TruCentive

Compensation for clinical trials

Benefits and guidelines for compensating research participants.

2020

- When to offer compensation
- Analyzing timing
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Compensation for research subjects in clinical trials is an old and established practice going back to the 18th century in which investigators offered favor in the form of money to encourage research participation. Today, not only is this practice common and widely accepted, but more extensive research has been done highlighting the benefits and guidelines necessary to correctly compensate research participants.

The main ethical question within the medical community remains this— at what point can a payment be considered excessive? Does this conflict with the obligation to minimize the possibility of coercion and undue influence during the informed consent process?[1]. The FDA advises that "other than reimbursement for reasonable travel and lodging expenses, IRBs should be sensitive to whether other aspects of proposed payment for participation could present an undue influence, thus interfering with the potential subjects' ability to give voluntary informed consent."[2]

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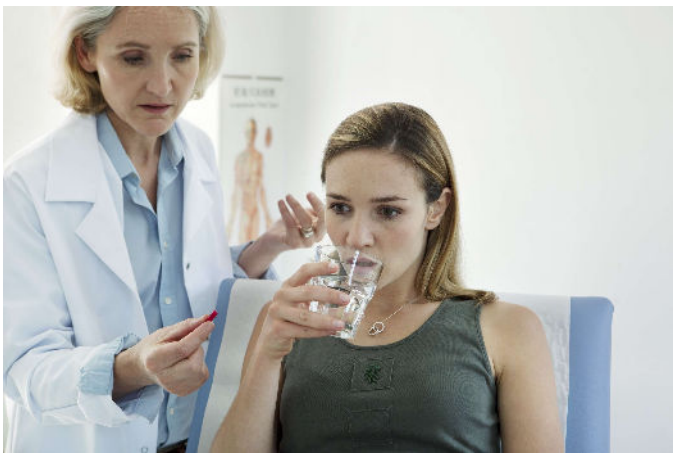
It is important to acknowledge the validity of these concerns as excessive compensation has the ability to compromise understanding or distort an individual's decision to participate in research, which in turn detrimentally undermines and invalidates informed consent.[3] To clarify, being motivated by payment to participate in research, even when an individual would not have elected to participate without the presence of compensation, is not a concern by itself. The concern arises when compensation distorts the participant's decision on whether or not to enroll in the study. We will highlight the most recent literature around providing compensation.

When to offer compensation

Due to the controversial nature of participant compensation, there is no official framework for how to adequately and ethically compensate research participants. Therefore, individual sponsors must make this decision independently. Fortunately, the Council for International Organizations for Medical Science (CIOMS), the World Health Organization (WHO), and the US Food and Drug Administration (FDA), offer some guidance in this department. Each organization states that compensation and reimbursement can be offered for participation in both intervention and observational studies, even when there are potential health benefits for the participant. [4]

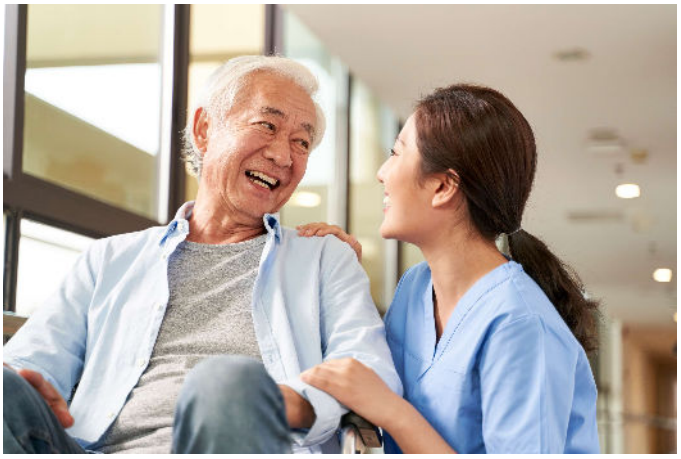


According to CIOMS, compensation is and should be directly related to the inconvenience incurred and time spent by the participant. This information is especially salient for high-risk studies. High-risk studies should not offer compensation that could lead to undue influence as doing so could cause participants to endanger themselves so as to keep receiving compensation.

As per CIOMS' recommendation: Research participants should be reasonably reimbursed for costs directly incurred during the research, such as travel costs, and compensated reasonably for their inconvenience and time spent. Compensation can be monetary or non-monetary. The latter might include free health services unrelated to the research, medical insurance, educational materials, or other benefits. Compensation must not be so large as to induce potential participants to consent to participate in the research against their better judgment ("undue inducement"). The Institutional Review Board (IRB) must approve reimbursement and compensation for research participants.

Timing and the Four Main Compensation Models

Regardless of which option trial sponsors elect to offer, the question of how much compensation a participant should receive remains. There are four main compensation models which can help trial sponsors sufficiently compensate their participants.[5]



4 Common Models:

The market model – based on supply and demand, compensation is determined by local conditions. This includes what, when, and how much is offered along with the ease of finding qualified participants. The more challenging it is to find participants, the larger the sum offered. It's common for there to be variation between locations in multi-site studies. In some instances, there has been a recorded difference of over $800 offered to participants depending on location.[6]

The wage model – based on egalitarian principles, the same compensation is offered to all participants. Research participation is treated as a job that requires unskilled labor and compensation rates are typically in line with an hourly minimum wage based on local conditions.

The reimbursement model – with this model participants are only reimbursed for expenses incurred during the trial. This can include parking, food, and travel costs. In some cases, it may also cover lost wages if a participant takes time off work to be part of the study. With this model participants are asked to track all their pre-approved trial related expenses and submit receipts in order to be reimbursed.

The appreciation model – based on the principle that participants should be acknowledged and appreciated for their time and commitment. It's typically offered at the end of a study and is best used with one of the models previously mentioned. It might include gift cards, thank you notes, small gifts or other meaningful gestures.

While these models can provide guidance, trial sponsors should weigh the pros and cons of each and make the decision that is best for their trial. Note the models can have a different impact on the length of time it takes to recruit qualified participants, which can have a more substantial effect on study completion.

Additionally, when considering the timing of payment, the risk of undue influence should be weighed against the importance of incentivizing study completion, taking into account safeguards that exist for identifying participants who should not continue in the study (e.g., ongoing monitoring by study staff).[7] There is nothing inherently wrong with offering recruitment incentives that go beyond what is demanded by fair reimbursement and compensation. Each research organization has ethical reasons to consider the positive role that payment might play in facilitating recruitment.

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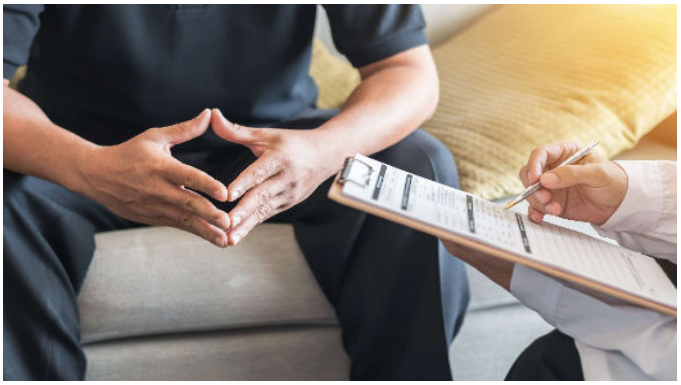
Benefits & Delivery of Compensation

Based on our experience, compensating participants for their time typically results in higher enrollment numbers, lower attrition rates, and a reduction in study timelines. Numerous research organizations have experienced the very real impact of compensation on enrollment and retention in their studies. More often than not, studies that do not utilize compensation strategies are unable to meet recruitment targets and, as a result, terminate early due to lack of engagement from participants. Therefore, by designing an effective compensation plan based on the industry guidance we've outlined, sponsors can boost enrollment, save time, reduce costs and improve study completion rates.

When deciding how to deliver compensation to participants, there are a multitude of considerations and options. For example, what form of compensation should be offered (e.g., cash or check, physical or digital gift cards)? How will compensation be delivered to participants (mail, email, or in-person)?



TruCentive offers a way for research organizations to deliver customized and branded digital gift cards including Amazon, Starbucks, or Target to research participants. Should travel and overnight stays be necessary, TruCentive can also provide eCards for lodging, airline travel, and in some cases, gas options. Additionally, the platform provides researchers with simple yet efficient methods of reporting and keeping track of participant information. Trial sponsors can utilize the different levels of role-based access to control finances and monitor approval or rejection of compensation items. Finally, TruCentive offers 100% refunds on the value of unopened compensation allowing research organizations to optimize the use of their funding.

Conclusion

While there are no hard and fast rules about compensation, utilizing a compensation strategy can prove essential to the success of any study. It is important to remember that as per the FDA's guidelines, the amount and schedule of all payments should be presented to the IRB at the time of initial review. The IRB should review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence. There are numerous ethical and practical issues to be considered with consensus showing that providing compensation during the study can result in significantly higher enrollment, reduce inefficiency costs, and provide more accurate data by encouraging subjects to stay through the trial's completion.

TruCentive offers research organizations an easier way to deliver customized and branded digital cards

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