From: OC GCP Questions
To: [redacted]
Subject: Toward a paperless system.
Date: Tuesday, November 03, 2015 11:23:43 AM

Good morning –

Please see the response below from the Center for Drugs (CDER) and the Office of Medical Policy (OMP).

First, FDA permits the interchangeable use of electronic and paper records for the archiving and protection of records provided that record keeping and retention requirements are met (see §§ 56.115, 312.57, 312.62, and 812.140). Second, no, you are not required to have paper back-ups of electronic source data. Electronic source data refers to data initially recorded in electronic format. When electronic source data are used, the electronic system and records must comply with 21 CFR part 11.

If the IRB intends to use an electronic scanned copy in lieu of the paper source data (i.e., destroy the paper source data), the electronic system and records must comply with 21 CFR part 11. FDA accepts the electronic scanned copies of documents without the original paper records, provided that there is a process in place to certify that the electronic copy is an accurate representation of the original paper document. 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. The person who makes the copy should sign or initial and date the copy to indicate it meets the requirements of a certified copy as described above. IRBs, sponsors and other regulated entities should have written procedures to ensure consistency in the certification process.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Wednesday, October 28, 2015 10:52 AM
To: OC GCP Questions
Subject: Toward a paperless system.

Hello FDA'ers,
I have a question regarding retaining paper copies of Regulatory documents, particularly IRB related documents.

Per CFR 21, Part 11, Section 11.1(a) states clearly that electronic records in compliance with Part 11 criteria shall be considered by the agency to be "trustworthy, reliable, and generally equivalent to paper records".

(a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

Further, CFR 21, Part 11, Section 11.1(d) states clearly that electronic records meeting the requirements "may be used in lieu of paper records": (d) Electronic records that meet the requirements of this part may be used in lieu of paper records, in accordance with 11.2, unless paper records are specifically required.

We utilize a very well-known electronic system for all of our IRB related documents. This system includes all correspondence to and from the IRB, all IRB submissions, all versions of the protocol, consents, Investigator brochure, etc... right from Day 1. This system is fully compliant with 21 CFR Part 11 (we have written verification of this matter from the company). This system also adheres to the highest privacy and security requirements required by leading Financial Institutions. Nightly backups are conducted to save all data and back up files are moved off-site to fire-rated facilities. Other back up services are utilized to assure confidentiality and long term storage per part 11. These documents can be stored for the FDA required time and longer if contractually agreed upon with a Sponsor. Destruction of files can be done at that time per regulations.

We are trying to be good stewards of finance (and the environment) are moving to a paperless system. In lieu of copying all of the IRB documents, we place a *Memo to File* in the IRB and related sections noting that these essential documents are maintained electronically in this 21 CFR Part 11 compliant system. We then provide one (or at most two) Sponsor representatives with READ only access to their respective protocol. They will be able to view 100% of what we do in this system. This also enables them to monitor without coming to the site as they can sign on remotely.

The majority of our Sponsors like this method. However, we have a few Monitors who are saying that the FDA will not permit this and require paper back up of all Regulatory documents. I keep reading the regulations and can't find this "paper back up" requirement anywhere and think what these Monitors are saying is a "misinterpretation" of the regulations.
So, in summary - can you please tell me, if we are following all of the requirements of 21 CFR Part 11, are we required to have paper backups of these noted documents?
Thanks again!
[redacted]