

## Purpose

To provide Investigators with the compliance requirements for applications that include reimbursement and payment to participants. This guidance encompasses all projects reviewed and approved by Bellberry, and the responsibilities of the Human Research Ethics Committee (HREC) as per the National Statement on Ethical Conduct in Human Research (2023) 2.2.2, 2.2.6 (j), and 2.2.10-2.2.11.

## Definitions

**Payments:** When participants receive monetary or other benefits for their participation in the clinical trial. Other benefits may include vouchers that are not intended as reimbursement for travel expenses, accommodation, and meals.

**Reimbursement:** Reimbursable expenses are those incurred by the participant in direct relation to their participation in a clinical trial. For example, reimbursement may cover: travel expenses; accommodation; meals.

## Guidance

Bellberry requires that participants be reimbursed for their costs in taking part in research: including costs such as travel, accommodation, and parking. Details on reimbursement for costs should be clearly stated in the PICF, inclusive of any conditions that may attach, like dollar limits or presentation of receipts.

It is generally appropriate to provide payment for participation when the research can have no possible therapeutic benefit to the participants; this is commonly the case in studies with healthy volunteers. However, payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take on risks is ethically unacceptable.

The amount and schedules of all payments should be disclosed to the Bellberry HREC.

All information about payments must be clearly stated in the Participant Information Sheet and Consent Form (PICF). They should be described as 'payments' as defined in this policy. Sites should remind participants to seek independent taxation advice.

Participants should be advised of any payment variation due to withdrawal from the research. It is recognised there are three likely withdrawal scenarios. These are shown below with the expected level of payment:

- Participant withdrawn by Investigator/Sponsor for non-compliance: pro-rata payment
- Participant withdrawn by Investigator/Sponsor for any reason other than non-compliance: full payment
- Participant withdraws: pro-rata payment

When an organisation undertaking research with healthy volunteers has access to an organisational database of persons who have previously consented to contact regarding research involvement opportunities, the site can disclose the payment in forms of contact. The payment should be discretely positioned in the advertisement and should not be in enlarged or emboldened print.

All other recruiting advertisements can state that participants will be paid for time and inconvenience, but they must not state dollar amounts. This information should be discretely positioned in the advertisement and should not be in enlarged or emboldened print.

## References

[National Statement on Ethical Conduct in Human Research \(2023\)](#)

[Payment of participants in research: information for researchers, HRECs and other ethics review bodies \(2019\)](#)