

Rochester General Health System

Reporting Form for Conflicts of Interest Related to Research Activities

Name: _____ Title: _____

Department(s): _____ Period: _____ annual
Or _____ ad hoc or anticipated in the next 12 months*

Purpose: The Rochester General Health System Policy on Conflict of Commitment and Interest, and this form, assists research personnel in identifying and managing potential conflicts of interest in their research activities. By reporting and managing conflict of interest relationships, RGHS and its research personnel can work together to avoid situations that may appear to compromise their integrity. Completion of this form also fulfills federal grant requirements for reporting of financial interests in research.

Who Must Complete This Form:

All RGHS research personnel who have a significant role in research activities (involved with development or impact on outcome) 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.

Timing:

- **Annually:** This form must be completed annually and submitted between **January 1 and March 1 of each year.**
- **Upon appointment/hire:** New personnel hired at RGHS who perform research must complete and submit this form within 60 days of joining Rochester General Health System.
- **Updates:** This form must be updated and resubmitted when there is a change in activities or financial interests that would change the answers to this form (e.g., establishment of a new financial relationship with an entity prior to accepting a research award from that entity).

Definitions:

- **Human subjects research** includes obtaining data or specimens identifiable to living individuals for research purposes. It excludes research with non-identifiable specimens.
- **Clinical trial** – for the purposes of this reporting form, a clinical trial is human subject research whose purpose is to evaluate the safety and/or effectiveness of a drug, biologic, device, treatment, procedure or other intervention.
- **Family members** – spouse, domestic partner, dependent children.
- **Financial interest** – anything of monetary value, including but not limited to:
 - salary or other payments for services (e.g. consulting fees, payment for educational lectures, expert witness payments and honoraria);
 - equity interests (e.g. stock, stock options or other ownership interests, but not investments in mutual funds); and

- intellectual property rights (e.g. patents, trademarks, servicemarks, copyrights, and related royalties)
- Other – Serve as management or on an advisory board or some appointment with a company
- 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.

Background/Assistance: For background on the policy requirements and activities permitted, or if you have any questions about how to complete this form:

- Refer to the RGHS Policy on Conflict of Interest.
- You may contact the Conflict of Interest Committee.

PART I: GENERAL QUESTIONS

Respond to the questions below if you conduct research at or on behalf of RGHS (this research may or may not involve the participation of human subjects) for any company whose value may be affected by this research, do you, your spouse, domestic partner or dependent children have any of the following association with this company(ies) during the *project period*:

| | Yes | No |
|--|------------|-----------|
| a. Own any shares of stock, stock options, partnership interest, or other ownership interest if a company is not publicly traded? | | |
| b. Own shares of stock, stock options, partnership interest, or other ownership interest of greater than 5% or > \$5,000 if a company is publicly traded? | | |
| c. Received or expect to receive > \$5,000 in compensation for consulting from a company? | | |
| d. Received or expect to receive > \$5,000 in compensation for any position in a company? | | |
| e. Serve as management or on the board of directors of a company? | | |
| f. Serve on an advisory board of a company? | | |
| g. Have an interest in a patent, copyright, or licensing agreement whose value may be affected by research? | | |
| h. Have assigned your interest in any invention, patent application etc to an outside entity? | | |
| i. Received or expect to receive > \$5,000 in honoraria or royalties for book, publications or lectures from a company? | | |
| j. Received or expect to receive > \$5,000 in personal income directly from a company for licensing your discoveries? | | |
| k. 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) | | |
| l. Research funding, educational grants, or contracts amounting to more than \$5,000. | | |
| m. Personal gifts, compensation or rewards in the amount of >\$5000 from a company. | | |

ALL RESPONSES WILL BE MAINTAINED ON A CONFIDENTIAL BASIS

PART II: FINANCIAL RELATIONSHIPS WITH RESEARCH ACTIVITIES

Complete this Part for each financial interest that resulted in a yes answer to any of the Part I questions. Do not list salary support or similar payments received under RGHS sponsored research agreements.

If you are actively involved in clinical trials conducted for any of the companies listed, or conducting basic research on drugs, devices or compounds for potential use in humans, you must also fill out Part III concerning these relationships.

| Name of Company or Sponsor | Type of relationship and services provided* | Who Self _____ Family _____ Member _____ | Amount of payments/ value of interest > \$5,000 | Managerial/ Board role? (if so, list role) |
|----------------------------|---|---|---|--|
| | | Self _____ Family _____ Member _____ | | |
| | | Self _____ Family _____ Member _____ | | |
| | | Self _____ Family _____ Member _____ | | |
| | | Self _____ Family _____ Member _____ | | |
| | | Self _____ Family _____ Member _____ | | |
| | | Self _____ Family _____ Member _____ | | |

* e.g. stock ownership, consulting, intellectual property; speaker’s bureau, advisory board, management role, educational grants as outlined in the Conflict of Interest Policy.

You may use this space (or add attachments) for further explanation of your responses.

PART III: ADDITIONAL INFORMATION - FOR CLINICAL TRIALS AND BASIC RESEARCH ON DRUGS/DEVICES/COMPOUNDS FOR POTENTIAL USE IN HUMANS ONLY

Complete this part if you have a financial interest in any entity named in Part II that sponsors your clinical trials, manufactures a drug or device that you study, or conducts research or other activities related to your clinical trials or basic research on drugs/devices/compounds for potential use in humans.

Please refer to RGHS's Guidelines for Managing Conflicts of Interest in Clinical Trials for guidance.

| Sponsor (or Manufacturer or Supplier, if government or foundation grant) | Drug, device, compound or procedure being evaluated | Phase of Trial (1-4) | Single or Multi-Center? | Role in Study* | Activities in Study** |
|--|---|----------------------|-------------------------|----------------|-----------------------|
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* e.g., Study PI; Site PI; Co-PI; Co-Investigator; Sub-Investigator; Blinded Evaluator; Backup Physician; Coordinator

** e.g., write protocol; input on study design; consent subjects; data collection, analysis, or interpretation; write and/or review manuscript.

For each study listed above, describe any unique qualifications, training or other circumstances that would justify your participation in the research notwithstanding your financial interest. Such compelling reasons might include 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 could be affected by the research.

PART IV: CERTIFICATION AND SIGNATURE

Certification:

I certify that (a) the above information is true and complete to the best of my knowledge, (b) I have read the Rochester General Health System Policy on Conflict of Commitment and Interest, and (c) I am in compliance with Rochester General Health System’s policies related to conflicts of interest and commitment. I will comply with any conditions or restrictions imposed by Rochester General Health System to manage actual or potential conflicts of interest.

I agree to update and submit this Conflict Reporting Form when my financial interests or relationships or activities with outside entities, or those of my family members, change in a way that changes the answers above.

Signature:

_____ Date: _____

Conflict of Interest Committee Chair signature: (required if any yes answers)

Approved:

_____ with Management Plan

_____ no Management Plan required

_____ Date: _____

Department Chair signature

_____ Date: _____