From: OC GCP Questions
To: [redacted].
Subject: Question about who fills out the ICF
Date: Monday, October 03, 2016 12:23:00 PM

Good afternoon again –

I think it is best to bring the situation up with your reviewing IRB. If they feel there is a protocol or IRB violation, your site and the IRB should have internal SOPS that address such issues.

Additionally, we have said in the past that subjects who are incapable of writing his/her name due to lack of training or education, can indicate their consent by "making their mark" on the consent form, when consistent with applicable State law. I think given the situation you describe, this might apply. In this situation, a progress note in the study records should indicate the reason for the lack of a signature, and include the date on which informed consent was obtained.

Physically challenged subjects (for example, unable to talk or write, or who have hearing or visual loss) may also enter a study if competent and able to signal consent, when consistent with applicable State law. In this situation, the study record must include documentation of the informed consent process and a description of the specific means by which the prospective subject communicated agreement to take part in the research and how questions were answered. Additionally, FDA recommends that investigators accommodate the specific needs of the study population, if possible (e.g., audiotaped informed consent form or enlarged font informed consent form depending on the level of impairment of subjects with visual impairment).

I hope this information is helpful.

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: Friday, September 30, 2016 3:29 PM
To: OC GCP Questions
Subject: Re: Question about who fills out the ICF

Good afternoon Doreen,

Thank you so much for taking the time to answer me. I've read the attachments and the only specific line I could locate was in the first document where is says "the subject or their representative should sign and date the form."

I certainly do not want to do anything wrong or illegal even, and the consent forms have

already been signed last year and months ago this year.

In each case, the subject actually signed the forms!

I made certain of that, but they asked me to fill out the other parts of the form, namely to Date and Print their Name. Is this illegal or wrong? What will an FDA auditor say to us about it?

Are these protocol deviations?

Since they were in pain, some had IVs in their hands, and they asked med specifically to Print their Name and Date the forms for them, would I be able to correctly say I was their Representative under these conditions? Since they specifically asked me to help them?

I was sitting with them in their hospital rooms and helping them to fill out a number of other non-legal forms like religious and meal preferences, after we completed my clinical research ICF Process first, which would take me over an hour to complete before they would decide if they wanted to sign.

If you could offer me an opinion or a little more clarification I would greatly appreciate it

Thank you!

[redacted]

On Fri, Sep 30, 2016 at 2:39 PM, OC GCP Questions <gcp.questions@fda.hhs.gov> wrote:

> Good afternoon –
>
> The subject and or the subject's legally authorized representative (LAR) should sign and date the ICD. You should not sign the form for them. Please see the two guidance documents below that address your question.
>
> Search for FDA Guidance Documents > A Guide to Informed Consent - Information Sheet
>
> http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf
>
> 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: Thursday, September 29, 2016 10:03 PM
To: OC GCP Questions
Subject: Question about who fills out the ICF

Hello,

Would you please advise me about something. I've completed the NIH HRP and GCP training.

I had a few inpatients who wanted to participate in a topical trial. These 2 or 3 had IVs in their hands and were not feeling well. They asked me to print their name and date the ICF so they could sign after I spent about an hour with each one reading the informed consent form line by line asking and answering questions. They participated through the whole informed consent process, and wanted to join but asked me to do those things for them.

I don't specifically remember seeing instructions about which parts of the writing they must do themselves. Could you please clarify for me? I looked on your website and could not find an answer to if I can print their name and date it. Is that any different than if I typed in their printed name and typd in date and they signed the signature part.

Sorry, I hope this makes sense.

Thank you very much,
[redacted]