

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,

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

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: 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]