

OCREB Participant Reimbursement Guidelines

Background & Purpose

There is growing recognition that participation in a clinical trial can create economic hardship.

Trial participants often incur costs that are directly related to trial activities, such as transportation, parking, supplies, meals, time away from work, caregiver expenses or childcare to attend the clinic. Reimbursement of these costs can remove financial obstacles, promote fair and equitable recruitment, and ensure that participants are not financially disadvantaged by taking part in the study.

This document is intended to guide the ethical review of participant reimbursement associated with clinical trial participation. It does not establish a framework for participant incentives or compensation.

Relevant Reference(s):

TCPS2 Article 3.1: https://ethics.gc.ca/eng/tcps2-epc2_2022_chapter3-chapitre3.html#1
FDA “Payment and Reimbursement to Research Subjects”:
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects>

Definitions

Direct Reimbursement

Direct reimbursement repays the participant for reasonable out of pocket expenses directly attributed to trial participation such as transportation, parking, childcare, care for disabled persons, or expenses incurred by a caregiver that accompanies the participant.

Indirect Reimbursement

Indirect reimbursement covers foreseeable economic losses arising from trial participation such as taking unpaid leave from work or other financial disadvantages and is meant to offset these losses.

Incentives / Compensation

Incentives / Compensation (e.g. stipends) are monetary and non-monetary items that acknowledge the time, effort, and any potential inconvenience of research participants.



Incentives / compensation are offered separately from, or over and above, any direct or indirect reimbursement the participant may receive and not tied to specific participant-incurred costs.

*If an applicant is considering incentives / compensation to study participants, please contact OCREB's Research Ethics Officer. Incentives will only be considered in exceptional, well-justified circumstances.

Ethical Considerations for Reimbursement

To prevent undue influence or undermine the voluntariness of consent, the following should be considered:

- a) Procedures to fully reimburse direct costs associated with trial participation should be prioritized and fully reimbursed prior to offering reimbursement of indirect costs.
- b) Reimbursement should not be contingent upon completion of the study.
- c) Participants who withdraw should receive reimbursement for costs already incurred for study related activities.
- d) Reimbursement should be provided to trial participants in a timely manner.
- e) Reimbursement should be applied fairly and consistently, while permitting accommodation for different participant needs and circumstances.
- f) Payment methods should not create barriers for participants who lack smartphones, stable internet access, banking access, or digital literacy.

When determining the type of reimbursement being offered, the following should be considered:

- a) The types of expenses to be reimbursed should not unduly influence a person to take part or remain in a clinical trial, or disregard risks that they would otherwise refuse if not for the reimbursement offered,
- b) Populations who are recruited to the study and who may experience financial hardship or structural barriers to trial participation,
- c) Customs and practices of the community to ensure reimbursements are culturally appropriate and respectful,
- d) Magnitude, likelihood and duration of burden associated with trial participation.

When pre-paid cards or payment platforms are offered, the following should be considered:

- a) The availability of an alternative and accessible reimbursement method if the participant prefers not to use a pre-paid card or participant payment platform,



- b) Ways to limit additional burden or requirements to input personal information to use the pre-paid card such as registering on a website or downloading a particular app to access the reimbursement(s),
- c) Maximization of the security of participant data if using a payment platform,
- d) Limitations on use of pre-paid cards for items such as annual fees.

The consent form should clearly convey:

- a) Whether reimbursements will be provided or not,
- b) What expenses are reimbursable, how reimbursement is calculated, and any limitations or conditions associated with reimbursement,
- c) If a payment schedule is used or payment is in proportion to participation,
- d) The expected timeline for receiving the reimbursement,
- e) The procedures the participant must take to receive the reimbursement (e.g. provide personal or banking information to a third party to submit expenses and receive payments, download an app etc.).