

Seattle Children's Hospital Institutional Review Board

Information Sheet

Who Pays for Research Related Injuries?

Who pays for research related injuries depends on who is sponsoring the study and whether the study provides a potential for direct benefit (e.g., treatment, diagnosis) to the participant. This information sheet will assist you in determining who will pay for research related injuries in your research project.

It is the responsibility of the IRB and researchers to ensure that the consent form accurately informs families of who will pay for the costs of treating research related injuries.

For purposes of this guidance, the “sponsor” of a study is the individual/entity who takes responsibility for and initiates a clinical investigation, usually by authoring the protocol. Studies may be funded by an individual/entity without that individual/entity being a study sponsor.

For Research that Provides the Prospect of Direct Benefit

When the research provides the prospect of direct benefit there are two alternatives for who will pay for research related injuries:

- The Sponsor, **or**
- The Family

Sponsor Pays

Currently only industry sponsors (for profit sponsors) have programs to pay for research related injuries that result from the studies they sponsor. Public sponsors (e.g., federal agencies) or private, non-profit sponsors (e.g., American Cancer Society) do not have programs to pay for research related injuries that result from the studies they sponsor.

For studies involving Category B medical devices, Seattle Children's requires industry sponsors to pay for research related injuries that result from device failure or malfunction. The details of the requirement to cover the costs of research related injuries resulting from device failure or malfunction are documented in the signed clinical trial agreements between Seattle Children's and the industry sponsor.

For all other industry sponsored studies, Seattle Children's requires sponsors to pay for research related injuries that result from the studies they sponsor. The details of the requirement to cover the costs of research related injuries are documented in the signed clinical trial agreements between Seattle Children's and the sponsor.

Family or Third Party Pays

Private (non-profit) and public sponsors do **not** have programs to pay for research related injuries. In these cases, families or their insurance company or other third party payer are responsible for the costs of treating these injuries. This applies when the research offers the prospect of direct benefit to the participant (e.g., clinical care, treatment, diagnosis).

In some circumstances with industry sponsored studies, families or their insurance company or other third party payer may be responsible for the costs of treating research related injuries. Again, this applies when the research offers the prospect of direct benefit to the participant (e.g., clinical care, treatment, diagnosis).

For Research that Does Not Provide Direct Benefit to Participant

When the research does not provide the prospect of direct benefit there are two alternatives for who will pay for research related injuries:

- The Sponsor, **or**
- Seattle Children's or the University of Washington's compensation programs for research related injuries

Sponsor Pays

For studies involving Category B medical devices, Seattle Children's requires industry sponsors to pay for research related injuries that result from device failure or malfunction. The details of the requirement to cover the costs of research related injuries resulting from device failure or malfunction are documented in the signed clinical trial agreements between Seattle Children's and the industry sponsor. (Note: Medical device studies involving risk would almost always involve the prospect of direct benefit and would not likely fall under this category.)

For all other industry sponsored studies, Seattle Children's requires sponsors to pay for research related injuries that result from the studies they sponsor. The details of the requirement to cover the costs of research related injuries are documented in the signed clinical trial agreements between Seattle Children's and the sponsor.

Compensation Plan Pays

Seattle Children's and the University of Washington each have their own program to pay for research related injuries that result from research involving no direct benefit to participant and no patient care or management. Seattle Children's compensation plan does not apply when there is an industry sponsor of the study. See the information sheet for details on Seattle Children's Policy on Compensation for Injuries Sustained by Research Participants. For information on the University of Washington's compensation plan for research related injuries go to their IRB web page <http://www.washington.edu/research/hsd/hsdman7.html>.

Consent Form Language Regarding Who Pays for Research Related Injuries

1. For studies where Seattle Children's compensation program applies:

If you or your child is injured as the direct result of this research study, we (Seattle Children's Hospital) will treat you or your child. If appropriate, we will refer you or your child for treatment. Neither you nor your insurance company will be responsible for the cost of this treatment. This is the only injury compensation offered. Please call NAME

OF PI at TELEPHONE NUMBER if you believe you or your child have been injured as a result of this study.

2. For studies where families or third party payers are responsible:

If you or your child is injured as the direct result of this research study, we (Seattle Children's Hospital) will treat you or your child. If appropriate, we will refer you or your child for treatment. You or your insurance company will be responsible for the cost of this treatment. Please call NAME OF PI at TELEPHONE NUMBER if you believe you or your child have been injured as a result of this study.

3. For industry sponsored studies involving Category B devices:

If you or your child is injured as the direct result of this research study, we (Seattle Children's Hospital) will treat you or your child. If appropriate, we will refer you or your child for treatment. You or your insurance company may be responsible for the cost of this treatment. Neither you nor your insurance company will be responsible for the cost of any treatment needed because of failure or malfunction of the study device. This is the only injury compensation offered. Please call NAME OF PI at TELEPHONE NUMBER if you believe you or your child have been injured as a result of this study.

4. For all other industry sponsored studies:

If you or your child is injured as the direct result of this research study, we (Seattle Children's Hospital) will treat you or your child. If appropriate, we will refer you or your child for treatment. Neither you nor your insurance company will be responsible for the cost of this treatment. This is the only injury compensation offered. Please call NAME OF PI at TELEPHONE NUMBER if you believe you or your child have been injured as a result of this study.