From: OC GCP Questions

Sent: Thursday, March 12, 2015 4:29 PM

To: [redacted]

Subject: RE: Informed Consent Questions

Dear [redacted]:

FDA's regulations only require the subject (or the subject's legally authorized representative) to sign and date the consent form (21 CFR 50.27(a)).

Sec. 50.27 Documentation of informed consent.

(a) Except as provided in 56.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form.

FDA's regulations do not actually require the investigator to sign and to note the date on the consent form. However, if the study protocol or the IRB require the investigator or other study staff who are delegated this task to sign the consent form, then the investigator and others are expected to comply with these requirements in the manner prescribed by the sponsor or the IRB.

You might find this guidance document useful (Informed Consent Information Sheet): http://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm

I hope that this information is helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions. Since many questions and concerns regarding good clinical practices have been addressed over time, some individuals may find it useful to access a set of redacted GCP inquiries found at the following web address: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm .

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

From: [redacted]
Sent: Monday, March 09, 2015 10:26 AM
To: OC GCP Questions
Subject: Informed Consent Questions

Good Morning,
I hope you will be able to answer my question regarding Obtaining Informed Consent.

- Does the person obtaining consent need to sign the informed consent at the same time as the subject?

I have been researching on all weskits, FDA, GCP, etc. I cannot find a definitive answer.
I hope that you will be able to enlighten me on this subject.
Thank you,

[redacted]