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Home > Research Subject Payments

Research Subject Payments

Research Payment Considerations

How to Pay Research Subjects: Accounts Payable Procedures

Sample Consent Form Wording

Research Payment Considerations

Subject payment raises ethical issues around voluntary participation and the individual's need to make informed choices about participation based on the risks and benefits of the research, not on financial incentives. The FDA cautions against payments that are "coercive or present undue influence," and the NIH similarly warns about payments that cause "undue inducement." However, the federal regulations set no strict limits on financial incentives, leaving PIs and local IRBs to decide how much payment is too much or not enough.

Following these general cautions and based on its own experience, the IRB has developed recommendations about subject payment.

How much should subjects be paid?

There are no hard and fast rules about how much subjects should or should not be paid. Subjects should be paid enough to make up for their time and trouble, but not so much that their decision to volunteer or continue in a study is influenced by the amount being offered.

Subjects should not see research participation as a way to make a living or regularly supplement their income. Large payments can suggest this possibility and can be coercive.

Residents of the Bay Area make an average of **\$15 to \$20 an hour**, and this is a reasonable upper limit for studies involving lengthy or periodic visits to the lab or clinic and fairly low risk procedures that are routine in clinical practice, such as venipuncture, physical exams, MRI or x-ray, ECG, interviews, or questionnaires. Other payments (to cover parking or transportation fees, child care expenses) can and often should be added to adjust this hourly amount.

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. The IRB has generally accepted procedure-specific payments for complex, invasive and uncomfortable procedures, but here it is difficult to advise. The question of "undue influence" begins to surface once \$200-300 per procedure is reached or when total study payment nears \$1000. One exception: the IRB does not allow paying subjects based on volume of blood taken.

No matter how payment is calculated (hourly, per procedure, or some combination of both), the Payment section of the consent form should state the maximum amount of payment available.

Rare Disease Exception: In 2015, a clinical trials compensation bill for rare-disease clinical trial participants was passed. The federal law allows patients with rare diseases to receive up to **\$2,000 per year**. This exception only applies to the income calculation for Supplemental Security Income (SSI) and Medicaid. Payment for study participation still counts toward *taxable* income for the IRS.

When should subjects be paid?

Just as the size of payment can put inappropriate pressure on subjects, so can the schedule of payment. Holding payment until the subject has completed every procedure in a long, multi-week, multi-visit study is inappropriate. For studies with more than two or three visits, payment should be prorated, that is, based on the amount of time subjects have spent participating so far.

It is acceptable to offer a small bonus for completing all study procedures, but the bonus should be no more than 30% of the total available payment.

Explain the payment schedule in the Payment section ^[1] of the consent form and specify any bonuses.

Restrictions on paying subjects from the SFVAMC

SFVAMC subjects may not be paid for participation in research when the research is integrated with the patient's medical care and makes no special demands on the patient.

Payment is permissible in the following circumstances:

- When the research is not directly intended to enhance the diagnosis or treatment of the medical condition for which the subject is being treated, and when the standard of practice in affiliated non-VA institutions is to pay subjects.
- If subjects at a collaborating non-VA institution are being paid for the same participation, in the same study, at the same rate proposed.
- In comparable situations when, in the opinion of the IRB, payment of subjects is appropriate.
- When the subject incurs transportation expense that would not be incurred in the normal course of treatment which are not reimbursed by another mechanism.

Special rules that apply to drawings/lotteries/raffles

There are various federal guidelines including IRS rules, State of California laws, and other statutes that apply to lotteries. When proposing to offer a research-related drawing as a form of compensation, researchers should use the following guidelines from the Office of the President to minimize the likelihood of triggering legal issues.

- a. Researchers should use the term "drawing" rather than "lottery" or "raffle," since the latter terms imply purchase of tickets by participants.
- b. To further avoid the possibility that a drawing would be perceived as a lottery, the protocol should describe procedures for ensuring that all individuals who are contacted concerning the research will be allowed to enter the drawing. This would encompass individuals who are invited to participate but decline, prospective subjects who are ineligible, and subjects who enroll but later withdraw/are withdrawn by the researchers. Additionally, the protocol should affirm that the drawing may be entered by any individual who asks to be included.
- c. The protocol and consent document(s) should also include the following information:
 - Description of the prizes, including estimated value, and the total number of prizes to be awarded.
 - The odds of winning a prize, if known, or explanatory language similar to this: "For any drawing, the odds of winning a prize depend on how many people are entered in the drawing. As we do not know how many people will participate in this study related drawing, we cannot predict what will be the odds of winning a prize."
 - The approximate timing of the drawing (e.g., month/year).
 - How prize winners will be notified.

How to Pay Research Subjects: Accounts Payable Procedures

Depending on the needs of the study, the Accounts Payable Office offers subject payments via debit card, check or petty cash (for on-site payments of \$150 or less per visit). Below is a summary of these payment methods. Complete information is available on the Accounts Payable's guidelines on Paying Research Subjects ^[2].

Debit card

Research subjects may be paid using the Human Study Debit Card Program. This program offers several advantages:

- Payment in the form of a Visa Prepaid Debit Card rather than paper check or petty cash
- Eliminates the need to submit check requests for research subjects
- Less risk than maintaining a petty cash account
- Empowers department(s) to manage transactions via a web-based portal compliant to HIPAA regulations
- Balances are backed by Visa's zero liability guarantees, virtually eliminating loss due to fraud or theft.

Contact Accounts Payable at scmap@ucsf.edu ^[3] or 415-476-2126 for more info on the procedures for registering and ordering cards.

Payment Timing for Prepaid Visa Card or Gift Card Using P-Card: 3-5 business days

Checks and petty cash

Other payment alternatives include using the Check Request U5-2 Form 5 ^[4] or via petty cash ^[5] (for on-site payments of \$150 or less a visit). The Accounts Payable's guidelines on How to Pay Research Subjects ^[6] explains the information required to process both types of payment and links to the required forms.

Timing of Checks Using Payment Request Form: Research subject payments are processed in Accounts Payable on a priority basis, and payments are made approximately 10 days after receipt of the properly completed paperwork. *Please do not ask research subjects to contact Accounts Payable directly*; the point of contact is the research unit. Note: Purchases associated with research subjects such as translation services must be procured through University Procurement processes.

Petty Cash Payments: Review the Petty Cash Procedures ^[7] section of the Accounts Payable website and refer to the Petty Cash and Change Funds ^[8] campus administrative policy 300-44.

Special Circumstances

Tax reportable payment (\$600+/year)

Regardless of payment method, of important note is that ?total payments equal or greater than \$600 in a calendar year period are tax reportable income to IRS.? The subject's home address and Social Security number must be provided to AP Manager using a secured file and emailing vendors@ucsf.edu ^[9]. For this reason, ***Pls should not make out-of-pocket direct payments to subjects and then seek reimbursement from UC.***

To comply with HIPAA requirements, only secured files will be accepted by AP and must be provided no later than January 31 of the year following the compensation period (e.g., all reportable payments for 2013 must be forwarded by January 31, 2014).

Circumstances that do not provide for this information must be discussed with the Accounts Payable Manager before proceeding with payment requests.

Anonymous subjects

Contact Accounts Payable ^[6] if you need to issue payment and the names of the subjects cannot be revealed. The petty cash fund should be accounted for by submitting a Summary Research Subject Participation List as follows:

Attach a list showing research subject reference (i.e. number, first name, and alternate name), date of payment, and amount paid. The check request description must include the following certification:

- "I certify that the (total number) research subject payments referenced on the attached list were payments made for participation in (study name) and that each received the amount indicated."
- Signature of PI or Co-PI
- Signature of witness to payments

Contact: UCSF Accounts Payable ^[6]
E-Mail: scmap@ucsf.edu ^[3]
Phone: 415-502-3331

Sample Consent Form Wording

The Payment section of the consent form should explain how subjects will be paid (i.e., by debit card, cash, check, or gift card) and how long they will have to wait for payment (i.e., whether they are paid immediately or after a delay of four to six weeks). The most frequent subject complaint heard by the IRB concerns the timing of payment, so it is important to make the payment plan clear from the start. See **sample wording**^[10].

Social Security Numbers: If subjects are paid by check, investigators must collect the subjects' Social Security numbers and home address for check processing purposes. This information will be shared with the UCSF Accounts Payable office. Social Security numbers and addresses also must be collected if payment is \$600+/year (see IRS reporting information). Explain these reporting requirement(s) in the Payment section of the consent form.

Payment, Reimbursement, Compensation?: The IRB prefers the term "payment" when discussing money given to a subject to offset time and inconvenience and/or to provide incentive to participate. The IRB reserves the term "compensation" for discussions of UCSF Treatment and Compensation for Injury policies. The term "reimbursement" suggests that subjects must provide receipts for particular out of pocket expenses (for instance, parking and transportation), which they often cannot.

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Source URL: <http://irb.ucsf.edu/research-subject-payments>

Links

[1] <http://irb.ucsf.edu/#consent>

[2] <https://supplychain.ucsf.edu/paying-research-subjects>

[3] <mailto:scmap@ucsf.edu>

[4] <https://supplychain.ucsf.edu/check-request-form-5-non-payroll-u5-2>

[5] <https://supplychain.ucsf.edu/paying-research-subjects#Petty%20Cash>

[6] <http://supplychain.ucsf.edu/paying-research-subjects>

[7] <https://controller.ucsf.edu/how-to-guides/accounting-reporting/cash-handling-credit-cards/petty-cash-procedures>

[8] <http://policies.ucsf.edu/policy/300-44>

[9] <mailto:vendors@ucsf.edu>

[10] <http://irb.ucsf.edu/consent-form-guidelines-and-suggested-wording>