From: OC GCP Questions
To: [redacted]
Subject: RE: Wet-Ink Signatures Required?
Date: Tuesday, October 01, 2019 12:59:00 PM
Attachments: [redacted]

Dear [redacted],

FDA regulations require very few signatures for site clinical trial documents, e.g., the clinical investigator's signature on the Form FDA 1572 (1572) or investigator agreement , and the study subject's signature on his/her informed consent document. Please note that Delegation of Authority logs are not an FDA requirement, although sponsors may require signatures and/or initials on these documents.
When the regulations are silent, IRBs, institutions, sponsors, investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met. There may also be local or state requirements regarding clinical research. Because sponsors and sites have the flexibility to adopt procedures that make the most sense to them and their existing business practices, I recommend you discuss how to address this issue with the appropriate intuitional officials at your sites, and then decide on the most appropriate method of documentation for your studies.
You may want to review FDA's draft guidance, *Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers Guidance for Industry (2017)*, which can be found at https://www.fda.gov/media/105557/download . This draft guidance, when finalized, will represent the current thinking of the FDA on this topic. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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From: [redacted]
Sent: Monday, September 30, 2019 1:46 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Wet-Ink Signatures Required?

Hello:
For clinical trials that utilize a network of sites comprised of sites in several states, is it acceptable for the delegation of authority logs to allow scanned signatures of KP, and initials & dates for PI oversight in lieu of wet-ink signatures?
Thank you,
[redacted]

[redacted]