From: OC GCP Questions
To: [redacted].
Subject: Thank you for an answer, one clarification from Doreen Kezer, of possible? Fw: Help with question re microsoft applications and source documentation, please
Date: Wednesday, July 20, 2016 6:09:00 AM

Good morning –

Please see the response below from the Office of Medical Policy at FDA.

Response: If you are using a personal computer to type study-related information (e.g., medication list/history) into an excel spreadsheet and you are printing out the excel spreadsheet so that you can use the paper printout as the source document for the study record (i.e. you are relying on the paper records to perform regulated activities), the computer system would not fall under the scope of part 11.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, July 15, 2016 10:38 AM
To: OC GCP Questions
Subject: Thank you for an answer, one clarification from Doreen Kezer, of possible? Fw: Help with question re microsoft applications and source documentation, please

Hello Doreen or Office of GCP,

I really, really appreciate your answer on Wednesday 13 July @ 9:56. I can't respond to it, because something happened to my email, so I'm sending this additional question attached to the last one.

Your answer said: It sounds like from your email you are creating source documents from excel worksheets. They may not necessarily be electronic documents just because you are typing the notes out on a computer.

That's what we said! It's equal to if I amend a memo on a MS Word doc and added it. They're just typed recordings because no one can read any of our handwriting. But 2

of these monitors really disagree with the other two saying every log or note about patient history or meds must be in handwriting! Sometimes the only information we have to include about con meds is when they bring all their Rx bottles in and we type in the Excel what they are, especially if their GP won't give us their medical records for months.

I read the rest of what the FDA has said before that you attached, but I'm still not really clear on paragraphs 8 & 9, about using an electronic system. Does my personal un-networked computer using Excel and Word, qualify under these 2 paragraphs? Is it an electronic system? This is where I'm confused. It's not really a "system." It's just me, typing notes for my patient's medical history in an excel spreadsheet, and adding to the history during the trial. I print out drafts until it's right, then I insert the correct version in the study patient's record.

[I think these paragraphs are talking about an EDC for CRF-type system to record visit data that needs to be Part 11 compliant. Not individual sites, adding the background supporting information in the paper patient binder by printing ou hardcopies from Excel]

Some of the CRA's say that excel spreadsheet is an "electronic record" and I must prove that my personal computer is Part 11 compliant with an audit trail, etc., for every time I add a row of information!

OK that's a second question here, do I have to include every draft I print out since that's an "audit trail?" I'm not a great typist, there could be 20 copies of an excel spreadsheet until I get the rows and columns correct.

I very much appreciate your help,

[redacted]

On Tuesday, July 12, 2016 2:50 PM, [redacted] wrote:

Hello Office of GCP,

I would really appreciate *any answe*r from someone there regarding source documentation -- as an investigator site -- on a clinical trial.

This is all theoretical at the moment, but it will determine what we agree to do or if we choose to work with a company that seems like they don’t know what they are talking about, or their different monitors disagree.

We are a small private practice. On this trial, their monitors disagree about source documentation. I have read all of the relevant sections of Title 21 Part 11 and cannot

find an answer to this specific idea.

It’s a very simple question: Is keeping a “log” of medical history or any other background information, as told to me by a patient, or other people, in microsoft excel where I type it as they are talking, and print it out to insert in the patient’s record/source considered an "electronic record” that must be compliant to the same level of electronic signatures in Title 21 CFR Ch 1 (especially “e”)? Some of them are saying that it does not meet the above rules, because it does not have an audit trail, etc.

What if I initial and date every condition added, print another copy out, and put it on top of the old hardcopy in the patient binder, and line out the old verion and initial that? No one is signing anything electronically, just maintaining a log and printing a hard copy for the record and initialing the latest with a date of entering data and into binder.

What if I have a footer that automatically updates which version and date it is printed?

For instance, I had a patient tell me 5 previous medical conditions for their history one day, and on the next visit tell me one he forgot (forgetfulness!), so I added that, printed a hard copy, initialed the new line and lined out the old, plus put the newer on top.

Some monitors said that is not allowed, that I have to write every condition on every log by hand. That’s 7 logs. Times let’s say 4 patients, with maybe 5 to 20 lines of entry on average per log, but it could have many lines of information added as time goes by... how is handwriting for entry any different than typing for entry on a non-networked laptop?

Every small site I’ve seen uses excel or word to create documents and do not have a "Title 21 CFR Ch 1 e" audit trail for every draft of the final memo or log. (This is all background information in the binders for history, not the CRF for each patient visit. Just some other documents, created, modified and printed on a single, not networked, laptop with only one password protected user for the entire laptop, and password encryption on the excel document, hooked up to a non-networked printer by cord. They also say I have to include and initial every draft version I print until I get column information or width correct etc.

Some of them also say if I insert a memo in my pt record, and update it to correct the way a sentence is phrased or to add information, I have to leave the old one in there “because all of it is source, all original documents are source.” Can’t I take out the old one and insert the new since it’s my note and the latest one is most accurate or correctly phrased?

Would some one there please, please help me with this question? They’re so confused, they’re confusing us and the SOP for documentation we have used!

Thank you so much,

[redacted]