

Wayne State University Human Investigation Committee	
Subject:	Compensation for Research Participation
Section:	
Form Date:	September 2008
Approvals	Steering Committee 11/12/97; Administrative Approval 5/5/98; Revised Steering Committee 11/3/06; Revised Administrative Approval 11/08/06, Administrative Approval 09/29/08, General Counsel Approval 10/01/08

Background:

The general requirements for the informed consent process, as outlined in the federal regulations, emphasize that investigators must seek consent under circumstances that minimize the possibility of coercion or undue influence. Thus, the issue of compensation for an individual's participation in research must be considered in evaluating the appropriateness of the consent process and the consent document for a given protocol. In the Federal Drug Administration's (FDA) Information Sheets (October 1, 1995), it is stated that:

"If subjects are paid for their participation in studies, the payment should accrue as the study progresses and should not be contingent upon completion of the entire study. Payment of a small proportion as compensation for completion of the study is acceptable to FDA, providing that such compensation is not coercive. The IRB should determine that the amounts paid are reasonable and the amount of any payment based upon completion should not be so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. Therefore, the amount and schedule of all payments should be presented to the IRB at the time of initial review and the IRB should determine their acceptability. The consent document should outline the schedule and conditions of earning payment."

Scope:

This policy and procedure applies to all research involving human participants who receive compensation for their participation at Wayne State University or its affiliate institutions.

This policy does not apply to compensation of research participants for a research-related injury. Compensation for research participation is distinct from compensation for an injury associated with participation in a research study. See FDA regulation 21 CFR 50 for further information and see the HIC consent templates for required language.

HIC Policy:

It is not required that a research participant be compensated for his/her time during a study. However, compensation can be provided and may be provided in any of the following forms including gift cards, toys, a pizza party, extra credit, cash, etc. When individuals are participating in a research study that has a sponsor, it is **not** appropriate to include a coupon good for a discount on the purchase price of the sponsor's product once it has been approved for marketing as compensation.

For the John D. Dingell Veterans Administration Medical Center (VAMC), compensation to research participants may be offered when [VA Handbook 1200.5 12(c)]:

- The research is not directly intended to enhance the diagnosis or treatment of the medical condition for which the participant is being treated, and when the standard or practice in affiliated non-VA institutions is to pay participants in this situation.
- The research is a multi-institutional study and participants at collaborating non-VA institutions are paid for the same participation in the same study at the same rate proposed by all other sites.
- In the opinion of the IRB payment of participants will be appropriate in other comparable situations.
- The participant incurred transportation expenses that will not be incurred in the normal course of receiving treatment and were not reimbursed by another mechanism.

Prospective VAMC investigators who wish to pay research participants must in their proposal [1200.5 12(b)]:

- Substantiate that proposed payments are reasonable and commensurate with the expected contributions of the participants
- State the terms of the participant agreement and the amount of payment in the informed consent form
- Substantiate:
 - Participant payments are fair and appropriate
 - They do not constitute (or appear to constitute) undue pressure or influence on the prospective research participants to volunteer for, or to continue to participate in, the research study
 - That payments do not constitute (or appear to constitute) coercion to participate in, or continue to participate in, the research study.

When research will be conducted on foreign soil, every effort must be made to ensure that participation is truly voluntary and that there is no potential for coercion resulting from compensation. When making payments in goods, local currency or services, the amount of the payments should be explained on the protocol submission form in terms of United States (U.S.) currency standards as well as the local economic standards. For example, if a person is to be paid in goods that far surpass anything that would be commonly available to that participant, that could be interpreted as coercion to participate in the study. Similarly, if the amount of local money that is paid to the participant is out of proportion to his/her normal income, the same holds true.

When research participants are to be given cash compensation for their participation, the total amount and the schedule of payment(s), if applicable, must be included in the consent document. The amount of the

compensation must be "reasonable", (i.e., adequate to offset expenses, such as the participant's and/or family's time and travel) and/or appropriate to serve as a modest compensation for participation. The amount should not be proportional to the risks of the study. The amount must not be so out of proportion to the participant's efforts that it seems coercive. If the study involves multiple study visits involving procedures or significant time commitments, then payment must not be contingent upon the participant's completion of the study. That is, partial payments at intervals throughout the study are appropriate. The IRB will judge the appropriateness of the proposed compensation for each protocol as part of its review.

Compensation for referrals for enrollment is not allowed. (See HIC Policy/Procedure entitled "Finders Fee").

Reasonable Compensation Guidelines:

The following ranges of compensation are suggested as guidelines for investigators and reviewers:

- Minimally invasive studies:

\$5-\$50 per study visit: Study visits involving minimally inconvenient or minimally invasive procedures (blood draws, urine specimens, vital signs, x-rays, anthropometry) and/or questionnaire/survey if lengthy. The lower end of the suggested range would apply to study visits with one or only a few such procedures and the top end of the range would apply to study visits that involve many procedures and/or take several hours of the participant's time.

- Actual Transportation Costs Regardless of Type of Study:

\$10-\$50 for transportation to performance sites that are distant from the participant's home. Compensation for actual travel expenses (or similar costs such as childcare) could be offered in addition to compensation to participate in the study procedures.

- Moderately or Extremely Invasive or Time-consuming Study Procedures:

\$50-\$250 per study visit if there are few visits but each of them involves relatively invasive procedures, or extremely long time commitments or inconveniences. Compensation for single-visit studies could fall into this range depending upon the invasiveness of the procedures, length of the time commitment, and/or inconvenience of participation. Compensation in this range could be offered for every day of **inpatient studies**, but should not exceed the recommended total (below).

- Total Compensation for Multiple Visits:

\$100-\$1000 total for a study involving multiple study visits, depending upon the invasiveness of the procedures, length and number of time commitments, and inconvenience of participation.

The IRS requires that compensation greater than or equal to \$600 be reported to the IRS-refer to <http://www.irs.gov/pub/irs-pdf/i1099msc.pdf>.

If the participant is not a U.S. citizen and/or not a U.S. tax payer 30% of the compensation will be withheld by WSU before the check is disbursed. The participant must be notified of this regulation in the consent form.