

University of Rochester Medical Center
Disclosure Form for Conflicts of Interest Related to Research Activities

Name: _____ Title: _____

School/Department(s): _____ Period: annual: Jan. 1 – Dec. 31, 20____
OR ad hoc: _____ - _____, 20____

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 disclosing 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 disclosure of financial interests in research.

Who Must Complete This Form:

- All University of Rochester Medical Center faculty members with academic, clinical or research appointments of half-time or more;
- All URMC 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 clinical study coordinator or other employee actively involved in negotiation of sponsored research at URMC 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 for the previous calendar 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:

- Clinical trial – for the purposes of this disclosure form, any research involving human subjects whose purpose is to evaluate the safety or effectiveness of a drug, biologic, device, treatment, procedure or other intervention. This definition includes obtaining data or specimens identifiable to living individuals for research purposes. Research with non-identifiable specimens/data is not considered a clinical trial.
- 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 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).

Assistance: If you have any questions about how to complete this form:

- Refer to the [Faculty Policy on Conflict of Interest and Commitment](#).
- See also the [Guidelines for Managing Faculty Conflicts of Interest in Clinical Trials](#)
- You may also contact your Department Chair or ORPA for assistance.

PART I: GENERAL QUESTIONS

NOTE:

For annual submissions, respond for the past calendar year.

For ad hoc disclosures, respond for January 1 of this year to the present.

For new appointees/hires, respond for the past 12 months.

1. List the number of days you engaged in outside consulting or other non-University business.

2. Did you or any of your family members receive any payments, such as salary, consulting 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?

NOTE:

Exclude: payments from the University of Rochester; income from authorship of scholarly works; and from the following activities if sponsored by non-profit or governmental entities: seminars, lectures, teaching engagements, and advisory committees and review panels.

If you do not conduct clinical trials, you do not need to report aggregate payments that were less than \$10,000 over a twelve month period.

No _____ Yes _____

3. Did you or your family members own or control any equity interests, such as stock, stock options or other ownership interests (excluding investments in mutual funds), in any outside entity that (a) sponsors your University research, or (b) conducts research or other activities related to your University teaching, research or administrative activities?

NOTE:

If you do not conduct clinical trials, you do not need to report equity interests that are less than \$10,000 in value or 1% of the ownership interests in the entity.

No _____ Yes _____

4. Did you or your family members have any intellectual property rights, such as patents, trademarks, servicemarks, copyrights, licenses and/or royalties that are related to your University research activities? (You may exclude intellectual property rights that directly arise from your University research and are known to the URMIC Office of Technology Transfer.)

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 your University research, or that conducts research or engages in other activities that are related to your University research?

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 _____

IF YES, name the individual and the outside entity, explain the individual's role with the entity, and state whether this has been approved by the Dean.

*If you answered YES to questions 2, 3, 4 or 5, go to Part II.
If all answers were NO, go to Part IV.*

PART II: FINANCIAL RELATIONSHIPS WITH RESEARCH ACTIVITIES

Please complete the information in this Part for each financial interest that resulted in a yes answer to questions 2-5 above. Also fill out Part III concerning these relationships if you conduct clinical trials.

Name of Company or Sponsor	Type of relationship and services provided*	Self or family member	Approximate amount of payments/ value of equity interest	Managerial/ Board role? (if so, list role)	Does the entity sponsor your research?	Is there a URM conflict management plan?

*E.g. stock ownership, consulting, intellectual property; speaker’s bureau, advisory board, educational grants.

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

PART III: ADDITIONAL INFORMATION FOR CLINICAL TRIALS

- If you have a financial interest in any entity named in Part II that sponsors your clinical trials, or that conducts research or other activities that are related to your clinical trials, complete this Part. If not, go to Part IV.
- Please refer to the URM [Guidelines for Managing Faculty Conflicts of Interest in Clinical Trials](#) for guidance in completing this section.

Sponsor	Drug/device being evaluated; manufacturer	Phase of Trial (1, 2, 3, or 4)	Single or Multi-Center?	Role in Study*	Activities in Study**

* E.g., Study PI; Site PI; 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 clinical trial 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 clinical trial, and the degree to which the interest could be affected by the clinical trial.

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 Disclosure 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.

Faculty member signature:

_____ Date: _____

Dean signature: (required if any yes answers)

Approved:

_____ with Management Plan
_____ no Management Plan required

_____ Date: _____