COMPENSATION OF RESEARCH SUBJECTS

This guidance document is intended for investigators planning to provide compensation to subjects for participation in research. Should you need additional assistance please contact OPHS at 510-642-7461.

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A. Scope

Federal regulations provide no clear limits 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). Research incentives at certain levels 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 to subjects as remuneration for time and inconvenience of participation, as well as an incentive to participate. Compensation can include monetary (cash, gift cards, vouchers, etc.) and/or non-monetary (gifts/promotional items, course credit, extra credit, etc.) remuneration.

There are two ways in which compensation can be problematic:

- **Undue Influence:** An offer of excessive or inappropriate reward in order to obtain compliance. For example, a researcher might offer a month’s salary to students for one-day participation in 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/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 situation 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: when third parties are paid for another subject’s participation, that third party could exert coercion over the subject in order to obtain payment. For example, a parent paid 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.

Many researchers base the payment amount on the acceptable 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.

2. **Timing and form of payments:** 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.

Compensation can also take the form of being entered in a drawing. In assessing whether drawings involve appropriate levels of compensation, the IRB and researchers should take into account the expected value (the prize amount divided by the number of subjects) not the size of the largest prize. For example, in a study with five $100 dollar gift certificates offered as prizes to 100 total subjects, the expected value of compensation would be $5, not $100. If using a drawing, researchers should ensure that there is a fair method of selecting winners and the consent document should include a description of the possible prizes, the odds of winning, the timing of the drawing/payment, and how subjects will be notified. When it is not possible to calculate the odds of winning, the reasoning behind this should be include in the protocol and consent form.

For studies involving students, class credit or extra credit may be offered as compensation under certain conditions. **Note:** Additional CPHS guidance on this topic is forthcoming.
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) or 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.

E. **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 participants 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 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 the 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:** Updated 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 ensure that they comply with this policy (see [http://technology.berkeley.edu/policy/online.html#ssn](http://technology.berkeley.edu/policy/online.html#ssn)).