From: OC GCP Questions
To: [redacted]
Subject: RE: Clinical Trial Record Inquiry
Date: Friday, September 29, 2017 11:23:25 AM
Attachments: [redacted]

Dear [redacted]
Responses are listed after each of your questions.

1. Can/should research subject records be kept in a regulatory binder?
   FDA regulations do not specify how a clinical site maintains its subject records. [For pharmaceutical studies, required investigator records are described at 21 CFR 312.62. For device studies, required investigator records for study subjects are described at 21 CFR 812.140(a).] The use of a regulatory binder is one method of organizing and maintaining subject records.

2. Can multiple research subjects research records be stored in the same binder?
   As noted above, FDA regulations don't specify how subject records are maintained. If more than one subject's records are within a single binder, a method to ensure that documents for each subject are organized and kept together should be employed (e.g., section tabs that are labeled for each subject).

3. If we are printing medical records off of our EMR for them to be stored in a study binder, should they be:
   a. Stamped with a certified copy stamp (as we are transferring from electronic format to paper)
   b. De-identified

   Copies of medical records printed from the EMR - sometimes referred to as shadow files - are often found in study records. In general, for inspection purposes, if simple screenshots or paper printouts of the EMR fails to capture important metadata (e.g., the data originator and the audit trail of the data) that are recorded in the electronic system, then such paper records would not be regarded as certified copies of the originals and would be considered incomplete unless the accompanying metadata are included. FDA would require access to the EMR used to produce those data to review the complete record (see 21 CFR 312.58, 312.68, 812.140, and 812.145).

   All records pertaining to the subjects should be identifiable, so they can be verified as belonging to a specific subject.

   The following guidance documents may be helpful to you:

   1. *Guidance for Industry - Use of Electronic Health Record Data in Clinical Investigations (draft)*

      https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm501068.pdf
   2. *Guidance for Industry - Electronic Source Data in Clinical Investigations*

      http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

   3. *Guidance for Industry - Part 11, Electronic Records; Electronic Signatures --Scope and Application (draft)* https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm563785.pdf

   4. *Guidance for Industry – Computerized Systems Used in Clinical Investigations*

      https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm070266.pdf

   When finalized, the draft guidances (#1 and #3) listed above will represent the current thinking of the FDA.

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 the Commissioner (OC)
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration
Tel: 301-796-6563
sheila.brown@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 21 CFR 10.85(k), which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Thursday, September 28, 2017 11:23 AM
To: OC GCP Questions
Subject: Clinical Trial Record Inquiry

Good Morning,

There has been some varying thoughts and opinions and I was hoping you could provide the ultimate ruling on the below questions:

1. Can/should research subject records be kept in a regulatory binder?
2. Can multiple research subjects research records be stored in the same binder?
3. If we are printing medical records off of our EMR for them to be stored in a study binder, should they be:
    a. Stamped with a certified copy stamp (as we are transferring from electronic format to paper)
    b. De-identified

Thank you so much!

Sincerely,

[redacted]