From: OC GCP Questions
To: [redacted]
Subject: Good Documentation Practice
Date: Thursday, March 08, 2018 11:11:00 AM
Attachments: [redacted]

Good morning –

Please see the response below from FDA's Office of Regulatory Affairs (ORA). This office performs our FDA BIMO inspections.

No, this would not be acceptable. In clinical research, observations or measurements must be recorded as they occur to ensure accurate case histories. The practice described would not adequately capture the data being generated in the study to be complete and reliable.

Kind regards,

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

U.S. FOOD & 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: [redacted]
Sent: Friday, March 02, 2018 9:46 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Good Documentation Practice

Hello, I have a question regarding GDP.

Would it ever be acceptable to the FDA, when reviewing documents that are part of clinical research, to see an arrow down the column of a page for consecutive repeated information made on the same page, by the same person, on the same day?

Thanks,
[redacted]

[redacted]