From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, May 09, 2006 4:52 PM
To: [purged]
Cc: Chhabra, Renu
Subject: RE: posting of inclusion/exclusion criteria

Dear Colleen,

Your email below has been referred to me for response. It's important for the IRB to know, at the time of study approval, how subjects will be recruited for a study as well as the inclusion/exclusion criteria. I believe that the IRB needs to review posters, directed at physicians, to (presumably) refer possibly eligible patients for inclusion in a study to ensure that the posters are appropriate, accurate, and not misleading. So, the answer to your question is "yes, the plan and poster need IRB review before they are implemented."

In one worst case scenario, I can imagine a situation where a physician could be offered incentives to refer patients that could lead to ineligible patients actually being enrolled. [I also understand it is against AMA policy for incentives to be offered for physician referrals.] Further, I'm not sure how one could limit the viewing of such posters to physicians alone. Thus, patients could also review their content and be influenced by them; they then become a direct recruitment tool for subjects and could be viewed as the beginning of the consent process which always requires IRB review.

I hope this is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
Note new email address: Bonnie.Lee@FDA.HHS.GOV
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-----Original Message-----
From: [purged]
Sent: Friday, May 05, 2006 11:44 AM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: If a site would like to post inclusion/exclusion criteria for a research trial in patient rooms directed to the physicians, would this posting need to be IRB approved first?