

DMID INFORMATION SHEET - PAYMENT FOR PARTICIPATION

OVERVIEW

Compensation for participation in research is a recruitment incentive, and never a benefit for participation in the research.¹ In accordance with 45 CFR 46.116(a)(8), participation in research must be voluntary, and refusal to participate or withdraw will involve no penalty or loss of benefits to which the subject is otherwise entitled.

Subjects decide to participate in research based on many factors, including purpose, types of procedures, risks to self, benefits to self or others, alternatives, cost to participate, and compensation for their participation. Information concerning compensation, including the amount and schedule of payments, should be set forth in the consent form. The plan for appreciation incentives or remuneration warrants integrity within the framework of basic ethical principles: Respect for Persons, Beneficence, and Justice.²

Any aspect of informed consent, including compensation, may not be coercive or introduce undue influence. As such, the overt or implicit threat to reduce the earned compensation is inappropriate. Penalties, also known as reduced or negative compensation, are also not appropriate.

GUIDELINES

- Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. In studies of considerable duration or that involve multiple interactions or interventions, payment should be prorated for the time of participation in the study rather than delayed until study completion, because the latter could unduly influence a subject's decision to exercise his or her right to withdraw at any time.³
- Any amount paid for completion of the study should be reasonable, and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn.
- No penalties may be imposed that affect voluntariness or decisions to withdraw. Penalty credits [or loss of payment], such as "no show" penalty, are in violation of 45 CFR 46.116(a)(8). Subjects must be free to communicate their decision not to participate in research in whatever way they choose.⁴

RELEVANCE

Coercion occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. **Undue influence** occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance.^{2,3}

Negative compensation, reducing the amount described in the informed consent for participation, is not appropriate. The amounts described in the informed consent are compensation for activities as they occur, and therefore already "earned" by the subjects. Negative compensation gives an impression of coercion, and therefore is never appropriate.

An *Appreciation Incentive* may be used to reward compliance, timeliness, and cooperation, which in turn reduces protocol deviations. The incentive should not be excessive or inappropriate, to minimize the possibility of undue influence. Appreciation incentives should be distributed at pre-determined timepoints during a study or at the end of the study, and in the consent form should be explained separately from an accrued "Payment for Participation".

¹ [Payment to Research Subjects - Information Sheet](#)

² [The Belmont Report](#)

³ [IC FAQ: When does compensating subjects undermine IC? What does it mean to minimize coercion or undue influence?](#)

⁴ [Use of Penalties for Students Who Fail to Show Up: Letter \(OHRP, January 8, 2010\)](#)