From: OC GCP Questions
To: [redacted]
Subject: FDA/GCP/IRB Question regarding Generic Recruitment Materials for Clinical Research
Date: Thursday, May 15, 2014 3:27:58 PM

Good afternoon –

This is an answer that we previously sent regarding internet posting of a clinical trial. I think this information can be applied to your situation.

Regarding recruitment: 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 listings about clinical trials on the internet, if the information is limited to basic trial information.

FDA does not require IRB review and approval of listings of clinical trials on the Internet when the system 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.

There is a difference between providing a clinical trial listing 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 Internet listings may require IRB review--it depends upon whether the information contained in those listings 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.

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

Kind regards,

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

From: [redacted]

Sent: Wednesday, May 14, 2014 1:43 PM
To: OC GCP Questions
Subject: FDA/GCP/IRB Question regarding Generic Recruitment Materials for Clinical Research

Good afternoon,

I am seeking information to clarify what type of IRB oversight, review and approval is required for very generic, non-study-specific, advertising materials that I would like to have generated for my company. The advertisements are not related to any particular study or any particular sponsor. The information found through the FDA website is not very clear about this type of recruitment material and a trusted resource with the Society of Clinical Research Sites has said that this type of advertisement does not have to be reviewed by an IRB.

If you would please send me some information on what is required per the Federal Regulation, that would be very much appreciated. If you have any questions or concerns, please call me at [redacted]

Thank you for your time.

Sincerely,
[Redacted]