

Rochester General Health Systems Guidelines For Managing a Researcher's Conflict of Interest in Clinical Trials

The guidelines for managing a researcher's conflict of interest in clinical trials are to be used as a supplement to existing policies on Conflicts of Interest. Rochester General Health System policy dictates that an actual or potential conflict of interest in a clinical trial, which arises when a researcher involved with the clinical trial has a significant interest (financial or other) in the research being conducted, must be disclosed by the researcher and managed or eliminated, as appropriate. If RGHS conflict of interest committee determines that a conflict can be managed, a management plan must be developed by the researcher and approved by the COIC.

An independent assessment of potential or actual conflict should be made for each clinical trial, which may result in the need for more than one plan for the investigator in question.

Most conflicts of interest created by academic-industry relationships are real, consequential, but tolerable, so long as they are managed to contain their risks while preserving their benefits. We must be vigilant against conflicts of interest that lead to bias and loss of objectivity. The integrity of research at RGHS depends on it.

What constitutes a Significant Conflict of Interest (financial or other)?

Significant Conflict of Interest as defined in the Conflict of Interest Policy (see Policy) includes the following association with a company(ies) whose value may be affected your research (such as financial *personal or indirect income*). The association would include that which you, your spouse, domestic partner or dependent children have with the company(ies) during the *projected period* of the study including:

- 1) Owning 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) Receive or expect to receive > \$5,000 in compensation for consulting from a company
- 3) Serve as management, on the board of directors or advisory board of a company
- 4) Have an interest in a patent, copyright, or licensing agreement whose value may be affected by research; have assigned your interest in any invention, patent application etc to an outside entity
- 5) Received or expect to receive > \$5,000 in honoraria or royalties for book, publications or lectures from a company
- 6) Received or expect to receive > \$5,000 in personal income directly from a company for licensing your discoveries
- 7) 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)
- 8) Research funding, educational grants, or contracts amounting to more than \$5,000
- 9) Personal gifts, compensation or rewards in the amount of >\$5000 or more from a company

Definitions:

Personal income is in addition to RGHS salary. The income can be from any organization or company that could benefit, appear to benefit, is benefited by, or appears to be benefited by the research activities or the results of the research.

Indirect income includes payment received and directed to the RGHS in which the donation could or could appear to benefit the research individual. This includes a RGHS discretionary account.

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.

Who needs to disclose a Conflict of Interest?

The general conflict of interest guiding principles (see COI policy) applied to all RGHS personnel who have a significant role in a study (involved in development or impact on outcome) must complete Rochester General Health System's Conflict Reporting Form including:

- Those involved with study planning, data analysis, data interpretation, or critical writing/editing of manuscript such that authorship is expected. (e.g., principal investigator, steering committee member, biostatistician)
- Those overseeing local or central coordination study activities, consenting subjects, limited or no review of manuscript such that authorship is **not** expected. (e.g., site principal investigator, study coordinator)
- Technical operator (e.g., surgeon, procedural specialist) in an unblinded study whose actions directly impact study outcomes

What are some of the plans that could be applied to manage a Conflict of Interest?

- 1) Disclosure of the financial interest to prospective subjects (i.e., in consent form)
- 2) Those that have a conflict of interest (COI) must identify their (COI) at meetings and recuse themselves from certain decisions
- 3) Temporary suspension of voting rights concerning study's issues
- 4) Temporary removal from committee chairmanship(s)
- 5) Additional oversight or monitoring of the research
 - a) External monitoring by independent reviewers such as biostatisticians
 - b) An independent data and safety monitoring committee
- 6) Modification of role(s) of particular research staff or changes in location for certain research activities, e.g., a change of the person who seeks consent, or a change of investigator investiture of specific assets
- 7) Separation of responsibilities for financial decisions and research decisions
- 8) Investigator removes self from participating in study activities. When an investigator decides to retain the financial interest but removes him/herself from the study he must assure that he has no real or perceived influence over those conducting the study and that those conducting the study have free and unrestricted right to analyze, interpret and publish the data
- 9) Reduction of financial interest
- 10) Severance of relationships that generate a serious conflict potential
- 11) If compliance not met, investigators could be removed from participation in study activities
- 12) Suspension of study if party with conflict of interest is not compliant