From: OC GCP Questions
To: [redacted]
Subject: RE: Remote Monitor Access to Electronic Medical Record (EMR) for remote source data review/verification
Date: Friday, March 30, 2018 3:56:01 PM
Attachments: [redacted]

Hi [redacted]

Under (21 CFR 50.25(a)(5), the informed consent process must describe the extent to which confidentiality of records identifying subjects will be maintained and should identify all entities, for example, the study sponsor, who may gain access to the records relating to the clinical investigation. This is considered one of the basic elements of informed consent.

Refer to the following additional information:

Informed Consent Information Sheet (Draft Guidance, https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf)
A Guide to Informed Consent – Information Sheet (https://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm#general)

Hope this is helpful,
Bridget

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From: [redacted]
Sent: Friday, March 30, 2018 10:35 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: RE: Remote Monitor Access to Electronic Medical Record (EMR) for remote source data review/verification

Thank you, can we get clarification to the statement below:

Such access (e.g., on site or remote access) to the EHRs must be described in the informed consent.

Currently, we have a local IRB in the US for a large institution which has pushed back in that we are not required to include the language that the specifically states that remote access to EMR would be available to the CRO.

Are we splitting hairs on this?

Kind Regards,

[redacted]

From: OC GCP Questions [mailto:gcpquestions@fda.hhs.gov]
Sent: Thursday, March 29, 2018 9:46 AM
To: [redacted]
Subject: RE: Remote Monitor Access to Electronic Medical Record (EMR) for remote source data review/verification

Dear [redacted]

Thank you for your email. We have consulted our subject matter experts on electronic systems and they have provided the following advisement related to your inquiry:

Sponsors and clinical investigators should ensure that policies and processes for the use of EHRs at the clinical investigation site are in place and there are appropriate security measures (e.g., access controls, encryption) employed to protect the confidentiality and integrity of the study data. EHR technology certified under the ONC Health IT Certification Program is required to meet certain privacy and security protection requirements for an individual's health information (see 45 CFR 170.314(d)(1) through (8) and 45 CFR 170.315(d)(1) through (11)). FDA encourages the use of such certified EHR systems together with appropriate policies and procedures for their use.

When EHR systems are used as a source of data in clinical investigations, FDA recommends that sponsors ensure that study monitors have suitable access to all relevant subject information pertaining to a clinical investigation as appropriate. Such access (e.g., on site or remote access) to the EHRs must be described in the informed consent. We suggest that you follow the clinical investigation site's policies and procedures for IRB review of remote EHR access for sponsor monitoring activities.

I hope that this information is useful.

Sincerely,
Bridget

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From: [redacted]
Sent: Monday, March 19, 2018 4:58 PM
To: OC GCP Questions <OCGCP.Questions@fda.hhs.gov>
Subject: Remote Monitor Access to Electronic Medical Record (EMR) for remote source data review/verification

Dear GCP Questions,
I am contacting you to better understand the US regulations in regards to institutions who are allowing remote monitor/CRA access to Electronic Medical Record (EMR) for remote source data review/verification.
What safeguards should a Sponsor/CRO have in place?
Does the consent require additional specific language to be included that specifically details the various ways PHI will be accessed by sponsor/CRO representatives since the subject's data would be accessed outside the investigator site?
Should the institutions have the process reviewed and approved by their IRB?

Any additional feedback would be immensely appreciated!

Kind Regards,

[redacted]

[redacted]