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Purpose and scope

This document is designed to provide information for researchers and reviewers of research to assist in decision-making about when payment of participants in research is ethically acceptable.

The approach taken in this document rests on the assumption that participation in research is desirable and a benefit to both the scientific community and the community at-large. This information also takes into account three core ethical principles of the [*National Statement on Ethical Conduct in Human Research 2007 \(updated 2018\)*](#) (National Statement): respect, beneficence and justice. Respect requires recognition that participation in research is voluntary and based on sufficient information about, and an adequate understanding of, both the proposed research and the implications of participating in it. Beneficence requires that the potential benefits of the research must justify the risks of participation. Justice requires that the benefits and burdens of research must be shared equitably and that opportunities for participation in research not be unjustly denied to those who are eligible for participation.

The payment models and options presented in this document are intended to reflect what may be reasonable and justifiable in the context of a specific research project, not what is required or expected. It remains the remit of Human Research Ethics Committees (HRECs) and other ethics review bodies to determine whether, for each research project, payment is ethically appropriate and, if so, whether the type/s and amount/s of payment proposed are optimal or acceptable.

The information in this document is not intended to replace or override guidance provided in the National Statement and should be understood as providing additional information to assist those designing and reviewing human research.

Explanation of key terms

The terms below appear frequently in literature and guidance on the issue of payment of research participants, but are used inconsistently. For the purposes of this document, the following terminology and associated definitions will be used:

Payment – An overarching term applied to all forms of monetary or in-kind support that is provided to participants in research encompassing remuneration, compensation, reimbursement and incentive.

Remuneration – Money that is paid to participants in recognition of their services as participants in research (comparable to wages). Remuneration could be provided in recognition of the contribution of time to the research and/or in recognition of any inconvenience experienced as a result of participation in research.

Compensation – Money or in-kind support that is provided to participants (a) to compensate participants for any documented loss of wages or other financial loss resulting from their participation in research OR (b) to compensate participants for any loss of wages or other financial loss resulting from an injury suffered as a direct consequence of participation in research.

Reimbursement – Money that is paid to participants toward their recovery of any expenses incurred as a result of participation in research (e.g. travel, accommodation, meals).

Incentive or inducement – These terms are often used interchangeably. In this context, they refer to money or in-kind support that is provided to participants to encourage their enrolment or continuing participation in research or completion of their participation in research.

Undue influence – A judgment that a payment made to a participant has, or is likely to have, an effect on a participant’s decision to participate in research in such a way as to cause the participant to:

- take risks that they would otherwise not take
- underestimate or de-emphasize those risks, or
- withhold or misrepresent information that is required in order to assess the participant’s eligibility to participate in or assess the merits of their continuing participation in research.

Undue inducement – An inducement that has an undue influence on a participant’s decision to participate in research.

Coercion – The deliberate imposition of one person’s will upon another via an overt or implicit threat of harm or a restriction of specific options in order to obtain compliance. Incentives and inducements are offers that expand, rather than limit a person’s options and, hence, are not coercive. To the extent that potential participants in difficult circumstances are vulnerable to the influence of researchers attempting to recruit them, this dynamic, with rare exceptions, is more accurately described as ‘exploitation’ rather than ‘coercion’.

Guidance statements

- 1.1. Payment of participants in research is ethically appropriate if it is equitable and proportionate to the burden of the research and
 - a) does not undermine a person’s capacity to provide voluntary and informed consent
 - b) does not unduly influence a person to accept a risk or burden that is greater than they would otherwise accept in everyday living or to compromise their fundamental values
 - c) does not unduly influence a person to make false representations about or conceal information that is relevant to:
 - i. their eligibility for the research
 - ii. their contribution to the research, or
 - iii. the risks related to participation.
- 1.2. Generally, payment of participants should be limited to reimbursement of documented expenses and remuneration for time and inconvenience in order to minimise the likelihood of a payment acting as an undue influence (or undue inducement). In cases where the research offers little or no benefit to individuals (e.g. early phase clinical trials) or where the research requires the participation of target populations that are difficult to recruit, payment may be offered as an incentive to participation, as long as adequate processes are in place to promote valid consent.
- 1.3. In cases where risk may be considered as a factor in determining payment, payment of participants based on the degree of risk associated with the research is not prohibited, so long as there is evidence that a participant’s ability to provide valid consent is not likely to be compromised.
- 1.4. Payment of participants may be monetary or non-monetary (in-kind) and may include credits or vouchers, if considered appropriate.
- 1.5. Researchers should provide potential participants with information on the payments that they will receive that is sufficient to enable participants to make an informed decision regarding their participation in the research.
- 1.6. Any proposal for payment of participants should be considered by whichever body is conducting the ethics review of the research. To inform reviewers’ consideration, researchers should provide them with a payment plan that includes
 - a) a rationale for the proposed payments
 - b) the method and timing of any disbursements, including how they have been calculated, and
 - c) information about how prospective participants will be advised of the provision of payment.

- 1.7. The objective of review bodies should be to assess whether proposed payments of participants are (1) adequate (2) proportionate (3) not excessive and (4) fair. In making these assessments, review bodies are not required to establish that there is no possibility of undue influence; rather, they should ensure that the potential for undue influence is minimised.
- 1.8. Payment of participants based on partial contributions ('prorating') is preferable to payment only upon completion of the research. Completion bonuses may be ethically defensible, but, if proposed, would need to be justified.
- 1.9. Additional payments may be made in recognition of unanticipated additional contributions of time by participants, so long as they are in accordance with the original approved payment plan or subsequently approved by the reviewing body.
- 1.10. Special conditions may apply with respect to payment of participants in research involving unapproved therapeutic substances. Specifically, it is recommended that payments to children (under 16 years of age) and adults who lack decision-making capacity and/or their parents/legal representatives should be limited to reimbursement for documented expenses.

Context and explanation

While recognising that payment of participants to participate in research is still controversial, both in Australia and internationally, this document recognises that payment of participants to participate in research is increasingly common in Australia and elsewhere. It also recognises that arguments that payment, or excessive payment, of participants in research is unethical must be balanced against arguments that non-payment, or insufficient payment, may also be unethical.¹ Additionally, the impact of payment on a participant's decision to participate in research should be considered in the context of the use of incentives to influence behaviour and decisions in society more generally, including decisions that carry a high degree of risk to the well-being of the decision maker.

Payments to children (under 16 years of age) or their parents, or to adults who lack decision-making capacity or their legal representatives, present complications related to the potential for the legal decision maker to inappropriately influence the participant and enrol the participant in research in order to obtain financial gain. This potential is of particular concern in the context of payment to these participants for participation in clinical interventional research involving unapproved therapeutic substances. For this reason, payment to these participants in this type of research should be limited to reimbursement for documented expenses and proposals for payments to these participants in other research should be scrutinised with special care.

Research involving participants with known addictions raises other concerns, many of which, however, are not substantiated by evidence. Reviewers should not normally insist upon the use of vouchers (or other non-cash payments) for participants who use addictive substances. This is because "in the absence of evidence to the contrary, people who use (addictive substances) should be assumed to be autonomous individuals able to make their own decisions about taking part in research and should not be treated differently to other participants in terms of payment for their participation".² This principle also applies to prisoners and other individuals whose autonomy is restricted, but who otherwise have the capacity to make decisions about participation in research.

1 The argument that the absence of payment or underpayment is unethical is based on two premises: (1) that non-payment/underpayment is exploitative, defined here as occurring when one party to a transaction insufficiently benefits from or assumes an unfair share of burdens relative to other parties in a transaction or relationship; and (2) that a potential outcome of non-payment/underpayment is insufficient or unrepresentative recruitment, compromising the scientific value of the research and/or depriving the community or specific individuals of the benefits of the research.

2 NHS Health Research Authority. HRA Ethics Guidance: Payments and Incentives in Research; 2014.

Research involving students, employees, people receiving government support payments or members of community or consumer advisory groups also requires special consideration in order to minimise the likelihood of undue influence or exploitation of such populations and to recognise roles and contributions to research that do not constitute direct participation.

Research with Aboriginal and Torres Strait Islander Peoples and communities requires consideration of several additional factors, including:

- The nature of the relationships between researchers, participants and Indigenous knowledge where participants are often subject matter experts and the potential need for payment to account for the contribution of this expertise.
- The prevailing standards and expectations with respect to payment and the need for consultation with appropriate community groups or representatives to design a payment model that meets these standards and expectations.

With respect to research occurring in another country, payments should be culturally sensitive and reflect prevailing standards and expectations. Consultation with appropriate bodies or individuals to design a payment model that meets these standards and expectations may be required. Researchers should also consult the guidance provided in Chapter 4.8 of the National Statement on the application of the National Statement to their research.

Clinical research presents considerations related to whether the participants are patients or healthy volunteers and, with respect to the former group, whether these patients may, or are likely to, obtain a health-related benefit directly from their participation in the research. Offering payment for participation in clinical research when many patients are already well disposed to participate, does not, in and of itself, make payment unethical. Equally, where the possibility exists that patients might benefit from the research intervention, it does not follow that they should not receive additional benefits, such as payment, or that, under these circumstances, these additional benefits would necessarily constitute an undue influence on their agreement to participate. Indeed, the (UK) Royal College of Physicians' *Guidelines on the practice of ethics committees in medical research with human participants* (Fourth edition) argues that "payment may help patients distinguish procedures that are done purely for research purposes from those done for their benefit, thus minimising vulnerability due to 'therapeutic misconception'." Another view, offered by the US Federal Drug Administration (FDA) is that "payment to research (participants) ...is not considered a benefit; (rather) it is a recruitment incentive."³

The association of payment for participation and risk is a particularly controversial aspect of the payment issue. A primary responsibility of ethics review bodies is to provide an overall assessment of risk for each research project. While it is widely accepted that ethics review bodies should not consider payment as a means to offset the risks associated with a research project, participants should have the opportunity to assess for themselves whether the risks associated with a research project are outweighed by the potential benefits and by any potential payment, as they relate to their individual circumstances. In making this assessment, participants can be expected to presume that research that carries an unacceptable risk profile will not be approved by an ethics review body.

The restriction of payment of participants to expenses, time and inconvenience in the context of a model that mixes remuneration and reimbursement is considered to be justified as a balance between concerns about overpayment (potentially creating an undue influence) and underpayment (potentially creating an unjust distribution of burdens and benefits). In this model, payment for time should be based on the time that is contributed to the research, not the time 'lost' from work⁴, nor a judgment as to what that time is worth, objectively or subjectively, to the participant. Payment for inconvenience should reflect the extent of the inconvenience according to a 'reasonable participant' standard. Payments for expenses should

3 Federal Drug Administration. Payment to Research Subjects - Information Sheet; 2016

4 The decision to base 'time' payments on the value of contribution to research, rather than on lost wages, is grounded in three principles: (1) it links payment to a fair exchange for actual contribution to research, reinforcing a partnership model, (2) it does not require creating a stratified payment system to differentiate between participants who ordinarily receive higher and lower wages, and (3) it neither rewards participants who are unemployed or receive low wages nor discourages participation by those at higher wage levels

reflect actual expenses, but research proposals should include an estimate of costs likely to be incurred by participants, for which consultations with community experts may be warranted.

If a payment model is proposed that includes different amounts of remuneration for time and inconvenience, then those differentials should reflect documented variations in frequency and duration of visits, meetings or project-related procedures or tasks, efforts that are required from the participants, or discomfort that is anticipated to result from participation, as relevant.

In some cases, non-monetary payments in the form of services unrelated to the research or educational materials may be more appropriate than monetary payments. Lotteries, prize draws or equivalent forms of payment may also merit consideration; however, there should be no presumption that these are intrinsically superior to payments to all individual participants.

Collective, rather than individual, payments, including lump sum payments to an organisation for its contribution to or participation in a research project, may be merited.

In general, the relative merits of types of payment or equivalent recognition of contribution to research should be considered in the context of community standards and expectations and determined by an ethics review body on a case-by-case basis.

As provided for in Appendix 1 – Recommended payment models for expenses, time and/or inconvenience could take the form of (a) a set amount, (b) a ‘base level’ only, or (c) levels with lower and upper limits, depending on the nature of the research and the project budget. For payment models utilising a base level, it is recommended that the base level be set at the current minimum wage.

There may be tax implications arising from receiving payment for participation in research. Researchers should understand these implications and inform potential participants of these implications and/or advise them to contact the Australian Tax Office for further information.

Considerations for researchers and reviewers

When proposing that participants in a research project receive payment, researchers need to present a justification for this and provide details of the proposed payments. In developing a payment model for research participants and in assessing whether the proposed payment of participants is ethically appropriate, researchers and reviewers may refer to some or all of the following considerations, as relevant to the individual project:

- Whether the form/s and level/s of payment that are proposed are
 - adequate, proportionate, not excessive and fair
 - neither calculated to provide or likely to have the impact of providing an undue inducement to participate in the research.
- Whether, in practical terms, the forms and levels of payment appropriately align with the objectives of providing the payment (e.g. to recognise contribution to the research or to maximise recruitment of participants in circumstances where recruitment is difficult).
- Whether the proposed payments adequately address any necessary distinctions between the type, status or characteristics of participants who will be recruited, such as
 - healthy volunteers in clinical trial research
 - patients in clinical research with a foreseeable benefit
 - patients in clinical research with little or no prospect of benefit
 - healthy volunteers in clinical trial research who are relatives/friends of a patient
 - children or young people
 - individuals associated with the organisation responsible for the research, such as employees or students.

- The appropriateness of the type of payment (including monetary and non-monetary forms of payment) and the timing of the payments for the participants who will receive the payments.
- In cases where gradations in payment related to risks of participation are proposed, whether the gradations in payment are appropriate to the risk level and the character of the individual research project.
- Whether there are standards, norms or practices (locally, nationally or internationally) related to the type of research for which participants will be paid and whether the proposed payments are aligned with those standards, norms or practices.

In designing their research and assessing proposed payments, researchers and reviewers should take account of the normative statements and advice in other sections of this document.

Resources

This document takes into account guidance relating to payment of research participants proposed in or by:

- International Council for Harmonisation of Technical Requirements For Pharmaceuticals for Human Use (ICH). *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) Step 4 version dated 9 November 2016*. 3.1.8-3.1.9
- Council for International Organizations of Medical Sciences (CIOMS). *International Ethical Guidelines for Health-related Research Involving Humans, Fourth edition*; 2016. Guideline 13
- Regulation (EU) No 536/2014 of the European Parliament and of The Council on clinical trials on medicinal products for human use; 2014 (repealing Directive 2001/20/EC)
- European Patients' Academy on Therapeutic Innovation (EU). *Compensation in clinical trials*; 2015
- U.S. Department of Health and Human Services Office for Human Research Protections. Revised response to FAQs; 2013
- Federal Drug Administration. *Payment to Research Subjects – Information Sheet*; 2016
- NHS Health Research Authority. *HRA Ethics Guidance: Payments and Incentives in Research*; 2014
- Nuffield Council on Bioethics. *Human bodies: donation for medicine and research*; 2011. 6.83-6.86
- Royal College of Physicians (UK). *Guidelines on the practice of ethics committees in medical research with human participants, Fourth edition*; 2007. 10.12-10.20
- National Health Research Ethics Council (South Africa). *Payment of trial participants in South Africa: Ethical considerations for Research Ethics Committees*; 2012
- Association for Human Pharmacology in the Pharmaceutical Industry. *Guidelines for phase 1 clinical trials*; 2014

Appendix 1: Examples of payment models

Both the appropriateness of payment for participation in research and the appropriate levels of payment must be assessed by the review body conducting the ethics review of each research project. When payment is offered, the proposed payment model should be consistent with the principles delineated in this document.

As indicated above, the payment models listed below are intended to reflect what may be reasonable and justifiable, rather than what is required or expected in the context of a specific research project.

Reimbursement for expenses should reflect actual, documented expenses for each individual. If a range of payments for time and/or inconvenience are offered, it is recommended that there be a small number of levels within that range, rather than each participant's contribution being individually assessed and differentially remunerated.

It is recommended that payment models be based on an hourly rate rather than on a daily rate in order to better reflect the character of research participation; for example, research projects that involve medical procedures, clinic visits, exercise regimens, physical or psychological therapy, survey completion or observation are more likely to involve single or multiple short time periods of 'participation' than participation over the course of a full day or multiple days.

The likely overall costs of payments to research participants should be taken into account when proposing that payments be provided and in determining payment models in order that a project is not intrinsically, or does not become, financially unviable. The use of payment caps may be useful for this purpose.

Option 1: No payment

No payment for expenses, time or inconvenience.

Option 2: Reimbursement of expenses only

Payment for actual expenses, stratified to account for variations in expenses incurred. No payment for time or inconvenience.

Option 3: Reimbursement of expenses plus remuneration for time and inconvenience (minimum wage)

Payment for actual expenses, plus a **set payment** for time and/or inconvenience based on the applicable minimum wage. In Australia, see <https://www.fwc.gov.au/awards-and-agreements/minimum-wages-conditions/national-minimum-wage-orders> for current rates. This amount could also include a 25% casual loading and/or a penalty rate that recognises weekend/holiday participation.

Option 4: Reimbursement of expenses plus remuneration for time and inconvenience (minimum wage as base level or lower limit)

Payment for actual expenses, plus a range of payments for time and/or inconvenience based on the applicable minimum wage. This would involve setting a 'base' payment (with or without a 25% casual loading and/or a penalty rate that recognises weekend/holiday participation) and then a number of payment levels above the base payment. If an upper limit to the payment range were imposed, that limit could be 1.5x or 2x the minimum wage.

Option 5: Remuneration for time and inconvenience only

Payment for time and/or inconvenience based on a standard as in Options 3 or 4 above. No payment for expenses. Note: This option may be most suitable for projects in which participants are paid a 'lump sum' for their contributions, some or all of which they may choose to use to offset their costs and/or undocumented expenses.

Appendix 2: Case studies

The case studies below are intended to provide guidance to researchers and ethics review bodies in considering possible options for payment of participants in research. They represent a small range of scenarios in order to illustrate different approaches to payment of participants in research that might be appropriate. The case studies include examples of research using the approach adopted in this document on payment of participants in research; hence, they are based on a modified reimbursement model not on a market model. Specifically, the case studies do not include scenarios wherein payments are market-driven and employed as incentives to recruit participants in high-risk commercial research. Nevertheless, users will note that the information at 1.2 and 1.10 and some of the content of the Context and Explanation section of this document address limitations on the use of a market-based payment model to promote participation in research.

These case studies are suggestive, rather than exhaustive or prescriptive and do not imply that payment is necessarily appropriate for an individual research project.

Rather than focusing on a correlation between the type or category of research and a payment model, these cases are examples of research that fall into one of four quadrants in a matrix that has risk⁵ and time/inconvenience as its two dimensions:

Risk / Time and/or inconvenience quotient (T/I)	Low-to-Moderate Risk	High Risk
Low T/I	Cases 1,2	Cases 5,6
High T/I	Cases 3,4	Case 7

Low-to-moderate risk / low time and/or inconvenience

Case Study #1 - Telephone survey

A market research style project using a phone survey that employs a randomly selected or convenience sampling method. The phone survey will take up to 15 minutes and will seek information in the form of knowledge, opinions and/or assessments relating to (a) mobile phone services conducted for a phone company or service provider or (b) views about publicly funded vocational education and training conducted for a state government.

Neither remuneration nor reimbursement of expenses is offered.

Case Study #2 - Post-fire regrowth monitoring

In a local government funded project, volunteers from the communities affected by recent bush fires agree to monitor regrowth of native grasses. Monitoring includes mapping species regeneration and gathering seed for further re-planting. Volunteers will form teams based on community affiliation and meet with researchers from the nearby university faculty in their teams and as a whole group over the years of the project in order to share their data and consider future actions.

Volunteers are not remunerated individually, but each team receives a voucher for the purchase of new tools and seed storage boxes.

⁵ Researchers and ethics review bodies should note that the 'low-to-moderate risk' and 'high risk' designations used for these case studies do not mirror the definitions used for low risk and greater than low risk in the National Statement.

Low-to-moderate risk / high time and/or inconvenience

Case Study #3 – Pharmacokinetic study with healthy volunteers

A specific form of ACE inhibitor (Ramipril) has just become available in a generic form and researchers propose to conduct a pharmacokinetic study to confirm its efficacy in healthy people. Ten healthy young participants are to be invited to attend an overnight study to be administered a low therapeutic dose of a new form of ACE inhibitor (used to treat hypertension and congestive heart failure). ACE inhibitors are usually well-tolerated by most individuals. Nevertheless, they are not free of side effects such as prolonged coughing, low blood pressure and dizziness. In rare cases, ACE inhibitors can cause kidney failure, allergic reactions and pancreatitis. The study involves:

- admission to hospital overnight to obtain baseline liver and renal function and to monitor individuals after a low therapeutic dose of Ramipril and to collect hourly blood samples during a pharmacokinetic study of Ramipril absorption and distribution
- monitoring for 14 days as an outpatient with daily administration of Ramipril, and
- re-admission to hospital at the end of the two weeks for repeat liver and renal function and pharmacokinetic blood testing of Ramipril for comparison with baseline testing performed two weeks prior.

Researchers plan to pay each participant for participation plus expenses; participants would receive the payment at admission and at re-admission. Prorata payments will be available to participants who must withdraw due to the impact of an adverse event.

Case Study #4 – Longitudinal study of social determinants of health

A longitudinal study of health and social determinants requiring a representative sample of individuals who commit to ongoing involvement in the project for a considerable period of time (initially five years, with an option for continuation for a longer period). Participation entails completing a detailed initial questionnaire and follow-up questionnaires at regular intervals (a minimum of 2-3 times per annum) plus some standard health-related tests, using a combination of on-line and/or phone methods and attendance at a research location. The study is the initiative of university-based researchers with specific funding for the project.

Participants will be offered remuneration for the substantial time/inconvenience involved, as well as reimbursement for travel and other expenses.

High risk / low time and/or inconvenience

Case Study #5 – Vaccine study

A commercially sponsored, hospital-based single arm phase 2 study of a new vaccine will recruit 100 participants. The participants will receive the vaccine and blood samples will be drawn two months later. Risks of the active ingredients of the vaccine are known to include heart failure, dizziness, hallucination and sleeping problems.

Participants will be paid for their time with consideration for the risks associated with the vaccine.

Case Study #6 – Sensitive interview

The project requires 100 adult women to participate in intensive face-to-face interviews in their homes or at a neutral, convenient location. The interviewers will seek to collect qualitative information on the subject of family and sexual relationships and/or experience of sexual violence.

The project is being run by a welfare or service agency and at least some of the participants will be clients of the agency. This may raise privacy and confidentiality issues, thereby increasing the risks to the participants, but there may also be benefits from the research.

Participants will be offered remuneration for the interview time with consideration for the attendant risks, in particular to recognise the psychological distress that the interviews are likely to cause.

High risk / high time and/or inconvenience

Case Study #7 – Gut-Brain Study on Depression

Background

Serotonin reuptake inhibitors (SRIs) are used in the treatment of major depressive disorders to prevent suicide and self-harm. Long term users of SRIs deal with unpleasant and quality of life inhibiting side effects such as nausea, dry mouth, insomnia, diarrhoea, nervousness, agitation or restlessness, dizziness and sexual problems.

Recent studies indicate gut microbiota play a major role in communication between the gut and the brain and in major depressive disorders. Credible research has shown that gut microorganisms are capable of producing and delivering serotonin and gamma-aminobutyric acid, which act on the gut-brain axis and prevent depression without the side effects of SRIs. These microorganisms can be altered by diets with specific properties, such as the Mediterranean Diet.

Research Project

Researchers from a University Department of Exercise and Dietetics and Department of Psychiatry propose to test the role of diet in replacing SRIs for the treatment of severe depression. A key risk of the study is that participants may experience a major depressive episode where self-harm or suicide ensues. To mitigate this possibility, researchers propose to support the dietary intervention with mindfulness training and aerobic exercise, as well as intensive monitoring over a period of 12 months. Monitoring will include close scrutiny of participants and crisis intervention, where necessary. The study has philanthropic funding.

Participants will be asked to:

1. Keep a daily mood diary to track depression levels.
2. Keep a daily food diary to track compliance with the proposed diet.
3. Commence a 4 hour per week exercise program under the supervision of a personal trainer paid for by the study.
4. Attend a weekly mindfulness training course at the Happy Mind Centre in a nearby suburb.
5. Use a watch monitor (Apple or equivalent) or maintain weekly contact with the research team.
6. Undertake fortnightly blood tests at the University Medical Centre.
7. Undertake monthly faecal tests at the Gastrointestinal Clinic in a major hospital to track changes in gut microbiota.

Participants will be paid in recognition of the burdens and potential risks of participation in the project.

