SOP 10.02 – Subject Compensation

1. Objective

The purpose of this SOP is to describe the review requirements and recommendations for the compensation of research subjects to help ensure equitable selection of subjects. All compensation procedures for non exempt research studies must be reviewed and approved by the IRB.

2. General Description

Compensation provided to study subjects for participation in research is not a requirement. When it is provided, compensation should be based upon the premise that participation in research requires time and effort from the subject. Compensation should be based on a reasonable consideration of the duration of time spent in preparation for, participation in, and recovery from, research activities, and then also, the effort expended during the research activities.

Compensation may include extra credit, cash, gift cards, or items. The type and amount of compensation is considered on a case by case basis in relation to the participant population, amount of participation time, and any risks related to the research.

The IRB will seek to determine that the possibility of coercion or undue influence are minimized within the compensation procedures, and that compensation is considered remuneration, or a recruitment incentive, and not a benefit of study participation.

3. Roles & Responsibilities

Execution of SOP: Principal Investigators (PI)/Research Team Members, IRB, IRB Chair, Office of Research Integrity – Human Subjects (ORI-HS) Staff.

Principal Investigator

Researchers must clearly describe the amount and processes for distribution of compensation to subjects in the protocol proposal form and informed consent materials.

Principal Investigator, IRS Regulations

"*Personal information about me, including my name, address, and social security number, will be released to the University for the purpose of payment and for tax reporting to the Internal Revenue Service (IRS). I understand that UNLV will issue me an IRS Form 1099, listing my payment as reportable income.*

4. Procedures

Basic considerations made by the IRB

Regardless of the form of compensation, the basic considerations related to compensation for participation in research remain the same. The IRB will seek to determine and document as appropriate

- whether subjects are compensated in a fashion that is commensurate with the time and effort required for participation;
- that compensation does not constitute undue inducement;
- compensation is not stated or treated as a research benefit; and
- overall, that compensation arrangements do not adversely influence subjects.

The following information should be disclosed to prospective subjects during the informed consent process and prior to enrollment whenever possible:

- amount of compensation, including the approximate value of non-cash gifts;
- compensation schedule;
- the approximate odds of winning a drawing or raffle;
- any participant requirements to receive compensation;
- conditions under which compensation will be reduced (e.g., early withdrawal, partial); and
- institutional requirements for the researchers to report participant information in order to properly disburse payment (UNLV Incentives for Human Research Subjects Policy and Procedures).

Additional considerations made by the IRB

Assessing the appropriateness of compensation will include consideration for the research environment, and subject population(s) as necessary. Compensation for participation in research that involves the assumption of greater than minimal risk or significant discomfort will involve a more thorough assessment.

The IRB will additionally consider the following as may be necessary:

- Are the conditions for research participation are consistent with standards for voluntary and informed consent?
- Is the compensation offered reasonable given the subject population, and anticipated risks of the study; is the compensation likely to induce an individual to participate when they might otherwise not?
- Should the IRB make extra provisions for monitoring subject recruitment and/or consent to evaluate

the schedule of disbursement and amount of credit;
appropriate non-research alternatives to study participation; and
notifying professors about their students' participation in a study.

Students cannot be required to participate in research for extra or course credit. If extra or course credit is offered for research participation, a comparable non-research alternative must also be discussed in the proposal. The alternative to participating in the research must be comparable to the research participation in time, effort, and amount of credit or fulfillment of course requirements.

The IRB will seek to determine that:

alternative non-research activities offered for credit are approximately equivalent in time and effort to participating in the research activity;
if extra or course credit is discussed during recruitment, then that the recruitment material(s) specifies the amount/value and type of credit that may be earned;
the informed consent materials adequately describe the conditions for earning the credit whether for the research or the alternative activity;
explain how and when professors will be notified of their students' research participation (when applicable), and
where research credit is provided as compensation, that the informed consent materials clearly state that research credit is still awarded either as partial credit despite partial participation or early withdrawal.

Additional information about different methods of compensation
For information about different methods of compensation, please see the UNLV Incentives for Human Research Subjects Policy and Procedures: http://www.unlv.edu/assets/research/policies/Research-IncentivesHumanResearchSubjects.pdf.

Special consideration for FDA regulated research
Subject compensation in a trial offered by a Sponsor cannot include a coupon good for a discount on the purchase price of the product under investigation once it has been approved for marketing.

Special considerations for DoD regulated research
When research involves U.S. military personnel, and in accordance with the Dual Compensation Act, 24 U.S.C 301: An individual cannot receive compensation for research participation that occurred during duty hours. An individual may be compensated for research if the participant is involved in the research when not on duty. Federal employees while on duty and non-federal persons may be compensated for blood draws for research up to $50 for each blood draw. Non-federal persons may be compensated for research participating

Institutional Review Board Management and Function, Bankert & Amdur Chapter 5-8
AAHRPP Element II.3.C.1