From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, December 27, 2006 4:56 PM
To: [purged]Subject: FW: recruitment incentives

Dear [purged],

My understanding is that it is inappropriate to give any type of incentive to hospital staff for referring patients to a research study for screening. I believe that the AMA passed a resolution to that effect, but in looking for it, I can't find it. Among other things, I would be concerned that inappropriate potential subjects could be referred, increasing risks to those subjects; and violation of privacy and confidentiality that the potential subject should otherwise expect could occur (or how else could the staff know the patient may be eligible for the study?). FDA does not have regulations on incentives, but its informed consent regulations do address disclosing the extent to which privacy and confidentiality will be maintained, and the practice you propose could violate that.

I hope this information is helpful to you.

Sincerely,

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgement of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: drugsinfo@fda.hhs.gov [mailto:drugsinfo@fda.hhs.gov]
Sent: Wednesday, December 06, 2006 6:00 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: An investigator site that I am conducting an internal audit for has asked my opinion on the practice of giving $10 starbucks gift card]as an incentive to hospital staff for referring patients to a research study for screening. After speaking with other CRAs and Auditors I find that I have a clear indication that it is not allowed - however I have no documentation to back up this opinion. Could you direct me to the specific regulation or guidelines that will spell out the specific allowances. Thanks

URL: