# COMPENSATION OF RESEARCH SUBJECTS

*This guidance document is intended for investigators planning to provide compensation (monetary or non-monetary) to subjects for participation in research. Should you need additional assistance, please contact OPHS at 510-642-7461 or ophs@berkeley.edu.*

**Table of Contents**



## A. Scope/Introduction

Federal regulations provide no clear guidance on the level of compensation that should be offered to research subjects. However, the regulations do require that researchers seek consent only under circumstances that minimize the possibility of coercion or undue influence (45 CFR 46.116(2)). Research incentives may limit the ability of the research subject to provide truly voluntary, informed consent. Subjects should be able to make informed decisions to participate based on the real risks and benefits of participation, not on compensation. Subject compensation should be equitable, and the confidentiality of information related to payments should be protected. Thus, the IRB will review protocol plans for subject compensation with these goals in mind, and researchers should be cognizant of the related issues, as discussed below.

## B. Important Concepts

**Compensation:** Payment or non-monetary reward is given to subjects as remuneration for time and inconvenience of participation, as well as an incentive to participate. Compensation can include remuneration that is monetary (cash, gift cards, vouchers, etc.) and/or non-monetary (gifts/promotional items, course credit, extra credit, etc.).

There are two ways in which compensation can be problematic:

- **Undue influence:** An offer of excessive or inappropriate reward is made in order to obtain compliance. For example, a researcher might offer a month's salary to subjects for one-day participation in a study to test the effects of an investigational drug with potentially serious side effects. Because the level of compensation could induce subjects to participate against their better judgment, this offer might present undue influence.

- **Coercion:** An overt or implicit threat of harm or negative consequences is intentionally presented by one person to another in order to obtain compliance. For example, an instructor might tell prospective subjects in a class that they will lose grade points if they do not participate in the research – this would be coercive. Compensation for research is not coercive in and of itself, since it does not involve a threat of harm. However, compensation can create potentially coercive situations, as when a third party is paid for another subject's participation, and that third party can exert coercion over the subject in order to obtain payment. For example, payment to a parent for a child's participation or incentives paid to a doctor or nurse for research recruitment could create coercion.

## C. Protocol and Consent Considerations

The CPHS protocol application should fully describe the plan for compensation of subjects as well as the reasoning behind amount, method, and terms of compensation. The informed consent document should disclose all information concerning payment, including the total amount, schedule/form of payment, and any plans for prorating payment if a subject withdraws. *Compensation is not considered a benefit to subject participation and is not taken into account when the IRB weighs the risks and benefits of the research.* Therefore, this information should be stated separately from the discussion of benefits in both the protocol and consent document.

It is also appropriate to disclose possible compensation in recruitment/advertising materials. In general, payment information should not be any more prominent than other elements (e.g., purpose, procedures, inclusion criteria, etc.). See CPHS Guidelines on Subject Recruitment for further information and examples.

## D. Ethical Considerations

1. **Amount of payment:** Compensation should be appropriate for the time and effort subjects devote to participation. The level of payment should not be high enough to cause subjects to accept risks that they would not otherwise accept or participate in activities to which they would otherwise strongly object based on personal values or beliefs. Excessive incentives may also be of concern since they could induce subjects to lie or conceal information that would disqualify them from the study in order to receive payment. This could in turn undermine the scientific integrity of the study or compromise the safety of the subject.

   On the other hand, if subjects are being asked to undergo a certain amount of risk or discomfort/inconvenience with no direct benefit, and no compensation of any kind will be offered, the IRB may ask the investigators to justify this. The same is true if it is

proposed to compensate subjects at a rate that is substantially lower than average local compensation for such activity, or to compensate subjects in one group less than another, even though subjects in both groups will carry out the same procedures (see below). The IRB will consider individual circumstances, including funding or lack thereof, for such studies.

Many researchers base the payment amount on the average wage in the location where the research is conducted or for the specific study population. This is often an acceptable level of payment that does not exert undue influence. When hourly payments are not suitable or feasible, compensation may be task- or procedure-specific (for example, some studies pay subjects per sample collection or survey). In general, all subjects completing the same tasks in a single research project should be compensated at equivalent rates. In some cases, distinct subject populations may be compensated at different rates, but clear justification for this is needed. For example, a research study with several international sites may have different payment levels depending on the average local wage.

Whenever possible, subjects should be *reimbursed* for costs incurred as a result of study participation (e.g., parking and transportation costs, meals, etc.). These payments should be differentiated from compensation in the study protocol and consent form(s).

2. **Timing and form of payment:** Consideration should also be given to timing of payment. Making payment conditional on completing a multi-session study could unduly influence a subject's decision to exercise his/her right to withdraw at any time. For studies that require extended time or multiple interactions/interventions, it is recommended that payment be prorated for the time of participation in the study rather than delayed until study completion. However, it would be acceptable to compensate subjects who withdraw early from a study at the time they would have completed it.

   While total compensation should not be contingent on completion of the entire study, it is acceptable to offer an additional incentive or completion bonus to subjects that remain for the duration of the study. For example, a researcher might offer a small bonus percentage of total compensation if subjects complete all sessions in a study. If offered, these amounts should be reasonable so as not to unduly influence subjects to stay in the study when they otherwise would have withdrawn.

   Alternative forms of compensation (such as gift cards, certificates, or other tangible gifts) are acceptable forms of payment and are considered by the IRB in the amount of their cash equivalent. Other online compensation schemes (such as through Mechanical Turk or a prepaid online code) may also be used, but researchers using these forms of payment should ensure that the method of payment can be readily used by participants (e.g., the store or outlet is easily accessible) and is appropriate to the population. **Note:** For clinical trials, FDA guidance prohibits payment in the form of coupons good for a discount on the purchase price of a test article (drug or device) once it has been approved for marketing.

   For studies involving students, class credit or extra credit may be offered as compensation under certain conditions. For more information in this regard, check with

UCB programs which operate student subject pools under protocols approved by CPHS, such as the Psychology Department's Research Participant Program (RPP), the Haas School of Business Experimental Social Science Laboratory (Xlab), and the Haas Management of Organizations Behavioral Lab.

3. **Compensation of minors and other vulnerable populations:** Federal regulations stipulate that the IRB must find "when some or all of the subjects are likely to be vulnerable to coercion or *undue influence*, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects" (45 CFR 46.111 (b)).

   Researchers including such vulnerable populations should pay special attention to the compensation scheme proposed in the protocol and subjects' economic status and resources. For example, researchers involving minors as participants will need to consider the ways children of different ages view the value of payment and ensure that the amount and method is age-appropriate and does not present undue influence. For younger children, a small gift/toy may be suitable, but for older adolescents/teens, a gift card or other form of payment may be more appropriate.

   In addition, researchers should consider whether payment will be made to the parent(s), the child, or both. Parents may receive compensation to defray expenses/inconvenience associated with their child's participation in the research. However, *caution should be used*: because parents have the authority to permit a child's participation in research, an excessive payment could cloud the parent's judgment or cause the parent to exert pressure on the child's decision to participate, negatively impacting the rights and welfare of these subjects.

4. **Withholding compensation**: In certain circumstances, it may be appropriate to withhold compensation if subjects have not appropriately followed instructions. For example, in the case of an online survey in which "attention check" questions have been included (e.g., "Select "C" when answering this question") to be sure that subjects are reading and answering the questions appropriately. This is acceptable when the consent form states that such "attention check" questions have been included, and that subjects will not be compensated if they don't answer them appropriately. Similarly, if a subject is told not to navigate away from their computer screen while participating in the study and does so, it may be appropriate to withhold compensation. Whenever compensation is dependent on following the study instructions, it's important that subjects are told up front (in the consent form) under what circumstances compensation will be withheld.

5. **Payment for subject referrals:** CPHS's non-exempt application includes the following question under section 6, Recruitment: "Will anyone who will be recruiting or enrolling human subjects for this research receive compensation for each subject enrolled into this protocol? If yes, please identify the individual(s) and the amount of payment (per subject and total)." While this information is gathered as part of the non-exempt submission, one should not infer that this practice will be allowed. CPHS will consider whether payment in exchange for subject recruitment/enrollment is appropriate on a case-by-case basis. In

many cases, it would be unethical to provide such payment. For example, if there is an imbalance of power between referrer and subject (e.g., a doctor/patient relationship, employer/employee, etc.), where the potential for undue influence or coercion to participate in research is already high. The American Medical Association, for example, has identified referral fees as unethical.[1] Furthermore, referral payments are illegal in certain circumstances. If federal healthcare programs are involved, for example, referral fees may violate the Federal Anti-Kickback Statute.[2] In general, payments for subject referrals are discouraged, and are allowable only in rare circumstances in which the potential for undue influence and/or coercion is negligible.

## E. Lotteries, Raffles, and Drawings

1. **General information:** 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 keep these guidelines in mind to minimize the likelihood of triggering legal issues.

   **Note:** California law (Penal Code §319) prohibits conducting lotteries. (Any person who prepares or operates a lottery, furnishes lottery tickets, or assists in conducting a lottery is guilty of a misdemeanor.) A "lottery" is defined as including three elements: (1) distribution of property/prize(s); (2) distribution of the property/prize(s) by chance; and (3) distribution of the property/prize(s) "among persons who have paid or promised to pay any valuable consideration for the chance of obtaining such property" (e.g., conditioning eligibility on purchase of an entry ticket or product). There is some question as to whether agreeing to participate in a research study constitutes "payment of valuable consideration." However, in consideration of this statute, UC Office of General Counsel has provided the guidance outlined below.

2. **Guidance**

   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:

[1] "Fee Splitting." Code of Medical Ethics Opinion 11.3. Retrieved on November 2, 2022 from https://www.ama-assn.org/delivering-care/ethics/fee-splitting.
[2] 42 U.S. Code § 1320a–7b - Criminal penalties for acts involving Federal health care programs. Retrieved on November 2, 2022 from https://www.law.cornell.edu/uscode/text/42/1320a-7b.

-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 prizewinners will be notified.

## F. IRS Reporting and Collection of Social Security Numbers

It is the responsibility of the PI to maintain accurate payment records according to University accounting standards and sponsor requirements. In addition, the IRS requires that UC Berkeley (or whoever is paying the research subjects for participation) report payments in excess of $600. If a PI anticipates reaching this threshold with a single subject in a calendar year, s/he should consult his/her department and/or University accounting regarding this to ensure the appropriate paperwork is filed. Historically, the majority of research projects at UC Berkeley do not meet this reporting threshold.

Because of the sensitive data associated with Social Security numbers, these should generally be collected for research payment *only when necessary to comply with IRS reporting requirements*. For projects that involve collection of SSNs, this should be explained in the protocol. The protocol should indicate that these data will be collected separately from the research records and should describe security measures that will be used to protect subject confidentiality. In addition, the consent form should indicate that subjects will be asked for their SSNs, why this information will be collected, and how it will be protected.

**Note:** University policy requires campus units to obtain Chief Information Officer (CIO) approval for all processes that collect, use, or store Social Security numbers associated with individuals. Researchers who plan to obtain this information should email security@berkeley.edu prior to CPHS submission in order to ensure that they comply with this policy.

## G. UC Berkeley Human Subject Prepaid Card Program (HSPC)

The Berkeley Human Subject Prepaid Card Program (HSPC) allows investigators to pay study participants (subjects) using Berkeley funds. In order to be eligible to participate, investigators must submit a request to Cash Handling and Banking Services for each research study for which they plan to issue payment. This request must include proof of CPHS approval, as well as a user agreement to register each employee who will have access to the Prepaid Card Program portal and the IP address of his/her workstation.

There are three types of payment options for investigators to choose from:

- **Instant Issue Plastic**
  Departments will issue a Visa debit card directly to subjects after they perform an easy-to-use activation and load process.
- **Personalized (Bulk) Plastic**
  Visa debit cards will be mailed directly to the subjects. This program is designed to pay a large number of study subjects.
- **Virtual Payment**
  Subjects will be provided virtual card payment information via email notification to allow for online purchases or the option to transfer funds to their personal bank accounts.

For more information please see:
Human Subject Prepaid Card Program

## H. Additional Resources

Berkeley Controller's Office Human Subject Payment Guidelines
FDA Guidance on Payment and Reimbursement to Research Subjects