From: OC GCP Questions
To: [redacted]
Subject: ICF issue
Date: Wednesday, October 05, 2016 11:21:00 AM

Good morning –

Yes it is okay for the study subject information be on the ICD. That said the sponsor's (and the others you mention in your email) receipt of copies of documents with patient identifiers, while not prohibited, does require the sponsor to have specific procedures in place to ensure the confidentiality of these documents, since they would contain sufficient personal information to allow for identification of the individual. To avoid the need for implementing special controls on study documents they actually receive, the sponsor usually limits documents they receive to documents which commonly identify the subject by a subject identification code. Review of the actual subject files/medical records is usually limited to monitoring activities performed at the study sites.

When the regulations are silent and in the absence of specific guidance, there is flexibility to adopt procedures to protect the confidentiality of records that make the most sense and that align with existing business practices. If SOPs don't currently exist, it is recommended that SOPs be developed to address how confidentiality of records is maintained. In developing such SOPs, it is important for you to be aware of any institutional, site, sponsor, IRB, and/or any other requirements for maintaining confidentiality of records. The SOPs can include specific instructions as to when patient identifiers must be redacted from records, and the exact manner in which such redaction is carried out.

I hope this information is helpful.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
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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: Monday, October 03, 2016 8:57 PM
To: OC GCP Questions
Subject: Re: ICF issue

Thank you for your response.

Do you have any comments/thoughts about the issue I presented from a GCP standpoint?
Have you seen something like this before?
Isn't it ok for monitors/sponsor/FDA and the like to review ICFs of study subjects with their information in order to properly do SDV?

Thank you

[redacted]