management Plans**

As appropriate, the FCOI Committee, with support from the Institutional Official, will develop plans for the management, reduction, or elimination of identified Significant Financial Interests (each a “FCOI Management Plan”). A FCOI Management Plan will focus on the steps by which the objectivity of the Research can be ensured which may include, but not be limited to:

- Public disclosure of an Investigator’s Significant Financial Interest;
- For Research involving human subjects, disclosure of Investigator Financial Interests directly to participants;
- Appointment of an independent reviewer of data, manuscripts, and/or presentations;
- Modification of any Research proposal or plan;
- Change in personnel or personnel responsibilities, or disqualification of an Investigator from participating in all or a portion of any Research;

- Reduction or elimination by an Investigator of a Financial Interest.

For any FCOI Management Plan, the affected Investigator must agree in writing to the FCOI Management Plan and the proposed management strategies contained therein before the Research goes forward.

#### **D. Research Involving Human Subjects**

Special precautions must be taken to avoid bias with respect to Research involving human subjects involving the evaluation of strategies or products that may affect or be affected by the Financial Interests of UMSDF or UMSDF Investigators. An UMSDF Investigator shall not ordinarily participate in any Research involving human subjects that encompasses evaluation of such a strategy or product if he/she has a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of the Research unless he/she presents a compelling justification for a waiver of this Policy based on his/her unique qualifications as an Investigator. The compelling justification will be reviewed by the FCOI Committee. If the FCOI Committee determines that compelling circumstances justify a waiver of this Policy, the FCOI Committee Research with support from the Institutional Official will develop a FCOI Management Plan with stringent management measures to ensure the safety of the human participants and the integrity of the Research.

For all Research involving human subjects, the outcome of FCOI Committee reviews and any recommended FCOI Management Plans will be communicated to the appropriate Institutional Review Board (IRB) for review and approval. The IRB may require additional measures to protect the safety and welfare of Research subjects under their purview.

#### **E. FCOI Reporting to Public Health Service**

Federal regulations require that UMSDF report to the funding agency Financial Conflicts of Interest related to PHS-sponsored Research. No expenditure of funding shall occur with respect to any PHS-supported Research project for which the FCOI Committee has determined that a FCOI Management Plan is required unless and until UMSDF has provided the funding agency with a FCOI Report containing the following information:

- i. Project Number
- ii. PD/PI or Contact PD/PI if multiple PD/PI model is used;
- iii. Name of the Investigator with the Financial Conflict of Interest;
- iv. Name of the entity with which the Investigator has a Financial Conflict of Interest;
- v. Nature of the Financial Interest (e.g. equity, consulting fee, travel reimbursement, honorarium)
- vi. Value of the Financial Interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value;
- vii. A description of how the Financial Interest relates to the PHS-funded Research and the basis for UMSDF's determination that the Financial Interest conflicts with such Research; and
- viii. A description of key elements of the Institution's FCOI Management Plan including:
  - a. Role and principal duties of the conflicted Investigator in the Research project;
  - b. Conditions of the FCOI Management Plan;
  - c. How the FCOI Management Plan is designed to safeguard objectivity in the Research project;
  - d. Confirmation of the Investigator's agreement to the FCOI Management Plan;
  - e. How the FCOI Management Plan will be monitored to ensure Investigator compliance; and
  - f. Other information as needed or requested by the funding agency.

For any Significant Financial Interest that is identified after the funding for the Research is awarded, including Significant Financial Interests identified by Investigators new to the project, UMSDF will determine whether a Financial Conflict of Interest exists and whether a FCOI Management Plan is required. For PHS-sponsored Research, UMSDF shall provide a FCOI Report with the information above to the PHS funding agency within sixty (60) days of identification of the Significant Financial Interest.

Additionally, each award year USDF must provide the PHS-funding agency an annual FCOI Report that addresses the status of the Financial Conflict of Interest and any changes to the FCOI Management Plan for the duration of the project period (including extensions with or without funding). The annual FCOI Report shall specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. UMSDF must report to the PHS-funding agency the annual FCOI Report at the time of the progress report.

## **F. FCOI Reporting to Other Sponsors**

With respect to Research funded by a sponsor other than PHS, the Institutional Official shall review the funding agreement and determine all required reporting to sponsor. The Institutional Official will implement procedures to ensure compliance with all reporting and other Financial Conflict of Interest requirements contained in the funding agreement.

## **G. Reports to the Public for PHS-supported Research**



As required by Federal regulations and upon written request, the Institutional Official shall provide to any requestor written information about Financial Conflicts of Interest, which were determined to be a Financial Conflict of Interest after May 1, 2021 of an individual who is listed as a Senior or Key Personnel on a PHS award. Requests must be in writing and received through the US mail. The request must identify the specific PHS project number and the name of Investigator for whom information is being requested. The request must include a named recipient and return address with a physical street address, P.O. Boxes are not acceptable. UMSDF will note in its written response that the information is current as of the date of the correspondence, and is subject to updates at least annually and within sixty (60) days of UMSDF identification of a new Financial Conflict of Interest, which must be requested under separate cover by the requestor.

The following information will be provided to the requestor:

- Project Number
- Name of the Investigator with a Financial Conflict of Interest;
- Investigator's title and role with respect to the Research project;
- Nature of the Financial Interest (e.g. equity, consulting fee, travel reimbursement, honorarium); and
- Value of the Financial Interest (in ranges), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

## **V. SUB-RECIPIENT MONITORING**

For Research covered by this Policy that involves subcontractors, sub-grantees or sub-awardees at other institutions (collectively "Sub-recipients"), UMSDF must take reasonable steps to ensure that any Sub-recipient Investigator complies with Federal regulations by:

- (1) Requiring a written agreement from Sub-recipients that establishes whether UMSDF's policy or the Sub-recipient's policy shall apply to the Sub-recipient's Investigators
  - a. If the Sub-recipient's policy is used, the Sub-recipient must certify that its financial conflict of interest policy is compliant with 42 CFR Part 50 and 45 CFR Part 94 and will be responsible for ensuring that the Sub-recipient institution and its Investigators comply with the Federal regulations. Sub-recipients must report to UMSDF as the awardee institution, any identified Financial Conflict of Interest no later than 45 days after identification of the Financial Conflict of Interest by the Subrecipient. The details of the Financial Conflict of Interest will be reported to the funding agency as required under applicable regulations or policies.
  - b. If UMSDF's policy is used, the Sub-recipient must ensure that its Investigators submit the SFI Disclosure Form to UMSDF at the time of application by UMSDF

or at the time the Sub-recipient signs an institutional letter of support if during an on-going award grant or contract.

(2) Reporting to the PHS funding agency any Sub-recipient Financial Conflicts of Interest prior to the execution of the sub-agreement or within sixty (60) days of identification of a new Financial Conflict of Interest by the Sub-recipient or UMSDF that arises during the term of the sub-agreement.

For Research funded by a sponsor other than PHS, the Institutional Official shall be responsible for determining and ensuring compliance with any additional Sub-recipient monitoring, disclosure or other requirements contained in the funding agreement.

**VI. TRAINING** Each Investigator must complete training prior to engaging in Research, at least every four years, and immediately when:

1. UMSDF revises this Policy in any manner that affects Investigator requirements;
2. An Investigator is new to UMSDF; or
3. An Investigator is not in compliance with this Policy or FCOI Management Plan.

Each Investigator is ultimately responsible for ensuring that he/she makes any necessary disclosures to UMSDF required by this Policy and follows any prescribed plan for the management, reduction, or elimination of an identified Significant Financial Interest. Failure to do so shall be deemed a violation of this Policy and may result in sanctions on the Investigator.

## **VII. COMPLIANCE**

### **A. Oversight**

The Institutional Official will maintain an up-to-date version of this Policy on UMSDF's publicly available Website and is responsible for training on and ensuring compliance with this Policy and the procedures contained herein. In cases where a FCOI Management Plan has been developed, it is the task of the Institutional Official to implement and oversee compliance with such FCOI Management Plan on an ongoing basis.

### **B. Review and Sanctions**

The FCOI Committee shall be responsible for investigating any alleged violations of this Policy. In investigating any violation of this Policy, the FCOI Committee shall determine if the violation has biased the design, conduct or reporting of the Research and whether such Research is funded by an outside sponsor such as PHS. The FCOI Committee will promptly report the results of such investigations to the Institutional Official along with any appropriate corrective actions to maintain the objectivity of the Research, sponsor reporting or other recommended notifications. The Institutional Official shall implement such corrective actions, including suspension of the Research project, as the FCOI Committee deems necessary to maintain the objectivity of the Research. The Institutional Official will promptly notify the applicable sponsor for any project in

which Research is suspended pending conclusion of the retrospective review process described below.

The Institutional Official, in consultation with the FCOI Committee and the President of the Board of Directors or his/her designee will decide on appropriate sanctions or disciplinary actions to be taken in accordance with established UMSDF policies and procedures. Sanctions for non-compliance may include reprimands or other appropriate measures, up to and including termination. The Institutional Official will promptly notify the affected Investigator in writing of the results of the investigation and plans for disciplinary action against the Investigator, if applicable.

C. Retrospective Review Procedures In addition the above review and sanctions, Investigators are subject to the following retrospective review procedures when a Financial Conflict of Interest is not identified or managed in a timely manner. This includes any failure by an Investigator to disclose a Significant Financial Interest that is determined by UMSDF to constitute a Financial Conflict of Interest, failure by UMSDF to review or manage such a Financial Conflict of Interest, or failure by the Investigator to comply with a FCOI Management Plan. The Institutional Official is responsible for overseeing the procedures outlined below.

1. UMSDF must implement, on at least an interim basis, a FCOI Management Plan that shall specify the actions that have been, and will be, taken to manage such Financial Conflict of Interest going forward;
2. Within 120 days of UMSDF's determination of noncompliance, UMSDF must complete a retrospective review of the Investigator's activities and the affected Research project to determine whether any Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research;
3. UMSDF must document the retrospective review and include, at minimum, the following information:
  - a) Project number;
  - b) Project title;
  - c) PD/PI or contact PD/PI if a multiple PD/PI model is used;
  - d) Name of the Investigator with the Financial Conflict of Interest;
  - e) Name of the entity with which the Investigator has a Financial Conflict of Interest;
  - f) Reason(s) for the retrospective review;
  - g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
  - h) Findings of the review; and
  - i) Conclusions of the review.
4. The Institutional Official shall promptly notify the FCOI Committee of the results of any retrospective review. Such notification shall include a determination of whether the violation appears to have biased the design, conduct or reporting of Research, a copy of the retrospective review documentation described above, and a description of corrective

actions taken. The Institutional Official will also submit recommendations for sponsor and/or other appropriate notifications, including affected UMSDF departments, for approval.

5. Based on the results of the retrospective review, if appropriate, UMSDF shall update the previously submitted FCOI Report, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward.

6. For PHS sponsored Research, if the results of the retrospective review indicate bias, UMSDF is required to notify the PHS funding agency promptly and submit a mitigation report to the PHS funding agency. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the Research project and UMSDF's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, UMSDF will submit to the PHS awarding agency FCOI Reports annually. Depending on the nature of the Financial Conflict of Interest, UMSDF may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded Research project between the date that the Financial Conflict of Interest or the Investigator's noncompliance is determined and the completion of UMSDF's retrospective review.

7. In any case that a clinical 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 conflicting interest that was not reported or managed as required by this Policy or the applicable regulations, then UMSDF shall, at minimum, require the Investigator involved to disclose the conflicting interest in each public presentation of the results of the Research and to request an addendum to previously published presentations. An Investigator who has failed to report a Significant Financial Interest related to clinical Research will also be subject to sanctions under this Policy.

## **VIII. GENERAL PRINCIPLES**

### **A. Confidentiality**

To the extent permitted by law, all SFI Disclosure Forms, FCOI Management Plans, and related information will be treated as privileged and confidential. However, UMSDF may be required to make such information available to PHS and/or HHS, to a requestor of information concerning Financial Conflict of Interests related to PHS funding or to the primary entity who made the funding available to UMSDF, if requested or required. If UMSDF is requested to provide SFI Disclosure Forms, FCOI Management Plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

### **B. Record Retention**

The Institutional Official shall be responsible for maintaining records, identifiable to each project, all transactional reports of Significant Financial Interests, and all actions taken by the FCOI Committee or other appropriate departments within UMSDF to manage any actual or potential Financial Conflicts of Interest at least three (3) years from: (a) the date of submission of the final expenditures report, for federally funded grants; (b) from the date of termination or completion of the award; or (c) from the date of the resolution of any action by any governmental agency involving the records; or (d) as applicable, from any other date specified in 45 CFR Section 74.53(b) for different situations, as appropriate.

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