From: OC GCP Questions
To: [redacted]
Subject: Clinical trials
Date: Monday, May 11, 2015 1:43:45 PM

Good afternoon –

Thank you for your email. Please see the link below that you can call or email your concerns to FDA for FDA-regulated clinical trials involving a drug, biologic, or device. Please note the contacts are specific to the product area.

Reporting Complaints Related to FDA-Regulated Clinical Trials

Kind regards,

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

From: [redacted]
Sent: Monday, May 11, 2015 1:40 PM
To: OC GCP Questions
Subject: Clinical trials

Good afternoon,

I am not quite sure if this is the correct email address for addressing such matters, but I would like to speak with someone regarding questionable documentation practices taking place at a large University research site, as pertaining to industry-sponsored clinical trials.

Please let me know where I can direct my concerns.

Thank you,

[redacted]