FDA Clarifies Participation Payments and Expense Reimbursement for Study Subjects

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When working on your clinical trial agreement budget exhibits (budget) and informed consent forms (ICFs), keep in mind that the Food and Drug Administration (FDA) views travel expense reimbursement and study participation payments as separate payment categories.

Travel Expenses

FDA recently updated its Payment and Reimbursement to Study Subjects – Information Sheet to address reimbursement of study subjects for reasonable travel and lodging expenses for travel to and from the study site, such as airfare, parking and lodging. The information sheet distinguishes between travel expense reimbursement, which does not raise issues of undue influence, and payment to subjects for participation in the study (referred to by FDA as recruitment incentives), which does.

Participation Payments

The information sheet provides welcome clarification regarding travel expense reimbursement, as the prior version focused only on recruitment incentive payments. Unfortunately, the revised information sheet does not shed any more light on the latter, which may cover the study subjects' time, inconvenience, discomfort and other considerations. The information sheet reiterates the following:

– payments to study subjects can pose ethical dilemmas;

– the IRB should review the amount, schedule and method of these payments to ensure that they are not coercive and do not present undue influence;

– payments should accrue as the study progresses;

– completion bonuses are permissible if they are proportionately small; and

– the ICF should disclose all payment information, including amount and schedule.

Best Practices

From a best practices standpoint, transparency is key. To increase transparency, we recommend the "bucket" approach. This means different types of payments go into separate buckets.

How does that apply here? Sometimes the ICF and budget do not differentiate between travel expense reimbursement and study participation payments. Rather, a line item for "payment to study subjects" might indicate, for example, that it covers the subject's time, effort and incidental expenses. Before combining a travel expense reimbursement and subject participation payment into one milestone payment in the budget, the sponsor should consider whether the combination could create undue influence or other compliance issues. Further, the sponsor should follow the bullet points above.

Finally, the ICF and budget need to be consistent. With the budget handled by one arm of the site and the ICF by another arm, mismatches are common in the payments, reimbursements and costs sections of the two documents. Inconsistencies tend to crop up more frequently in the "costs" and "subject injury" sections of the ICF (as insurance may or may not be involved) than in the "compensation" or "payments to study subject" sections. All sections of both documents that address study subject costs, payments and reimbursements should be reviewed for consistency. In addition, the subject injury provisions of the ICF should not expand the scope of the sponsor's obligations beyond the subject injury provision in the clinical trial agreement.

You may access the information sheet at:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects

If you have any questions or would like more information about these developing issues, please contact the following:

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