From: OC GCP Questions
To: [redacted]
Subject: Recruitment Ads
Date: Monday, September 28, 2015 5:49:26 AM

Good morning --

Regarding recruitment in addition to IRB oversight: FDA regards recruitment as the first step in the informed consent process. The statement does not say whether there is Institutional Review Board (IRB) oversight. An IRB should review the methods and material that investigators/sponsors propose to use to recruit subjects, as stated in FDA's Information Sheet Guidance accessed at: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm.

However, we have previously advised IRBs that they do not need to review the recruitment ads if the information is limited to basic trial information.

FDA does not require IRB review and approval of recruitment ads for clinical trials when the format limits the information that is provided to basic trial information. Basic trial information is: the study title; purpose of the study; protocol summary; basic eligibility criteria, study site locations, and how to contact the site for further information.

When descriptive information is to be added for recruiting subjects, IRB review and approval of that information is necessary. The purpose of IRB review is to ensure the added information is balanced and not misleading, for example, that it does not promise or imply a benefit beyond that expected from the research, which by adding the word “free” might do.

There is a difference between providing clinical trial information that is limited to basic trial information--which provides a range of options to individuals looking at that listing--and recruitment materials for a single study. The latter need to be reviewed for their mode of communication and format as well their content in order to allow the IRB to determine that the procedure for recruiting subjects is not coercive or misleading.

In summary, some recruitment ads may require IRB review--it depends upon whether the information contained in those ads goes beyond basic trial information. Other forms of recruitment materials (e.g., direct advertisements for recruiting subjects to an individual study) also require IRB review.

Lately, I believe that if the protocol includes other ages besides “Ages 40-50” providing this limited information in a recruitment ad might be considered misleading.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional information.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Friday, September 25, 2015 12:50 PM
To: OC GCP Questions
Subject: Recruitment Ads

Dear FDA Representative,

1. If a clinical study protocol (drug or device) does not specify age restrictions as part of criteria for qualifying, is it acceptable for a clinical site to create a recruitment ad for the study noting only a specific age group (e.g., Study Qualifications: Ages 40-50) and not consider other ages allowed by the protocol?

2. Is the wording "FREE study" acceptable in recruitment ads?

Thank you,

[redacted]