

Children's

Hospital & Regional Medical Center
Office of the Vice President for Research

OPERATING PROCEDURES/POLICIES

Committee:	<u>Institutional Review Board</u>
Policy Number:	<u>IRB-36</u>
Effective Date:	<u>June 20, 2005</u>

POLICY TITLE:

PAYMENTS TO TAKE PART IN RESEARCH

The IRB shall review all requests to provide payment to research participants or their legally authorized representatives to ensure that payment for research participation does not unduly influence or coerce the decision to take part.

DEFINITIONS:

Reimbursement is a form of payment to research participants that is intended to pay for out-of-pocket expenses directly related to taking part in a research activity. Typical out-of-pocket expenses are transportation, food, childcare, or lodging.

Inducement is a form of payment to research participants to encourage enrollment in the research. Inducements may also be referred to as **incentives**. Typical inducements range from specific payment for the participants' time and efforts, a thank-you gift or payment from the researchers to the participants, or a study bonus for completing the entire study.

PROCEDURE:

- 36.1 Researchers shall provide the IRB information on their plans to pay research participants. The information shall be provided in the IRB application form at the time of initial review or in a modification proposal (amendment) to an existing approved IRB application.
- 36.2 The researchers shall provide information on the amount and timing of payment.

- 36.3 The IRB shall review the information provided by the researchers regarding payment to participants to ensure that the amount, type, and timing of payment does not unduly induce or coerce participants or their legal representative to enroll or remain in the study.
- 36.4 The level of risk to which a child is exposed is an important consideration for the IRB in determining the appropriateness of payment. The IRB shall ensure that the amount, type, and timing of payment does not unduly pressure or influence the decision making of parents or legal guardians to enroll their child in the research activity.
- 36.5 Reimbursements shall be made to the person who incurs the out-of-pocket expenses. In pediatric research, payments for out-of-pocket expenses are usually made to the parents or legal guardian of the child.
- 36.6 Inducements shall generally be made to the person taking part in research. In pediatric research, inducements are generally tailored to the child participant. Inducements may also be made to the parents or legal guardians of children taking part in research. For example, researchers may provide a payment that represents partial compensation to parents for their time away from work for example when a research study visit requires a full day of the parent's time to accompany their child for a research visit.
- 36.7 Inducements to children shall be age appropriate and respectful and sensitive to children and families. Researchers providing inducements to children shall be encouraged to have several options available for children and families that allow children and families to choose an inducement that is consistent with the family's values. The IRB encourages non-cash payments, e.g., gift certificates, movie tickets, toys, books, as forms of payment that are respectful to children and reduce the potential for unduly influencing the child's legal representative's decision regarding participation.
- 36.8 Payments to research participants or their legal representatives shall be prorated so that payment is provided for the research activities completed. Participants who are withdrawn from the research by the researchers or who choose to withdraw shall be paid for the activities they completed.
- 36.9 The IRB may approve a bonus payment to participants who complete the entire study as long as the bonus is not of a magnitude that could unduly induce participants or their legal representatives to take part in research or stay in the research when otherwise they would have not participated or withdrawn.
- 36.10 The IRB shall not consider payments to participants as a benefit to taking part in research. Payments may not be portrayed in the consent or assent

