



**POLICY STATEMENT REGARDING COMPENSATION
OR MEDICAL TREATMENT IN THE EVENT
OF INJURY DUE TO PARTICIPATION
IN A RESEARCH STUDY**

01/03/2008

The Duke University Health System (DUHS) Institutional Review Board (IRB) interprets responsibility for the costs of treatment for a study-related injury as a risk of study participation, and the potential subject must be fully apprised of this risk before making an informed decision on study participation (45 CFR 46.116(a)(2) and if applicable, 21 CFR 50.25(a)(2)).

The DUHS IRB has determined that IRB-approved consent forms must contain wording consistent with DUHS policy on compensation for payment or treatment in the event of injury arising from participation in a research study. Unless specific wording that legally commits the study's sponsor to payment for expenses related to treatment of study injuries is present in the research contract with the sponsor, the IRB-approved consent form will contain the following standard language:

"Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. Further information concerning this and your rights as a research subject can be obtained from the Duke University Health System Institutional Review Board (IRB) Office at (919)668-5111."

If the research contract contains specific wording that legally binds the sponsor to payment for treatment of study-related injuries, the IRB-approved consent form will contain language that accurately conveys to the potential subject his/her and the sponsor's responsibilities for the payment of such costs. Such wording will be clear, concise, and presented at a reading level consistent with the rest of the consent form.

The IRB will not approve a consent form that contains exculpatory language in which the subject is made to waive or appears to waive any of his/her legal rights or releases the researchers, sponsors or DUHS from liability for negligence (45 CFR 46.116 and if applicable, 21 CFR 50.25).

The DUHS IRB office will work with both the Office of Corporate Research Collaborations and the Office of Research Compliance to ensure that the wording in the IRB-approved consent form is consistent with the relevant wording in the

fully executed research contract with the sponsor. An IRB Notice of Approval will not be issued for a study until a fully executed research contract is in place and consistency between the research contract and the IRB-approved consent form has been assured.