Department: UAMS Institutional Review Board

Policy Number: 14.2

Section: Recruitment Practices

Effective Date: July 31, 2002

Revision Date: October 10, 2002; June 24, 2004; February 8, 2005; January 24, 2011;

February 15, 2016; July 21, 2020

SUBJECT: Subject Compensation

POLICY

Compensation or payment to research subjects for study participation is considered compensation for time and inconvenience, and should not be considered a benefit. Investigators and the IRB shall develop and review compensation plans with the goal of adequately compensating subjects while not unduly influencing the subject's decision whether or not to participate or to continue in the research, or to appropriately weigh risks and benefits of the research.

PROCEDURE

- A. All study submissions that involve compensating subjects shall fully describe the planned compensation, including the amount, timing, and method of payments.
- B. Payment shall not be contingent upon completion of the entire study. However, payment of a small proportion as an incentive for completion of the study is acceptable, provided such incentive is not so large as to unduly influence a decision to complete the research.
- C. Payments must be pro-rated where appropriate, with payment accruing with the amount of time and inconvenience in the study.
- D. Compensation may not include a Sponsor coupon good for a discount on the purchase price of the study product once it has been approved for marketing.
- E. The amount and schedule of all payments is to be presented to the IRB at the time of initial review. The IRB will review the payment amount and the proposed method and timing of disbursement to payment to ensure they are proportional to the time and inconvenience involved in study participation. The IRB may request changes in the proposed payment timing or amount.
- F. Unless it creates undue inconvenience or a coercive practice, payment to subjects who withdraw early may be paid at the time they would have completed the study (or completed a phase of the study) had they not withdrawn.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days, an IRB may find it permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date.
- G. Payments shall be fully described in the informed consent process and in any associated informed consent materials.
- H. Advertisements may state subjects will be paid or compensated, but may not emphasize the payment or its amount by such means as larger or bold type.
- I. Any alterations in subject payment or payment schedule must be reported to the IRB prior to implementation as Modification.

REFERENCES

AAHRPP Elements II.3.C, III.1.E

OHRP Informed Consent FAQs, specifically *When does compensating subjects undermine informed consent or parental permission?*

FDA Information Sheet Payment and Reimbursement to Research Subjects

SACHRP Guidance Addressing Ethical Concerns Regarding Offers of Payment to Research Participants