
Policy & Procedures

Section: Office of General Counsel CIBMTR and Administration

National Marrow Donor Program® Financial Conflict of Interest Policy Applicable to Sponsored Research Awards

Issue Date: July 12, 2017

Effective Date: July 12, 2017

Replaces: February 14, 2014

Approved by: Brian Lindberg	Approved by: Patrick Reinken	Issued by: Nancy Poland/Julie Clark
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Policy

It is National Marrow Donor Program® (NMDP) policy to ensure that its research is conducted and reviewed with integrity and is free from any actual or apparent Financial Conflicts of Interest that could influence the conduct or review of Public Health Service (PHS) research.

Purpose

In response to adopted regulations by the U.S. Public Health Service (PHS), all Institutions receiving research award funding under federal contracts, grants, or cooperative agreements must adopt a written policy on conflict of interest.

Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F, "Promoting Objectivity in Research," describes the requirements for compliance with the regulation. For contractors receiving research funding under PHS contracts, the corollary regulation is Title 45 CFR Part 94, "Responsible Prospective Contractors."

In response to this regulation, the NMDP, including the Minneapolis campus of the Center for International Blood and Marrow Transplant Research (CIBMTR), must maintain a written, enforced policy on conflict of interest that:

- Complies with the regulation;
- Informs each Investigator of the NMDP policy;
- Informs each Investigator of his or her reporting responsibilities; and
- Informs each Investigator of the regulation.

The NMDP maintains this written, enforced policy to manage Financial Conflicts of Interest in compliance with the above regulation.

For purposes of this policy, the NMDP Senior Vice President/General Counsel shall make the final determination on whether a Financial Conflict of Interest exists.

Scope

This policy applies to NMDP, CIBMTR, and Subcontractor Investigators participating in any PHS funded research contracts, grants, and cooperative agreements in which

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the NMDP is the prime recipient of the award, or if the NMDP is the sub-recipient of a PHS funded award, to the extent the FCOI requirements are flowed down to the NMDP.

Definitions

Awarding Component: An organizational unit of the PHS that funds research subject to this policy.

Contract Manager: Any person in Office of General Counsel – Contracts and Procurement having a responsibility as defined by their job description to manage government proposals, contracts, cooperative agreements, grants or subcontracts.

Financial Conflict of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.

Financial Conflict of Interest Report (FCOI Report): The NMDP's report of a FCOI to PHS.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

Institution: Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding. For purposes of this policy, "Institution" means and refers to the NMDP and/or CIBMTR, except where otherwise specified.

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on FCOI, 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: 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 PHS, or proposed for such funding, including but not limited to, Subcontractor Investigators, co-investigators, collaborators, consultants, or Key Personnel.

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Key Personnel: The project director or principal investigator and any other person identified by the NMDP as key personnel in the grant application, progress report, or any other report submitted to the PHS.

Public Health Service: The Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

Related Entity: With respect to Sponsored Research, includes any supplier of equipment, materials, or services; any business commercializing a product that the research is intended to evaluate or further develop; or any party whose Financial Interests would reasonably appear to be affected by the research.

Research: A systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. Research covered under this policy includes basic and applied research and product development that is funded from a sponsored component through a prime contract, grant, or cooperative agreement.

Significant Financial Interest:

(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 (12) 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 (12) 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

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- (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. This disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, any known monetary value associated with the travel, the destination, and the duration.
- (3) The term **does not** include the following types of Financial Interests:
 - (i) 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;
 - (ii) any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
 - (iii) 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;
 - (iv) 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
 - (v) 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.

Sponsored Research: Research funded by any component of the PHS for which the NMDP is the prime recipient or the subrecipient of a PHS funded award to the extent the FCOI requirements are flowed down to the NMDP.

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Subcontractor: Subcontractor, subgrantee, collaborator, or supplier including but not limited to NMDP donor center and transplant center site Investigators, clinical study sites, or other individuals or entities entering into a contract or agreement with the NMDP.

Procedure

1. General

- 1.1. In the manner(s) described herein, the responsible NMDP Contract Manager assigned to administer the prospective prime contract, grant, or cooperative agreement shall solicit initial and subsequent financial disclosures from an Investigator who participates or plans to participate in Sponsored Research.
- 1.2. Where applicable, the responsible Contract Manager will provide the Investigator with a copy of the appropriate disclosure forms and ensure that the Investigator has access to or has been provided with a copy of this policy.
- 1.3. NMDP and CIBMTR Investigators must sign and return the Investigator Significant Financial Interest Disclosure Statement (F00664) and, if applicable, the Description of Significant Financial Interest Form (F00665).
- 1.4. If the NMDP carries out Sponsored Research through a Subcontractor, at any time from pre-submission of the application for funding to completion of the research, the Subcontractor must certify, by written agreement or by completing and returning the Subcontractor Financial Conflict of Interest Certification (F00719), whether the NMDP's FCOI policy or that of the Subcontractor will apply to the Subcontractor's Investigators. The written agreement between NMDP and the Subcontractor shall incorporate language that reflects the Subcontractor's certification, including time periods for reporting FCOIs to the NMDP.

2. Investigator Responsibilities

2.1. **Investigator Disclosures to the NMDP**

- 2.1.1. Prior to submitting the initial proposal for award to the sponsoring component, the responsible NMDP Contract Manager (see Section 1.1) shall solicit any necessary information and appropriate financial

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disclosure forms (see Sections 1.3-1.4) from Investigators that are known at the time of proposal submission to the sponsoring component.

- 2.1.2. During the period of the award, Investigators shall also complete and submit subsequent financial disclosures (a) annually, and (b) within thirty (30) days of the occurrence or acquisition of a new reportable Significant Financial Interest. The forms referenced in Section 1.3 shall be used for subsequent disclosures by NMDP and CIBMTR Investigators. For Subcontractor Investigators, the forms used to complete such disclosures shall depend on the written agreement between the NMDP and the Subcontractor and the Subcontractor's identification of the governing FCOI policy in that agreement, pursuant to Section 1.4.

2.2. Training

- 2.2.1. Investigators following this FCOI policy must complete training on this policy at least every four (4) years, and within a month of any of the following circumstances:
- The NMDP revises its FCOI policy in any manner that affects the Investigator's responsibilities;
 - An Investigator is new to the NMDP (training for the affected Investigator alone); or
 - The NMDP finds that an Investigator is not in compliance with this policy or management plan (training for the affected Investigator alone).

3. NMDP Responsibilities

3.1. Review of Investigator Disclosures

- 3.1.1. The NMDP Senior Vice President/General Counsel, or his/her designated representative, must:

- 3.1.1.1. Review all disclosures to determine whether an Investigator's Significant Financial Interest is (i) related to the Sponsored Research and (ii) if so, whether the Significant Financial Interest is a FCOI.

- 3.1.1.1.1. An Investigator's Significant Financial Interest is related to the Sponsored Research when the designated official reasonably determines that the Significant Financial Interest could be affected by the Sponsored Research or is in an entity whose Financial Interest could be affected

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by the research. The NMDP may involve the affected Investigator in the designated official's determination of whether a Significant Financial Interest is related to the research.

- 3.1.1.1.2. A FCOI exists when the designated official reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the Sponsored Research.
- 3.1.1.2. If a FCOI exists, take such actions as necessary to manage, reduce, or eliminate the FCOI, including developing and implementing a management plan that specifies the actions that have been, and shall be, taken to manage such FCOI.
 - 3.1.1.2.1. Conditions or restrictions that might be imposed to manage, reduce, or eliminate actual or potential FCOIs include but are not limited to:
 - Public disclosure of FCOI;
 - Disclosure of FCOI directly to research participants;
 - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
 - Modification of the research plan;
 - Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - Divestiture of the Significant Financial Interest; or
 - Severance of relationships that create actual or potential conflicts.
 - 3.1.1.3. Forward the results of his/her review and any plan to manage, reduce, or eliminate the FCOI to the Chair of the IRB, the NMDP Chief Executive Officer, and Chief Financial Officer for approval.
 - 3.1.1.4. Report the FCOI and management plan, in accord with the requirements of this policy.
 - 3.1.1.4.1. The Chair of the IRB shall inform the convened IRB of the results of the review, as well as the management plan, if any. The IRB's review of a Sponsored Research project shall include review of any FCOI identified pursuant to this Section 3.1, during which review the IRB shall have the final authority to decide whether the FCOI and its management (if any) allows for the Sponsored Research project to be approved.

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3.2. Monitoring

3.2.1. Whenever the NMDP develops and implements a management plan for a FCOI, the NMDP Senior Vice President/General Counsel or his/her designee shall monitor the Investigator's compliance with the management plan on an ongoing basis until the completion of the Sponsored Research project.

3.3. Unreviewed Significant Financial Interests

3.3.1. Whenever the NMDP identifies a Significant Financial Interest that was not timely disclosed by an Investigator or, for whatever reason, was not previously reviewed by the NMDP during an ongoing funded research project, the designated official shall, within sixty (60) days:

- 3.3.1.1. Review the Significant Financial Interest;
- 3.3.1.2. Determine whether it is related to the funded research; and
- 3.3.1.3. Determine whether a FCOI exists.

3.3.2. If a FCOI is found to exist, the NMDP shall:

- 3.3.2.1. Implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage the FCOI going forward; and
- 3.3.2.2. Whenever a FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a Significant Financial Interest that is determined to be a FCOI, failure by the NMDP to review or manage such a FCOI, or failure by the Investigator to comply with a FCOI management plan, the NMDP shall, within 120 days of the NMDP's determination of noncompliance, complete a retrospective review of the Investigator's activities and the Sponsored Research project to determine whether any Sponsored Research conducted during the period of noncompliance was biased in the design, conduct, or reporting of such research.

3.3.2.2.1. The NMDP must document all of the following in any such retrospective review:

- Project number;
- Project title;
- Principal Investigator;
- Name of Investigator with FCOI;
- Name of the entity with which the Investigator has a FCOI;
- Reasons for the retrospective review;

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- Detailed methodology used for the retrospective review;
- Findings of the review; and
- Conclusions of the review.

3.4. Reporting of FCOI

3.4.1. PHS-Funded Awards

- 3.4.1.1. Prior to the NMDP's expenditure of any funds under the award, the NMDP Senior Vice President/General Counsel or his/her designee shall provide to the PHS Awarding Component a FCOI Report regarding any Investigator's Significant Financial Interest found to be conflicting and ensure that a management plan has been implemented.
 - 3.4.1.1.1. In cases in which the NMDP identifies a FCOI and eliminates it prior to the expenditure of PHS-awarded funds, the NMDP shall not submit a FCOI Report to the PHS Awarding Component.
- 3.4.1.2. For any Significant Financial Interests the NMDP identifies as conflicting subsequent to the initial FCOI Report and during an ongoing PHS-funded research project, the NMDP shall provide a FCOI Report to the PHS Awarding Component within sixty (60) days.

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- 3.4.1.3. Any FCOI Report required under Sections 3.4.1.1 or 3.4.1.2 shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI, and to assess the appropriateness of the NMDP's management plan. Elements of the FCOI Report shall include, but are not limited to, the following:
- Project number;
 - Project title;
 - Principal Investigator;
 - Name of the Investigator with the FCOI;
 - Name of the entity with which the Investigator has a FCOI;
 - Nature of the Financial Interest;
 - Value of the Financial Interest or a statement that the interest is one whose value cannot readily be determined through reference to public prices or other reasonable measures of fair market value;
 - A description of how the Financial Interest relates to the PHS-funded research and the basis for the NMDP's determination that the Financial Interest conflicts with such research; and
 - A description of the key elements of the NMDP's management plan, including:
 - Role and principal duties of the conflicted Investigator in the research project;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the Investigator's agreement to the management plan; and
 - How the management plan will be monitored to ensure Investigator compliance;
 - Other information as needed.
- 3.4.1.3.1. Where the FCOI Report involves a FCOI that was not disclosed timely by the Investigator or, for whatever reason, was not previously reviewed or managed by the NMDP, the NMDP shall also complete a retrospective review to determine whether any PHS-funded research was biased in the design, conduct, or reporting of such research. If bias is found, the NMDP shall notify the PHS

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Awarding Component promptly and submit a mitigation report.

- 3.4.1.4. For any FCOI previously reported to a PHS Awarding Component, the NMDP shall provide an annual FCOI Report, for the duration of the project period, that addresses the status of the FCOI and any changes to the management plan. The annual FCOI Report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists.
- 3.4.2. Non-Federally Funded Awards
 - 3.4.2.1. Disclosure shall be on a case-by-case basis as determined by the type of disclosure, requirements of the funder, and NMDP senior management.

3.5. Public Accessibility

- 3.5.1. The NMDP shall make this policy available via a publicly accessible website at http://bethematch.org/About/NMDP_FCOI_POLICY_FORMS_pdf.aspx.
- 3.5.2. Prior to the expenditure of any funds under a PHS-funded research project, the NMDP shall provide, within five (5) business days, a written response to any request for information concerning any Significant Financial Interest that was disclosed to the NMDP and that meets the following criteria:
 - The Significant Financial Interest was disclosed and is still held by the Investigator or Key Personnel;
 - The NMDP determines that the Significant Financial Interest is related to the Sponsored Research; and
 - The NMDP determines that the Significant Financial Interest is a FCOI.
- 3.5.2.1. The NMDP's response to the requestor shall include, at a minimum, the following:
 - The Investigator's name;
 - The Investigator's title and role with respect to the research project;
 - The name of the entity in which the Significant Financial Interest is held;
 - The nature of the Significant Financial Interest;
 - The approximate dollar value of the Significant Financial Interest or a statement that the interest is one whose value cannot be readily determined through reference to

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public prices or other reasonable measures of fair market value; and

- A note that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty (60) days of the NMDP's identification of a new FCOI, which should be requested subsequently by the requestor.

- 3.5.2.2. Information concerning Significant Financial Interests that must be publicly disclosed upon written request, as provided for in Section 3.5.2., shall remain available for at least three (3) years from the date that the information was most recently updated.

4. **Enforcement of Policy**

- 4.1. Failure by an NMDP or CIBMTR Investigator to disclose a Significant Financial Interest is a serious matter which may, in certain instances, be considered a violation of the NMDP Code of Business Conduct and Ethics and/or NMDP policies, resulting in disciplinary action up to and including termination.
- 4.2. Failure by a Subcontractor or its Investigator to comply with the terms of the agreement regarding FCOI may be considered a violation of the agreement between the Subcontractor and the NMDP and may result in termination of the Agreement.

5. **Records**

- 5.1. The NMDP shall maintain records of all disclosures and all actions taken with respect to a FCOI in research under this policy, for at least three (3) years from the date of the final expenditures or later, as required by applicable laws or regulations.
- 5.2. The NMDP agrees to make available to the funding agency, upon request, records regarding all FCOIs that have been identified and the manner in which those interests have been managed, reduced, or eliminated to protect the research from bias.

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6. **Control/Areas of Responsibility**

- 6.1. This policy shall be managed by the NMDP Senior Vice President/General Counsel.
- 6.2. All Investigators receiving sponsored funding shall be responsible for disclosing all Significant Financial Interests, in accord with this policy.
- 6.3. The applicable Contract Manager shall be responsible for obtaining such disclosures.

7. **Contacts**

- 7.1. Questions related to this policy may be submitted to the NMDP Senior Vice President/General Counsel, his/her designated representative, or the applicable Contract Manager.

Related Forms

F00664, *Investigator Significant Financial Interest Disclosure Statement*
F00665, *Description of Significant Financial Interest or Management Interest*
F00719, *Subcontractor Financial Conflict of Interest Certification*

**National Marrow Donor Program® (NMDP) and Center for International
Blood and Marrow Transplant Research® (CIBMTR)**

**SUBCONTRACTOR FINANCIAL CONFLICT OF INTEREST
CERTIFICATION**

This form requires _____ (“Subcontractor”) to identify whether it has and will ensure its Investigators follow a financial conflict of interest policy or whether it will comply with NMDP’s Financial Conflict of Interest Policy Applicable to Sponsored Research Awards with respect to its Investigator(s)’s work with the NMDP and CIBMTR on _____ (“Study”) funded by _____. The two options below detail the obligations of each certification, respectively. Please review the sections below, mark which is applicable, and sign at the bottom.

Subcontractor certifies that it has a written, active, and enforced Financial Conflict of Interest policy that complies with Title 42 Code of Federal Regulations (C.F.R.) Part 50, Subpart F, “Promoting Objectivity in Research” and, if applicable, Title 45 C.F.R. Part 94, “Responsible Prospective Contractors”; its Investigators are required to comply with said policy or policies; and its Investigators will comply with said policy or policies with respect to research activities undertaken pursuant to this Agreement.

Subcontractor shall, within the time periods identified herein, identify to NMDP any interest(s) it determines constitute Financial Conflicts of Interest, for each Subcontractor Investigator who is planning to participate in the funded research.

Subcontractor acknowledges and agrees that NMDP shall use the identified conflicts in furtherance of management and reporting obligations under 42 C.F.R. Part 50, Subpart F and, if applicable, 45 C.F.R. Part 94. Subcontractor specifically acknowledges and agrees that NMDP may take any action necessary to manage, reduce, or eliminate any Financial Conflict of Interest identified by Subcontractor, pursuant to 42 C.F.R. § 50.604(g) and, if applicable, 45 C.F.R. § 94.4(g).

Subcontractor shall identify in writing such conflicts for any affected Investigator:

- a. no later than the time of application for funded research, if Subcontractor is known prior to submission of the application;
- b. at least thirty (30) days prior to NMDP’s annual update of Significant Financial Interests; and
- c. at any updated disclosure of Significant Financial Interests that are newly discovered or acquired, within thirty (30) days of the discovery or acquisition.



Subcontractor shall comply with NMDP’s Financial Conflict of Interest Policy Applicable to Sponsored Research Awards. Subcontractor shall submit to NMDP, within the time periods identified herein, all Subcontractor Investigator disclosures of Significant Financial Interests that are related to research activities under this Agreement, in conformity with that policy and using forms provided by NMDP for such reporting. Subcontractor shall submit said disclosures on forms provided by NMDP (Investigator Significant Financial Interest Disclosure Statement and, if applicable, the Description of Significant Financial Interest Form).

Subcontractor acknowledges and agrees that NMDP shall use the disclosed information for review, management, and reporting obligations under 42 C.F.R. Part 50, Subpart F and, if applicable, 45 C.F.R. Part 94. Subcontractor specifically acknowledges and agrees that NMDP may take any action necessary to manage, reduce, or eliminate any Financial Conflict of Interest that NMDP identifies from information disclosed by Subcontractor, pursuant to NMDP’s Financial Conflict of Interest Policy Applicable to Sponsored Research Awards; 42 C.F.R. § 50.604(g); and, if applicable, 45 C.F.R. § 94.4(g).

Subcontractor shall provide such information for any affected Investigator:

- a. no later than the time of application for funded research, if Subcontractor is known prior to submission of the application;
- b. at least thirty (30) days prior to NMDP’s annual update of Significant Financial Interests; and
- c. at any updated disclosure of Significant Financial Interests that are newly discovered or acquired, within thirty (30) days of the discovery or acquisition.

By: _____
 Authorized signature

 (Typed/Printed Name)

Title: _____

Date: _____