

Issuing Department: Human Subjects Protection Office
Policy Number: 2011-015.1
Policy Title: Payment to Research Personnel for Subject Recruitment

Purpose

The purpose of this policy is to address the issue of payment to research personnel for subject enrollment.

Definitions

See policy 2011-007.0 for definition of IRB Approval

Policy

Recruitment of subjects into a study may not begin prior to final IRB approval. Payments to investigators and research staff that are tied to the rate or timing of enrollment (i.e. bonus payments) are designed to accelerate recruitment and are prohibited.

Likewise, payment or receipt of a finder's fee for the referral and ultimate enrollment of subjects into a study are prohibited. For example, investigators may not award a treating physician with a financial payment or other incentive for referring a subject to the investigators study. Likewise, investigators may not accept payment or other incentives for referring a subject to another study.

It is however acceptable for the sponsor to pay the institution for the reasonable costs associated with subject enrollment (e.g. research induced procedures, administrative time to manage subjects etc.). Any such arrangements must be delineated in a Clinical Trial Agreement or similar contractual arrangement.

Procedure

Within the IRB application the principal investigator must disclose whether any financial or other benefit is to be received by the research personnel from the sponsor for subject recruitment.

- If a benefit (financial or otherwise) is to be received, the principal investigator must disclose the value of the benefit and explain how it is justified, e.g. that the payment covers the administrative cost of subject enrollment and management.
- The IRB will determine on a case-by-case basis whether such payment places undue influence on the investigator(s) or research staff to recruit subjects.
 - The IRB reviewer sheet distributed to the assigned primary reviewers by the IRB staff prompts for consideration of this issue.

The IRB will conduct its review of the application in accordance with standard procedures.

Related Policies

2011-009.2 – Institutional Review Board - Exemptions
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by Convened Board
2011-015.0 – Recruitment and Payment to Research Subjects

Basis

45 CFR 46.116

Document Attributes:

Date Created: 3/1/2011

Replaced Version: Section in HSPO manual dated 11/14/2008

Reviewed and Approved By: _____ **Signed RS 7/21/11** _____ **Date:** _____
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