From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, April 07, 2004 10:48 AM
To: [Redacted]
Subject: RE: Advertisements

Dear Mr. [Redacted],

In answer to your question, FDA's regulations and guidance are silent on the issue of whether advertising a study to healthcare professionals would require IRB approval.

From a practical standpoint, you might want to contact your institution to find out if it has already developed a policy or policies on such advertisements and specific recruitment practices. How such recruitment is actually carried out, and how patients' medical information is shared, may raise privacy issues. For example, if the site is recruiting subjects for a sleep study, will the patients' private physicians give them information about the study so that the patients can contact the study staff for more information if they are interested, or will the patients' physicians give names of potential subjects to the study staff, who would contact the patients directly? (The latter seems more invasive, in terms of protecting patients' privacy.)

Recruitment practices may also raise other ethical questions, for example, if the patient's physician would receive an incentive payment for referring patients to the study. Again, the institution may already have established policy as to whether such incentive payments are allowed.

Thus, I'd recommend that you first check with your institution to find out if it has specific policies in these areas.

In addition, you may wish to check with various healthcare professional organizations as they may have ethical guidelines or recommendations on recruitment practices that may help you and your institution formulate your own policy.

I hope this is helpful.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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-----Original Message-----
From: [Redacted]
Sent: Friday, April 02, 2004 4:56 PM
To: gcpquestions@oc.fda.gov
Subject: Advertisements

Dear Sir/Madam:

I have a question regarding the IRB approval of advertisements. I am confused after reading the IRB information sheet 9/98 (http://www.fda.gov/oc/ohrt/irbs/toc4.html) as to whether IRB approval is necessary for advertisements addressed to healthcare professionals. Without a doubt, I understand that direct advertising to prospective subjects is an extension of the informed consent process and requires prior IRB approval. Would, for instance, a sign placed in a doctors' lounge or behind a nurses' station in which the language used was not directed toward potential subjects (but, was worded to solicit study subjects), need IRB approval? Thank you in advance for your response.

Sincerely,
[Redacted]