From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, October 03, 2002 10:47 AM
To: [purged]
Subject: RE: general advertising for clinical trials

Dear [purged],

I apologize for the delay in replying to your e-mail (below). FDA considers advertising such as you have described to be part of the recruitment process for subjects and, thus, subject to IRB review. The IRB(s) that need to review such a notice/advertisement would be those IRBs responsible for the review and approval of the study. While one could use a central IRB to review this notice/advertisement, any other IRB that is responsible for the review and approval of the study could exert its jurisdiction over the notice/advertisement and require that it be reviewed and approved by that local IRB. I hope this information is helpful to you.

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Office for Good Clinical Practice
OSCC, Office of the Commissioner
5600 Fishers Lane, HF 34
Rockville, MD 20857
Phone: 301-827-3340
Fax: 301-827-1169

-----Original Message-----
From: [purged]
Sent: Tuesday, September 10, 2002 10:19 AM
To: gcpquestions@oc.fda.gov
Subject: general advertising for clinical trials

hi,

i have a question regarding adverts for clinical trials. we have a newsletter that goes out every quarter to a specific disease population (worldwide), and we are contimplating adding a notice/ advert for a new clinical trial to the newsletter... Our intention is to be very general.. mention a study with limited inclusion criteria, no drug name, no promise of the best thing since

sliced bread, etc... here's what we face:

1. do we need to get IRB approval for this ???
2. If the answer to 1 is yes, then what IRB/ how many ??? this newsletter goes out worldwide to a huge pt. population.....
3. will one central IRB be sufficient ???? or do we have to go out and seek approval from every IRB in the Nation ????

thanks for your time and thoughts in advance,

[purged]