From: OC GCP Questions
To: [redacted]
Subject: using computer tablets to deliver and document informed consent
Date: Monday, October 20, 2014 9:01:57 AM

Good morning –

We consulted our IT experts in the Center for Drugs (CDER). Please see their answer below.

In short, we agree with the statement you provided below: "…the basic approach of linking a subject-applied signature to an electronic consent form using a computer tablet's stylus feature (can be)… considered (to be) 21 CFR part 11 compliant (if consistently used correctly as intended)."

Kind regards,

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

From: [redacted]
Sent: Thursday, October 16, 2014 5:39 PM
To: OC GCP Questions
Subject: using computer tablets to deliver and document informed consent

Good evening,

There are a number of vendors offering systems designed to use a tablet computer to display the informed consent form for the study-subject to review during the informed consent process and then to allow the subject "sign" the electronic record of informed consent using their finger or a stylus applied to the tablet computer screen. (The same as one signs their signature after swiping a credit card at a grocery store.) The vendors say that their systems are part 11 compliant, of course, and that the FDA is fine with their system. I have difficulty aligning the specific requirements in part 11 for e-signatures with their process. Subjects do not log onto the system by entering their ID (logging-on is done by study staff) and the subject does not establish a password known only to them for the purpose of signing. If the subject's name is displayed in printed form associated with their applied signature it has been entered by someone else. So, assuming that the other requirements of 21 CFR part 11 are fulfilled such as linking the "signature" to the electronic record (part 11.70) does the fact that the subject physically scribes their signature fulfill the requirement in part 11.200 (a) for being based on biometrics and therefore not subject to the requirement for an ID and password? What does the system need to do to fulfill part 11.200 (b) which requires that e-signatures based on biometrics be designed to ensure that they cannot be used by anyone other than their genuine owner? I always thought this was intended to require evidence that the system used biometrics that were sophisticated enough and acute enough to prevent forgery such as finger prints or retinal scans or, if signatures were used, the expectation was that the system required establishing a reproducible biometric signature in the system prior to authorizing the individual to electronically sign (so that signers could not refute the signature as not applied by them).

We have no expectation that the FDA endorse any particular system but since an informed consent signature is required by predicate rule it is important to know if the basic approach of linking a subject-applied signature to an electronic consent form using a computer tablet's stylus feature is being considered 21 CFR part 11 compliant.

Thank you for offering this means of requesting clarification to regulations,

[redacted]