From: OC GCP Questions
To: [redacted]
Subject: Question on EMR and research records
Date: Monday, March 20, 2017 7:08:00 AM
Attachments: [redacted]

Good morning -

With regard to placing study information into a subject's EMR, we actually recommend that be done. Specifically, the guidance document on investigator responsibilities (www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf) even recommends that the clinical investigator directly inform the subjects' personal physicians if the subjects 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.

We recommend you develop a standard operating procedure so that all study staff will be knowledgeable with the new procedure.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Friday, March 17, 2017 1:15 PM
To: OC GCP Questions; [redacted]
Subject: Question on EMR and research records

Hi,

I am writing as a sponsor representative for a small [redacted] cancer group. I have a question about registration source materials and documentation. If there is an instance when non-clinical staff (such as a CRA) writes a consent note and included in the note documents AEs, medical history and eligibility information- information which given their role they are unable to document as they are non-clinical, but then the treating physician physically signs the note with a date, is this considered suitable per the FDA and GCP. I do understand the physician signature certifies the note and then the note becomes the physicians and not the CRAs so I believe this is

suitable. My question is, is it required that the signed note (by the physician) be uploaded to the EMR if the unsigned note (note by CRA and not signed by physician) is in the EMR? In short, is the signed note in the research record, but not in EMR sufficient or should it be uploaded to EMR to align with the research record and the EMR will only include the unsigned note by the non-clinical person?

Thank you very much

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