From: OC GCP Questions
To:
Subject: Request of information

Date: Tuesday, April 28, 2015 10:56:03 AM

Good morning -

You will need to contact the clinical investigator of the study or the sponsor. I cannot give information on ongoing clinical trials. I can point you to NIH's website. You can search for your trial on this website. This should provide you with additional information as well. Please see the web link below.

Home - ClinicalTrials.gov

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

Kind regards,

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

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:

Sent: Monday, April 27, 2015 5:02 PM

To: OC GCP Questions

Cc:

Subject: Request of information

Dear Sr,

I am currently in the process of advising my Mum to enter or not in the clinical trial with identifier attached in this email. In order to make the best decision we need all kind of information regarding the new drug proposed.

Thank you very much in advance.

Best regards