

CHILDREN'S HOSPITAL INSTITUTIONAL REVIEW BOARD

Information Sheet

Policy On Compensation For Injuries* Sustained by Research Participants

Children's Hospital and Regional Medical Center provides necessary medical care (to a maximum of \$20,000) at no cost to research participants who sustain injury as a direct result of an authorized research activity when:

- The study has been approved by Children's IRB.
- There is no direct benefit to the research participant.**
- There is no external sponsor to cover the costs of such treatment .***

The principle behind this policy is that families should not be expected to pay for the costs of treating research-related injuries when their child takes part in a research project that offers no direct benefit to the child.

* **Injury** is defined as bodily harm. The term does *not* include:

- impairment of mental processes or emotional distress,
- injuries from normal therapeutic or diagnostic procedures that would be performed as part of patient management
- injuries from the normal course of a disease or condition; or
- injuries resulting from non-compliance with study procedures.

** **No direct benefit** means that the research procedures offer no diagnostic or therapeutic benefit to the participants in the research study.

*** **External sponsors**. Children's requires that pharmaceutical companies sponsoring research cover all costs of treating research related injuries for the studies they sponsor.

Research-related injuries must be reported to the IRB whether or not the investigator believes the compensation plan applies.

Refer to the information sheet on Adverse Event Reporting and the Adverse Event Reporting Guidelines for details on how and when to report adverse events to the IRB. Adverse effects should be reported on Children's Adverse Event Report Form. The IRB will refer adverse event reports to the Office of Risk Management to determine if the compensation plan applies.

Children's compensation plan may not apply to research carried out by researchers under grants administered through other institutions. Children's compensation plan does not apply to research carried out in foreign countries.

The program operates on a "no-fault" basis. The research participant for whom a claim is made (claimant) does not need to establish negligence. Rather, the claimant or the researcher must demonstrate only that the research participant has suffered an injury as a result of participation in an IRB approved study.

The University of Washington has its own compensation plan for addressing compensation for injuries to research participants. This plan applies to authorized research activities (IRB approved) when the research does not provide direct patient management. See the information about the University's plan for compensation for adverse events on their web site <http://www.washington.edu/research/hsd/hsdman7.html>. If a research related injury occurs at the University of Washington on a project approved by Children's IRB, the University's compensation plan would apply. ****

**** Children's Hospital and Regional Medical Center and the University of Washington have an institutional agreement that allows Children's IRB to review studies involving patients seen at Children's and the University. The University will accept Children's IRB review allowing the researcher to avoid duplicate IRB review.