Guidance on payments and incentives in research

The ethical principles of Respect for Persons and Justice require that those involved in research treat participants fairly and with respect.

The LSHTM REC is aware that over the past few years there has been a move to rebalance discussion of the ethical issues around payments and incentives away from a primary preoccupation with avoiding undue influence and coercion to give greater emphasis to also ensuring that the payments and incentives need to be fair to participants and can facilitate the conduct of better studies by ensuring higher response rates. At the end of this document there are a number of references that advocate this change in emphasis.

Reflecting this, it is the view of the LSHTM Research Ethics Committee (REC) that research participants should not be disadvantaged or left out of pocket by their participation in a research study. In addition, participants may be reasonably compensated for their time, inconvenience, and for the discomfort they may experience while taking part in the research. However, undue influence and coercion must still be avoided.

Any reimbursement, compensation, incentives, or other payments to be made to participants must be approved by the relevant LSHTM REC. The opinion of within country ethics committees is very important, as they will have a better understanding of the cultural and economic context, and the potential risks and benefits of payments. Some countries have guidelines about participant payment, which must be adhered to (see references).

The aim of this guidance is to highlight a few of the ethical considerations around participant payment, and offer points to consider when planning research and preparing an ethics application. These guidelines should be read alongside the LSHTM Standard Operating Procedures (SOPs).

Please note, this guidance does not cover compensation in the event of injury sustained while taking part in a research study. For guidance on this please contact the RGIO, or where the research is externally sponsored, please contact the legal sponsor.

1. Types of payment

When considering whether and what payments or incentives to offer, it is important for researchers to be clear about the different types available. The most common are covered below:

Reimbursement: Payment to cover expenses incurred by the participants, such as travel expenses, meals and lost earnings. Reimbursement should return the participant to the same financial position they would have been in had they not taken part. As participants should not be disadvantaged or left out of pocket by their participation in a research study, reimbursement of expenses such as travel is generally expected, and the ethics committee will require justification where this is not the case.

Compensation: Payment to a participant in recognition of the time spent, and any inconvenience and discomfort they have incurred. Compensation can be monetary, but other forms of compensation such as refreshments/food (particularly if the research involves fasting), vouchers*, gifts of toys or books can also be considered.

Incentive: Something that would motivate or encourage someone to take part. Examples of incentives can include (but are not limited to) cash payments, gifts, vouchers, or prize draws. Provision of items required for the research, for example food if it must be consumed, are not considered incentives.

Remuneration or reward: Material advantage gained by a participant by taking part in the research study, where this is calculated as a wage or equivalent.

*When offering vouchers the amount on the voucher should always be sufficient so that the participant is not out of pocket from redeeming the voucher. The voucher should be able to be used locally by the participant.

2. Coercion and Undue Influence

The ethical principle of respect for persons centres around the concept of autonomy, which refers to a person's ability to make free choices about themselves and their life. This means that individuals must be able to choose to take part in research voluntarily, in an environment free from coercion or undue influence.

- **Coercion** refers to when a threat of harm is presented to the participant in order to gain compliance. This harm does not necessarily have to be physical, but could be economic, psychological, legal etc.
- **Undue influence** refers to when a participant is encouraged to consent to research/take risks that they normally would deem unacceptable through the offer of an excessive, unwarranted or inappropriate reward. Undue influence can also include pressures put on the participant by other persons in positions of authority to pursue a particular course of action. For example, "if you join the study and we will provide free health care" could* be considered an undue influence to someone with an existing health condition who otherwise does not have access to healthcare (*this must be considered on a case by case basis as some countries will require the provision of healthcare for research participants. If healthcare beyond treating study related conditions will be provided, the level of provision should be clearly explained in the informed consent process and justified in consultation with the local ethics committee).

If compensation or incentives are to be offered, the type and amount must be carefully considered to ensure that it will not act as an undue inducement for participation or retention, and will not encourage deceptive behaviours.

It must be made clear to participants during the informed consent process that taking part is voluntary, with no negative consequences should they choose not to take part, or if they later decide to withdraw.

If participation involves multiple visits or prolonged participation (e.g. keeping a diary over multiple weeks), any payment should be staggered so that participants are adequately compensated for the time spent, even if they choose to withdraw before the study end. For example, if the research involves 5 interviews, it would be more appropriate to offer £20 per interview, than £100 after completing all 5 interviews.

When small gifts, such as soap or food, are given instead of financial payment, they should be provided to all participants, regardless of study completion.

Researchers should be conscious that what may not constitute a coercive situation or be an undue inducement to one group, could become so for another.

3. Research in the UK

The Health Research Authority (HRA) have published guidance on Payments and Incentives in Research.

Based on this guidance, payments made to participants in research can be acceptable (with the exception of children and incapacitated adults in clinical trials of investigational medicinal products), provided that the payment offered is proportionate to the burden imposed by the research e.g. number of visits, tissue samples taken etc.

However, it is also acceptable to not offer compensation to competent adults taking part in research, where the risk and burden of the research is considered justified by the benefit.

Offering payments is not considered coercive or as presenting an undue influence, provided the risks and burdens involved are those a competent adult might reasonably accept without the payment.

When considering offering payments (including to young people of working age), consider whether this could impact their entitlement to benefits or tax, and if applicable make this clear in the informed consent process. The HMRC Employment Income Manual contains a section on research volunteers, lay participants and participants in clinical trials taking place in the UK that may be useful.

4. Research outside the UK

There is no uniform approach to payments of research participants across different countries.

When deciding on payment arrangements, the legal framework and cultural norms of the country in which the research will take place should be followed. Some countries/places have set minimum levels for compensation, so researchers should check if such a requirement is in place. Alternatively, there are countries/places where providing a monetary compensation/incentive is not allowed, so researchers may need to consider alternative forms of compensation if appropriate.

Where no in-country guidelines exist, it is strongly recommended that researchers seek guidance through community engagement and/or from the in-country ethics committee to ensure that whatever payments are offered are appropriate to the setting and community involved.

5. Vulnerable groups

5.1 Children

For clinical trials of investigational medicinal products (CTIMPS) conducted in the UK, The Medicines for Human Use (Clinical Trials) Regulations (2004) prohibit giving incentives or financial inducements to children (under 16 years of age) or to a person with parental responsibility for that child (including legal representatives).

For non-CTIMP research, the Royal College of Paediatrics Ethics Advisory Committee advise that families are not offered financial incentives for their children to take part in research, but that expenses should be reimbursed for the child and any accompanying adult, as appropriate.

In the case of reimbursement, researchers may want to consider covering expenses in advance, for example purchasing rail tickets, to avoid young people having to claim reimbursement.

It is the view of the LSHTM REC that, where possible, children and young people (persons under the age of 18) participating in research should have their contribution recognised in an age-appropriate manner.

It is recommended that when planning a research project involving children and young people that the target age groups are consulted about how they would like their contributions to be recognised.

Examples of possible ways to recognise the involvement of children and young people are:

- Vouchers
- Financial reward
- Group meals or other leisure activities
- Tickets to events
- Providing opportunities to learn new skills
- Providing certificates that acknowledge their contribution

If an activity is chosen as a reward, such as meal out or tickets for an event, they should be planned so as not to interfere with the parents'/guardians' responsibilities for the child/young person.

If offering cash payments please ensure that the method of payment is appropriate (not all children will have a bank account), and be mindful of legal restrictions around the amount of hours children under 16 can undertake as paid activity.

Information about recognition should be provided in the consent/assent forms and included in the informed consent process.

For research conducted outside the UK, researchers should investigate population-specific norms. It is unlikely that the LSHTM REC will approve plans for compensation (beyond reimbursement of expenses) of children or their parents/guardians without knowing the opinion of the in-country ethics committee. It is therefore strongly recommended that researchers discuss plans for compensation/recognition with the in-country REC before applying to the LSHTM REC.

5.2 Adults with capacity who are financially and or/socially vulnerable

Determining appropriate compensation for financially and or/socially vulnerable groups can be challenging. This is due to having to balance the need to be respectful of autonomy (the right of individual's to make decisions about their own life), prevent undue influence, treat participants fairly, and to ensure there are protections in place for vulnerable individuals.

For people who use recreational drugs, there are often concerns that cash payments will facilitate their drug purchases. This has led to many RECs preferring non-cash alternatives, such as vouchers.

In reality, the evidence suggests that cash reimbursements do not promote the purchase of drugs nor lead to relapse (see relevant references at the end of this document).

In addition, the use of non-cash reimbursement when cash would have been acceptable compensation for a non-vulnerable group, can be seen as discriminatory and damage the development of trust between the research team and participants.

There may be some groups who are vulnerable by virtue of their circumstances and for whom receiving compensation/gifts/incentives may increase their vulnerability. This could include (but is not limited to) people who are in exploitative (labour) situations, for example people who have been trafficked, women and children experiencing violence etc. Any form of compensation may expose these individuals to attention/scrutiny/violence/suspicion etc which could impart negative risks on their personal wellbeing and safety.

Unless there is evidence suggesting otherwise, or there is a belief that offering compensation could negatively impact the participants safety, adults who are financially and or/socially vulnerable should be assumed to be autonomous individuals able to make their own decisions about taking part in research and in how they use compensation. They should not be treated differently to other participants in terms of payment.

5.3 Incapacitated adults

For clinical trials of investigational medicinal products (CTIMPS)in the UK, The Medicines for Human Use (Clinical Trials) Regulations (2004) prohibit giving incentives or financial inducements to incapacitated adults or their legal representatives.

Payments for non-CTIMP research will be considered by the REC on a case-by-case basis.

The CIOMS International Ethical Guidelines for Health-related Research Involving Humans, advises that a legally authorized representative is asked to give permission on behalf of a person who is incapable of giving informed consent. One permission is obtained, reimbursement for expenses such as travel can be offered, but no compensation or incentive beyond this should be offered. Where it would be reasonable to provide compensation to the participants themselves, their lack of decisional capacity must not preclude researchers from doing so. Compensation must be provided in such a way that the participants can benefit from it.

For research conducted outside of the UK, researchers should investigate local norms and seek the advice of the in-country ethics committee.

6. Additional points to consider

6.1 Review of payments by the LSHTM ethics committee

The primary responsibility of Research Ethics Committees (REC) is to safeguard the rights, safety, dignity and well-being of all potential and actual research participants. This includes ensuring that the benefits and burdens of research are fairly distributed amongst the community, and that participants are recruited into research voluntarily, fairly and free from undue inducement and coercion. As such, as part of their review of research applications, the committee will consider whether payments made to participants are appropriate and fairly reflect the burden being asked, as well as whether they could be considered an undue inducement.

In order to allow the REC to make an assessment it is important that the following are included in the ethics application:

- Whether participants will be reimbursed for expenses
- Whether any additional compensation beyond reimbursement will be offered.
- Whether there are plans to offer incentives or rewards for participation.

If payments beyond reimbursements will be offered please include:

- What is being offered (e.g. cash, vouchers, gifts etc.)
- How much is being offered. Where compensation/incentive is being offered as either cash or voucher, the applicant should include an idea of local purchasing power e.g. equivalent to two coffees etc.
- How often payments will be made. If payment is staggered, this should be explained.
- If amounts will differ across sites this should be explained (e.g. in-line with the different in-country requirements)

Where there is a precedent for a certain type or amount of payment based on similar ethically approved research, it is strongly recommended that that applicants include this information in the ethics application.

6.2 Informed consent

The REC will also review the informed consent process and materials to ensure that the following (where applicable) will be explained to potential participants:

- If payments/gifts etc. will be provided
- What they will be paid
- When they will be paid (including any pro rata payments and any payments for extra visits or sessions)
- How they will be paid (e.g. cash, voucher, bank transfer etc.)
- What will happen if they do not meet the eligibility criteria (will they still be paid/ receive the gift for the screening visit?)
- How payment is affected if the participant is withdrawn from the study (either by themselves or the researcher)
- Any conditions of payment
- That compensation is meant to reimburse research participants for their time/inconvenience

The informed consent process should be clear that accepting payment does not impact their rights, or ability to withdraw.

For more guidance on informed consent and template information sheets and consent forms, please see SOP-005 Informed Consent for Research.

6.3 Advertisements

Payments should never be the main headline of any recruitment materials and should not be presented in a way that will detract from other important study information, particularly those relating to risks and discomforts associated with the research.

All advertisements must be submitted to the REC for review to ensure that they are appropriately worded.

6.4 *Feasibility of payment type*

Not all forms of payment will be feasible from a finance department perspective. Researchers are advised to speak to the finance department in advance to determine which types of payment are feasible for their study and ensure they are familiar with the relevant institutional processes.

7. Resources/additional reading

General

CIOMS International Ethical Guidelines for Health-related Research Involving Humans: https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

UK

NIHR, Payments guidance for researchers and professionals, Version 1.4, July 2023, https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392

HRA Ethics Guidance, Payments and Incentives in Research: https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/hra-guidance-payments-incentives-research.pdf

The Medicines for Human Use (Clinical Trials) Regulations (2004): https://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf

HMRC Employment Income Manual: Research volunteers, lay participants and participants in clinical trials: https://www.gov.uk/hmrc-internal-manuals/employment-income-manual/eim71105

Canada

University of Toronto: Compensation & Reimbursement of Research Participants: https://research.utoronto.ca/compensation-reimbursement-research-participants

Malawi

A Malawi guideline for research study participant renumeration:
Gordon SB, Chinula L, Chilima B, Mwapasa V, Dadabhai S, Mlombe Y; Malawi Research Ethics Workshop 2018 Participants. A Malawi guideline for research study participant remuneration. Wellcome Open Res. 2018 Dec 19;3:141. doi: 10.12688/wellcomeopenres.14668.2. PMID: 30662959; PMCID: PMC6329041.

Compensation of subjects for participation in biomedical research in resource – limited settings: a discussion of practices in Malawi:
Nyangulu, W., Mungwira, R., Nampota, N. *et al.* Compensation of subjects for participation in biomedical research in resource – limited settings: a discussion of practices in Malawi. *BMC Med Ethics* **20**, 82 (2019). https://doi.org/10.1186/s12910-019-0422-6

Participant compensation in global health research: a case study:
Sepeedeh Saleh, Henry Sambakunsi, Deborah Nyirenda, Moses Kumwenda, Kevin Mortimer, Martha Chinouya, Participant compensation in global health research: a case study, *International Health*, Volume 12, Issue 6, November 2020, Pages 524–532, https://doi.org/10.1093/inthealth/ihaa064

Uganda

Uganda National Council for Science and Technology National Guidelines for Research involving Humans as Research Participants: https://www.uncst.go.ug/manage/files/downloads/Human%20Subjects%20Protection%20Guidelines%20July%202014(1).pdf

South Africa

NHREC (2012). Payment of trial participants in South Africa: Ethical considerations for Research Ethics Committees (RECs). NHREC.: https://www.ru.ac.za/media/rhodesuniversity/content/ethics/documents/nationalguidelines/National_Guidelines_for_Payment_of_Participants_in_Clinical_Trials_(2012).pdf

SAHPRA (South African Health Products Regulation Authority). Clinical trial participant time, inconvenience and expense (TIE) compensation model: https://www.sahpra.org.za/clinical-trials-guidelines/.

Vietnam

Lucy J Sansom, Trang Pham Nguyen Minh, Iona E Hill, Quyen Nguyen Than Ha, Thuan Dang Trong, Celine Vidaillac, Nhu Dong Quynh, Hugo C Turner, Jennifer Ilo Van Nuil, Dung Nguyen Thi Phuong, Evelyne Kestelyn, Towards a fair and transparent research participant compensation and reimbursement framework in Vietnam, *International Health*, Volume 12, Issue 6, November 2020, Pages 533–540, https://doi.org/10.1093/inthealth/ihaa066

Nepal

National Ethical Guidelines for Health Research in Nepal 2022: https://nhrc.gov.np/wp-content/uploads/2022/04/National-ethical-guidelines-4-Aug-28-2022.pdf

Informed consent

SOP-005 Informed Consent for Research: https://lshtm.sharepoint.com/sites/intranet-research-governance-and-integrity/SitePages/Standard-Operating-Procedures-(SOPs).aspx

Children

Royal College of Paediatrics, Child Health: Ethics Advisory Committee: Guidelines for the ethical conduct of medical research involving children: https://adc.bmj.com/content/82/2/177.full

INVOLVE: Reward and recognition for children and young people involved in research – things to consider: https://www.invo.org.uk/wp-content/uploads/2016/04/INVOLVECYPrewardandrecognitionFinalApril2016.pdf

YorOK: REWARDING AND RECOGNISING THE INVOLVEMENT OF CHILDREN AND YOUNG PEOPLE: https://www.yor-ok.org.uk/downloads/Involvement/Reward%20and%20Recognition%20General.pdf

LSHTM Guidance for Research involving Children: https://lshtm.sharepoint.com/sites/intranet-research-governance-and-integrity/SitePages/Ethics-Guidance-Documents.aspx

People who use drugs

Australian Injecting and Illicit Drug Users League (AIVL). National Statement on ethical issues for research involving injecting/illicit drug users Canberra: Australian Injecting and Illicit Drug Users

League (AIVL), 2003.: https://aivl.org.au/wp-content/uploads/2021/10/AIVL-National-Statement-on-Ethical-Issues-for-Research-involving-injecting-and-illicit-drug-users-FINAL.pdf

Abadie, Brown, and Fisher, '"Money Helps": People Who Inject Drugs and Their Perceptions of Financial Compensation and Its Ethical Implications';
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6774386/

Festinger et al., 'Higher Magnitude Cash Payments Improve Research Follow-up Rates without Increasing Drug Use or Perceived Coercion';
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2475801/

Webinars

LactaHub via the Global Health Network: 'Ethics in Health and Breastfeeding Research Series: Webinar II Offering Financial Incentives to Participants in Health and Breastfeeding Research':
https://www.youtube.com/watch?v=B0Cg3ZXoqw8&t=1s

Other

A Penny for Your Thoughts? Moving Research Payment Transparency from Idiom to Policy (2023)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10618000/

Participants' Perspectives on Payment for Research Participation: A Qualitative Study (2022)
https://pubmed.ncbi.nlm.nih.gov/36316972/

Paying Research Participants: Regulatory Uncertainty, Conceptual Confusion, and a Path Forward (2017) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5728432/

MONEY, COERCION, AND UNDUE INDUCEMENT: A SURVEY OF ATTITUDES ABOUT PAYMENTS TO RESEARCH PARTICIPANTS https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4214066/