

Conflict of Interest Statement for IRB Members

Date: _____

Name of Person giving Statement: _____

Position of person giving Statement:

- IRB Chair
- IRB Member
- Other (specify position)

Federal regulations require that IRB members abstain from participating in an initial or continuing IRB review for a project in which the member has a conflicting interest (45CFR46.107e) except to provide information as requested. IRB members who have a conflicting interest regarding a project, which is scheduled to undergo IRB review, should disclose the conflicting interest to the IRB.

To maintain the Rochester General Health System IRB's independence from researchers and sponsors and to avoid a conflict of interest, IRB members (including the spouse and dependent children of the IRB member) either do NOT have a conflict of interest or will disclose a conflicting interest.

A conflict of interest involves any situation where an IRB member has any significant personal or financial interest.

Examples of conflicting interest would be if the IRB member is a:

- Principal Investigator
- Co-Principal Investigator
- Investigator receiving funding from the study, as listed in the study budget
- In a supervisory role over the PI of the study or
- Family member of PI

A conflict of interest is also whenever an IRB member has a significant financial interest in the research proposal. A financial interest is defined as anything of monetary value, including but not limited to:

- Salary or other payments for services (e.g. consulting fees or honoraria)
- Equity interests (e.g. stocks, stock options or other ownership interests, excluding any interest arising solely by reason of investment in a business by a mutual, pension, or other institutional investment fund over which the IRB member or his/her immediate family does not exercise control)
- Intellectual property rights (e.g. patents, copyrights and royalties from such rights)

Conflict of interest does NOT include:

- Salary, royalties, or other remuneration from Rochester General Health System
- Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities
- Income from service on advisory committees or review panels for public or non-profit entities
- An equity interest that when aggregated for the IRB member and the IRB member's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public process or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity
- Salary, royalties or other payments that when aggregated for the IRB member and the IRB member's and dependent children over the next 12 months, are not expected to exceed \$10,000

I also recognize that the protection of human subjects requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing and reporting data. Therefore, I will consider conflict of interest issues in my deliberation of applications, and when appropriate, will recommend that researchers include suitable disclosure statements and relevant information related to conflicting interests in informed consent documents.

By signing this document, I acknowledge that I have read the statement on conflict of interest and that I will notify the IRB of any potential conflicts of interest I may have on a protocol by protocol basis.

Signature of IRB member

Date

The IRB Chair and each IRB member should complete this form annually.
A copy of the signed statement should be given to the person giving the affidavit.