

RFMH Institutional Conflict of Interest Policy

Scope of the Policy:

Situations where RFMH may have or be perceived to have a conflict of interest relating to research or other corporate programs conducted by RFMH.

Definition: RFMH may have a conflict of interest whenever the financial or business interests of RFMH might affect or reasonably appear to affect, institutional processes for the conduct, direction, review or oversight of research or other corporate programs.

This policy does not cover actual or perceived conflicts of interest of individuals affiliated with RFMH. Conflicts of Interest of individuals are covered by policies including the following:

- Conflict of Interest Policy
- Outside Activity Policy
- Article VI of the By – Laws: Duties of Directors and Officers, and Conflicts of Interest
- Policy on Disclosure of Financial Interest

Policy:

RFMH acts through the actions of people with administrative authority and responsibility. If an individual has significant administrative authority and responsibility over issues involving research or other corporate activities, including decisions with respect to research contracting, allocation of resources, acceptance or monitoring of risk derived from research, an institutional conflict of interest will be deemed to exist if that individual has a personal financial conflict of interest, real or apparent, in a particular research project. Significant administrative authority and responsibility means the type of authority normally exercised by an Officer, Director, Board Committee Member, or other senior officials.

RFMH will seek to eliminate or manage any institutional conflicts of interest. RFMH will disclose in an appropriate manner and form to the relevant concerned individuals or organizations all institutional conflicts of interest related to research or other corporate activities.

If human subject research is involved RFMH will take particular care with respect to management of any potential institutional conflict of interest to assure that the welfare of human subjects and the integrity of the research are not compromised.

RFMH will separate the functions and administrative responsibilities related to research from those related to investment of RFMH funds and to institutional purchasing.

If any person believes that RFMH as an institution may have a conflict of interest which is not being appropriately addressed with respect to the conduct, direction, review or oversight of research or other corporate activities he or she should inform the chairperson of the Governance Committee or the President.

Process

If the Chairperson of the Governance Committee determines that a significant possibility exists that there is an institutional conflict with respect to research or other corporate activities, the Chairperson will notify the people involved to refrain from making a decision or taking any action until the situation can be investigated and a decision made as to whether a conflict of interest exists and, if it does, the plan for managing the conflict put in place.

The Chairperson will ensure that the matter is appropriately reviewed either by the Governance Committee or by a Committee appointed by the Governance Committee for the purpose of reviewing the conflict. The Committee shall include at least three members, and may include people not affiliated with RFMH, to ensure appropriate expertise and consideration of the conflict.

The Committee shall report its findings to the Chairperson of the RFMH Governance Committee and/or the President as appropriate.

If the potential conflict involves the Chairperson of the Governance Committee, the President or a person specifically designated by the President will assume the role and functions designated for the Chairperson under this policy.

Special Consideration for Clinical Trials

If human subject research is involved, RFMH will take particular care with respect to management of any potential institutional conflict of interest to assure that the welfare of human subjects and the integrity of the research is not compromised.

If an institutional conflict of interest exists regarding any clinical trial, RFMH will only lead, direct or control a Phase I or Phase II study if compelling scientific reasons exist and an institutional conflict of interest plan is in place. If an institutional conflict of interest exists regarding any clinical trial, RFMH generally will not lead, direct or control a Phase III or IV clinical trial (e.g. be the lead site or serve on the Executive Committee of the study) except in extraordinary circumstance where not to do so would seriously jeopardize the science and the potential public benefit and then only if an institutional conflict of interest management plan is in place. If an institutional conflict of interest exists regarding any clinical trial, RFMH may participate in any phase of a clinical trial solely as a study site if another institution(s) leads, directs and controls the study and an institutional management plan is in place.

Factors to be considered in determining whether compelling reasons exist for continued RFMH involvement include, but are not limited to:

- Whether the trial is at multiple sites and, if so, whether RFMH's role is relatively passive or is the site gathering and/or monitoring the data from all other sites.
- Whether RFMH's resources are fundamentally important to the progress of the science or the RFMH investigator is uniquely qualified or necessary to administer the trial.
- Whether the interests of the human subjects will be adversely affected by use or non-use of RFMH as a site.
- The proportion of the total subjects in the study that are under the supervision of RFMH.

If the decision is made for RFMH to conduct the study when an institutional conflict of interest exists, the Chairperson of the Governance Committee shall appoint a monitoring committee to formulate, adopt and oversee compliance with an institutional conflict of interest management plan to protect human subjects and the integrity of the research from any influence from the Institutional conflict. The institutional conflict of interest management plan must be shared with the RFMH Institutional Review Board(s) that is responsible for review and oversight of the study and must include a requirement of full disclosure of RFMH's interest to research subjects and, if appropriate, to others. Monitoring of institutional conflict of interest shall be coordinated with monitoring of any related individual investigator or key personnel conflict management plans. The monitoring committee must be chaired by a respected scientist from outside RFMH who has no real or apparent conflict of interest in the study.

Potential Sources of Institutional Conflict of Interest

A RFMH financial interest in a commercial entity, in and of itself, does not automatically present a conflict of interest. Potential sources of institutional conflict of interest include, but are not limited to:

1. RFMH ownership of equity interests, other corporate securities or entitlements in entities that sponsor RFMH research that are obtained through technology transfer or transactions with such entities other than through decisions made by disinterested outside investment advisors who have been instructed not to take RFMH research activities into consideration in their decision making.
2. RFMH receipt of royalties (or potential royalties) that depend on future sale of products or technology related to RFMH ongoing research or other consideration from sale of products or technology related to RFMH ongoing research.
3. RFMH receipt of substantial or recurring gifts, equipment donations or promises thereof (direct or implied) that are not a part of a disclosed sponsorship or sponsored program from commercial sponsors of research if there is an actual or implied quid pro quo owed to the donor that relates to or could give rise to the appearance of relating to the research.
4. RFMH investment, or ownership in lieu of taking royalties, in a start-up company related to RFMH research
5. Investment of RFMH funds in entities which sponsor research conducted by RFMH or with which RFMH has other business relationships.
6. Purchasing goods or services from a company that sponsors research or a company that licenses RFMH technology.

Examples

The following are examples of institutional financial interests that may affect, or reasonably appear to affect, institutional processes for the conduct, direction, review, or oversight of research or other corporate activities and, therefore, constitute potential conflicts of interest:

1. A company proposes to provide research funding to RFMH for further development of a technology previously licensed by RFMH to the company and from which company RFMH derives a financial interest, e.g. a royalty stream.
2. A company in which RFMH has a significant equity interest (not acquired, held and controlled by an outside investment manager precluded from considering information related to RFMH's research activities) proposes to provide funding for research of any kind, whether or not the

proposed research or clinical trial is related to the technology that was previously licensed to the company and from which the equity is derived.

3. A company proposes to provide funding for a clinical trial of a product or device that was developed by the company with the use of RFMH technology previously licensed to the company and from which RFMH financial interest is derived.
4. Material purchase of goods or services from a company which is also providing funding for a research project or clinical trial.