From: OC GCP Questions
To: [redacted]
Subject: Completion of ICF and individual insurance policy number
Date: Tuesday, September 09, 2014 11:34:51 AM

Good morning --

FDA regulations do not specifically address the situation that you describe in your email. When the regulations are silent, institutions and sites are free to develop their own standard operating procedures (SOPs) to address a specific situation or issue.

You may want to check with your sponsor and your EC to make sure that they are in agreement with what you plan to do. Additionally you should check with your local and national laws to make sure you are in compliance with their requirements.

You may want to review two FDA guidance documents
"Screening Tests Prior to Study Enrollment," available at
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm,

"Recruiting Study Subjects," available at Guidances > Recruiting Study Subjects - 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: Monday, September 08, 2014 3:58 AM
To: OC GCP Questions
Subject: Completion of ICF and individual insurance policy number

Dear Sir or Madam,

I would like to ask your help concerning the following question related to the sequence of steps related to the obtaining of the subject's consent.

In [redacted] we have the individual insurance policy which should be completed for each enrolled subject and given to subject as usual on Screening visit.

We have the instruction from the Insurance companies where stated that individual screening number that should be entered to the policy should consist the site's number and serial number of subject at site (this instruction is common for both studies – with IWRS and with Randomization

envelopes).

This policy consist the individual insurance number which also includes the individual screening number of subject. This individual insurance number should be also included to ICF.

So I would like to ask you to imagine the following sequence of procedures in SD of subject in the study where IWRS is used:

1. ICF was given to subject
2. All questions were discussed and all answers were given to subject
3. Subject signed ICF
4. One exemplar was given to subject
5. Subject was registered in IXRS and individual screening number was allocated to subject.
6. Individual insurance policy was completed and original was given to subject. Copy was filed to SD at site.

So my questions are the following:

1. From DFA's point of view is this sequence of procedures provided above correct? Because I have concerns due to fact that Screening number that should be obtained after registration of subject in IXRS is obtained after one exemplar was given to subject. Does not it mean from auditor's point of view that not fully completed exemplar of ICF was given to subject because Screening number can be obtained only form IWRs if it is used in study. I was explained by site that they were using instruction from insurance company which is common for both studies – with IWRS and without it – and is not customized for each study. Is it correct form FDA's point of view?

2. Another my question is if in case Screening number can't be created manually and should be obtained only from IWRS, subject is able to sign not fully completed ICF? Moreover I would like to ask you if we should consider registration in IWRS as study specific procedure and we are not able to perform it before signature was obtained?

In case of questions please contact me.

Looking forward for your answer!

Thank you very much in advance,

[redacted]