From: Brown, Sheila (OGCP)
To: [redacted]
Subject: RE: Entries to eCRFs by the study monitor and EMR printed copies certification
Date: Friday, July 17, 2015 4:20:00 PM

Dear [redacted],
My responses are below your questions.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Wednesday, July 15, 2015 2:07 PM
To: OC GCP Questions
Subject: re: Entries to eCRFs by the study monitor and EMR printed copies certification

Good afternoon,

I will appreciate your recommendation in the following matters:

1) We are conducting a trial where the CRO monitor entered the Protocol Deviations into e-CRFs. **It is acceptable**? as our QA Department stated that all information captured in e-CRFs should be entered **only** by the site personnel delegated by the Principal Investigator .

   It isn't clear what you mean by "entered the protocol deviations into e-CRFs". The CRO monitor should not be entering or changing data in the e-CRFs. If there is a data quality check system in the e-CRF program that the monitor can use to "flag" data entry errors, that would be acceptable. As noted in the guidance, *Electronic Source Data in Clinical Investigations*:

   > Only a clinical investigator(s) or delegated clinical study staff should perform modifications or corrections to eCRF data. Modified and/or corrected data elements must have data element identifiers that reflect the date, time, originator and reason for the change, and must not obscure previous entries [21 CFR 11.10(e)]. A field should be provided allowing originators to describe the reason for the change (e.g., transcription error). Automatic transmissions should have traceability and controls via the audit trail to reflect the reason for the change.
   > http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf

2) If a site Electronic Medical Record is restricted by individual unique username and password, and when printing data the print out has the user name and date, do we also require the person printing to sign and date the document?

   The purpose of printing the Electronic Medical Record (EMR) is not clear from the limited information provided. If the intent is to provide a source document for the study record, the document should be a "certified copy" of the original EMR. The term "certified copy" is defined in FDA's Final Guidance Computerized Systems Used in Clinical Investigations (the one you referenced) as: "A certified copy is a copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original." See: www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf .

   The use of certified copies generally applies to situations where original records are copied to a different media for archiving purposes and the originals are destroyed. However, if it is decided to have a certified copy substitute for the original, it would be desirable to have a "standard operating procedure" (SOP) describing how such copies would be made, verified, and documented. The person who certifies the copy as an accurate and complete representation of the original, having all of the same attributes and information should be the same person who actually made the copy from the original. Certification should be accomplished by having the

person who makes the copy sign or initial and date the copy to indicate it meets the requirements of a certified copy as described above. This should be described in the SOP, and can be accomplished by initialing and dating each copy or by initialing and dating a document certifying copies in bulk. The SOP should describe the procedure, whichever method is used. (There are many ways to accomplish this, and the procedures described above are only suggested examples.)

Please also see guidance on Part 11 -Electronic Records
www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf and the

Guidance for Industry - Electronic Source Data in Clinical Investigations
http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf

In advance thank you for your help.

Kind regards,

[redacted]