

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Standard of Care procedures
Date: Thursday, January 15, 2015 1:40:54 PM

Good afternoon –

I am not sure what Marsha was referring to in her email and she has since left the agency. Sara's email is accurate. There is a new draft guidance on informed consent. Please see the link below. Although draft and still out for public comment, it discusses standard of care procedures that should be addressed in the ICD.

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf>

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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From: [REDACTED]
Sent: Thursday, January 15, 2015 11:30 AM
To: OC GCP Questions
Subject: Standard of Care procedures

Dear OGCP,

In researching a related issue, I reviewed two letters from OGCP that seem inconsistent, and I was hoping you could resolve the inconsistency.

A letter dated Feb. 17, 2011, regarding "Usual Care" risks in research consent forms, stated that "Even if the research protocol included the risks of the 'usual care' procedures, the research consent form would not need to include those risks. The reviewing IRB may determine whether or not to include in the research consent form the risks associated with 'usual care' procedures but those risks are not required, even if described in the protocol." The letter was signed by Marsha Melvin.

In contrast, a letter dated August 8, 2013, Re: Informed Consent and risks for standard of care procedures", stated that "information about the risks of standard of care procedures

that are required by the protocol, must be provided during the informed consent process." This response, from Sara G. Goldkind, is consistent with other letters from OGCP and with what I thought was FDA's interpretation of 21 CFR 50.25(a)(2).

Is there a difference between a "usual care" and a "standard of care" procedure that would account for the apparent discrepancy in these responses?

Thank you

[REDACTED]