From: OC GCP Questions
To: [redacted]
Subject: Please advise. Site Signature Sheet/Log and GCP Staff Exemptions
Date: Wednesday, January 24, 2018 8:11:00 AM
Attachments: [redacted]

Good morning –

Your email about site signature logs were forwarded to my office for a response. FDA does not define "site signature logs" in regulation, and thus, there are no regulations describing them or stipulating who should be included.

As you mention, signature sheets are mentioned in FDA's official guidance the ICH E-6, "Good Clinical Practice: Consolidated Guidance." See section 8.3.24, which recommends maintaining a "Signature sheet, [t]o document signatures and initials of all persons authorized to make entries and/or corrections on CRFs."

In general, to avoid record keeping problems, a study site should have established expectations and procedures for how data will be collected, by whom, and how the data will be documented. As long as data are handled consistently in accordance with those expectations and procedures, a site should have no problems. Data should be attributable to the individual who collected it, should be accurate, legible, contemporaneous, and original.

The purpose of a signature sheet is to document the signatures and initials of all persons authorized to make entries and/or corrections on the Case Report Forms and other study records so that the entries can be traced back to the individual who collected and recorded the data. Although an individual may have only a "temporary" role (e.g., they are substituting for a research staff member), it would still be important to include them if they are performing study related functions (e.g., maintaining case histories, dispensing study drug to the subjects, completing case report forms). If the substitute performs such functions, then his/her signature should be included in the log. Should FDA subsequently review the study records, FDA would be able to verify whether entries and changes to study documents were made by individuals authorized to do so.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hs.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

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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: Tuesday, January 23, 2018 2:35 PM
To: [redacted] OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: RE: Please advise. Site Signature Sheet/Log and GCP Staff Exemptions

[redacted],
Thanks for reaching out to FDA about this question.
I am forwarding your question to the mailbox of the Office of GCP within the Office of the Commissioner.
https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/officeofscienceandhealthcoordination/ucm2018191.htm

You may have gotten my contact info from a conference (Socra, Peds GCP) or from my slides posted on the web.
Although I will answer questions during the conferences and by e-mail shortly after, it is best that I forward your question to OGCP so that you can get a more formal reply.

FDA's mission is to provide answers to your questions so that you can use guidance and regulations to practice GCP.
I anticipate that the turnaround time will be within 2 weeks, so please get back to me if you do not receive a reply within this timeframe or if I can be of further assistance.
Regards,
[redacted]

From: [redacted]
Sent: Tuesday, January 23, 2018 11:35 AM
To: [redacted]
Subject: Please advise. Site Signature Sheet/Log and GCP Staff Exemptions

Dear [redacted],

The purpose of this e-mail is to clarify the use of the essential document titled "Site Signature Log" and clarify if there are any GCP related Team Member exemptions from using this form.

The Signature Log is widely used in GLP, GCLP (CGP & CLP) and GMP,GCP, GxP areas; however, in industry, most facilities a use Signature Sheet. We refer to the document as a "Signature and Initial Sheet/log". Generally, it gets used for on-boarding a new team member &/or as part of the new hire SOP training on Good Documentation Practices (GDP).

Years ago, the Signature/Initial Log included a start date and end date so you could track the time an employee/contractor/consultant was on a clinical project so that the FDA could identify all team members and the exact time they managed a study/study-related materials.

Please advise.

1. With Technological advances and large companies now utilizing sophisticated software's, such as, ZenQMS , Veeva Vault, or Catweb/Enova/Trackwise…is this Signature and Initial Sheet Log still a requirement (Is the essential document now equivalent to the new software system) ? &/or would a large company still be required to use this form since they have e-signature request forms for their sophisticated systems with audit trails created to track new employees date of hire/termination and all training records?

2. Sometimes, QA gets questions and there seems to be a difference between expectations of small company practices vs large sponsor practices.
   As a small company, I utilize this form. Please clarify. Is this form still acceptable and does it apply to both internal or remote (such as a CRA) employees who work at the same company? Please confirm would a Clinical Research Associate be exempt from completing this form?

   The reason for the clarification is because I need to know if I have to rewrite and SOP to include this form is not applicable to CRA staff members.

I believe I have a signed signature/initial log at every company I worked at since I've been told it's a source of an individual's handwriting as well as a record in case multiple people have the same initials (this source would make it clear to the FDA who made the changes/edits on documents (ie. Lab reports, CRFs, etc) since its evidence of personal handwriting and the way someone dates and writes their numbers).

Below is the current link to the FDA Guidance weblink re: this topic. Its not clear if the intended purpose is for inhouse staff vs remote staff.

> As per current **INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2)** Current Step 2 version dated 11 June 2015
> https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf Page 58, Section 8.3.24
>
> **8.3.24 SIGNATURE SHEET To document signatures and initials of all persons authorised to make entries and/or corrections on CRFs X X**

Thank you for your insight into this topic.

[redacted]