

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,

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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: [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]