IRB Member Tip Sheet: Payment for Research Participation

According to The Belmont Report "an agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence." **Coercion** is an overt or implicit threat of harm that is intentionally presented by one person to another in order to obtain a certain outcome. **Undue influence** is an offer of an excessive or inappropriate reward or other overture in order to obtain a certain outcome.

Neither the Common Rule nor the FDA regulations offer specific limitations on payment of research subjects. The Common Rule states that researchers "shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence." (45 CFR 46.116(a)(2)).

In their document, *Addressing Ethical Concerns Offers of Payment to Research Participants*, the HHS Secretary's Advisory Committee On Human Research Protections (SACHRP) noted that investigators and IRBs must be vigilant about minimizing the possibility of coercion and undue influence. In studies that are of considerable duration or involve multiple interactions or interventions, payment should be prorated for the time of the subjects' participation in the study rather than delayed until study completion. Delaying payment until study completion could unduly influence a subject's decision to exercise their right to withdraw from the study at any time.

In its information sheet, *Payment and Reimbursement to Research Subjects: Guidance for Institutional Review Boards and Clinical Investigators*, the FDA cautioned that IRBs must be sensitive to whether aspects of proposed payment for research participation could present an undue influence, thus interfering with the potential subjects' ability to give voluntary informed consent. The FDA recommended that any credit for payment should accrue as the study progresses. It should not be contingent upon the subject completing the study in its entirety.

International Guidance on Payment to Subjects: The 2013 revision of the *World Medical Association Declaration of Helsinki* states that "the protocol should include information regarding . . . incentives for subjects" and be submitted to a research ethics committee (IRB) for review and approval. The Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO), published the *International Ethical Guidelines for Health-related Research Involving Humans*, which notes that "compensation can be monetary or non-monetary…compensation must not be so large as to induce potential participants to consent to participate in the research against their better judgement."

IRB Member Responsibilities When Reviewing Payment Information in Study Documents

- Review the amount and schedule of all payments at the time of initial review. Payment information, like the method and timing, should be clearly described in the applicable study documents.
- Verify the plan for compensation, including the method, the timing of distribution, and the amount of compensation provided to research subjects, to ensure that it is consistent with NIH policy and does not present undue influence to research subjects. The protocol and consent must state that compensation will not be provided *if* this is the case.
- Verify that the amount, schedule and language regarding payment is consistent and ethically acceptable.
- When reviewing recruitment materials, ensure that payment described is not overly emphasized (e.g., use of larger or bold type font), not coercive and will not unduly influence subjects to enroll on the study.
- Review the justification for and the amount and schedule of payment and decide whether these variables are appropriate given the particular study and the subject population being recruited.
- Ensure that compensation is not so high that it creates an undue influence that could compromise a prospective subject's examination and evaluation of the risks or affect the voluntariness of their choices. Ensure that the consent process includes a detailed account of the terms of payment, including a description of the conditions under which a subject would receive partial or no payment (e.g., what will happen if a subject withdraws part way through the research, or the investigator removes a subject from the study for medical or noncompliance reasons).