From: OC GCP Questions
To: [redacted].
Subject: RE: informed consent
Date: Wednesday, November 30, 2016 1:38:00 PM
Attachments: [redacted]

Dear [redacted],

FDA regulations for documenting informed consent are found at 21 CFR 50.27 www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=50.27 and generally require that the informed consent process 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.

The regulations are silent on the issue of additional documentation of the informed consent process (e.g., a notation to the subject's record by the person obtaining consent). Some sites/sponsors/IRB may impose additional record keeping requirements, but this is at their discretion. If additional documentation is required, then the CI must comply with the protocol and/or directions of the IRB.

You may also wish to review FDA's information sheet guidance, *A Guide to Informed Consent*, which can be found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm#documentation .

There is also a draft guidance that is an update on the information sheet noted above. The draft guidance, when finalized, will represent the FDA's current thinking on this topic. The draft information sheet guidance on informed consent can be found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm

The ICH E6 Good Clinical Practice Guidance, which is recognized by FDA, discusses the informed consent process in section 4.8. It may be helpful for your new investigators. You can find the document at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073122.pdf

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov.

Best regards,

Sheila

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From: [redacted]
Sent: Tuesday, November 29, 2016 4:31 PM
To: OC GCP Questions
Subject: informed consent

Good afternoon.
I work on [redacted] oncology trials. We have some new investigators who are questioning exactly what needs to be documented regarding obtaining consent from subjects before participating in clinical trials. They think that as long as the subject signs the consent that is suffice. Where in the regulations does it spell out exactly what needs to be documented, by whom and where it needs to be documented.

Thank you in advance
[redacted]

[redacted]