AAH RSPP GUIDANCE
Payment of Research Subjects

PURPOSE
This document outlines the RSPP position on the payment of research subjects.

Per FDA Guidance (Payment and Reimbursement to Research Subjects) paying research subjects in exchange for their participation is a common and, in general, an acceptable practice. Payment to research subjects for participation in studies is not considered a benefit and is therefore not part of the risk/benefit consideration. Rather the FDA sees payment of subjects as a recruitment incentive.

Definitions of Italicized words can be found in the AAH RSPP Glossary.

GUIDANCE
May AAH subjects receive payment for their participation in a research study?

Per FDA guidance, payment to research subjects that is fair and just is appropriate. Payment for research participation may raise difficult questions that the IRB needs to consider. For example, how much money should research subjects receive, and for what reason should they receive payment, such as their time, inconvenience, discomfort, or some other reason.

If the proposed payment to a subject is not coercive or presents undue influence to the subject such that it could cloud his/her judgement in providing voluntary informed consent, the AAH RSPP does allow for payment to research subjects.

What must the IRB consider in making their decision?

The IRB should be sensitive to whether aspects of proposed payment could present an undue influence to the prospective subject. The IRB must consider 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].

NOTE that neither the FDA nor the AAH RSPP considers 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.

May payment to subjects be contingent upon them completing the entire study?

No. Credit for payment should accrue as the study progresses and not be contingent upon the subject completing the study. Ideally the subjects should be paid as they complete study milestones (for example after each study visit). However the IRB may consider other options of paying subjects as long as the amount to be paid is equal to the subject’s participation.

While the entire payment should not be contingent upon completion of the study, payment of a small proportion as an incentive for study completion may be acceptable, providing that the incentive is not coercive. Any amount paid to subjects as a bonus for completion has to be
reasonable, and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn.

How is the IRB made aware of payment to subjects?

Any payment or other incentive proposed to be offered to prospective research subjects for their part in the research study must be disclosed to the IRB at the time of initial submission or as a Change in the approved study (RSPP SOP #9). The IRB shall review the amount of payment and the proposed method and the timing of disbursement to ensure that they are neither coercive nor present undue influence.

The subject should be informed of the payment via notification in the informed consent document. The IRB must approve both the payment plan as outlined in the submission form, as well as the language provided to the subject via the informed consent document. The AAH consent form template includes language about subject payment.

REQUIREMENTS

- FDA guidance: Payment and Reimbursement to Research Subjects
- AAHRPP Accreditation Standards/Elements: II.3.C
- AAH RSPP SOPs: 9