

Jan 29, 2008

Compensation for Injury – Standard Required Consent Form Language for Industry-sponsored Studies

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.

Compensation for Injury – Standard Required Consent Form Language for NON-Industry-sponsored Studies

The above standard wording is for industry-sponsored studies only. The following consent form paragraph should be included in consent forms for federally funded and investigator-initiated studies that are submitted for approval after January 31, 2008 where the affiliated drug or device company, if any, declines full indemnification.

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 not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for this care from your health insurer or third parties. Decisions regarding care and compensation for any other research related injury will be made on a case-by-case basis.

Please note that the Compensation for Injury section of consent forms will only have one (1) of the choices above. The old format with two paragraphs is no longer authorized for new studies, i.e., the standard wording paragraphs that have been used for the past few years are no longer to be used for new submissions, but they will remain in on-going studies.

Clarifying Note (October 29, 2009): The intent of the above phrase “will remain in on-going studies” is to indicate that the RSRB will not automatically initiate a demand to change approved consent forms to update the wording. If the investigator requests a change to the consent form or for “five-year reviews,” the RSRB will request an update at that time.