

## System

Fairview Health Services

## Policy

# Conflict of Interest: Research Policy

### Purpose:

Fairview, its employees, and others affiliated with Fairview, are committed to conducting themselves and Fairview activities in accordance with the highest standards of integrity and ethics and in compliance with applicable state and federal laws related to conflict of interest and objectivity in research. It is the purpose of this policy to set forth the principles for identifying the potential for conflicts and the procedures for reviewing and addressing those potential conflicts that occur to assure that they do not improperly affect Fairview research and other activities.

### Policy:

Employees and others affiliated with Fairview who are responsible for, or in a position to influence, the design, conduct or reporting of research or other scholarly activity must comply with all applicable state and federal laws and regulations, including those related to conflict of interest and objectivity in research, and must disclose potential conflicts of interest and otherwise comply with the terms of this policy.

A conflict of interest occurs when a Fairview Researcher compromises professional judgment in carrying out teaching, research, outreach, or public service activities because of an external relationship that directly or indirectly affects the financial or business interest of the Fairview Researcher, a family member, or an associated entity.

Fairview assumes that potential for conflicts will occur regularly in the normal conduct of activities. However, it is essential that the potential for conflicts be disclosed and reviewed. After disclosure, Fairview can then make an informed judgment about a particular case and require appropriate oversight, limitations, or prohibitions on the activity in accordance with this policy.

### Definitions:

**Associated Entity:** "Associated entity" means any trust, organization, or enterprise over which the Fairview Researcher, alone or together with a family member, possesses a business or financial interest that would be required to be disclosed under this policy.

**Business:** "Business" means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other nongovernmental legal entity organized for profit, nonprofit, or charitable purposes.

**Business Interest:** "Business interest" means holding an executive position or membership on a board regardless of compensation.

**Executive Position:** "Executive position" means any position that includes responsibilities for a significant segment of the operation or management of a business.

**Fairview Researcher:** "Fairview Researcher" means any Fairview employee and any non-employed medical staff member or other person conducting or participating in research in whole or in part at a Fairview facility or using

Fairview non-public information, patients or resources for purposes of research. This definition does not include personnel of the Academic Health Center.

**Family:** "Family" means the person's spouse or domestic partner, or dependent children.

**Financial Interest:** "Financial Interest" means anything of monetary value, whether or not the value is readily ascertainable, for example:

A. an interest in a business consisting of any stock, stock option, or similar ownership interest in such business, but excluding any interest arising solely by reason of investment in such business by a mutual fund, pension, or other institutional investment fund over which the employee does not exercise control; or

B. receipt of, or the right or expectation to receive, any income from such business in one or more of the following forms: a consulting fee, honoraria, salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing technology or other processes or products, rent, capital gain, or any other form of compensation.

**Financial Conflict of Interest:** "Financial conflict of interest" means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

**Institutional Responsibilities:** "Institutional responsibilities" means the Fairview Researcher's professional responsibilities on behalf of Fairview Health Systems, including: research, research consultation, teaching, professional practice, Fairview committee memberships, and service on panels such as an Institutional Review Board or Data and Safety Monitoring Board.

**Participate:** "Participate" means to be a part of the described activity in any capacity including, but not limited to, serving as the principal investigator, co-investigator, research collaborator, or provider of direct services or patient care, or having authority over any of the above. The term does not apply to the study participants, unless they are in a position to influence the study's results or have privileged information as to the outcome.

**University Conflict Policy:** "University Conflict Policy" means the University of Minnesota Board of Regents Individual Conflicts of Interest Policy as adopted April 8, 1994 and amended last on March 12, 2010 or any subsequent policy amending or superseding such policy.

## **Procedure:**

### I. General

Employees responsible for, or in a position to influence, the design, conduct, or reporting of research or other scholarly activity must comply with all applicable state and federal laws and regulations, including those related to conflict of interest and objectivity in research. These laws include, but are not limited to, Federal Public Health Service regulations 42 CFR, part 50, subpart F, and 45 CFR, part 94, and National Science Foundation Grant Policy Manual 510 as amended by 60 FR 35820 (1995).

### II. Potential Conflicts of Interest

Potential conflicts of interest arise when a Fairview Researcher participates in teaching, research, outreach or public service activities and the Fairview Researcher, family members, or associated entities have any discloseable financial

or business interest in the technology, process, product, or other subject matter of the activity or in any business supporting the activity. In general, a potential conflict exists if the Fairview Researcher, family member or associated entity has a business or financial interest that could be enhanced based on the outcome of the activity. Some activities that raise potential conflicts of interest are ordinarily allowable following disclosure and, where necessary, the implementation of oversight or other management procedures. Other activities and external relationships require case-by-case review and only some of the specific relationships may be approved. Special oversight or management procedures are likely to be required.

### III. Disclosure Requirements

#### A. Interests that Require Disclosure:

Financial or business interests that require disclosure are defined as follows:

1. The Fairview Researcher, a family member, or an associated entity holds, in the 12 months preceding the disclosure, an equity interest in any amount in a business that is privately held, or an aggregated equity interest in a publically held company with a value of \$5,000 or more, as determined through reference to public prices or other reasonable measures of fair market value;
2. The Fairview Researcher, a family member, or an associated entity received an aggregated annual income of all types from a business equal to or exceeding \$5,000 in the 12 months preceding the disclosure;
3. The Fairview Researcher, a family member, or an associated entity has intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests;
4. The Fairview Researcher or family member has a business interest; or
5. The Fairview Researcher had an occurrence of travel paid for or reimbursed by a business entity, as this must be reported unless the trip was paid for or reimbursed by a governmental agency, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

When Fairview Researchers participate in sponsored research involving sub-grantees, contractors, or collaborators outside of Fairview, Fairview, 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 Fairview's policy or obtaining written assurances from the outside entity that it complies with applicable federal regulations or sponsor policies on conflict of interest.

In addition to the disclosure requirements set forth in this policy, various government agencies and sponsors may have additional disclosure requirements. All Fairview Researchers are required to comply with such additional requirements.

Funding for the project will not be accessible to the employee until the disclosure of the financial or business interest is reviewed and approval is given, and other appropriate measures have been implemented in accord with this policy.

## B. Making Disclosures:

Any time a Fairview Researcher plans to initiate research activity, the Fairview Researcher must disclose financial or business interests related to their Institutional responsibilities before commencing the activity.

- No later than the time of application for research funds from the U.S. Public Health Service (PHS);
- Prior to submitting an application to the Institutional Review Board (for non-PHS-funded research);
- Annual renewal of disclosures on March 1 of each calendar year following the initial disclosure; and,
- Within 30 days of acquiring a new financial or business interest as defined below which requires disclosure.

Whenever substantial changes occur that the Fairview Researcher believes may alter the financial or business interests previously disclosed, an updated form must be submitted within 30 days.

The Form attached as Exhibit A should be used and such disclosures should be made to Fairview Research Administration.

Disclosure of financial or business interests must also be made by any Fairview Researcher at the time of appearance, either in person, or by way of a written communication, before any public body, commission, group, or individual, to present facts or to give an opinion respecting any issues or matters up for consideration discussion, or action.

## IV. Procedures for Resolving Conflicts of Interest

Fairview Research Administration will forward all disclosed potential conflicts of interest to Fairview's Chief Compliance Officer who shall bring such matters forward to Fairview's Research Conflict of Interest Review Committee for resolution. The Committee shall either decide:

A. that no potential conflict of interest exists; or

B. that an impermissible conflict of interest exists and the research project cannot go forward; or

C. that an impermissible conflict of interest exists but a management plan can be provided that allows the project to go forward.

- Examples of conditions and restrictions that might be imposed to manage a financial conflict of interest include:
  - Public disclosure of financial conflicts of interest (e.g., when publishing or presenting the research);
  - Disclosure of the conflicts of interest directly to the 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 financial conflict of interest;
  - 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;
  - Reduction or elimination of the financial interest (e.g., sale of an equity interest);
  - Severance of relationships that create financial conflicts.
- Fairview Health Services will monitor all management plans on an ongoing basis.

The Fairview Research Conflict of Interest Review Committee shall consist of Fairview's Chief Compliance Officer; System Director, Research Administration; General Counsel; Chief Clinical Integration Officer; and one or more members appointed by the Chief Compliance Officer.

The Fairview Research Conflict of Interest Review Committee shall be accountable to the Audit and Compliance Committee of the Fairview Board of Directors regarding conflicts related to board members and senior Fairview management.

The Chief Clinical Integration Officer will maintain records of all disclosure statements filed and all actions taken by the institution, for at least three years beyond the final expenditure report of the award or until resolution of any action by Fairview or governmental agencies involving the records. All records will be maintained in a manner to protect confidentiality but will be accessible to sponsoring agencies as required by federal regulations or sponsor policies.

Prior to the expenditure of sponsored research funds, Fairview, to the extent required by the sponsor, will notify it of the existence of any potential conflict of interest and provide assurance that the interest has been managed, reduced or eliminated.

#### V. Sanctions

Breaches of this policy include, but are not limited to, failure to file, intentionally filing an incomplete, erroneous, or misleading disclosure form, or failing to provide additional information as required by the approving authority. A violation of this policy may be the basis for discipline of an employee or other person acting as a Fairview Researcher. If sanctions are necessary, they will be imposed in accordance with other applicable Fairview policies and procedures. The potential sanctions may include, but are not limited to the following:

A. Implementation, on at least an interim basis, of a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict going forward;

B. Submittal to a retrospective review within 120 days of the disclosure to determine whether any research conducted during the period of noncompliance was biased in the design, conduct, or reporting of such research;

C. Letter of admonition;

D. Requirement of additional training regarding financial conflicts of interest;

E. Ineligibility of the Fairview Researcher to use Fairview facilities for research, the imposition of conditions on or supervision of such research, ineligibility for grant applications, or other appropriate sanctions;

F. Suspension; or

G. Dismissal

In any case in which the U.S. Department of Health and Human Services determines that a PHS-funded project of clinical research 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 financial conflict of interest that was not managed or reported by Fairview as required by federal regulations, Fairview shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

If a Fairview Researcher who is involved with sponsored research fails to comply with this policy, then Fairview's Director of Research must promptly inform the Chief Compliance Officer of the violation. To the extent required by the sponsoring agency, the Chief Compliance Officer will then notify the agency of the violation and any corrective action taken or to be taken.

#### VI. Educational Requirements

All Fairview Researchers who are required to report business and financial interests under this policy must complete training regarding Fairview's policies and procedures on conflicts of interest and any applicable state and federal laws at least once every three years.

#### VII. Public Disclosure

Prior to the expenditure of any funds under a PHS-funded research project, Fairview shall make information concerning identified financial and business conflicts of interest publicly accessible within 5 days of receiving a written request for such information.

#### **Policy Owner(s):**

Chief Compliance Officer & System Director, Research Administration

#### **Approved By:**

Chief Clinical Integration Officer

#### **Date(s):**

**Date Effective:** December 16, 1999

**Date Reviewed:** 4/2007; 5/2011; 8/2012