INFORMATION SHEET

Payment and Reimbursement to Research Subjects

Guidance for Institutional Review Boards and Clinical Investigators

JANUARY 2018

Final

Issued by:

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Office of Good Clinical Practice

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The Institutional Review Board (IRB) should determine that the risks to subjects are reasonable in relation to anticipated benefits [21 CFR 56.111(a)(2)] and that the consent document contains an adequate description of the study procedures [21 CFR 50.25(a)(1)] as well as the risks [21 CFR 50.25(a)(2)] and benefits [21 CFR 50.25(a)(3)].

Paying research subjects in exchange for their participation is a common and, in general, acceptable practice. Payment to research subjects for participation in studies is not considered a benefit that would be part of the weighing of benefits or risks; it is a recruitment incentive. FDA recognizes that payment for participation may raise difficult questions that should be addressed by the IRB. For example, how much money should research subjects receive, and for what should subjects receive payment, such as their time, inconvenience, discomfort, or some other consideration. In contrast to payment for participation, FDA does not consider reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging to raise issues regarding undue influence. 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. Payment for participation in research should be just and fair. 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 [21 CFR 50.20].

Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a coercive practice, payment to subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn. For example, in a study lasting only a few days, an IRB may find it permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date.

While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable to FDA, providing that such incentive is not coercive. The IRB should determine that the amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document.

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Also see these FDA Information Sheets:
"A Guide to Informed Consent" (/regulatory-information/search-fda-guidance-documents/guide-informed-consent)
"Recruiting Study Subjects." (/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects)

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