## Guidance Payment – Ethical Considerations

Federal regulations require that "An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence." (45 CFR 46.116; 21 CFR 50.20)

Paying research participants for their participation is a common and, in general, acceptable practice. Payment for research participation should be just and fair and should not be promoted as a way of offsetting risks, meaning it should not be considered a benefit to be weighed against the study risks. The level of payment should not be so high as to cause a prospective participant to accept risks that he or she would not accept in the absence of the payment.

While no clear line distinguishes between proper and unreasonable payments and what may be excessive in one situation may not be in another, payment amounts should be reasonably commensurate with the time and effort required of the participants in the study. Undue influence occurs "through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture" (Belmont Report).

Protocols submitted to the IRB should indicate and justify proposed levels and purposes of payment, pursuant to the following four categories:

- Reimbursement for direct expenses (e.g. actual costs for parking, meals, lodging and transportation). If the amount a participant will be reimbursed is limited, include this information in the consent form.
- Compensation for time and inconvenience (e.g. payment in an hourly amount for all or some of the hours required of the research participant that represents time away from work).
- Appreciation payments at token levels or token gifts (e.g. movie coupons, toys, gift certificates)
- Incentive payments (designed to act as incentives and are in amounts above the participant's actual costs incurred and above token levels.)

In general, reimbursement for direct expenses, compensation for time and inconvenience in reasonable amounts and token gifts are usually justifiable and acceptable forms of payment. It is when proposed payment amounts are not reasonably related to the time and effort required of participants that financial considerations may become a coercive factor or unduly influence a participant's decision to participate in research. To avoid unduly influencing decisions about research participations, incentive payments should be in reasonable amounts.

When children are research participants, consider whether the payment will be made to the parent(s) or the child, or both. If the child is paid, be aware of the different ways children of varying ages view the value of a payment and ensure the payment is age-appropriate.

In research with considerable duration or that involves multiple interactions or interventions, it is recommended that payment be prorated over the course of the study, rather than holding payment until study completion. Conditioning payment on completing the study could unduly influence a participant's decision to exercise his or her right to withdraw at any time.