

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Recruitment Ads
Date: Tuesday, September 29, 2015 10:28:46 AM

Good morning [REDACTED] –

I checked with our ethicist in my office. Please see our comments below.

Our first concern is that the protocol does not specify any age restrictions. If the protocol is silent on age then we would assume that enrollees can be of any age, including newborns (which is likely not what is intended). It is recommended that the protocol better define the limits relative to ages eligible for enrollment. The lack of clarity on the age limitations for enrollment and the fact that the condition under study “is one we get as we get older” may have lead the IRB to erroneously believe the study was being limited to subjects 40 to 50 years of age. Of course we don’t know all the facts so we can’t really speak to the IRBs motivation, but we suspect it wasn’t to be purposively misleading or to potentially affect the study results for their site. Once the protocol is clear as to the age restrictions for enrollment then the recruitment materials should correctly reflect the enrollment criteria as it is stated in the protocol (i.e., the IRB should not limit the ad to 40 to 50 year old subjects).

We are not fond of the phrase “Free study.” Whether the phrasing is acceptable is likely contextual based on the specifics of the study (e.g., is this a study that subjects would normally be expected to pay for?). However, in general we think it is promotional in nature as it seems designed to draw people into the research by offering them something for free (in reality the subjects are likely giving up their time and putting themselves at risk for nothing).

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

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From: [REDACTED]
Sent: Monday, September 28, 2015 10:51 AM
To: OC GCP Questions
Subject: Re: Recruitment Ads

Doreen,

Thank you for your response. My questions below intentionally left out the IRB as they are one of the parties interested in your guidance.

In question #1, the 40-50 year old age group is not prohibited by protocol; however, the protocol doesn't limit inclusion to this age group. The condition being treated is one we get as we get older,

so a 20 year old won't likely have it. If a statistically significant clinical site only enrolls only 40-50 year olds and excludes potential candidates over or under that age, could this not potentially affect the data/study results? Could this be considered cherry picking subjects or not really? So aside from this being potentially misleading in an ad, is it in any other way acceptable for a site or a sponsor to target the specific age group? I want to ensure clarity on the real issue.

Regarding question #2, the word free is in capital letters. The IRB is familiar with the FDA's guidance materials noted below. The specific question is whether the FDA has an opinion about the use of the following wording as quoted: "FREE study." The IRB would like to know if the FDA is okay with an ad stating "This is a FREE study"? If the answer is no, would make a difference if it said "This is a free study"? Assume the rest of the ad is acceptable.

Your guidance is truly appreciated on these gray area issues.

Many Thanks,

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