From: OC GCP Questions
To: [redacted]
Subject: Physician-Investigator Dual Role
Date: Friday, August 29, 2014 12:59:21 PM
Importance: High

Good morning –

Many institutions and sites are going to a fully electronic record system. It appears that the situation you describe is not specifically addressed in FDA regulations. With regard to placing study information into a subject's EMR, we actually recommend that be done. Specifically, the guidance document on investigator responsibilities
(
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf
) even recommends that the clinical investigator directly inform the subjects' personal physicians if the subject agrees. The purpose for including study information in the EMR is to allow others who would need to treat the individual, on either a routine or emergency basis, to be aware of study treatments and/or any AEs that were observed to better inform their diagnosis and treatment. There should be no issue of confidentiality in placing study information in the EMR since EMRs need to be maintained to at least the same level of confidentiality as study records.

EMRs are not specifically addressed in FDA regulations. 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 to make sure that they are in agreement with what you plan to do.

The guidances listed below might be helpful to you.

Part 11 –Electronic Records --
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

Computerized Systems Used in Clinical Investigations –
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Electronic Source Data in Clinical Investigations –
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov for additional questions.

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From: [redacted]
Sent: Friday, August 29, 2014 11:04 AM
To: OC GCP Questions
Subject: Physician-Investigator Dual Role
Importance: High

Good Morning,

Much discussion has arisen with regards to the Physicians in our private practice setting also participating in clinical trials as Principal and Sub- Investigators. I have done much searching online and have found many articles that offer guidance regarding Physician-Investigators and conflicts of their dual role. However, I have not come across much guidance in the area of which I am in need.

Our private practice utilizes an electronic medical records system. We have over 40 physicians & 400 staff in our private practice at 21 offices.
5 of our offices actively participate in clinical research . We create a separate source – in which we utilize our EMR to obtain medical history information etc..

Our current practice is and has been to pull from our EMR certified copies of medical information for research subjects case history but, never to put information in EMR collected/obtained during their participation in a clinical trial. The only exception(s) to this is:

- in the event a protocol required procedure/test is considered Standard of Care as defined in the contract with the Sponsor or
- if any procedure or testing as part of the trial result (Standard of care testing or not) unveils new clinically significant medical information that could jeopardize the patients health (if one of our physicians can not address the concern than we refer patient out to a Physician that can).

Having given you this information we need guidance on the following issue:

Our Physician-Investigators are asking the research staff to document in EMR the following :

- Lab testing results
- Procedure results
- Investigational Product/Procedure performed on XX/XXX/XXXX date

(ex. PSA collected at a Week 13 trial visit – results should be placed in EMR)
(ex. Under Surgical History in EMR should state – [redacted]

Our Physician-Investigators argue that this information can only benefit the patient if the NON-Investigator , Physician, in our practice (whom is treating the patient medically)

has access/knowledge of this information and that is it unethical to deny access/knowledge to treating physician of the patient.

Our research team argues that a patients participation in a clinical trial should not replace medical care and that any procedures or testing results collected as part of participation in the clinical trial is property of the Sponsor. We also argue that if NON-Investigator, Physicians, want to know what their patients PSA level is – they should order the test- regardless of whether the patient had blood work 3 weeks ago as part of his/her participation in a clinical trial.

Any guidance on this issue is welcomed. I appreciate your time in reading this email and I am available for questions.
Thank you.

Kind Regards,
[redacted]