MessageFrom: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, August 31, 2005 3:14 PM
To: [Redacted]
Subject: FW: Telephone Screening Tools

Dear [Redacted],

Your email (below) has been referred to me for response. It seems to me that if you are going to pre-screen potential subjects who respond to a newspaper ad, there ought to be a script, approved by the IRB, to follow in that pre-screening process. That script could be based, as you've suggested on the informed consent information and the protocol's inclusion/exclusion criteria. But, I would encourage you to have the pre-screening script approved by the IRB. In the same way that the IRB needs to approve the newspaper ad, it ought to approve the telephone screening tool, if the telephone is going to be used for pre-screening.

I hope this is helpful to you.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
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-----Original Message-----
From: [Redacted]
Sent: Tuesday, August 23, 2005 11:32 AM
To: pharrell@oc.fda.gov
Subject: Telephone Screening Tools

Good Morning Ms. Harrell,
Per our telephone conversation just now, I am forwarding questions regarding the use of a telephone screening tool in clinical research.
I am aware that if a telephone screening form is designed for use in a particular study, that form would need to be IRB approved prior to use. What I am wondering is what the guidelines are for contacting patients who have responded to an IRB approved newspaper ad if there is no telephone screening tool IRB approved for use. If we use information contained in the informed consent or the protocol inclusion and exclusion criteria to pre-screen responders to the ad, would we be within the appropriate guidelines for GCP's?
Please advise us of what our options are in this situation.
Sincerely,
[Redacted]

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