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# USING THE NATIONAL STATEMENT 1:

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## Payments to participants in research, particularly clinical trials

**Relevant Guidelines:**            **Clause 2.2.10 – 2.2.11, 3.3.18**  
**Relevant Principles:**           **Clause 1.6, 1.7, 1.10, 1.12.**

### Background

The Australian Health Ethics Committee (AHEC) has received advice of several examples of payments for participation in early phase clinical trials and of advertisements from a company seeking to supply paid research subjects. These payments appeared to be disproportionate to the participants' involvement, an inducement to participate and possibly to risk exposure to harm. AHEC sought further information to determine if further clarification was needed relative to the *National Statement of Ethical Conduct in Human Research* (2007) (*National Statement*), namely clauses 2.2.10-2.2.11 and 3.3.18.

Responses to a survey sent to Human Research Ethics Committees (HRECs) in early 2009 indicated that there was a range of payment and reimbursement practices and that HRECs found the National Statement to be helpful. Some respondents thought further guidance about reimbursement, compensation and inducements would be helpful to both researchers and HREC members. This is the response to that request.

### Purpose and scope

This advice poses questions for consideration to better inform researchers' and HRECs' deliberations as to whether or not payment (monetary or in kind) for participation in research is ethically acceptable. The ethical issue does not arise where payment is no more than reimbursement of documented out-of-pocket expenses. It does arise, however, where payment other than reimbursement may be considered compensation for involvement or an inducement to be involved.

## Ethical considerations

The relevant guidelines in the *National Statement* express the principles of respect and of beneficence.

Respect requires recognition of the intrinsic worth or value of the person, including their body and hence their safety. It also includes recognition that participation in research is voluntary and based on sufficient information about, and adequate understanding of, both the proposed research and the implications of participation in it. Where the promise of payment of compensation for taking a risk leads to a decision that is motivated by that promise of payment, a participant's decision would not meet that requirement of respect.

Beneficence requires that the potential benefits of the research must justify any risks for participants. Where there are no likely benefits to participants, the risks should be lower than where there are such benefits. The promise of payment can lead participants to accept risks that exceed this level of ethical acceptability, especially in early phase clinical trials.

The questions posed below are intended to encourage reflection on these elements of the *National Statement* and on the following specific ethical considerations:

- that there is a moral difference between taking a risk for an altruistic reason, and taking a risk in order to receive payment
- that a person might reasonably take risks in the hope of medical research being of benefit to the community, but not for the purpose of receiving payment for taking those risks
- that those who are economically disadvantaged might be exploited if payment were such that it provided what, in effect, would be a perverse incentive to take risks that they would otherwise not take, for example, payment that is greater than the current minimum wage<sup>1</sup>
- that payment for a person's time and services is similar in some ways to employment, and employers have ethical (and legal) obligations for the safety of their employees, for example:
  - compliance with relevant occupational health and safety laws
  - informing participants that they need to retain receipts and declare payments in income tax returns
  - determining if the payment is likely to affect any government benefits the participant may be receiving, eg students, pensioners, and people who are unemployed.

It is particularly important therefore that HRECs carefully assess whether or not any payment to participants is payment for risking discomfort or harm or compensation for discomfort or actual harm done.

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<sup>1</sup> <http://www.fairpay.gov.au/fairpay/WageSettingDecisions/General/2008/>

## Questions for Consideration

HREC members and researchers are likely to better inform their decisions about the ethical acceptability of payment to research participants if they consider all of the following questions.

1. Does the proposed research include any kind of payment (monetary or in kind) to participants other than reimbursement of documented expenses?
2. Will the participant, or their community, receive actual monetary payment or a voucher with a dollar value (as opposed to, say, a raffle ticket or a small gift or donation to a charity of their choice)?
3. Is the payment a payment in kind, (e.g. cheaper or earlier access to treatment)?
4. Is payment offered for the participant's time spent participating in research?
5. When will the participant be made aware that they will receive payment (other than reimbursement of documented expenses): before or at the time of recruitment, or later?
6. Does the participant have to complete their participation in the research in order to receive payment?
7. Is the nature of the payment ethically similar to employing the participant?
8. Is the nature and extent of the payment such that it encourages the participant to enrol in the research?
9. Is the payment for participation in the research commensurate with similar research?
10. Is it probable that the payment will encourage participants to take risks that they would not otherwise take?
11. Do any participants have a connection with, or special knowledge of, the research area which would explain their having altruistic interest in the research?
12. Is the payment consistent with the cultural practices of the community in which the research is to be conducted?
13. Will the payment be made directly to the participant or to others, eg to a community elder?

NHMRC welcomes comments on the usefulness of the relevant clauses of the National Statement and this advice to researchers and HREC members.

Please email comments to: [ethics@nhmrc.gov.au](mailto:ethics@nhmrc.gov.au)

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