

Guidance and Procedure: Payment for Participation in Research

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Ethical Considerations

Once an investigator decides to pay a research participant, a number of points need to be considered. First and foremost, **participant payment raises ethical issues pertaining to the requirement for voluntary participation** and the individual's ability to make informed choices about research that are based on the real risks and benefits of participation, not solely on the financial incentives. Both the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) caution against undue inducement. By federal regulation and guidance, payment to research subjects is not considered a benefit of participation, but is instead compensation for time and inconvenience, or a recruitment incentive.

Federal regulations and commentaries offer guidance about such incentives, but set no strict limits. Thus the Principal Investigators and the local IRBs must decide how much payment is too much or not enough. The OHRPP has developed the following guidance about participant payment.

Legal Considerations for Clinical Studies that Bill Insurance

In addition to ethical considerations, there are also legal considerations governed by Federal and State Fraud and Abuse statues that come into play for the subset of clinical studies that bill medical insurance providers, including government payers. That is, some arrangements to reimburse travel, lodging, or *per diem* expenses may be interpreted as unlawful inducements if associated with the delivery of standard of care services *billed to a third party payor (e.g., Medicare, MediCal or private insurance)*.

While such arrangements may be acceptable, any such proposed arrangements should first be vetted with the UCLA Office of Clinical Trials Administration (CTAO). The CTAO will coordinate with UCLA and/or UCOP Counsel and the IRB, and other offices as needed, and help the study team establish the documentation needed to support why these arrangements are made. This vetting must occur before making any offers to the research participants or making any reimbursement proposals to the sponsor to reimburse travel, lodging, or *per diem* expenses.

By way of example, if you know when designing the study that participant safety might necessitate that a subject *not* drive on the day of the investigational drug administration, then you need to be prepared to make reasonable accommodations. If the subject does not have someone reliable to drive him or her home that day or if the person lives far away, it would be prudent for the study team to help make travel and/or lodging arrangements if needed. This situation would need to be vetted as described above and then described appropriately in the consent form. For example, in the consent form, the section **“What Will Happen If I Take Part in This Study?”** should include information something like, “You must refrain from driving the day of the investigational drug administration. Because of this you must make arrangements to have a relative or friend drive you home or the research staff can arrange a taxi ride home and/or make hotel accommodations for you if you live too far away.” In **“What Kinds of Risks or Discomforts Could I Expect?”** you should describe the risks associated with the drug administration and specify that because of those risks, participants cannot drive that day.

On the other hand, if something unforeseen comes up during a study and it becomes important to make travel or lodging arrangements for a particular subject’s safety, you should talk with the CTAO and the IRB as described above and then submit an incident report via webIRB describing the reason for the deviation from the approved protocol.

Methods of Payment and Reimbursement

Method of payment

Investigators can pay participants by various methods including cash, check, or gift card. When determining the method of payment, consider factors such as:

- The characteristics of the subject population (Are they likely to have bank accounts? Can they easily cash checks? What type of gift card would be best for the group? What types of gift cards are available through UCLA Business and Finance Services?);
- The amount of payment (i.e., large sums are best not paid in cash); and
- The study procedures (internet surveys should not require a face-to-face interaction in order to provide payment).

Restrictions on Types of Payment

- Do not provide subjects with private industry sponsor’s advertising materials (i.e., items containing the sponsor’s name, logo, commercially identifiable marking or drug name) as a method of payment.
- Do not provide or allow payment in the form of a coupon good for a discount on the purchase price of the test article once it has been approved for marketing.

Reimbursement of Expenses

Investigators often wish to and are encouraged to provide reimbursement for parking, transportation and childcare costs for research-related visits (with the possible exception of the legal considerations for “clinical studies” described in the above section). Actual reimbursement may require that participants provide copies of the receipts. These costs can and often should be added to adjust the hourly amount paid to subjects (see “amount of payment” below).

Amount of Payment

There are no hard and fast rules about how much participants should or should not be paid. Participants should be paid enough to make up for their time and inconvenience. Participants should not view research participation as a way to earn a living or regularly supplement their income. Large payments can suggest this possibility, and can be coercive. As noted above, restrictions may apply for clinical studies that bill insurance.

- **How much payment?**

When appropriate, follow a “wage payment model”¹ which requires structuring payment “on a scale commensurate with that of other unskilled but essential jobs,” since participation in research “requires little skill but does require time, effort, and the endurance of undesirable or uncomfortable procedures.”

However, in some cases, an hourly range is clearly not appropriate. A half-hour spent with an endotracheal tube in place or undergoing a biopsy is not comparable to a half-hour having height, weight, and blood pressure measured. Even so, you should be cautious when considering whether “undue influence” begins once subjects are paid \$200 to \$400 per procedure or when the total study payment nears \$1,000. One exception to procedure-specific payment is payment for blood samples: the UCLA IRB does not allow subjects to be paid based on volume of blood taken.

- **Prorating payment**

UCLA investigators are encouraged to implement a prorated system of payment for studies involving several tasks or office visits. In this way, subjects who do not finish the study are paid in proportion to the part completed. While a small bonus for completion might be acceptable, large bonuses or withholding of payment until the end of the study are not.

- **When is prorating not appropriate?**

Prorated payment may not be appropriate for all research activities. As [45 CFR 46.116\(a\)](#) and [21 CFR 50.25\(a\)](#) requires that participants' voluntary refusal to participate or discontinue participation involve no penalty, the UCLA IRB/OHRPP will require full payment for subjects' partial completion of surveys or questionnaires or for "inadequate" participation in group discussions.

Special Guidelines Regarding Lotteries/Raffles/Drawings

Lotteries, raffles and drawings pose the same considerations as other forms of payment. However, University of California legal counsel has advised that instances where only those study participants who have signed up for a study can enter the related lottery or raffle *may not be permissible* under California state law, which essentially prohibits lotteries where participation is conditioned on some form of “consideration” that limits eligibility to win a prize.

The UCLA OHRPP recommends that researchers include the following in applications that propose to include a lottery/raffle/drawing:

- (1) Study procedures must not preclude from the raffle individuals who either refuse to participate in the research project or fail to complete the project;

¹ The “wage payment model” is endorsed by the authors Neal Dickert and Christine Grady in their article “What’s the Price of a Research Subject? Approaches to Payment for Research Participation” published in the *New England Journal of Medicine* (NEJM, 199; 341:198-203).

- (2) Outline procedures for the inclusion of an individual who is not asked to participate in the study but wishes to be included in the lottery, raffle, and/or drawing;
- (3) Include a description of a fair method of choosing the winner and explain how the winner will be notified;
- (4) Include language in recruitment and consent documents that states that it is not necessary for a subject to complete the project in order to participate in the raffle (e.g., “Participation in the study is not required in order to participate in the raffle”) and discloses the approximate chance of winning (e.g., no less than 1 in 1000).

Departmental Procedures for Requesting Payment for Research Participants

UCLA departments may request checks, cash, gift cards or deposits on BruinCard for human research participant payments.

- For check payments, contact [Accounts Payable](#) for instruction.
- For cash, gift cards, or depositions on BruinCard, click [here](#) instructions for requesting payment from the Business and Finance Office or for a copy of the [Research Human Subject Disbursement Request Form](#).

Investigator Responsibilities

webIRB Application details

UCLA investigators must include the following information in their webIRB application:

- A description of all plans to pay subjects:
 - The amounts of any financial inducement, payment, services or other non-cash benefits ;
 - Reimbursement for travel and other expenses, such as parking, transportation, lost wages, child care; and
 - The timing and method of disbursement and
 - The conditions, if any, which the participants must fulfill in order to receive either full or partial payment.
- If payment will differ for different groups of subjects, then clearly describe all of the above for each group.
- For research involving minors, specify whether the payment is provided directly to the subjects or to their parent or legal guardian.
- For studies involving a lottery, raffle or drawing, information addressing the special considerations is outlined in the Special Guidelines section above.

Consent form details

- ***Will I Be Paid for My Participation?*** If participants will be paid, the consent forms should include such a section. If no payment and/or reimbursement will be provided, the consent forms should clearly state this (or, the investigator could make an argument for not including such a section in webIRB). The following details should be provided in the consent form:

- The amount of payment, including a description of any pro-rating or completion bonuses (which, as stated above) may not be so large as to exert an undue influence;
 - The method of payment (i.e., in cash or by check, or with a gift card);
 - The timing of payment (i.e., whether subjects are paid immediately or, for example, after a delay of four to six weeks) and
 - Any conditions that the subject must fulfill in order to be paid (i.e., provide receipts, provide Social Security Numbers if paid by check).
 - The fact that participants will have to provide their Social Security Numbers if they are paid by check.
- **Will information about me and my participation be kept confidential?** If participants are paid by check, the following information needs to be included in the section:
 - As stated above, inform subjects that Social Security Numbers (SSNs) will be collected if they are paid by check.
 - Explain how their SSNs will be protected and describe the limits to the protection of their confidentiality.
 - If participants are paid \$600 or more for participation in the study, advise them that their payment will be reported to the IRS.

Collection of Social Security Numbers (SSNs) for Payment Purposes

Because large amounts of sensitive personal information, including tax information, credit information, school records, and medical records, are keyed to Social Security Numbers ("SSNs"), SSNs should be collected for research purposes **only when necessary to comply with IRS reporting requirements**. For further information about such requirements, please contact UCLA Corporate Accounting.

If payment will involve collection of SSNs, this should be explained in webIRB and the following safeguards should be implemented:

- **Store records containing SSNs securely and separately from research records.**
 - Do not copy unnecessarily.
 - Destroy as soon as feasible.
- **Inform participants** of the limitation to the confidentiality of their information.
- Indicate in the consent form that participants will be asked for their SSNs, why SSNs will be collected, and how this information will be protected.
- **When completing check requests** or other paperwork using SSNs, staff should take care not to include extraneous but potentially damaging information such as the study title, the nature of the research or the names of procedures undergone.

It is not clear that a Certificate of Confidentiality will protect from discovery of study information through an IRS audit of accounting records. For research into sensitive matters requiring a Certificate of Confidentiality, the study team is strongly encouraged to contact UCLA Corporate Accounting regarding methods of payment and recordkeeping that may both protect the subjects and serve the University's interests.

UCLA IRB/OHRPP Responsibility

During its review, the UCLA IRB/OHRPP will ensure that:

- Payment offered for participation in research, monetary or otherwise, does not constitute undue influence.
- Payment offered is reasonable, given the complexity and the inconvenience of the study and the subject population.
- Payment is made on a schedule appropriate to the length or intensity of the study.
- Credit for payment accrues as the study progresses and is not contingent upon completion of the entire study.
- Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
- The payment described in the protocol, the recruitment documents and the consent form are consistent and complete.

The UCLA IRB/OHRPP may request justification for payment amounts from the investigator in order to assess the appropriateness of the proposed payment plan. The UCLA IRB/OHRPP may refer payment considerations for studies that bill insurance to CTAO, Legal Affairs or other offices to ensure that they do not conflict with the legal, contract or other requirements.

References

- [UCLA Business and Finance Research Subject Payment](#)
- UCLA Health, Office of Legal Affairs, [Fraud and Abuse Laws and Regulations](#)
- UCLA Hospital System Patient Financial Services, [Financial Assistance Policy](#)
- Office for Human Research Protections' (OHRP, formerly OPRR) [Protecting Human Research Subjects Guidebook \(1993\), Chapter 3](#).
- Food and Drug Administration, [IRB Information Sheets: Payment to Subjects](#), September 1998.
- The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, [The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#), April 18, 1979.
- Neal Dickert and Christine Grady in their article "What's the Price of a Research Subject? Approaches to Payment for Research Participation" published in the *New England Journal of Medicine* (NEJM, 199; 341:198-203). (<http://www.ncbi.nlm.nih.gov/pubmed/10403861>, Accessed 5/16/2016)

Change history:

6/9/2016: Added guidance re: raffles/lotteries; fixed broken links