

PUBLICATION

Taking Pills for Pay: FDA Releases Information Sheet on Paying Research Subjects

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In clinical research, compensating research subjects as an incentive for their participation is a common practice. However, paying research subjects can also pose ethical issues and create the potential for abuse such as undue inducement.

The Food and Drug Administration (FDA) does not provide firm guidance to institutional review boards (IRBs) and clinical investigators as to how they should calculate payments or the specific factors that should be considered in setting that compensation. Recently, however, the FDA updated their [guidance](#) for IRBs and clinical investigators on appropriate practices for paying or reimbursing research subjects. It is important to note that the information sheet is non-binding and meant to serve as a guide on how to approach payment and reimbursement to clinical research subjects.

The FDA does not consider reimbursement for travel expenses to and from the clinical trial site, such as airfare, parking and lodging, as compensation that would constitute undue influence or coercion. Travel expenses are considered acceptable forms of payment provided the costs are reasonable and approved by the IRBs at its initial review of the study.

When considering other types of payments outside of travel costs, IRBs and clinical investigators need to consider whether aspects of the payment could present an undue inducement in the research subject to participate that effectively clouds the research subject's ability to give voluntary and informed consent. Bonus payments should not be so large as to influence the research subject to remain in the study when the subject may otherwise have dropped out. All payment schedules, including payment amounts, must be approved by the IRBs and explained in the informed consent form provided to the research subject.

The FDA also provides insight into the timing of payments. Any credit for payment should accrue as the study progresses and should not be contingent upon the subject completing the entire study. It is acceptable for IRBs and clinical investigators to pay a small portion of the payment as an incentive to complete the study, provided the incentive is not coercive.

Baker Donelson Comments

While this information is non-binding, IRBs and clinical investigators should still consider and follow the suggestions outlined in the FDA's fact sheet. IRBs and clinical investigators need to carefully examine all potential payments to research subjects when developing a research study to ensure the payments are not considered coercive or present undue influence on the research subjects.