From: OC GCP Questions
To: [redacted]
Subject: Form FDA 1572 and SOPs
Date: Wednesday, August 16, 2017 6:13:00 AM
Attachments: [redacted]

Good morning –

Please see FDA's 1572 guidance link below.

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf It states --

32. Should research nurses, other nurses, residents, fellows, office staff, or other hospital staff be listed in Section #6?
Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the clinical data, do not need to be listed individually. It is not necessary to include in this section a person with only an occasional role in the conduct of the research, e.g., an on-call physician who temporarily dealt with a possible adverse effect or a temporary substitute for any research staff (see ICH E3, Section 6) (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073113.pdf).

FDA has no regulations or guidance on the use of signature/date stamps, it is up to the institution to determine the circumstances under which using a signature stamp would be allowed, appropriate procedures for its use, and how access to the stamp would be controlled.

Again we would suggest that if your site is contemplating the use of date or signature stamps for other trial documents, from a practical standpoint, you might wish to consider developing standard operating procedures (SOPs) for their use. If a signature stamp were to be employed, the SOPs should address any necessary controls over the stamp, for example, who is authorized to use the stamp, where the stamp is stored and how access to the stamp is controlled, the type(s) of correspondence on which it may be used, and the circumstances for its use (e.g., cover letters providing routine or general information). If your site subsequently follows the SOPs that you develop, then it would appear to be acceptable and in keeping with good clinical practice.

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

From: [redacted]
Sent: Tuesday, August 15, 2017 6:48 AM
To: OC GCP Questions

Subject: Form FDA 1572 and SOPs

Dear FDA,

Can you please provide your thoughts on study staff adding a "Note" to the Form FDA 1572 that states they may have residents that provide care for subjects who are enrolled on a clinical trial under the supervision of a physician who is listed on the 1572? In addition, there is no protocol training noted for any of the residents at this facility.

Furthermore, the facility refuses to share their Standard Operating Procedures for Clinical Research with anyone outside of the facility. They have "Policies and Procedures" that they share, but these consist mostly of notes-to-file, some signed, some not, and even some that are signed were signed/dated using a stamp.

Sincerely,

[redacted]