From: OC GCP Questions
To: [redacted]
Subject: RE: Non-Study Specific advertising
Date: Friday, April 01, 2016 3:55:45 PM

Hello,

FDA addresses the issue of IRB review of advertisement in the FDA Information Sheets, specifically under the heading of Recruiting Study Subjects - see www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm. As noted there, FDA considered any advertisement to potential study subjects to be the start of the informed consent process for the study. As such, an IRB needs to confirm that the advertisement does not falsely portray the study or its expected outcomes.

I hope that this information is helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions.

Sincerely,
Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Tuesday, March 29, 2016 1:37 PM
To: OC GCP Questions
Subject: Non-Study Specific advertising

Good afternoon,

Is it a requirement to have IRB approval on a non-study specific advertisement? The advertisement is to advertise a research center that conducts research studies and includes indications the research site works in.

Thank you,
[redacted]