

UNIVERSITY OF ROCHESTER POLICY ON ENROLLMENT INCENTIVE PAYMENTS BY OR TO UNIVERSITY CLINICAL TRIAL RESEARCHERS

The following outlines the University's policy with respect to clinical study incentives or "enrollment bonuses". This policy is intended to ensure that enrollment practices by University investigators and research personnel do not, or are not perceived to, bias the enrollment process or jeopardize overall research integrity. For the purposes of this policy, incentives are defined as payments from study sponsors (or their contract research organizations) to either the University or University researchers for purposes of increasing the numbers and/or rate of enrollment of subjects into clinical research. Incentives may also include reimbursements for travel or other expenses that may or may not be related to the study. Incentives may also include other payments in kind, irrespective of whether they have current or future value (e.g., stock options). There are legal and ethical issues associated with incentives.

It is the University's policy not to accept or permit incentive bonus payments for investigators, study coordinators, research administrators, or other research personnel in order to encourage recruitment of subjects to clinical trials. Bonus payments for subject recruitment may compromise the integrity of that study by giving an appearance of affecting the judgement of the investigator/research team, and in some cases may violate regulations and institutional policies. Also, University health care professionals shall not offer and accept "finder's fees" (payment to referring physicians). These types of payments generally are made directly to physicians and not referenced in any clinical study agreement. Personal monetary payments, whether proposed via a University agreement or made directly to investigators or support staff, are not permissible.

In summary, the following are common types of incentives offered by clinical study sponsors to researchers (or used in clinical trial agreements) that are prohibited by University policy:

- Finder's Fees: payment to physicians (or other health care professionals) for referring subjects to investigators.
- Bonus Payments: payment either to the investigator or the institution for enhanced enrollment.
- Bonus Payments to Study Coordinators/Enrollers: payment made to study coordinators for enhanced enrollment. Sometimes payment is made directly from the company and is not associated with contract costs.

The University will accept additional per subject payment for actual costs associated with enhanced/accelerated enrollment or additional procedures required by the sponsor. Studies sometimes demand more effort than originally anticipated and additional payment can be made to offset these costs. These costs may include additional personnel time required to actively enroll subjects, evaluate eligibility of subjects and to conduct follow-up visits. Payments provided by a study sponsor in support of a clinical study must be consistent with fair market value for the services performed and documented by the University department in accordance with standard operating practices. All contract provisions associated with additional payment to offset study expenses must be reviewed in advance by ORPA. In addition, any offers for compensation and/or expense reimbursement outside of the agreement should be reviewed by either the Research Subjects Review Board or ORPA prior to acceptance.

September 2002
ORPA

