From: OC GCP Questions
To: [redacted]
Subject: ACRP
Date: Friday, January 09, 2015 12:50:29 PM

Good afternoon –

Yes this information is still accurate.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, January 08, 2015 12:06 PM
To: OC GCP Questions
Subject: RE: ACRP

Is the below still accurate?

From: Toth-Allen, Jean [mailto:Jean.Toth-Allen@fda.hhs.gov]
Sent: Wednesday, May 18, 2011 2:14 PM
To: [redacted]
Subject: RE: ACRP

Dear Ms. [redacted]

FDA does not inspect electronic medical records (EMRs) for Part 11 compliance. The main point about EMRs is that they are developed and maintained by the "institution" for general patient medical records. As such, they are a part of the practice of medicine and FDA does not regulate the practice of medicine. HHS does have an office which is specifically working on a national system for electronic health records - the Office of National Coordinator for Health Information Technology, referred to simply as ONC. (The have a website (http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__home/1204) if you are interested in them.) Hopefully the system(s) they help develop will have the major elements found in Part 11 that are pertinent to the integrity of data. However, since FDA does not regulate the practice of medicine, we cannot dictate the ground rules for EMRs, even when they hold data relevant to clinical studies. Right now that is mainly information pertinent to inclusion/exclusion criteria and/or in-patient information about a study subject. It is expected that such information will be useable as collected and maintained in the institution's EMRs. We do not expect study sites to provide validation of these systems or any evidence relevant to Part 11. We only ask that FDA investigators be given the ability to review any information in them that is source data for the study in question. As I stated at the forum, we instruct our investigators to have someone at the site bring up the files and allow them to look at them. They may then request for some files or portions of files to be printed out as exhibits for their establishment inspection report (EIR). Using such a process to allow sponsor representatives to review EMRs precludes the temptation to wander around patient files without cause and/or to files of those not involved with study in question.

If you have other questions related to clinical studies, you might find it beneficial to use our official GCP queries box gcp.questions@fda.hhs.gov. It is sorted daily by someone in the office and so if a particular person is on leave you can get an answer without waiting for her return. 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.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Office of Good Clinical Practice
Office of the Commissioner, US FDA

From: [redacted]
Sent: Wednesday, May 18, 2011 1:15 PM
To: Toth-Allen, Jean
Subject: ACRP

Dr. Toth-Allen

At the ACRP conference you stated that Electronic Medical Records did not have to be compliant with Part 11, did I hear your correctly?

Thank you.
[redacted]