Conflict of Interest

Minneapolis Medical Research Foundation

Conflict of Interest Policy
Effective date 1991
Revised 1993, 1999, 2002

Policy

Personnel shall not enter into relationships or use their positions for purposes that are, or give the appearance of being motivated by a desire for private financial gain for themselves or others such as those with whom they have family, business or other ties.

If Personnel wish to initiate or continue such a conflicting relationship and remain associated with the Foundation, they shall disclose the relationship and seek a suitable leave of absence, reduction of appointment or make other arrangements with the Foundation to manage, reduce or eliminate the conflict.

General Principles

The Minneapolis Medical Research Foundation, its employees and all persons working under its auspices are committed to the highest standards of ethical conduct in all their activities and to compliance with all applicable local, state and federal laws related to conflict of interest and objectivity in research. The MMRF promotes objectivity in research by establishing standards to ensure that there is no reasonable expectation that the design, conduct, or reporting of research conducted under its auspices will be biased by any conflicting financial interest of an investigator.

The purpose of this document is to provide guidelines for determining what constitutes a conflict of interest; the levels at which this conflict must be disclosed, reviewed and approved; a procedure for disclosure, review and approval; and information relating to disciplinary actions which may be taken in the event of policy violations. This policy applies to all persons appointed, employed and/or compensated by the Foundation or who are engaged in the conduct of research under its auspices, who are responsible for, or in a position to influence, the design, conduct or reporting of research or other scholarly activity; and all persons who have direct or indirect influence over purchasing decisions, or contracts, or otherwise have official involvement in the purchasing or contracting process.

It is recognized that the involvement of individuals in outside professional activities, both public and private, often serves not only the participants but also MMRF as a whole and that no one benefits from undue interference with the legitimate, external activities of individuals who fulfill their primary full-time duties.

It has been, and continues to be, assumed that all individuals will be alert to the possible effects of outside activities on the objectivity of their decisions, their obligations to the MMRF and MMRF's responsibility to others.

Definitions

1. PERSONNEL shall mean all persons appointed, employed and/or compensated by the Foundation and all persons engaged in the conduct of research under the auspices of the MMRF who are in a position to influence the design, conduct or reporting of research or other scholarly activity, and all persons who have direct or indirect influence over purchasing decisions or contracts made on behalf of the Foundation.

2. ASSOCIATED ENTITY shall mean any trust, organization, or enterprise over which the employee, alone or together with an immediate family member, exercises a controlling interest.

3. BUSINESS INTEREST shall mean any corporation, partnership, proprietorship, firm, association, or other legal entity worldwide, excluding government entities in the United States, organized for profit, nonprofit, or charitable purposes.

4. INTEREST shall mean any of the following interests in the aggregate held in a BUSINESS INTEREST, but not in a mutual, pension or other institutional investment fund whose investment policies are beyond the control of the individual, by PERSONNEL and/or PERSONNEL'S spouse and/or dependent children:

- (a) an investment comprising equity or options to purchase equity with a total current value of more than $10,000.00 or representing more than 5% of the total BUSINESS INTEREST equity as determined through reference to public prices or other reasonable measures of fair market value; and/or
- (b) the receipt of, or the right or expectation to receive personal payments (excluding consulting fees), gifts, and other benefits, including personal loans and services, from a BUSINESS INTEREST to PERSONNEL within the previous twelve months with a total current value of more than $10,000.00; and/or
- (c) a consulting arrangement with a BUSINESS INTEREST or other agreement to provide services to a BUSINESS INTEREST with annual compensation of more than $10,000.00 (this does not include normal forms of professional activity such as attendance at professional meetings; the writing of books or articles; or the giving of lectures or speeches); and/or
- (d) status as a director, scientific director or member of the scientific board of advisors, officer, partner, trustee, or employee (other than a consultant) of a BUSINESS INTEREST.

5. SPONSORED RESEARCH shall mean research, training, and instructional projects involving funds, materials, or other compensation from outside sources under agreements that contain any of the following: The agreement binds the MMRF to a line of scholarly or scientific inquiry specified to a substantial level of detail; a line-item budget is

involved; financial reports are required; the award is subject to external audit; unexpended funds must be returned to the sponsor at the conclusion of the project; or the agreement provides for the disposition of either tangible or intangible properties that may result from the activity.

Relationships Requiring Disclosure

PERSONNEL may form relationships with BUSINESS INTERESTS, including acquiring an INTEREST in a company, provided that such relationships satisfy this policy and any other applicable policies, and state and federal laws. The Foundation encourages all PERSONNEL to form relationships with BUSINESS INTERESTS which further its research and education missions. For example, effective transfer of technology may require that the PERSONNEL who originally developed the technology have a consulting agreement with or otherwise assist the BUSINESS INTEREST in acquiring rights in the technology. Under such circumstances, equity in the BUSINESS INTEREST may be an appropriate means to compensate the PERSONNEL. The BUSINESS INTEREST may also desire to fund further Foundation research concerning the technology to be conducted by those PERSONNEL. These combination relationships and other relationships are permissible, and may indeed be desirable to meet Foundation objectives, provided that the disclosure requirements in this policy are satisfied. Disclosure will allow the opportunity for review to ensure that the performance of PERSONNEL'S duties is not compromised.

Following are examples of relationships requiring disclosure/review:

- 1. SPONSORED RESEARCH and INTERNALLY FUNDED Proposals. PERSONNEL with an INTEREST in a BUSINESS INTEREST who propose SPONSORED or INTERNALLY FUNDED RESEARCH shall disclose the existence of the INTEREST. To the extent allowed by law, such disclosure shall be considered private until the project is awarded or internal funds are made available for the work. The disclosure shall be public information after the project is awarded or internal funds are made available.
- 2. RESEARCH Participation. PERSONNEL with an INTEREST in a BUSINESS INTEREST and who participate in RESEARCH which may affect the BUSINESS INTEREST shall disclose the existence of the INTEREST. Such disclosure shall be considered public information.
- 3. Technology Transfer. PERSONNEL with an INTEREST in a BUSINESS INTEREST shall disclose the existence of that INTEREST in the instance that the FOUNDATION is considering the transfer of rights, by license or otherwise, in technology developed by PERSONNEL to the BUSINESS INTEREST. To the extent allowed by law, disclosure shall be considered private.
- 4. Contributions. PERSONNEL must provide disclosure when a contribution is given from a BUSINESS INTEREST in which they have an INTEREST if:
    - (a) the contribution exceeds a value of $10,000 in a given year; and

    - (b) the employee knows or reasonably should know that any portion of the contribution will be used to benefit the employee's teaching, research, outreach, or public service activities.
- 5. Other Written Agreements. In addition to restrictions in applicable law, PERSONNEL with an INTEREST in a BUSINESS INTEREST shall not propose, negotiate, or approve on behalf of the FOUNDATION a contract or other commitment concerning that BUSINESS INTEREST without full disclosure of the INTEREST. The disclosure shall be considered public information. This paragraph applies to all written agreements, including, but not limited to, lease agreements, and orders and requests for goods, services, or personnel from BUSINESS INTERESTS (including equipment, consulting services, and legal services). (Other applicable policies: the conditions of Hennepin Faculty Associates policy P-110, Gifts and Gratuities, is incorporated in this policy by reference. See Appendix I for full text.)
- 6. Public Statements. PERSONNEL with an INTEREST in a BUSINESS INTEREST are expected to refrain from making public statements (statements for use by the press and/or to individuals with an interest in the stock of the BUSINESS INTEREST) regarding SPONSORED and INTERNALLY FUNDED RESEARCH prior to publication of the results in recognized scientific literature or presentations at recognized scientific meetings.
- 7. PERSONNEL with an INTEREST in a BUSINESS INTEREST, shall state such INTEREST when reporting research results and when providing expert commentary on a subject that may affect the BUSINESS INTEREST.
- 8. PERSONNEL whose research was sponsored by a BUSINESS INTEREST shall disclose such sponsorship when reporting research results and when providing expert commentary on a subject that may affect the BUSINESS INTEREST.
- 9. PERSONNEL with an INTEREST in a BUSINESS INTEREST who are proposing to perform research involving human subjects or animal subjects where the research may affect the BUSINESS INTEREST, shall disclose that INTEREST in the approved human subjects informed consent form or the animal usage form.
- 10. Research Collaborations. When PERSONNEL participate in sponsored research involving sub-grantees, contractors, or collaborators outside the MMRF, the MMRF, to the extent required by the sponsor, will take reasonable steps 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 the 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.
- 11. The Foundation requires members of the MMRF Board of Directors, its Chief Operating Officer, Controller, and all MMRF Administrators at the Division Director level or above and all PERSONNEL to provide an annual disclosure/certification regarding conflict of interest.

Disclosure Process, Review, and Notification of Change

It is essential that actual and potential conflicts of interest be disclosed and reviewed to assure that they do not improperly affect MMRF research and other activities. PERSONNEL may also disclose and seek review where conflict or potential conflict exists that does not meet MMRF's stated disclosure criteria. Review will occur and approval will be granted or denied within two weeks of submission of complete disclosure documents to the Vice President of Operations.

Disclosure shall be made in the format prescribed by the MMRF Conflict of Interest Disclosure Checklist with an attached memo outlining the INTEREST of the PERSONNEL and defining the nature of the contract or other agreement and the BUSINESS INTEREST involved. Where possible, appropriate documentation shall be attached. This memo shall be submitted in a timely manner to permit consideration by appropriate administration officials prior to consummation of the proposed relationship.

The disclosure memo and any associated documentation such as contracts or proposals shall be submitted to the appropriate department chief for review and approval and forwarded to the Vice President of Operations. All disclosures shall be reviewed by the Committee on Conflict of Interest and such consultants as deemed necessary.

Annual disclosure/certification shall be in a format recommended by the Conflict of Interest Committee and approved by the MMRF Board of Directors.

It is the responsibility of all Board members and all PERSONNEL to notify the Foundation of any changes in INTEREST originally reported. Such notification shall be made in a timely fashion (usually within a month) and in writing to permit reassessment by appropriate Foundation officials. Change in INTEREST notifications should be sent to the Vice President of Operations.

The Committee on Conflict of Interest

The FOUNDATION will maintain a Committee on Conflict of Interest 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:

- 1. to assist in the implementation of this policy;
- 2. 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);
- 3. to review disclosures of conflict of interest;
- 4. to develop and approve any plans to manage, reduce or eliminate conflicts;
- 5. 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;
- 6. upon the request of affected PERSONNEL, to review a decision by an administration official that an INTEREST constitutes an actual conflict of interest; and

- 7. to periodically review this policy, including the set financial thresholds.

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 of the Foundation), the Chair of the IRB and the Chair of the ACURS Committee 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.

Outcomes of Review and Disciplinary Action

Possible recommendations: One possible recommendation as a result of the review is 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. 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.

Appropriate disciplinary action may be taken by the FOUNDATION against PERSONNEL who violate this policy. Disciplinary actions, in addition to any legal penalty(ies), may include oral admonishment, written reprimand, reassignment, demotion, suspension or termination. 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.

Revised Policy Approved by MMRF Board of Directors, 12/16/02.