

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: GCP question_EMR and Certified copy-FDA and GCP R2 interpretation
Date: Friday, November 03, 2017 10:36:44 AM

Good morning --

See below for the cleared response (in red) from FDA's Office of Medical Policy. Thank you for your patience.

Kind regards,

The OGCP Group

From: [REDACTED]
Sent: Monday, October 23, 2017 5:55 AM
To: OC GCP Questions
Subject: GCP question_EMR and Certified copy-FDA and GCP R2 interpretation

Dear Sir / Madam,

I have few general questions on the use of EMR system and certified copies. We request you to clarify on the following issues:

a) FDA does not inspect electronic medical records (EMRs) systems for Part 11 compliance. Is this information still accurate?

Yes, this is correct. FDA does not intend to assess EHRs for compliance with part 11.

b) It is expected that sites will be using EMR systems to maintain important information relevant for patient enrolment (Inclusion/Exclusion, medical history). Sponsors do not need to verify the system for part 11 compliance but they can still review the system to ensure the confidence in the quality, reliability and integrity of data. Is this correct?

Yes, this is correct. For more information on this topic, please see draft guidance for industry on the use of EHR data in clinical investigations.

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM501068.pdf>

c) The term "Certified Copy" is now defined in ICH-GCP (E6-R2). ICH definition allows for certification via use of a "validated process", not requiring a dated signature to certify each and every copy. FDA definition of a certified copy differs from the ICH addendum definition. What is FDA's current thinking on this definition and the certification process?

FDA has adopted ICH's definition in ICH E6 (R2) for certified copies. A copy of an original record can be generated through a validated process to produce an exact copy having all of the same attributes and information as the original record. Alternatively, the copy of the original record can be verified (e.g., by a dated signature) as an exact copy having all of the same attributes and information as the original record. For either certification method described above, you should have written procedures to ensure consistency in the certification process.

d) Some sites maintain the original records in EMR system but also print the records for medical files and for monitors review. If a printed record identifies who created/entered the data, when and who printed it out (With username, date and time) is it still necessary to certify the printed copy with "dated signatures" as per FDA definition? As per ICH GCP addendum text (#8.1) it appears that there is no need to sign the copies if the printed copy is not actually replacing the original record and if the printed

copy is only being filed in addition to the original record which is still available in EMR system and accessible to sponsor/inspectors for spot checks. Is this the correct understanding?

It is not necessary to maintain paper copies of the EMR if the original EMR can be accessed electronically.

However, if you plan to retain and archive the paper copy of the EMR (e.g., if the original EMR is no longer accessible), then the certification process should ensure that copies of electronic originals have the same attributes and information as the original, including any associated metadata (e.g., units of the data, date and time stamps, data originator, and other audit trail information associated with the data).

During inspection, FDA may request to review and copy records, including all associated metadata and audit trail information, in a human readable form, where applicable, using electronic system hardware. If screenshots or paper printouts are used to serve as a paper record and that record fails to capture important metadata, including the audit trail information that are recorded in the electronic system, such paper records would be regarded as incomplete unless the accompanying metadata and audit trail information are included. FDA would require access to the electronic system used to produce those data to review the complete record (see 21 CFR 312.58, 312.68, 812.140, and 812.145).

e) If sites are replacing the original copies with certified copies then it is recommended that site develops the SOP on this process for team members training and awareness. The SOP should describe process on handling such copies with verification and certification process. Is it accepted if sites do not wish to document their process or cannot describe the process to sponsor or inspectors?

No this would not be acceptable. We recommend that the site has written procedures to ensure consistency in the certification process.

We look forward to hearing from you and appreciate any guidance and advice you can provide.

Thank you

[REDACTED]