From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, January 29, 2004 4:53 PM
To: [Redacted]
Subject: RE: internet postings

Dear Ms. [Redacted] :

To paraphrase the information in FDA's Information Sheet, "Recruiting Study Subjects," IRBs have the authority to review, approve, require modifications in, or disapprove all research activities covered by the IRB regulations. This includes the authority to review the methods and material that investigators propose to use to recruit subjects.

FDA has said that IRBs need not review listings of clinical trials on the internet if the database used precludes any information beyond the "basic trial information", e.g., study title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information. If the database system allows additional descriptive information to be included, however, then IRB review and approval may assure that the additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.

Perhaps [Redacted] is trying to ensure that the material your client wishes to post on the [Redacted] site falls within the scope of the "basic trial information," mentioned above. In any case, FDA would defer to the IRB regarding the IRB's policy for review of material intended to be posted on the internet. Although your client may have had a different experience with another IRB, FDA would expect him to comply with the review requirements of the IRB that is currently reviewing his study.

I hope this is helpful,

Sincerely,

Carolyn Hommel
Consumer Safety Officer
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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Rockville, MD 20857

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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 judgment 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: [Redacted]
Sent: Monday, January 26, 2004 5:20 PM
To: gcpquestions@oc.fda.gov
Cc: [Redacted]
Subject: internet postings

We have a client who wishes to post study information on the website for the [Redacted] . The study has previously been approved by [Redacted] . [Redacted] requires review & approval of all study-specific recruiting materials, including internet postings. However, the client seems to believe that this is not necessary given their experience with [Redacted] IRB.

In reviewing paragraph 3 of the FDA Information Sheet entitled Recruiting Study Subjects, we find the information confusing.

Can you please provide clarification as to when internet postings require IRB approval?

Regards,
[Redacted]