

Minneapolis Medical Research Foundation

Conflict of Interest Policy

Effective date January 1, 2012

Revised 1993, 1999, 2002, 6/2011, 10/2011

Purpose

The purpose of this policy is to enable and facilitate the research and education missions of the MMRF by assuring their objectivity and independence from competing financial interests. The stakeholders considered in this policy are the public, our patients and research subjects, the scientific community, the agencies who fund our activities, and our faculty, staff and trainees. An equally compelling purpose is to maintain compliance with all applicable federal and state laws and regulations related to conflicts of interests and with the policies and requirements of the regulatory agencies which oversee our activities, including but not limited to the USPHS and FDA (42CFR50 and 21CFR54.2)..

Conflict of interest. The specific goal of this policy is to address financial conflicts of interest. For this policy, financial conflict of interest refers to competing financial interests or incentives. Specifically, it is a situation in which a covered individual (see Definitions, page 8) has financial incentives that may compete with his/her academic or professional interests or obligations. A conflict of interest does not imply wrong-doing or improper relationships, but does require disclosure, evaluation and sometimes mitigation.

Appearance of conflict of interest. Some situations fall outside the definition of COI but may raise questions in the mind of a reasonable observer which are best addressed in order to assure that the situation has been considered. The COI committee reserves the right to include such issues of appearance in its deliberations and approaches to managing the financial relationships of investigators.

Policy

This policy is applicable to:

- all persons appointed, employed by or compensated by the MMRF;
- all persons engaged in the conduct of research activities under the auspices of the MMRF who are in a position to influence the design, conduct or reporting of research or other scholarly activity;
- all persons who have direct influence over purchasing decisions or contracts made on behalf of MMRF;
- all holders of MMRF Research and Education accounts,
- all members of MMRF's Board of Directors, members of MMRF's Conflict of Interest Committee, and members of regulatory committees including the IRB, IACUC and the IBC.

- For purposes of reporting financial interests under this policy, covered individuals also include a spouse or domestic partner, dependent children, and any other family member whom the covered individual knows may personally benefit from actions taken by the covered individual.

Covered individuals at MMRF must comply with MMRF's Policy on Conflict of Interest and all applicable federal and state laws related to conflict of interest and shall not engage in activities that compromise their professional judgment or compete with the fulfillment of their obligations to MMRF.

Relationships constituting a potential COI must be reported to the MMRF COI Committee **prior to their initiation**. Changes in existing relationships must also be reported before the changes take place. The purpose of this requirement is to avoid COI when possible, or to make all parties aware of the proposed relationship and any possible mitigation requirements.

Covered individuals may not participate in relationships with business entities that:

- result in payments to the covered individual which are intended to influence how the covered individual conducts institutional activities;
- constitute ghost writing (having one's name and institutional affiliation associated with a publication or other article where the covered individual has no substantial input into the publication or article). Authorship should be restricted to those individuals who meet the following criteria:
 - made a significant contribution to the conceptualization and/or design or conduct of the project;
 - participated in the analysis and interpretation of the data, or other substantial scholarly work;
 - participated in drafting, reviewing and/or revising the work; and
 - approved the final version of publication.
- involve the covered individual's endorsement of a product or service developed and/or sold by a particular business. This applies to both written and oral endorsements when the product or service relates to the covered individual's institution- related expertise and/or institutional activities, whether or not the individual uses his or her institutional title in making the endorsement;
- involve acceptance of gifts of any amount or value from industry doing business or seeking to do business with the MMRF. Examples include but are not limited to pens, pads, other promotional items, cash, food and drink, entertainment such as tickets to events, golf and other sports outings, medical or research equipment, devices or other products or services or discounts on same, use of company vehicles or vacation facilities, hotels, transportation and other travel expenses, stocks, equity, and other such financial offerings, group gifts, textbooks, biological samples, software, computer hardware and accessories, electronic devices such as cell phones, pagers, music and video players, PDA's consulting, financial and other services and office and research supplies.
 - It is recognized that there are circumstances when individuals have no control over receipt of gifts and may inadvertently violate this policy, such as attendance at Industry Sponsored professional meetings where a mandatory lunch is provided and there is no practical alternative.

Covered individuals must report all external relationships annually via the Report of External Professional Activities. Annual reporting is intended to be inclusive of all financial relationships

and not confined to relationships relevant to specific ongoing or proposed projects. In addition, when proposing or conducting a specific research project, investigators must identify any financial interests *related to that specific research project*. This includes any financial interests in the sponsor, product or service being tested, or in any direct competitor of the sponsor, product or service being tested. This reporting will be done via the Compliance Committee Standardized Reporting Form found in application materials for the IRB, IACUC, and IBC and in the Grant and Contract Application for External Support. Also, substantial changes in a financial or business interest (see Definitions, page 8) must be reported within 30 days of occurrence.

This information (the name of the business with which the relationship exists but without disclosure of actual dollar amounts) will be placed on a publicly accessible website, the primary purpose of which is to make the information available to colleagues, collaborators, trainees and research subjects.

Where a conflict of interest is identified, the covered individual may be required to follow an approved conflict mitigation plan which provides mechanisms to manage, reduce or eliminate the conflict.

When covered individuals participate in sponsored research involving sub-grantees, contractors or collaborators outside the institution, MMRF will take reasonable steps to ensure that these outside associates comply with appropriate conflict of interest reporting, disclosure and review requirements.

Appropriate disciplinary action may be taken by the Foundation against covered individuals who violate this policy. Disciplinary actions, in addition to any legal penalty(ies), may include oral admonishment, written reprimand, or reassignment, demotion, suspension, or termination. Investigators may also be prohibited from further grant or contract proposal submission or participation in research activities. Policy violations which involve PHS funded projects shall be reported to a responsible grantee official and shall specify the type of administrative action taken. Policy violations which involve other sponsored funds shall be reported to the sponsor as directed by the terms and conditions of the award.

Reporting and Evaluating a Covered Individual's Relationships with External Entities

On an annual basis, all covered individuals must complete a Report of External Professional Activities covering current relationships, those that occurred in the previous year, and those that can reasonably be expected in the next 12 months.

The covered individual must report

- financial and / or business relationships and those of immediate family members which relate to or compete with the covered individuals institutional responsibilities including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria);
- equity interests (e.g., stocks, whether publically traded or not, stock options, or other ownership interests);
- intellectual property rights (e.g., patents, copyrights and royalties from such rights); and
- other arrangements under which financial benefits have been received (e.g., gifts, loans or services).

Reporting will consist of listing the entity with which the relationship exists, or is anticipated in the next 12 months, and the dollar amount. There is no minimum dollar threshold for reporting; all covered financial relationships must be reported. The dollar amount may be reported as a range:

- up to \$4,999
- \$5,000 – \$9,999
- \$10,000 – \$19,999
- \$20,000 – \$99,999 by increments of \$20k
- \$100,000 – \$250,000
- > \$250,000

If needed to adequately evaluate or manage a conflict, the Conflict of Interest Committee may ask for more detailed information, including information going back as far as three years.

Relationships that fall outside MMRF's reporting guidelines, such as those of a non-business or non-financial nature (e.g., close friend, immediate or extended family member – see Definitions, page 8), that may create a conflict of interest or that might influence the way a covered individual allocates institutional resources, must be reported and may require consideration by the COI Committee.

The COI Committee reserves the right to make further inquiries into the nature of the covered individual's report should additional information be required.

The following activities are exempt from these reporting requirements:

- Salary, royalties or other remuneration from the covered individual's institution;
- Income from activities sponsored by governmental agencies or entities;
- Income for serving as special reviewer or on a review panel for governmental agencies or entities;
- Travel expenses paid as part of a research project;
- Equity interest in mutual funds, pension or other institutional investment funds whose investment practices are beyond the control of the individual.

Covered individuals who are temporarily on a leave of absence, sabbatical or reduced appointment must also report these external relationships. The COI Committee will take into consideration the covered individual's status when reviewing reported information.

The Conflict of Interest Committee

The MMRF will maintain a Conflict of Interest Committee to deal with issues concerning this policy. This committee shall be chaired by the President of the Foundation, and shall have the following principle functions:

- to assist in the implementation of this policy;
- to answer questions concerning this policy (the identity of personnel asking questions and the specific facts of questions shall be kept private to the extent allowed by law);
- to review disclosures of conflict of interest;
- to develop and approve any plans to manage, reduce or eliminate conflicts;

- to recommend to the MMRF Executive Committee any disciplinary action to be taken under this policy; disciplinary actions to be approved by the MMRF Board of Directors;
- upon the request of affected personnel, to review a decision by an administration official that a disclosed situation constitutes an actual conflict of interest;
- to periodically review this policy, including the set financial thresholds; and
- to work in cooperation with campus compliance officers

This Committee shall be comprised of: the Executive Committee of the Foundation (the Chairman and Chief Executive Officer of Hennepin Faculty Associates and the President, Vice President, Secretary/Treasurer, and Vice President of Operations/COO of the Foundation), the Chair of the Institutional Review Board (IRB) and the Chair of the Institutional Animal Care and Use Committee (IACUC) and a community member to be appointed by the President of the Foundation. Should the Committee require additional expertise, including legal counsel, ad hoc members may be asked to participate as non-voting members.

Determining Whether a Conflict of Interest Requires Management or Elimination

The COI Committee's criteria for evaluating disclosures will include but not be limited to 1) risks to research subjects; 2) risks to the scientific integrity of study design, data collection, analysis and reporting; and 3) expected benefits of activity.

Whenever a covered individual's activities or relationships are under review by the COI Committee, the covered individual will have an opportunity to provide information to the committee either in person or by submission of a written statement and/or the provision of other written information.

Managing Conflict of Interest

When the COI Committee determines that a conflict of interest exists, the committee will evaluate the conflict situation considering factors including: the nature of the activity; the nature of the financial interest; and the potential for the conflict to influence the activity in question. Where research is involved, the committee will evaluate the risk the research poses to research subjects and the degree to which the outcome of the research may be affected by any financial interest.

The committee will determine whether the conflict situation 1) can be effectively managed through development and implementation of a conflict mitigation plan; 2) can be managed by changing the covered individual's terms of participation in an institutional activity; or 3) needs to be eliminated. Possible recommendations include approval of the activity as proposed if it is concluded that the potential for conflict is so remote or inconsequential that there is minimal probability for biasing the objectivity of the activity. Other possible recommendations are to require periodic peer review of the activity (oversight) by individuals independent of the employee, outside monitors for the activity, divestiture of the financial or business interest, modification of the plan of work, or assignment of different employees without a financial or business interest to control the activity, or limiting the individual's role and responsibilities in the project. To the extent possible and reasonable under the circumstances, and in light of the importance of the activity, the review committees and responsible administrators will work with

employees to develop means for the activity to take place while protecting the integrity and the reputation of the employees and the MMRF.

If the COI Committee determines that a conflict mitigation plan can effectively manage the conflict situation, the committee will work with the covered individual to develop a conflict mitigation plan that will:

- describe the circumstances that give rise to the conflict of interest under institutional policy;
- set forth specific mandatory mitigation mechanisms;
- set forth a plan for monitoring and follow-up;
- address any disclosures required;
- require a written confirmation of consent from the covered individual to all requirements of the management plan.

When personnel participate in sponsored research involving sub-grantees, contractors or collaborators outside the MMRF, reasonable steps will be taken to ensure that investigators working for these outside entities comply with appropriate conflict of interest disclosure and review requirements. These steps may include requiring the investigators to comply with MMRF's policy or obtaining written assurances from the outside entity that it complies with applicable federal regulations or sponsor policies on conflict of interest.

The outcome of the COI Committee deliberations and any mitigation plan(s) will be shared with the covered individual's supervisor/department head.

Disclosure Outside the Institution

Covered individuals must disclose their conflicts of interest when submitting research reports, reviews, opinion pieces, and letters to the editor or other types of communications for publication. Such disclosures must be made to the audience for educational presentations, and to the responsible reporter or editor for news articles, interviews or press releases. Journal articles and research reports may follow individual journal or funding agency reporting formats.

Institutional Conflict of Interest

Institutions such as the MMRF may have financial conflicts of interest independent of those of specific individuals. Examples include gifts or royalties accruing to the institution rather than to an individual or specific lab or department, or support of institutional educational conferences. Institutional COI raises issues similar to those raised by individual COI, and should be subject to the same scrutiny, disclosure and management procedures.

Educational activities – When an educational activity is conducted by MMRF as the sole organizer, these activities may not be supported by funds from vendors doing business with MMRF. When educational activities are co-sponsored by MMRF and other institutions (e.g. Hennepin Health System) which do not have a similar prohibition, the criteria of the Accreditation Council for Continuing Medical Education (ACCME) for COI in continuing medical education must be adhered to by all organizations involved (see APPENDIX I).

Gifts – The MMRF may not accept gifts or contributions from vendors with which it conducts business, such as the purchasing of common equipment, on an institutional level. This policy

would not apply to vendors providing goods or services to individual faculty or staff or laboratories (in which MMRF as an institution does not influence the choice of vendor other than by guaranteeing competitive bidding when required) but would apply to vendors in the case that the MMRF makes purchasing decisions as an institution, e.g. common equipment, biohazard disposal services.

An Institutional Conflict Committee consisting of the MMRF Conflict of Interest Committee plus 2 additional external non-institutional members will review all institutional conflicts of interest. The MMRF COO will report all institutional financial conflicts of any amount to the committee for review.

Definitions

Business	Any corporation, partnership, sole proprietorship, firm, franchise, association or organization, holding company, joint stock company, receivership, business or real estate trust or any non-governmental legal entity organized for profit, non-profit, or charitable purposes.
Business Interest	<p>Holding any executive position in a business or membership on a governing board of directors of a business whether or not such activities are compensated.</p> <p>The term “governing board of directors” refers to the board of a business including boards or trustees, scientific advisory boards, medical advisory boards, and boards of professional societies.</p>
Covered Individual	<ol style="list-style-type: none"> 1. all persons appointed, employed by or compensated by the MMRF; 2. all persons engaged in the conduct of research activities under the auspices of the MMRF who are in a position to influence the design, conduct or reporting of research or other scholarly activity; 3. all persons who have direct influence over purchasing decisions or contracts made on behalf of MMRF; 4.. all holders of MMRF Research and Education accounts, 5. all members of MMRF’s Board of Directors, members of MMRF’s Conflict of Interest Committee, and members of regulatory committees including the IRB, IACUC and the IBC; and 6. for purposes of reporting financial interests under this policy, covered individuals also include a spouse or domestic partner, dependent children, and any other family member whom the covered individual knows may personally benefit from actions taken by the covered individual.
Financial Conflict of Interest	Refers to competing interests or incentives. Specifically, it is a situation in which a Covered Individual has financial incentives that may compete with his/her academic or professional interests or obligations.
Immediate Family Member	The covered individual’s spouse or domestic partner, dependent children, and any other family member whom the covered individual reasonably knows may benefit personally from actions taken by the covered individual.
Institutional Responsibilities	Research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards and Data Safety and Monitoring Boards; and 2) relationships of a non-business, non-financial nature which relate to or compete with his or her institutional responsibilities.

Selected Bibliography

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APPENDIX I

The ACCME Standards for Commercial Support SM

Standards to Ensure Independence in Continuing Medical Education (CME) Activities

STANDARD 1. Independence

- 1.1 A CME provider must ensure that the following decisions were made free of the control of a Commercial Interest. (See www.accme.org for a definition of a 'Commercial Interest' and some exemptions.)
- (a) Identification of CME needs;
 - (b) Determination of educational objectives;
 - (c) Selection and presentation of content;
 - (d) Selection of all persons and organizations that will be in a position to control the content of the CME;
 - (e) Selection of educational methods;
 - (f) Evaluation of the activity.
- 1.2 A Commercial Interest cannot take the role of non-accredited partner in a joint sponsorship relationship.

STANDARD 2. Resolution of Personal Conflicts of Interest

- 2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any Commercial Interest to the provider. The ACCME defines “‘relevant’ financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.
- 2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.
- 2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the educational activity being delivered to the learners.

STANDARD 3. Appropriate Use of Commercial Support

- 3.1 The provider must take all decisions regarding the disposition and disbursement of commercial support.
- 3.2 A provider cannot be required by a Commercial Interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a Commercial Interest as conditions of contributing funds or services.
- 3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

- 3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.
- 3.5 The written agreement must specify the Commercial Interest that is the source of commercial support.
- 3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

- 3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.
- 3.8 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.
- 3.9 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

- 3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.
- 3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bone fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

- 3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

STANDARD 4. Appropriate Management of Associated Commercial Promotion

- 4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.
- 4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.
 - **For print:** *advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity.*
 - **For computer based:** *advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content.*
 - **For audio and video recording:** *advertisements and promotional materials will not be included within the CME. There will be no "commercial breaks."*
 - **For live, face-to-face CME:** *advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.*
- 4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.
- 4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules

and content descriptions, may include product-promotion material or product-specific advertisement.

4.5 A provider cannot use a Commercial Interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.

STANDARD 5. Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a Commercial Interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If one CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

STANDARD 6. Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the Commercial Interest(s);
- The nature of the relationship the person has with each Commercial Interest.

6.2 For an individual with no relevant financial relationship(s), the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity.

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is “in-kind” the nature of the support must be disclosed to learners.

6.4 ‘Disclosure’ must never include the use of a trade name or a product-group message.

Timing of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity.

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