

University of Rochester  
Reporting Form for Conflicts of Interest Related to Research Activities

Name: \_\_\_\_\_ Title: \_\_\_\_\_

School/Department(s): \_\_\_\_\_ Period: \_\_\_\_\_ annual: Jan. 1, 2008 – present  
OR \_\_\_\_\_ ad hoc

**Due: March 1, 2009 (for annual reporting process)**

Purpose: The [University of Rochester Faculty Policy on Conflict of Commitment and Interest](#), and this form, assist faculty members in identifying and managing potential conflicts of interest in their University activities. By reporting and managing financial relationships, the University and its faculty 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 University of Rochester faculty members with academic, clinical or research appointments;
- All University students, post-doctoral fellows, residents and scientists who are principal investigators or co-investigators, or are responsible for the administration, design, conduct or reporting of University research; and
- Any study coordinator or other employee actively involved in negotiation of sponsored research at the University who has a financial relationship with a study sponsor.

Timing:

- Annually: This form must be completed annually and submitted between January 1 and March 1 of each year.
- Upon appointment/hire: New faculty/hires must complete and submit this form within 60 days of joining the University.
- 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 subjects 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).

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 [Faculty Policy on Conflict of Interest and Commitment](#).
- If you conduct clinical trials, see also the Medical Center's [Guidelines for Managing Faculty Conflicts of Interest in Clinical Trials](#). You may also contact your Department Chair or the Office of Research and Project Administration.

PART I: GENERAL QUESTIONS

1. Number of days you engaged in outside consulting or other non-University business:
  - a. during the previous calendar year: \_\_\_\_\_
  - b. anticipated during the current calendar year: \_\_\_\_\_.

2. RESPOND TO QUESTIONS 2a & 2b IF YOU CONDUCT HUMAN SUBJECTS RESEARCH AT OR ON BEHALF OF THE UNIVERSITY OF ROCHESTER

- 2a. Did you or any of your family members receive **any** payments (such as salary, consulting fees, speakers fees or honoraria) from any outside entity that sponsors any of your University research, or whose interests or business are related to your University research? You should include payments received by the University that indirectly benefit you or your family members, such as income for your consulting activities that is paid to the University. *Exclude University salary support received due to research agreements between the University and the sponsor; income from authorship of scholarly works; and payments from the following if sponsored by non-profits or the government: seminars, lectures, teaching engagements, advisory committees, or review panels.*

No \_\_\_\_\_ Yes \_\_\_\_\_

Do you expect to receive any such payments during the next 12 months?

No \_\_\_\_\_ Yes \_\_\_\_\_

- 2b. Did you or your family members own or control **any** equity interests (such as stock, stock options or other ownership interests, but excluding investments in mutual funds) in any outside entity that sponsors any of your University research, or whose interests or business are related to your University research ?

No \_\_\_\_\_ Yes \_\_\_\_\_

Do you expect this to occur during the next 12 months?

No \_\_\_\_\_ Yes \_\_\_\_\_

3. RESPOND TO QUESTIONS 3a & 3b IF YOU CONDUCT RESEARCH NOT INVOLVING HUMAN SUBJECTS AT OR ON BEHALF OF THE UNIVERSITY OF ROCHESTER

- 3a. Did you or any of your family members receive any payments (such as salary, consulting fees, speakers fees or honoraria) that, in the aggregate, **exceed \$10,000** from any outside entity that sponsors any of your University research, or whose interests or business are related to your University research? You should include payments received by the University that indirectly benefit you or your family members. *Exclude salary support received due to research agreements between the University and the sponsor; income from authorship of scholarly works; and from the following if sponsored by non-profits or the government: seminars, lectures, teaching engagements, advisory committees, or review panels.*

No \_\_\_\_\_ Yes \_\_\_\_\_

Do you expect to receive any such payments during the next 12 months?

No \_\_\_\_\_ Yes \_\_\_\_\_

3b. Did you or your family members own or control any equity interests (such as stock, stock options or other ownership interests, but excluding investments in mutual funds) valued at **\$10,000 or more** in any outside entity, or that ***exceed 1%*** of the ownership interests in an outside entity that sponsors any of your University research, or whose interests or business are related to your University research ?

No \_\_\_\_\_ Yes \_\_\_\_\_

Do you expect this to occur during the next 12 months?

No \_\_\_\_\_ Yes \_\_\_\_\_

4. Did you or your family members have, or expect to have, any intellectual property rights, such as patents, patent applications, trademarks, servicemarks, copyrights, licenses and/or royalties, which are either related to your University research activities, or which might be considered related to other University activities? *Exclude intellectual property rights that directly arise from your University research and have been reported to the Office of Technology Transfer.*

No \_\_\_\_\_ Yes \_\_\_\_\_

Do you expect this to occur during the next 12 months?

No \_\_\_\_\_ Yes \_\_\_\_\_

5. Did you or any of your family members serve as an officer, director, partner, manager or employee of an outside entity that sponsors any of your University research, or whose interests or business are related to your University research?

No \_\_\_\_\_ Yes \_\_\_\_\_

Do you expect this to occur during the next 12 months?

No \_\_\_\_\_ Yes \_\_\_\_\_

6. Are University students, staff or faculty members who you directly advise or supervise involved in business activities with outside entities in which you have a financial interest?

No \_\_\_\_\_ Yes \_\_\_\_\_

Do you expect this to occur during the next 12 months?

No \_\_\_\_\_ Yes \_\_\_\_\_

IF YES to either or both questions, name the individual and the outside entity below, explain the individual's current or anticipated role with the entity, and state whether this has been approved by the Dean.

**NOTE THAT QUESTIONS 7 AND 8 ARE NOT LIMITED TO FINANCIAL INTERESTS RELATED TO RESEARCH. THESE FINANCIAL INTERESTS MAY BE RELATED TO CLINICAL, TEACHING OR OTHER UNIVERSITY RESPONSIBILITIES.**

7. Since 1/01/08, have you received payments (for example, consulting fees) from pharmaceutical, medical device companies or medical education companies (or entities that disperse funds for pharmaceutical or medical device companies) in the amount of \$50,000 in the aggregate or more, or do you expect to receive such payments during the next 12 months? *Exclude University salary support received due to research agreements between the University and the sponsor.*

No \_\_\_\_\_ Yes \_\_\_\_\_

IF YES, name the company(ies) below:

8. Do you own or control an equity interest (e.g. stock or other ownership) in any pharmaceutical or medical device company that is valued at \$50,000 or more or do you serve as an officer, director or partner in such companies?

No \_\_\_\_\_ Yes \_\_\_\_\_

IF YES, name the company(ies) below:

**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 questions 2-5 above. Do not list salary support or similar payments received under University sponsored research agreements.

**If you are actively involved in clinical trials conducted at the University 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	Approximate amount of payments/ value of equity interest	Managerial/ Board role? (if so, list role)
		<input type="checkbox"/> self <input type="checkbox"/> family member**		
		<input type="checkbox"/> self <input type="checkbox"/> family member**		
		<input type="checkbox"/> self <input type="checkbox"/> family member**		
		<input type="checkbox"/> self <input type="checkbox"/> family member**		
		<input type="checkbox"/> self <input type="checkbox"/> family member**		

\*E.g. stock ownership, consulting, intellectual property; speaker’s bureau, advisory board, educational grants.  
Do not list University research funding.

\*\*If family member, are they a University employee? \_\_\_\_\_ If so, please name: \_\_\_\_\_

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 the Medical Center’s [Guidelines for Managing Faculty 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**

\* E.g., Study PI; Site PI; Co-PI; Co-Investigator; Sub-Investigator; Blinded Evaluator; Backup Physician

\*\* 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 University of Rochester Faculty Policy on Conflict of Commitment and Interest, and (c) I am in compliance with University of Rochester policies related to conflicts of interest and commitment. I will comply with any conditions or restrictions imposed by the University 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: \_\_\_\_\_

Department Chair or Director signature (required if any yes answers) (SMD and College Only)

\_\_\_\_\_ Date: \_\_\_\_\_

Dean signature: (required if any yes answers)

Approved:

\_\_\_\_ with Management Plan  
\_\_\_\_ no Management Plan required

\_\_\_\_\_ Date: \_\_\_\_\_