From: OC GCP Questions
To: [redacted]
Subject: RE: EMR access
Date: Monday, July 11, 2016 9:05:00 AM

Dear [redacted] -

Thank you for your question. The regulations for drugs and biologics at 21 CFR 312 Subpart D (Responsibilities of Sponsors and Investigators) and for devices at 812 Subpart C (Responsibilities of Sponsors) require sponsors to be responsible for ensuring proper monitoring of a clinical investigation.

The *ICH GCP E6 Good Clinical Practice: Consolidated Guidance*, (which is recognized as official FDA guidance – see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) addresses sponsor monitoring in section 5.18. FDA also has a guidance document titled, "*Guidance for Industry – Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring*" which can be found at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm269919.pdf. Both of these guidance documents provide for flexibility in how studies are monitored and state that the monitor should follow the sponsor's SOPs for monitoring processes.

FDA also has a Draft guidance document titled, "*Use of Electronic Health Record Data in Clinical Investigations – Guidance for Industry*" which can be found at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm501068.pdf. Although this guidance is draft, it currently recommends that sponsors should ensure that study monitors have suitable access to all relevant subject information pertaining to a clinical investigation as appropriate.

As you can see, neither the regulations nor the guidance prescribe a specific monitoring technique and don't address your question with specificity. When the regulations are silent, sponsors, investigators and institutions are free to develop their own procedures and practices as long as applicable regulatory requirements are met. **HOW** the sponsor monitor and the investigator site interact to ensure adequate monitoring should be addressed in SOPs and considered upfront when developing a monitoring plan.

As far as whether the scenarios you describe in Examples 1 and 2 violate HIPAA, you should consider contacting the Office of Civil Rights (OCR) as they are responsible for the HIPAA regulations (see http://www.hhs.gov/hipaa/index.html). FDA cannot offer legal advice so it is best that you consult your legal counsel regarding your question as well.

You may also find the following FDA guidance documents helpful in developing your SOPs to address your question:

> "*Guidance for Industry – Computerized Systems Used in Clinical Investigations*" found at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070266.pdf
>
> "*Guidance for Industry – Electronic Source Data in Clinical Investigations*" found at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
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Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Tuesday, July 05, 2016 11:36 AM
To: OC GCP Questions
Subject: EMR access

To GCP Questions:

In many instances today, patient records and source data are contained in an Electronic Medical Record (EMR). At some clinical research sites monitors are given limited access to the EMR for only those Patients/study subjects enrolled in a specific study after training and orientation to the institution's EMR. The monitors/CRAs are given a unique username & password for a limited time. At some research sites, no such access is provided, and study data is printed out from the EMR for the monitor to use in the data verification process. [In these studies the study subject has signed an IRB approved Informed Consent Form, which stipulates the subject is allowing sponsor

access to their Protected Health Information (PHI)

At some sites, the monitor is given access to the data in the EMR in one of the following methods.

Example 1] A study coordinator logs into the EMR using their unique username and password (and not shared with the monitor/CRA). Using at dual screen the coordinator reviews the data with the monitor/CRA and controls the navigation. The monitor/CRA is allowed to review only selected sections and not allowed to freely navigate away from a specific record. The coordinator always maintains control of EMR access.

Example 2] In other situations, a monitor is given limited access to the EMR in the following manner. The coordinator logs onto the EMR using their unique username and password, and does not share these with the monitor. The monitor is allowed to review data for a select set of subjects who are enrolled in a specific study. Navigation away from this select group to other locations/files/records in the EMR is blocked. If the review is timed out, the monitor cannot log back in, and the coordinator must repeat the process of logging in using their credentials.

Is the process used in either Example1 or Example 2, a violation of GCPs, 21CFR 50 or Part 11 , HIPPA , ICH or "illegal in any way? In both cases the coordinator does not share their password with the monitor. The access to the data and the subject's Protected Health Information (PHI), in effect seems no different than if the monitor were to be presented with a paper file to review.

Would you please comment on this process.

Thank you for your time.

Sincerely,