Investigator Guidance
May 24, 2023

PAYMENT FOR PARTICIPATION IN RESEARCH

Payment for participation in research is common and generally accepted. Currently, the federal regulations do not provide clear guidance on how research subjects should be paid nor do the regulations set strict limits on the amount of payment subjects may be paid. The regulations do require that the IRB ensures that researchers seek informed consent only under circumstances that provide prospective subjects sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence.

Compensation

- Compensation is defined as payment (money or item) given to subjects for time and inconvenience for participating in a research study. It **is not** a benefit to participation.

- Compensation **is not** the same as reimbursement. Reimbursement is money to subjects to cover out of pocket expenses associated with participating in a research study (e.g., parking, transportation costs, childcare costs, etc.).

- Include the following information in the protocol/iStar application:

  - ☐ **Amount of payment**. The amount of payment should be appropriate for the subject's time and inconvenience for participating in a research study. Excessive payment should be avoided because it could influence an individual to accept risks that they would otherwise not expose themselves to, to participate in activities that they would otherwise not participate in or could influence individuals to not provide information that would disqualify them from participating in a research study.

  - ☐ **Method of payment.** Describe the method that will be used to pay subjects (e.g., cash, gift card, ClinCard, toys, etc.). Consider the age of the subjects when determining the method of payment. For example, a toy may be appropriate for a younger child but not for an adolescent or teenaged subject. If the method of payment is non-monetary (e.g., FitBit, toy, etc.) include the estimated market value of the item(s).

  - ☐ **Timing/Schedule of Payment**. Describe when payment will be made (e.g., after each study visit, etc.). It is recommended that payment be prorated for the time of participation rather than delayed until the end of study. Waiting to pay subjects until the end of participation could interfere with a subject's right to withdraw from participation at any time (i.e., they may continue participating in a research study to receive payment even when they no longer want to participate). If the investigator intends to pay subjects at the end of the study, provide the

rationale as to why it is necessary to do this (when applicable).

- ☐ **Who is receiving the payment**. If the research study is enrolling minors, specify whether the minor subjects will receive the payment directly or if the payment will be provided to their parent/legal guardian on their behalf.

- If the research study involves multiple cohorts, ensure that the protocol/iStar application describes the plans for payment for each cohort and include the rationale(s) for any differences in payment (when applicable).

- Ensure that the consent and assent documents provide information about payment for participation. See the "CHLA Consent Form Standards and Sample Language" guidance document and consent and assent form templates on the HSPP website.

- Recruitment tools (e.g., flyers, brochures, etc.) may include payment for participation; however, payment/the amount of payment may not be emphasized such as by using larger font. See the "Identification and Recruitment of Research Participants" guidance document on the HSPP website.

- **FDA Regulated Studies**: Subjects may not be given a coupon for a discount on the purchase price of the product once it is approved for marketing.

IRS Reporting

- Payments for research participation are considered taxable income and investigators are responsible for maintaining accurate payment records.

- If subjects are paid more than $600 total in a calendar year (January to December) for participation in research studies, CHLA will report this as subject income to the IRS.

- The consent form must include IRS reporting language when payments are greater than $150 per visit or if there is a possibility that a subject could receive $600 or more for participation in any CHLA studies. See the "CHLA Consent Form Standards and Sample Language" guidance document on the HSPP website.

Lotteries/Raffles/Drawings

- California law (Penal Code §319) prohibits conducting lotteries.

- A "lottery" is defined as: distribution of property/prize(s); distribution of the property/prize by chance; and 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). Participation in a research study can be

considered a type of "consideration."

- When investigators intend to use lotteries/raffles/drawings as an incentive for subjects, the following should be done:

  - ☐ Use the term "drawing" rather than "lottery" or "raffle" in the study documents.

  - ☐ Describe the procedures for ensuring that **all** people who are contacted about the research study will be allowed to enter the drawing. This includes all people who were invited to participate but declined participation, ineligible people, those that didn't complete the study, and people that consented/assented to participation but later withdrew or were withdrawn by the investigator.

  - ☐ Describe the procedures for choosing the winner of the drawing and notifying the winner.

  - ☐ Describe the prizes, including the estimated market value, and the total number of prizes to be awarded.

  - ☐ The approximate chance of winning (if known) or provide an explanation as to why the approximate chance of winning cannot be determined (e.g., *"The odds of winning a prize depends on the number of people that enter the drawing. Therefore, it is unknown what the chance of winning a prize will be.).*