

REB Guideline on Research Subject Reimbursement and Compensation

I. Background

As part of its review of applications, the REB considers any proposed reimbursement and compensation plan for participation in research studies. To establish a more consistent approach to its review, and to provide guidance to the research community, the REB convened a workgroup to develop this document. All the recommendations were approved at the REB's September 8, 2006 meeting.

Reimbursement: money given to the research subject or guardian that reflects out of pocket expenses associated with participating in a research study i.e. transportation, parking.

Compensation: money or item given to the research subject or guardian that acknowledges the time and effort of research subjects and or their guardians in participating in the research.

The REB reserves the right to reject, or propose amendments to, any monetary or non-monetary compensation plan that does not reflect the values of this guideline, or is otherwise deemed to be ethically problematic.

II. Values

The SickKids Research Subject Reimbursement and Compensation Guideline is informed by the values of voluntariness, emerging autonomy, transparency, justice and research communitarianism:

a) Voluntariness: Requires that subjects not be unduly influenced into consenting to participate in research or be offered compensation so valuable as to make it very difficult to refuse to participate (this is especially important with a vulnerable population like children).

b) Emerging autonomy: Recognizes the fact that children's ability to make autonomous decisions are unique to each child and not necessarily tied to an age. Research activities should aim to recognize the autonomous decision making potential of research subjects by matching compensation plans and consent/assent opportunities with the capacity levels of the potential subjects.

c) Transparency: Reflects the REB's commitment to being open and honest with potential research subjects.

d) Justice: The time and effort of children is valuable and worthy of recognition.

e) Research communitarianism: Participation in research is a benefit to society.

III. Recommendations:

1. Subjects and guardians shall be offered reimbursement for reasonable out of pocket expenses – unless investigators can justify why circumstances make this impossible. Subjects should not be reimbursed to a set amount - recognizing that out of pocket expenses will vary among research subjects because of personal factors e.g., home location.
2. The REB will accept protocols offering compensation – money or otherwise. The compensation plan for each protocol must be described within the REB protocol submission and will be reviewed for compliance with the values of voluntariness, emerging autonomy, transparency, justice and research communitarianism as described above.
3. Recognizing the role that research subjects play in the betterment of society, the participation of all research subjects should be acknowledged with a thank you letter or certificate.
4. As part of its review, the REB attempts to ensure that the prospect of compensation will not pressure a subject to remain in a study when that subject would like to withdraw. To that end, any compensation plan should be prorated.
5. The type of compensation should be matched appropriately with the age and mental capacity of potential research subjects. For example, guidance for appropriate compensation for a 12 year old may be taken from current fees for babysitting.
6. To ensure transparency, disclosure of any reimbursement or compensation to research subjects is required in both the assent and consent forms.

IV. Key References:

TriCouncil Policy Statement, September 1998 <http://www.pre.ethics.gc.ca/english/>
ICH -Good Clinical Practice Guidelines <http://www.ich.org/cache/compo/276-254-1.html>
US Federal Regulations (45 CFR 46.116)
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>
American Academy of Pediatrics Committee on Drugs, 1995
<http://pediatrics.aappublications.org/cgi/content/abstract/95/2/286>
Institute of Medicine 2004 - The Ethical Conduct of Clinical Research Involving Children <http://www.iom.edu/CMS/3740/4864/19422.aspx>

V. REB Research Subject Compensation Workgroup Members

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