The Penn IRB is responsible for reviewing the rates, forms and schedules of remunerations to subjects participating in research at the university. It is the IRB’s charge to ensure that the amount of remuneration and the proposed method and timing of disbursement do not present undue influence to subjects.

Definitions:
As defined in the OPRR Institutional Review Board Guidebook Glossary:

**Compensation**: Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research.

**Remuneration**: Payment for participation in research. (NOTE: It is wise to confine use of the term "compensation" to payment or provision of care for research-related injuries.)

This guidance refers to remuneration as defined Institutional Review Board Guidebook above. Determinations of forms and rates of payment to subjects for participation in research present some of the more challenging ethical issues in human subjects research design. It is accepted that, under many circumstances, subjects should receive payment for research participation, as a way to reciprocate for time, effort and inconvenience and demonstrate gratitude to subjects as well as help researchers fulfill study objectives. While subject remuneration has its merits and benefits, paying subjects for their participation can also present negative ethical consequences, as payments have the potential to impinge upon the free choice and autonomy of subjects.

Current regulations do not provide guidance on appropriate methods or rates of subject payment. Department of Health and Human Services (DHHS) [45 CFR 46.116] regulations state that “an investigator shall seek 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” (emphasis added).

Food and Drug Administration (FDA) regulations state that IRBs have the responsibility to “review both the amount of payment and the proposed method and timing of disbursement to assure that either are coercive or present undue influence [21 CFR 50.20].” As such, neither regulatory source endorses, prohibits or provides direction on acceptable practices regarding payment to subjects.

Given the lack of direct guidance on the matter, the charge within DHHS and FDA regulations for IRBs to review payment practices, and the challenging nature of establishing these practices in protocol design, the purpose of this document is to outline guidance and factors that the IRB will consider when reviewing payment to subjects participating in research.

Guidance: Reasonable Remuneration and the Avoidance of Undue Influence:
The main ethical concern with remunerating subjects for participation in clinical research is that payment has the potential to constitute undue inducement, distorting the judgment of subjects and affecting the voluntary nature of their informed consent.

Commonly the concern is stated that payment has the potential to represent “coercion.” Coercion, in its simplest definition, involves a threat that makes a certain choice irresistible. The concept of coercion identifies situations where the intentional threat of harm is used to compel someone to do something, i.e., the classic “your money or your life” scenario.
Considering this definition and today's regulatory systems, coercion is not the chief concern when considering remuneration to subjects. The potential for “undue inducement,” therefore, is the main concern when considering the effects of payment to subjects. In order to prevent the undue inducement of subject, the IRB offers the following guidance:

- The IRB considers remuneration as an undue inducement if the nature of the payment is such that it has the potential to alter a subject’s decision-making process such that she or he may not appropriately consider the risks of participating in the research.
- It is the IRB’s position that remuneration to subjects participating in research should be reasonable, equitable and comparable to other studies involving equivalent time, effort and inconvenience.
- Remuneration should not be contingent upon the subject completing the entire study. Payment of a small proportion as an incentive for completion of the study has been stated as acceptable to FDA, providing that such incentive is not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. For short studies involving one visit, depending on the nature of the study, it may be acceptable to provide payment contingent upon completion, provided that if subjects are disqualified through no fault of their own they receive appropriate payment for their time and effort prior to their exclusion.
- Payment to subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn, unless this may create undue inconvenience or a coercive practice. Payment to subjects who withdraw should be prorated to reflect the time, effort and inconvenience to the subjects participation to the point of withdrawal.
- Payment should be prompt.
- The amount, method, schedule, form and prorating of remuneration should be described clearly in the informed consent form.
- Non-monetary forms of remuneration such as gift cards/certificates are acceptable forms of payment. The monetary value of these forms should be considered as equal to cash payment. The form of payment should be clearly described in the consent form.
- All information regarding remuneration to subjects should be detailed in the appropriate field of the IRB application for each submitted protocol.

Links:
OPRR Guidebook: http://www.hhs.gov/ohrp/irb/irb_glossary.htm