OCREB Participant Reimbursement Guidelines

Background & Purpose

The broader context for this guideline is the growing recognition in recent years that, for individuals facing economic hardship, regular non-medical and additional medical expenses related to participation in clinical trials pose obstacles to enrollment.

Trial participants often incur costs that are directly related to trial activities, such as transportation, parking, supplies, meals, etc. 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 research.

Relevant Reference(s):

TCPS2 Article 3.1: https://ethics.gc.ca/eng/tcps2-eptc2_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 incurred by necessary trial activities such as transportation, parking, childcare, care for disabled persons, or expenses incurred by a caregiver that accompanies the participant.

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

Incentives
Incentives (i.e. "compensation' or 'stipends') are monetary or non-monetary items that acknowledge the time, effort, and any potential inconvenience of research participants. This would be consideration offered separately or over and above any direct or indirect reimbursement the participant may receive and not necessarily tied to specific costs incurred.

Ethical Considerations for Reimbursement and Incentives

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

- Procedures to fully reimburse direct costs associated with trial activities should be prioritized.

- Procedures to address indirect costs associated with trial participation should then be prioritized.
- When considering the type of reimbursement or amount of incentives being offered, the following should be considered:
    - The amount offered 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 incentive being offered,
    - The economic and social circumstances of prospective participants to assess the potential influence of incentives,
    - Customs and practices of the community to ensure reimbursements and incentives are culturally appropriate and respectful,
    - Magnitude and probability of harms and burden associated with trial participation.
- When prepaid card or payment platforms are being offered, the following should be considered:
    - Limitations on purchases that may exist with pre-paid cards, such as annual fees, security features, as well as clarity on any additional potential burden from steps such as registering on a website or downloading a particular app to access the reimbursement(s) or incentive(s).
    - Security of participant data if using a payment platform
    - The availability of a cash alternative if the participant prefers not to accept a pre-paid card or to use any participant payment platform.
- The consent form should clearly convey:
    - That reimbursements and/or incentives are provided or not.
    - The amount and/or type of reimbursement or incentive.
    - If a payment schedule is used or payment is in proportion to participation, participants should be informed of the amount and when each payment is made.
    - The expected timeline for receiving the reimbursement or incentive.
    - The procedures the participant must take to receive the reimbursement or incentive (e.g. provide personal or banking information to a third party to submit expenses and receive payments, download an app etc.)
    - Potential tax implications or impact on fixed income or social assistance programs of incentives should be disclosed.
- Reimbursement and incentives should be evenly applied to all trial participants.
- Reimbursement and incentives should be provided to trial participants in a timely manner.

Note: The Canadian Revenue Agency's (CRA) document no. 2021-877921E5 indicates that T4A filing for monetary compensation to participants in clinical research studies is waived if the payment is $500 or less and no income tax was deducted from the payment. Otherwise, amounts over $500 are taxable.