

Industry-sponsored Studies

Standard Required Consent Form Language:

The following consent form paragraph should be included in consent forms for industry-sponsored studies that are submitted for approval after January 31, 2008.

(Current forms should not be changed to the new wording.)

If you are directly injured by the drugs [or devices] that are being studied, or by clinical procedures solely required to participate in the study, you may need to pay for treatment of your injuries, but you will be reimbursed for the reasonable and necessary medical expenses for such treatment. You will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for treating study-related injuries from your health insurer or the study sponsor.

Notes:

For studies conducted at Highland Hospital, substitute “Highland Hospital” for “the University” in the last sentence.

It is acceptable to insert the actual sponsor’s name in place of the words “the study sponsor” and it is acceptable to remove “or devices” for drug studies or “drugs or” for device studies.