

From: OC GCP Questions
To: [REDACTED]
Subject: source documents
Date: Tuesday, April 04, 2017 1:08:00 PM
Attachments: [REDACTED]

Good afternoon –

FDA regulations do not require a photocopy of ECG tracing along with the original. However if the protocol requires it then the EKG should be photocopied. When the regulations are silent, sites and institutions can develop their own standard operating procedures to address a specific situation or concern.

Kind regards,

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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, April 03, 2017 4:22 PM
To: OC GCP Questions
Subject: source documents

Hello-

It is a requirement that sites file a photocopy of ECG tracings along with the original ECG report? After time, the print on the original ECG tracing can fade. If sites do not do this, is it considered an audit finding? Thank you!

[REDACTED]