From: OC GCP Questions
To: [redacted]
Subject: Informed Consent Signature question
Date: Wednesday, February 10, 2016 8:23:48 AM
Attachments: [redacted]

Good morning –

As you mention FDA regulations do not require a witness signature unless a "short form" consent document is used. I am unclear as to why you would want to use the procedure outlined in your email rather than having the individual who administers the consent just sign the form. It seems a bit cumbersome. That said when FDA regulations are silent institutions and sites are free to develop their own standard operating procedure to address specific situations.

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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 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: Monday, February 08, 2016 4:04 PM
To: OC GCP Questions
Subject: Informed Consent Signature question

I understand the FDA does not explicitly require the individual who administers/conducts the informed consent process to sign and date the consent form. However, if the form is manually signed, would a signature consisting of a handwritten unique identifier (e.g., employee ID) and initials, rather the full name of the consenter, be adequate? A separate log linking the unique identifier and initials with the identity of the individual (i.e., full name) would be maintained.

Kind Regards,
[redacted]

[redacted]