



Memorandum

OFFICE FOR HUMAN SUBJECT PROTECTION

Date: January 6, 2003
To: Sponsor Representatives
From: Jeanine Arden-Ornt, Esq., University General Counsel 
Thomas Pearson, MD, PhD, Senior Associate Dean for Research 
RE: Compensation for Injury

The University of Rochester is pleased that you have chosen to place your study here. The University is committed to conducting leading edge science and ensuring that the data produced in its research programs are of the highest quality. This commitment to scientific integrity and validity of studies, as well as the University's national reputation for its human subject protection program are benefits to sponsors placing research studies at the University.

The University incorporates high standards into its program for the protection of human subjects involved with research. The system of Institutional Review Boards has been established by the University President and the Board of Trustees to oversee the ethical review of human subjects research. The Office of Research and Project Administration negotiates contracts that comply with the University's policies, including its policies for the protection of research subjects.

The University has seriously considered the standard for compensation for human subject injury related to research studies. Because of the University's commitment to conducting ethically sound and scientifically robust studies, it is very rare that events occur that require compensation. Nonetheless, the University has established a policy that the University will provide emergency care, if needed, and that the subject will not have to pay for that care. This policy is conveyed to research subjects in the consent form through use of a standard paragraph which has been reviewed and approved by the senior leadership of the University and has been in use for several years (see attachment, second paragraph).

As part of the University assessment and continuing monitoring of subject safety and rights issues, the University identified that contract language from sponsors sometimes does not match the language proposed in model consent forms. To ensure that study subjects were being informed correctly, the University developed a standard for indemnification and adopted a paragraph for use in both contracts and consent forms that conveys that standard (see attachment, first paragraph). All University contracts are negotiated to this standard. Sponsors may indemnify the University to a higher level, but the University has determined that any a lesser level of indemnification is unacceptable.

As stated in the standard paragraph, the University requires that sponsors reimburse the University for reasonable and necessary expenses for injuries related to a research study. The University does accept the condition that payments may be first sought from insurers, if any. The University does accept responsibility for its investigators complying with the study plan but cannot guarantee that all study subjects will follow the protocol. Further, the University does not accept limitations by sponsors of device studies where reimbursement is conditional upon the injury being solely related to a defect or malfunction in a study device, rather than from any injury sustained for undertaking procedures outlined by the protocol. Thus, the level of indemnification required for industry-sponsored device studies is the same as that required for drug studies.

Thank you for your commitment to the University and your dedication to upholding regulatory and ethical standards in the important field of human subject research.

Compensation for Injury (standard paragraphs)

If you are injured by the study drug(s) or device(s), or have an adverse reaction directly related to the study, your reasonable and necessary medical expenses will be reimbursed by the [Sponsor] through the University. The [Sponsor] requires that the University use the drug(s) or device(s) according to the study plan. The [Sponsor] will not pay for expenses caused by negligence or misconduct of the University, or for expenses covered by your medical or hospital insurance. No other compensation of any type is provided for you by the [Sponsor].

The University of Rochester Medical Center will provide medical care for any emergency medical problem that you may experience as a direct result of your participation in this research. You do not have to pay for this emergency care, but the University may seek reimbursement for this care from your health insurance carrier or the study sponsor. Decisions regarding care and compensation for any other research related injury will be made on a case-by-case basis.

Note: For Highland studies, substitute “Highland Hospital” for “the University” and “the University of Rochester Medical Center”.