



I. Policy

A. Introduction

Recruitment incentives paid to Institutions or individuals to boost recruitment into a study takes many forms. This policy primarily deals with personal incentives that are given to individual Investigators, Co-Investigators, research staff members or Clinicians who may or may not be affiliated with the research study. Incentives are defined as any monetary payment, gift or gift certificate that may be given to the individual by the study sponsor or by the research sponsoring Institution. Federal statute does not cover this area in sufficient detail for firm guidance to Researches, Institutions and Sponsors. See "Recruiting Human Subjects, Sample Guidelines for Practice", Office of the Inspector General, Department of Health & Human Services – June 2000, (OEI01-97-00196). This is an area where ethical principals must guide Investigators, Sponsors, Institutions and IRB members. The Belmont principals of justice, beneficence and equality must be guided by truthfulness, moderation and wisdom.

In principal, the Office of Research Integrity (ORI) of MUSC discourages and disapproves of recruitment incentives to boost subject numbers participating in all forms of human research. Such recruitment incentives give the appearance of conflict of interest, raising questions of coercion of subjects for personal gain. Several medical associations, including the AMA have prohibited fees paid either to or by consultants for referrals and have branded them as unethical. Many states and some countries also have laws prohibiting this practice in the clinical setting. However, in the spirit of moderation and wisdom, the ORI of MUSC recognizes there may be some circumstances in which incentives for recruitment may serve the public interest, benefit individual subjects and the acquisition of scientific knowledge for possible future gain to humanity.

B. Payment to Clinicians, Investigators, Co-Investigators, Study Staff and Other Personnel Directly Involved in the Research Study

The ORI of MUSC does not condone the routine payment of incentives to individuals connected or not connected to a particular study. These

incentives give the appearance of conflict and could lead to adverse consequences for individual subjects, study personnel and the Institution.

If an Investigator and or Sponsor wish to provide financial or non-financial incentives for recruitment the following steps must be taken and reviewed and approved by the IRB of jurisdiction. This will require full board approval by majority vote. The IRB members with a conflict in this area will recuse themselves.

The Investigator will provide evidence that the sponsor approves of the practices and will give justification for the incentive, will specifically identify the incentive and its cash value. The Principal Investigator will identify how this incentive may be used by the recipient. Example: the recipient may receive a cash amount which will be spent at their discretion, receive income into an account that will provide for travel, books, educational materials, etc. or some other purpose. The incentive amount, source and its purpose must be clearly stated in the informed consent agreement in plain language for the subject to understand. This information must also be contained in the protocol. The full board of the IRB will determine whether to allow this practice for any particular study.

C. Incentives Paid to Research Subjects, Patients to Boost Enrollment

Word of mouth recruitment by present or former research subjects in a study is often one of the most effective methods of recruiting new subjects into a study. Some forms of this type recruitment are often called “snowball” recruiting. It is permissible to allow this form of recruitment for studies by providing cash, gift certificates or other incentives to subjects to promote their aid in recruiting new individual subjects into studies. Such practices are allowable. The incentive to any subject should be picked with moderation, with justice and autonomy being considered. The level or amount of the incentive should be based on current local norms and must be reviewed by an IRB Chair, Vice Chair or full board depending on the type of application.

II. Conclusions

Incentives are not advised. The investigator may wish to seek further guidance on the matter of incentives from the IRB Manager, ORI Director, individual Chairs of IRB’s, the Director of the Office of Research and Sponsored Programs and/or the Office of General Counsel of the University. Other useful resources may be the Office of Public Relations at the University and the Office of Risk Management. **Caution:** discretion and consultation with incentives is always prudent.

III. References

- A. [“Recruiting Human Subjects, Sample Guidelines for Practice”](#), Office of the Inspector General, Department of Health & Human Services – June 2000, (OEI01-97-00196).