From: OC GCP Questions
To: [redacted]
Subject: Clinical site website
Date: Monday, June 16, 2014 1:06:14 PM

Good afternoon --

Thank you for your question. FDA has guidance about recruiting study subjects that may be of interest to you – see FDA Information Sheets, Recruiting Study Subjects found at the following web location http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm.

Generally, FDA does not consider informational postings of basic information about clinical investigations to be advertising for recruitment. So, a web site with general information about clinical trials and basic information about studies does not automatically require IRB review and approval. As described in the guidance mentioned above, IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as the study title, purpose, protocol summary, eligibility criteria, investigational site locations, and how to contact the site for further information. That being said, the guidance also says that when the opportunity to add additional descriptive information is not precluded by the data base system, IRB review and approval may assure that the additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.

The decision about whether or not IRB review and approval of information provided on your company web site or provided in company publications is required depends on the content of the information. Some IRBs and institutions may require review by the IRB or other institutional representative(s).

Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [Redacted]
Sent: Monday, June 16, 2014 9:28 AM
To: OC GCP Questions
Subject: Clinical site website

Does the entire contents on a clinical site website need to be IRB approved? Of course any advertisement for trials and or recruitment statements would be IRB approved but does the entire website need IRB scrutiny? I thank you in advance for any comments or suggestions.

Kind Regards
[illegible]