From: OC GCP Questions
To: [redacted]
Cc: CDER DRUG INFO
Subject: Pharmacy and Laboratory Temperatures
Date: Tuesday, July 15, 2014 10:01:01 AM

Good morning [redacted],

It is acceptable to transfer to an electronic system from paper. And yes you should work with the sponsor to make sure they are involved. An electronic data capture system for FDA-regulated studies should be Part 11 compliant. FDA's regulations for electronic records and electronic signature can be found at 21 CFR Part 11 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11). Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations, as well as electronic records submitted to the Agency under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in Agency regulations.

I've listed below a few FDA guidance documents that you may find helpful:

FDA's Guidance for Industry – Computerized Systems Used in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

FDA's Draft Guidance for Industry – Electronic Source Data in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

FDA's Guidance for Industry -- Part 11, Electronic Records; Electronic Signatures --Scope and Application found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

For you second question, FDA regulations require very few signatures and the timeframe for a PI to sign off on information is also not addressed in FDA regulations. Therefore, as you state, and SOP would be appropriate in this situation.

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

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

From: CDER DRUG INFO
Sent: Monday, July 07, 2014 4:58 PM
To: OC GCP Questions
Subject: FW: Pharmacy and Laboratory Temperatures

Hi GCP,

Can you help us with the questions below? Please let me know if this should go somewhere else instead.

Thanks so much!
Cherryn

Cherryn Chang, Pharm.D.
Division of Drug Information
FDA/CDER/OCOMM

From: [Redacted]
Sent: Monday, July 07, 2014 4:12 PM
To: CDER DRUG INFO
Cc: [Redacted]
Subject: Pharmacy and Laboratory Temperatures

To whom it may concern:

We are in the process of switching to an online managed electronic temperature monitoring device for our pharmacy and laboratory. We are able to download the temperatures (maintained daily) to a CD/DVD instead of printing them. We normally have a print out of the temperatures for the duration of the clinical trial, but would like to just have a DVD or CD. Is this allowed? Or do we need to complete additional electronic paperwork to maintain our logs electronically? Or is this up to the Sponsors that we directly work with?

The second issue I wanted to just confirm is lab ad ECG result signing. When we receive the subjects lab and ECG reports, our PI or MDs sign off on them. Is there a required timeframe of when they have to sign off? Or is it just per our SOPs or practice?

I appreciate your time and please let me know if you need more information.

Thanks in advance,

[Redacted]