

From: OC GCP Questions
To: [REDACTED]
Subject: Content of the Trial Master File - remove Meeting Minutes?
Date: Monday, May 08, 2017 6:27:00 AM
Attachments: [REDACTED]

Good morning –

Generally we would not recommend removing clinical trial documents. If the sponsor consulted FDA staff (Regulatory project manager of the IND) this conversation should have been documented. I suggest asking the sponsor for this documentation.

Kind regards,

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From: [REDACTED]
Sent: Friday, May 05, 2017 5:48 PM
To: OC GCP Questions
Subject: Content of the Trial Master File - remove Meeting Minutes?

Good Afternoon,

We serve as a coordinating center for an IND industry sponsor trial. We have the delegation of maintaining the TMF for the IND study. We are preparing for data lock and study closure activities. The sponsor asks us to remove the sections of the TMF related to meeting minutes, claiming this is internal correspondence between the sponsor and the CRO (we are a SMO) and that they have consulted FDA staff verbally and gained feedback this practice was acceptable. The meeting minutes contain discussions on recruitment, design of the study, actions on both the sponsors and CRO, etc. Please advise.

Thank you so much,

