COMPENSATION FOR RESEARCH PARTICIPANTS	SOP 5.1.02

1. Purpose & Policy

The purpose of this SOP is to provide guidance on compensation / incentives given to research participants to help ensure equitable selection of participants. IRB Policy *Section 5.1*.

2. General Information

Compensating research participants for their involvement in research studies is common and generally accepted practice in research. The regulations require investigators to recruit and obtain consent from participants while minimizing the possibility of coercion or undue influence.[1] Research incentives may limit the ability of the research participant to provide truly voluntary, informed consent. Participants should be able to make informed decisions to participate based on the real risks and benefits of participation, not on compensation. Compensation should be equitable, and the confidentiality of information related to payments should be protected, except as required by law, e.g., for tax reporting. The IRB will review plans for compensation with these goals in mind, and investigators should be cognizant of the related issues, as outlined below.

Compensation: Payment or non-monetary compensation is given to participants 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:

A. Undue Influence: An offer of excessive or inappropriate compensation is made in order to obtain compliance. For example, an investigator might offer a month's salary to participants 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 participants to participate against their better judgement, this offer might constitute undue influence.

B. 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 participants in a class that they will lose grade points if they do not participate in the research – this would be coercive.

[1] 45 CFR 46.116 An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Compensation for research is not coercive in and of itself since it does not involve a threat of harm. Compensation can also create potentially coercive situations, as when a third party is paid for another participant's participation, and that third party can exert coercion over the participant 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 patient research recruitment could create coercion.

3. Training Requirements

Other than the normally required and study specific training for all human subjects research, there are no additional specific training requirements associated with compensation for research participants; however, investigators should carefully read and follow this guidance.

4. Procedure

A. IRB Application

Investigators should fully describe the plan for compensation of participants as well as the reasoning behind the amount, method, and terms of compensation. The informed consent document should disclose all information concerning payment or other forms of remuneration, including the total amount or value, schedule/form of disbursement, and any plans for prorating payment or other remuneration if a participant withdraws. Compensation is not considered a benefit to 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 the consent document.

It is also appropriate to disclose possible compensation in recruitment materials. In general, payment information should not be any more prominent than other elements (e.g., purpose, procedures, inclusion criteria, etc.). See IRB *SOP: Recruitment Materials*

i. Amount/Value of Compensation: Compensation should be appropriate for the time and effort participants devote to their involvement. The level of payment should not be high enough to cause participants 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 participants to lie or conceal information that would disqualify them from the study in order to receive compensation. This could in turn undermine the scientific integrity of the study or compromise the safety of the participant.

   If investigators propose to compensate participants at a rate that is substantially lower than average local compensation for such activity, or to compensate

participants in one group less than another, even though participants in both groups will carry out the same procedures, investigators must provide justification for such level of compensation.

Many investigators 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 participants per sample collection or survey). In general, all participants completing the same tasks in a single research project should be compensated at equivalent rates. In some cases, distinct participant 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.

On the other hand, if participants 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 will ask the investigators for justification.

Whenever possible, participants 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).

ii. Timing and Form of Disbursement: Consideration should also be given to timing of disbursing compensation. Making disbursement conditional on completing a multi-session study could unduly influence a participant's decision to exercise their right to withdraw at any time. For studies that require extended time or multiple interactions/interventions, it is recommended that disbursements be prorated for the time of participation in the study rather than delayed until study completion. However, it would be acceptable to compensate participants 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 participants that remain for the duration of the study. For example, an investigator might offer a small bonus percentage of total compensation if participants complete all study sessions in a study. If offered, these amounts should be reasonable so as not to unduly influence participants to stay in the study when they otherwise would have withdrawn.

Alternative forms of compensation (e.g., gift cards, certificates, or other tangible gifts) are acceptable forms of remuneration and their value is considered by the IRB in the amount of their cash equivalent. Other online compensation methodologies may also be used, but investigators using alternative forms of remuneration should ensure that the method of providing the remuneration can be readily used by participants and is appropriate to the population.

iii. Vulnerable Populations: Federal regulations stipulate that the IRB protocols must provide that "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)).

Investigators including such vulnerable populations in their research studies should pay special attention to the compensation method proposed in the protocol and participants' vulnerabilities, including their economic status and resources. For example, investigators involving minors as participants will need to consider the ways children of different ages view the value of remuneration 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, investigators should consider whether compensation will be provided 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, and excessive compensation 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 participants.

iv. Pilot Studies: No compensation is necessary for participants of pilot studies. See IRB *SOP: Pilot Studies*

v. Drawings

Incentives to participate may include drawings, but not lotteries. While both distribute prizes by chance, a lottery requires participants to pay for their chances, while a drawing does not. Thus "free drawings" may be used as a form of incentive compensation consistent with these guidelines. However, conducting a lottery is prohibited under California's Penal Code, so it is critical to ensure the incentive would not be construed to be a lottery.[2]

Guidance

a. Investigators 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 participants who are ineligible, and participants who enroll but later withdraw/are withdrawn by the investigators. 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:

- All advertising must indicate that no purchase or donation is required to participate in the drawing and that the drawing is open to the campus community.

- 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

[2] California 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."

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.

B. Reasonable Compensation/Incentive Guidelines

The following value ranges for study compensation are suggested as guidelines for investigators:

Online Studies:
$10-50 per hour. Studies involving online surveys, questionnaires, tests, or activities that are not overly time-consuming.

Minimally Invasive Studies:
$10-50 per hour. Studies involving minimally invasive or inconvenient procedures (fMRI, biospecimen collection) and/or lengthy (more than 1 hour) surveys, questionnaires, or tests. The lower end of the suggested range would apply to study visits with one or a few procedures and the high end of the suggested range would apply to study visits that involve multiple visits or many procedures.

Moderately, Extremely Invasive, Painful or Time-Consuming Studies:
$50-250 per hour or more. Studies involving relatively invasive or painful procedures, or extremely long time commitments or inconveniences.

Transportation:
$10-100 for transportation to performance sites that are distant from the participant's home. Compensation for actual travel expenses could be offered in addition to compensation.

Bonus:
A small percentage of total compensation. It is acceptable to offer an additional incentive or completion bonus to participants that remain for the duration of the study. If offered, these amounts should be reasonable as not to unduly influence participants to stay in the study when they otherwise would have withdrawn.

5. Informed Consent (IC) Language

A. When compensation and/or incentives are given, a description of the compensation must be included in the IC. The description should include the amount and nature of the compensation, along with the timeframe of when the participant will receive the compensation. The Protocol Application System (PAS) will provide you with the following template text to use:

Your compensation will be $xx/hour. Extra rewards in increments of $xx/hour will be given for the successful completion of xx tasks. You will be compensated by [cash, check, gift card, other] which will be provided to you [immediately, in about a month, other] after your participation.

If compensation is not provided to participants, justification must be provided and approved by the IRB; however, this information will not be included in the IC.

A description of travel cost reimbursement must be included in the IC, if given. The description should include the type of travel costs that are reimbursed (e.g., parking, mileage) and at what rate, along with the timeframe of when the participant will receive the compensation.

B. PAS will automatically populate the following text in the IC when compensation is given:

If you receive more than $600 in one year for taking part in these research studies, Caltech must report this income to the IRS and you will receive an Internal Revenue Service (IRS) Form 1099. You are responsible for paying any tax that is due on payments for such participation. You are encouraged to consult with your tax advisor to determine your tax obligations on this income whether or not you receive a 1099.