

BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

STANDARD OPERATING PROCEDURES

Recruitment Incentives		RSP.028.00
Effective Date	May 2016	
Last Revision/Review	07/26/2023	

1. Purpose/Scope

Purpose: This SOP provides information for the investigator and the IRB on the use of recruitment incentives to encourage enrollment and participation in a research study.

Scope: Burrell agents involved in human subject research, IRB members

2. Related Policy/Authority

45 CFR Part 46: Protection of Human Subjects

3. Faculty/Staff Responsibilities

Responsible Official(s)- Institutional Official, Director of Research, IRB members, IRB Staff

4. Definitions/Abbreviations

5. Procedural Steps

- 5.1 **Use of Recruitment Incentives:** Recruitment incentives may be allowed to encourage participation in a study, provided that the use of incentives is neither coercive nor imposes undue influence on the recruitment process. Recruitment incentives for researchers may also be included in some studies as a means of encouraging clinicians, investigators, and other personnel to recruit subjects. All incentives, whether paid to the researcher or to the research subjects, must be fully disclosed, reviewed, and approved by the IRB prior to the start of the study.
- 5.2 **Payment to Clinicians, Investigators, Co-Investigators, Study Staff and Other Personnel Directly involved in the Research Study:** Recruitment incentives include bonuses that sponsors give to investigators to boost enrollment and referral fees given to doctors for referring their patients to another investigator's study. Burrell College does not condone the routine payment of incentives by investigators or research sponsors to individuals directly or indirectly connected to a particular study. Incentives give the appearance of conflict and could lead to adverse consequences for individual subjects, study personnel, and Burrell. Investigator and/or Research Sponsor incentives, whether financial or non-financial, for recruitment of research subjects must be reviewed and approved by a full board review process. The investigator must provide evidence that:
1. the sponsor approves of such practices;
 2. identifies the incentive and its cash value;
 3. justifies the payment of an incentive; and
 4. the incentive amount, source and purpose are explained in plain language in the informed consent process.

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Information regarding the incentive program for clinicians, researchers and study staff must also be incorporated into the IRB study protocol.

- 5.3 **Recruitment Incentives Paid to Research Subjects:** It is not uncommon for subjects to be paid for their participation in research, especially in the early phases of investigational drug, biologic or device development. Payment to research subjects for participation in studies is not considered a benefit, it is a recruitment incentive. Financial incentives are often used when health benefits to subjects are remote or non-existent. The amount and schedule of all payments should be presented to the IRB at the time of initial review. The IRB should review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence. Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a coercive practice, 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. For example, in a study lasting only a few days, an IRB may find it permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date. While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable, providing that such incentive is not coercive. The IRB should determine that the amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document.
- 5.4 **Accounting Practices Related to Recruitment Incentives:** Investigators must account for funds disbursed in the course of a project in accordance with BCOM financial policies and procedures, as well as sponsors' policies and procedures, as these funds are subject to financial audits. It is paramount that the accounting practice does not compromise participant confidentiality. Each expense should be tracked by participant ID, the amount paid, and date of payment. Payment information should be retained in the protocol file and not the individual research subject file.

6. Reports/Charts/Forms/Attachments/Cross References

7. Maintenance

This SOP is reviewed at regular intervals but no less than annually.

8. Signature

Approved by

Assistant Dean for Research

8/9/2023

Date

9. Distribution List

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Internal/External

10. Revision History

Revision Date	Subsection #	Summary of Changes	New/Cancellation/Replacement Procedure? (if applicable)	Approval Date
7/26/23		Converted from May 2016 policy		8/9/2023