From: OC GCP Questions
To: [redacted]
[redacted]
Subject: Medical Records/History as Source Documents
Date: Wednesday, July 25, 2018 1:13:00 PM

Good afternoon -

In answer to your question regarding a study monitor's access to EMR files - yes, we expect the sponsor's representatives - monitors and auditors - to have access to electronic records of subjects participating in clinical trials. It is the only way they can verify study information. You will see, on the Office of Civil Rights' site with regard to HIPAA, a discussion on clinical trials which discusses this. (See www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html.)

One way to provide monitors and audits access to electronic medical files is to provide a monitor-specific login to the electronic record system (e.g. read-only, limited access to subject records). If this is not practical or allowed by your institute's policy, study staff could access the records while the monitor/auditor observes, printing out copies if and when requested. It is important to be able to demonstrate the audit trail for the data as well. The monitor/auditor should be concentrating on data fields that contribute to regulatory decision-making and not need to do a 100% review of the source vs. the CRF, so that staff time should not be tied up too radically. We suggest that our FDA investigators use the latter method, as we prefer they do no access site computers.

Here (below) are links to various FDA guidance documents related to electronic records and electronic health records.

Use of Electronic Health Record Data in Clinical Investigations:
https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm501068.pdf

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

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

FDA compliance manual for FDA inspections of Clinical investigators:
www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133562.htm Electronic records starts on Page 9 of Part III.

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

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

otherwise obligate or commit the agency to the views expressed.

-----Original Message-----

From: [redacted]

Sent: Wednesday, July 25, 2018 8:43 AM

To: OC GCP Questions <gcpquestions@fda.hhs.gov>

Subject: Medical Records/History as Source Documents

Dear Sir or Madam,

Hello! I have a general clinical trials question (from the coordinator's perspective) about the extent to which a subject's medical records should be immediately accessible to our monitors. Our site is unique in that we have direct access to nearly all medical records of our subjects (and associated progress notes, labs, etc.), including records from outside providers. Therefore, we often have subjects whose information goes back 2 or more decades, with dozens or hundreds of visits and "problems." I understand that the FDA has relatively general language concerning this issue -- I've searched the forum and found some similar inquiries. That being said, do you have any advice as to what criteria should determine which information from the medical history should be transferred over to a CRF? Or, are you aware of how other sites have handled such a situation or have related SOPs? How might one systematically go through this process (as opposed to doing it differently for each subject)? Clearly, there at least needs to be information relevant to screening, inclusion/exclusion, etc. This is assuming that the monitors will eventually be given access to EMR for a full review.

Thank you very much for your time!

Best regards,

[redacted]