MUSC
Medical University of South Carolina

I. Policy

A. Introduction

Payment of human subjects for participation in research must be fair and equitable.

B. Requirements

Any and all payments made to research participants in MUSC studies must be reviewed by IRB and monitored for fairness and equitability.

C. Memorandum of Understanding

In aspects where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current "Memorandum of Understanding Between The Ralph H. Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina's Institutional Review Boards".

II. Guidance on Additional Requirements of Federal Funding Agencies

Please note that protocols conducted by MUSC and sponsored by any of the following federal agencies

- the Department of Defense (DOD),
- Department of Education,
- Department of Energy,
- Department of Justice (DOJ) / National Institute of Justice (NIJ) and Bureau of Prisons (BOP) or
- Environmental Protection Agency (EPA)

have additional operational and review requirements. In addition, protocols following the International Committee on Harmonisation – Good Clinical Practices (ICH-GHP) have additional requirements. Further information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>)

III. Procedures

A. Criteria for IRB Review of Payments for Participation

1. The amount of payment and the proposed method and timing of disbursement is neither coercive nor presents undue influence.

2. Credit for payment accrues as the study progresses and not be contingent upon the participant completing the entire study.

3. Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.

4. All information concerning payment, including the amount and schedule of payments, is set forth in the consent document. Disclosure regarding IRS reporting regulations shall be included in the Payment to Participants section of the Informed Consent Document. The Research Study Payment Information Document may be used when a Waiver of Signed Consent is approved by the IRB.

5. In the case of VA research, payment to research participants is prohibited when the research is integrated with a patient's medical care and when the research makes no special demands on the patient beyond those of usual medical care.

B. Allowable Criteria for Payment to Participants

1. 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 of practice in affiliated non-VA institutions is to pay participants in this situation.

2. 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.

3. In the opinion of the IRB, payment of participants is appropriate in other comparable situations.

4. The participant will incur transportation expenses that would not be incurred in the normal course of receiving treatment and are not reimbursed by another mechanism.

5. The IRB allows non-veterans to be entered into VA-approved research studies only when there are insufficient veterans available to complete the study or when the researcher can present a

compelling argument to the IRB for the inclusion of non-veterans (e.g., survey of VA employees; study of active duty military; study involving veterans' family members), and the research is relevant to the care of veterans or active duty military personnel.

III. References

MUSC Finance & Administration Policies:

Section: 6-Purchasing & Accounts Payable
Policy Procedure: 6-13.0
Subject: Remuneration for Research Trial Participants
Established Date: 06/01/2010