

From: OC GCP Questions
To: [REDACTED]
Subject: RE: Clinical trial site
Date: Tuesday, February 25, 2014 1:42:00 PM

Good afternoon,

FDA does not approve the sites where clinical trials are conducted. The sites are chosen by the sponsor but FDA does not approve each site. FDA regulations do require that the institutional review board (IRB) overseeing the trial to consider the adequacy of the research site. FDA's guidance document "IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed" discusses this topic. This guidance document may be found on the FDA website at http://www.fda.gov/RegulatoryInformation/Guidances/ucm366335.htm#_ftn13

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

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Office of Good Clinical Practice
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: F9857H98Q
Sent: Tuesday, February 25, 2014 5:39 AM
To: OC GCP Questions
Subject: Clinical trial site

Hi,

I would like to know if FDA approves site to conduct clinical trials.

Regards,
JTGFCEVGF_