From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, January 28, 2003 3:48 PM
To: [Redacted]
Subject: RE: advertisement vs. information

Dear Ms [Redacted] ,

I apologize for the delay in responding to your email below. One of the IRB's responsibilities is to ensure that information given to subjects as part of informed consent is in accordance with FDA's regulations. Further the IRB may require that additional information be given to subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects. See 21 CFR 56.109(b). From the description of your interaction with this potential subject (below) it sounds as though you have begun providing information that should have been reviewed by the IRB responsible for the review of your study. Whether you call it advertisement, recruitment, or informed consent, your IRB needs to be involved. I hope this information is helpful to you.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: [Redacted]
Sent: Tuesday, January 07, 2003 2:21 PM
To: gcpquestions@oc.fda.gov
Subject: advertisement vs. information

I have recently been discussing a study I am recruiting for with a potential subject. The subject has requested additional information to be sent to his house so that he may review it. Does this fall under advertisement and therefore has to be passed by the IRB or can I send an informational document without passing through IRB?

Thank you very much
[Redacted]