From: OC GCP Questions
To: [redacted]
Subject: Protocol required but also standard of care procedures in the consent
Date: Tuesday, June 10, 2014 2:24:14 PM

Good afternoon –

All study related procedures should be listed in the informed consent under 21 CFR 50.25 Elements of Informed Consent.

Please see the guidance document link below.

Guidances > A Guide to Informed Consent - Information Sheet

Kind regards,

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

From: [Redacted]
Sent: Tuesday, June 10, 2014 12:22 PM
To: OC GCP Questions
Subject: Protocol required but also standard of care procedures in the consent

I've got a question about study procedures being described in the Informed Consent.

Would it be acceptable to not list certain study procedures that are required by the protocol but that are expected like being asked about drugs and side effects, performance status, medical history, vital signs, height, and weight in order to shorten the ICF and improve patient readability.

Or should all protocol procedures be explained in the consent document?

Thanks for your input.

[redacted]