From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, August 31, 2005 3:19 PM
To: [Redacted]
Subject: RE: Recruitment Materials - Search Engine Question
Dear [Redacted],

Because the search engine sentence and link does not contain any substantive information that has not previously been reviewed by the IRB (in fact, it doesn't contain any substantive information at all), there is no need to have it reviewed and approved by the IRB.

I hope this is helpful to you.

Sincerely,

Bonnie
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 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: Friday, August 26, 2005 12:17 PM
To: gcpquestions@oc.fda.gov
Subject: Recruitment Materials - Search Engine Question
To whom it may Concern:

The IRB has previously approved a website for a particular study. The sponsor would now like to place in the Google search engine Sponsored Links section (right side of results screen) a couple of sentences (from the previously approved website) and the URL that would link the potential subject to the website that gives information about the study. The question is whether or not the search engine sentence and link would need to be reviewed and approved by the IRB (would this be considered a different format or mode of communication from the website???) or if this could be considered a part of the web site approval (since the language had already been approved by the IRB).

We have never had a question about a search engine before - but I'm sure we will have it again. Any assistance you can give me on this matter would be greatly appreciated.

Thanks,
[Redacted]