From: OC GCP Questions
To: [redacted]
Subject: GCP, FDA and industry standards for the omission of protocol required data from the CRF
Date: Wednesday, October 11, 2017 9:13:22 AM
Attachments: [redacted]

Good morning –

Each study design is different and the protocol should be adequate to meet the scientific and regulatory requirements for which that particular protocol was written to meet. And I agree with your statement not to expose study subjects to assessments unless there was a justifiable reason to do so from the standpoint of supportive data to fulfill the goals of the study.

You may wish to review the FDA link below on clinical trial protocols.
FDA and NIH Release Final Template for Clinical Trial Protocols | FDA Voice

You may also wish to review ICH-E6 guidance. Please see section 6. It discusses protocol development.
https://www.fda.gov/downloads/drugs/guidances/ucm073122.pdf

And lastly, IND applications and clinical protocols.
Investigational New Drug (IND) Application > IND Applications for Clinical Investigations: Clinical Protocols

If an assessment is outlined in the protocol, it is my opinion that this assessment should be documented in the clinical trial study records.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Tuesday, October 10, 2017 3:13 PM
To: OC GCP Questions
Subject: GCP, FDA and industry standards for the omission of protocol required data from the CRF

Dear FDA,

When I received my training as a CRA, I was taught that the 'gold standard' for protocol design and

data reporting was to design study protocols that collected the minimum data necessary to fulfill study endpoints and objectives. In other words, not to expose study subjects to assessments unless there was a justifiable reason to do so from the standpoint of supportive data to fulfill the goals of the study.

Question: Is this consistent with the Agency's expectation for study sponsors in the design of clinical trials?

I'm looking to advance my understanding of current industry standards and practices in the approach to clinical trial design and protocol development.

Question: Is there any regulatory or GCP mandate that requires every protocol specified assessment be reported in the CRF? In other words, is it acceptable to require an assessment be performed as outlined in the protocol, but not require the outcome of the assessment to be recorded in the CRF and subsequently the final study report?

I cannot locate any guidance, regulation or industry standard that addresses this question; and I would like to understand both the agency's thinking on this point as well as applicable FDA/GCP/ICH guidance for future reference (if available).

Thank you for your assistance.

Kind regards,

[redacted]