

Incentives in Phase I Trials

The National Research Ethics Advisors Panel endorsed the following guidance regarding payments and incentives in phase I studies produced by the Phase I Advisory Group:

Generic advertisements:

Payments made to participants in phase I trials must never be related to risk.

Payment amounts can be detailed in generic advertisements in the form of a daily rate (in this context the term "daily" refers to a 24-hour period). A minimum daily rate should be used in all generic advertisements and stated as being "from £X". The group recommends that the minimum amount to be stated is £100. Therefore, generic advertisements should not normally give a range but instead solely state that the payment amount would be "from £100". (This minimum amount would need to be regularly reviewed to ensure its continuing relevance).

Study specific advertisements:

The group agreed that specific payment amounts could be used in the context of study specific advertising. Such specific amounts should be backed up with clear reasons in any submission to an ethics committee clearly explaining how the amount had been calculated.

Payment amount should be discreet and not prominent within the advertisement i.e. it should not be the headline or very first line of the advert.

Terminology:

The terminology proposed by the Nuffield Council on Bioethics in their report "Donation - Human bodies: donation for medicine and research (October 2011)^[1]" should be used in any advertising materials. i.e.:

- **Payment:** a generic term covering all kinds of transactions involving money, and goods with monetary value, whether those transactions are understood as recompense, reward or purchases.
- **Recompense:** payment to a person in recognition of losses they have incurred, material or otherwise. This may take the form of the reimbursement of direct financial expenses incurred in donating bodily material (such as train fares and lost earnings); or compensation for non-financial losses (such as inconvenience, discomfort and time).
- **Reward:** material advantage gained by a person as a result of donating bodily material, that goes beyond 'recompensing' the person for the losses they incurred in donating. If reward is calculated as a wage or equivalent it becomes remuneration.
- **Purchase:** payment in direct exchange for a 'thing' (e.g. a certain amount for a kidney, or per egg)^[2].

^[1] <http://www.nuffieldbioethics.org/donation>

^[2] Donation - Human bodies: donation for medicine and research (October 2011), p. 2 para. 7