Rochester General Health System's Conflict of Interest Policy

(Words and phrases that appear in *italics* are defined in the Definitions section of the policy.)

I. Prologue

The integrity of Rochester General Health System's research requires the open exchange of ideas in an atmosphere free from commercial conflict and influence. Therefore, RGHS must ensure that reports of research and scholarship can be disseminated on an open and timely basis without externally imposed requirements of restriction or review, in keeping with RGHS long-honored research traditions. To this end, all *research personnel* at RGHS who have a significant input in research are expected to be open about any involvements with, and obligations to, external parties that could be interpreted as leading to such restrictions. This is especially important in those cases where relationships with external parties could lead to personal financial benefit from their scholarly work or ideas, or from the scholarly work or ideas of colleagues.

The primary intent of this policy is to help *research personnel* more effectively manage potential conflicts in the course of their RGHS activities. By reporting financial interests and managing conflicts from the start, RGHS and the *researcher* can work together to prevent outcomes that may be harmful to either the *researcher* or RGHS. Further, this policy fulfills federal grant requirements to report certain financial interests.

II. Introduction

This statement contains RGHS policies and procedures governing conflict of interest. These policies apply to all *research personnel* at RGHS who have a significant input in research. RGHS Conflict of Interest Committee (COIC) is responsible for ensuring implementation of these policies and may suspend all relevant activities until the conflict of interest is resolved or other action deemed appropriate by the COIC is implemented. Violation of any part of these policies may, in extreme cases, constitute cause for actions to mitigate the situation.

Conflicts of interest (financial or other) are common and often unavoidable in a modern research facility. They can arise from the fact that one mission is to promote the public good by fostering the transfer of knowledge gained through research and scholarship to the broader world, which includes the private sector. Two important means of accomplishing this mission are *Investigators* consulting and the commercialization of technologies derived from their research. It is appropriate that *Investigators* be rewarded for their participation in these activities through consulting fees and sharing in royalties and other financial devices resulting from the commercialization of their work. It is not appropriate, however, for an individual's professional objectivity to be affected by considerations of personal financial gain.

While this policy addresses the management of conflicts of interest for *research personnel*, RGHS also has an obligation to ensure that its own financial interests are not inconsistent with or detrimental in any way to its core missions.

Definitions

Clinical trials refers to all research studies that involve both interaction with human subjects and the concurrent use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

Confidential information refers to confidential information of RGHS. It includes, but is not limited to, medical, personnel, or security records of individuals; proprietary knowledge about anticipated material requirements or price actions; and proprietary knowledge of possible new sites for government operations or information about forthcoming programs or selection of contractors or subcontractors in advance of official announcements.

Conflict of Interest Committee refers to RGHS committee that reviews conflict of interest matters. The committee will consist of nine members. The committee will include four members from the Clinical Investigation Committee (CIC) including the Chair of the CIC, one RGHS administrator, an attorney, a member of nursing research, a professional staff member from Rochester Institute of Technology, and a community member.

Family members refers to members of the immediate family, specifically dependents, spouses, and domestic partners.

Research Personnel refers to all individuals holding a research position at RGHS. It would include the ***Investigator*** such as the principal investigator(s) (PI), co-investigator, and any other person (e.g., post-doctoral fellows, senior scientists, graduate students) who is responsible for the administration, design, conduct, or reporting of sponsored research; research involving the use of RGHS resources that are not generally available to the RGHS community; internally funded research that involves human subjects; or proposals for funding. This definition is not limited to those titled or budgeted as investigator on a particular proposal. Residents and other relevant personnel may be considered investigators where, in the judgment of a supervisor, the resident or other personnel is working relatively autonomously and should be considered an investigator.

Project period is defined as the start of the study until one month after the publication of the main study results in a peer-reviewed journal or if the study is closed prematurely due to extenuating circumstances (e.g. efficacy of investigation drug or safety issues) one month after study termination.

Significant Conflict of Interest (financial or other) includes the following association with a company(ies) whose value may be affected your research. The association would include that which you, your spouse, domestic partner or dependent children have with the company(ies) during the project period:

1) Own shares of stock, stock options, partnership interest, or other ownership interest of greater than 5% or > $5,000 if a company is publicly or not publicly traded
2) Received or expect to receive > $5,000 in compensation for consulting from a company
   Received or expect to receive > $5,000 in compensation for any position in a company
3) Serve as management or on the board of directors of a company
4) Serve on an advisory board of a company
5) Have an interest in a patent, copyright, or licensing agreement whose value may be affected by research
6) Have assigned your interest in any invention, patent application etc to an outside entity
7) Received or expect to receive > $5,000 in honoraria or royalties for book, publications or lectures from a company
8) Received or expect to receive > $5,000 in personal income directly from a company for licensing your discoveries
9) Appointment to a company sponsored Editorial Board or Speaker's Bureau (defined as more than one lecture affiliated with the same company in the past year)
10) Research funding, educational grants, or contracts amounting to more than $5,000
11) Personal gifts, compensation or rewards in the amount of >$5000 from a company

Significant interest does **NOT** include:

1) Salary, royalties, or other remuneration from Rochester General Health Systems
2) Income from the authorship of academic or scholarly works
3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
4) Income from service on advisory committees or review panels for public or nonprofit entities
5) Equity managed by an unrelated, unbiased third party (e.g., invested in a mutual fund); or
6) Equity interests and/or remuneration that does not affect, appears not to affect, is not affected by, and appears not to be affected by, the *researcher's* teaching, research, clinical, administrative, or other job related activities

III. General Principles of Conflict of Interest

A conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to RGHS. The conflict may be either actual or apparent—apparent conflicts of interest arise in circumstances in which an independent observer (such as *COIC*) might reasonably question whether the individual's professional objectivity in that situation is affected by considerations of financial gain.

The goal of the policy is to avoid or to manage situations that call into question the credibility and objectivity of the research and findings by the *researcher*. *Research personnel* must respect this principle and conduct their affairs in ways that do not compromise the integrity of RGHS. In addition RGHS recognizes that even the perception that a *researcher* has financial interests in the outcome of their research can call into question the credibility and objectivity of this research.

Research personnel are to conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise.

To that end, the purposes of this policy are to inform the *researcher* about situations that generate conflicts of interest, to provide mechanisms for a *researcher* and RGHS to manage those conflicts of interest that arise, and to describe situations that are prohibited. Every *researcher* has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, a *researcher* may contact the *Conflict of Interest Committee*.

IV. Discussion and Details

1) Who Should Complete a Conflict of Interest Form?

All *research personnel* who have a significant role in a research study (involved in development or impact on outcome) must complete Rochester General Health System's Conflict Reporting Form including:

- All students, post-doctoral fellows, residents, scientists and staff who are responsible for the administration, design, conduct or reporting of research; and
- Any study coordinator or other employee actively involved in conducting sponsored research.

Researchers who are not investigators but who play a significant role in the research are required to complete the Conflict of Interest form.

2) Annual and Ad hoc Reports

An individual, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of inappropriate behavior. (*Research personnel* are encouraged to ask for guidance from the *Conflict of Interest Committee*.)

a) Annual Disclosures

The conflict of interest form must be submitted to the *Conflict of Interest Committee (COIC)* by March 1 for the previous calendar year, or within 60 days of appointment.
If the annual reporting form reveals a potential conflict, a conflict management plan will be required (see Guidance on Developing a Conflict Management Plan).

b) Ad hoc Reports

In addition to annual reporting, certain situations require Ad hoc reporting. Prior to entering into sponsored projects where the relevant *research personnel* such as the investigator, coordinator, student, postdoctoral fellow, resident, staff, or *family member* has a *significant financial interest*, that individual must submit to the *COIC* a complete written report of his or her current or pending *significant financial interest* with the outside entity, the relationship of the proposed activity to the entity, and a conflict management plan.
While the potentially conflicted individual is responsible for submitting the management plan, he or she may seek the assistance of the *COIC*.

3) Procedures and Decisions of the *Conflict of Interest Committee*

The *Conflict of Interest Committee* may decide to eliminate, reduce, or manage any conflict. The *COIC* will send their decision, in writing, to the *researcher* (or other relevant party) and, as appropriate, to relevant individuals (CIC, chairperson of investigator's department or nursing research administration). The written decision must include an explanation of the reasons for the decision.

If the *COIC* determines that there is a conflict that can be managed, the COIC must approve a management plan before any arrangement goes forward. The *researcher* is entitled to expect relatively prompt action. If the *COIC* needs additional information from the *research* individual, the committee must request that information within one month of receipt of the management plan. In the event that the *COIC* has not reached a decision within 45 days after a conflict of interest management plan is submitted and the *researcher* has provided all relevant information to the *COIC*, the requester may make an appeal to the *COIC* to move the process forward.

If time is of the essence, the *COIC* may approve an interim management plan and update the plan as more information becomes available.

If the *research* individual believes that improper procedures have been applied or that bias or prejudice influenced the procedures in the decision of the *COIC* regarding a potential conflict of interest, the *research* individual may appeal the decision through the *COIC.* Appeals regarding Rochester General Health System's *Conflict of Interest Committee* decisions can be submitted in writing to the *COIC* by a principal investigator. This process allows the *research individual* to bring issues or concerns to the *COIC* for reconsideration without compromising the integrity of the *COIC* review process. The outcome of the appeal will be reported to the *researcher* making the appeal, CIC, chairperson of investigator's department or nursing research administration.

If this appeal does not bring satisfaction to the *researcher*, he/she has the option to appeal to the Chief Executive Officer (CEO) of Rochester General Health Systems Chief or his designee who will adjudicate the issue.

The Committee shall have authority to recommend suspension or terminate of approval of research by the Clinical Investigation Committee if it is felt the study is not being conducted in accordance with the *Conflict of Interest Committee's* requirements. Any recommendation of suspension or termination shall include a statement of the reasons for the *Conflict of Interest Committee's* action and shall be reported promptly to the investigator, the CIC and appropriate institutional officials.

4) Other RGHS Officials Encountering Conflicts

Senior administrators also may seek the advice of the *Conflict Of Interest Committee* if a potential conflict has emerged in the course of exercising their RGHS responsibilities.

5) Management of Conflicts

The *Conflict of Interest Committee* will assess management measures proposed by those with a conflict of interest (see form Guidelines for Managing Conflict of Interests).

6) Clinical Trials

Clinical trials involve particularly sensitive issues in those cases where the *investigator* has personal financial interests related to the *clinical trial*. *Research personnel,* who have a significant financial interest, when conducting *clinical trials*, must report their *significant financial interest* in accordance with this policy. (This reporting requirement is in addition to any disclosures required by the Rochester General Health System's IRB.)

An individual who holds a *significant financial interest* in *clinical trial* research may not conduct such research at the RGHS unless he or she can show compelling reasons to do so. This prohibition extends to all who report (directly or indirectly) to the financially conflicted individual. The determination of whether or not there exist compelling circumstances for the financially conflicted individual to conduct the trial will be made by the *COIC* after examining the *investigator's* written justification. In the event of compelling circumstances, an individual holding a *significant financial interest* in *clinical trials* research may be permitted to remain involved in the research. Whether the circumstances are deemed compelling will depend in each case upon the nature of the science, the nature of the interest, how closely the interest is related to the research, and the degree to which the interest may be affected by the research (e.g., the phase of the *trial*). However, when the *significant financial interest* is an equity interest in a start-up company that licenses or manufactures the investigational product, participation in any manner other than a consulting role is prohibited.

If the *COIC* determines that the circumstances are compelling, a conflicted *researcher* seeking involvement in a *clinical trial* must devise a written conflict management plan to be approved by the *COIC* in advance of initiating the *trial*. In all *clinical trials* with a conflicted individual, the conflict management plan must include at a minimum, a full disclosure of the interest (to research subjects and others as appropriate, and in publications). In most circumstances, the management plan should also require informed consent by a clinician with no financial ties to the research. The *COIC* may permit the conflicted individual to obtain consent only in situations where the financial interest is de minimus and no other qualified individual would be available to explain the risks, benefits and alternatives to participating in the trial. The management plan may seek to identify another principal *investigator* to oversee the administration of the trial, including enrollment of subjects, the subject consent process, testing of the drug or device, and analysis of results. The appointed *investigator* must be qualified to administer the study protocol, and must not be someone over whom the conflicted *investigator* has supervision. A conflicted individual may, with the approval of the *COIC,* continue his or her involvement in the *clinical trial*, typically in a technical advisor role. Only when there is a critical need for the conflicted *investigator* to remain the principal *investigator* may the *COIC* approve such a role. A written management plan that allows for the conflicted *investigator* to be the PI must include a justification for this departure from standard protocol. Also, the conflicted *investigator* must submit his or her approved conflict management plan to the IRB at the time the protocol is submitted for review.

7) Record Retention

The Conflict of Interest Committee will retain all reporting forms, conflict management plans, and related documents for a period of three years after the completion of the relevant research or three years after the conflict has ended.

8) Confidentiality

To the extent permitted by law, all reporting forms, conflict management plans, and related information will be confidential. However, such information will be made available to an agency funding research of the *research personnel* upon written request if permitted or otherwise required by law.