From: OC GCP Questions
To: [redacted]
Subject: Study Procedures
Date: Wednesday, March 25, 2015 11:16:23 AM

Good morning –

21 CFR 312.23 describes what should be in the protocol. (6)(g) states "A description of clinical procedures, laboratory tests, or other measures to be taken to monitor the effects of the drug in human subjects and to minimize risk." Blood draws could be considered a risk to subjects.

Any procedures that are being conducted as part of the clinical investigation should be outlined in the protocol.

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

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, March 24, 2015 12:45 PM
To: OC GCP Questions
Subject: Study Procedures

Would it be permissible to include study procedures in an informed consent form but not include them in the protocol?

I'm referring to procedures like blood draws with samples being held for future testing. Would that type of procedure need to be included in the protocol or could we just include in the consent form?

Thanks for your guidance.

[redacted]