From: OC GCP Questions
To: [redacted]
Subject: Subject number on source documents
Date: Wednesday, January 08, 2014 12:45:09 PM

Good afternoon –

There should be adequate provisions in place to protect the privacy of subjects and to maintain the confidentiality of data. Note that neither the regulations or even guidance do not specifically address the methods used to maintain the confidentiality of records identifying the subject nor do they prohibit sponsors/CROs from receiving subject information, even with identifiers. Typically, study sponsors, CROs, and sites usually follow their own Standard Operating Procedures (SOPs) that direct document handling and maintaining confidentiality.

I am not sure how you can identify a subject's record when it has been de-identified without some type of number. It might be helpful to develop a SOP for all sites to follow to avoid confusion and add consistency to the study records review process.

You might be interested in FDA's guidance document on Protecting the Rights, Safety, and Welfare of Study Subjects. Link below.
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

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: Wednesday, January 08, 2014 10:55 AM
To: OC GCP Questions
Subject: Subject number on source documents

Hello,

Could you please indicate where in the GCP guidelines I may get confirmation of handling source documents submitted by sites to a CRO. (I am unable to locate)

Scenario:

Sites submit Documents (hospital records, lab reports etc) for safety review. After de identifying pt's personal information, we ask the sites to label documents w study subject number to confirm whom they belong to. I have sites refusing to label documents and stating this is not indicated in GCP guidelines

Your assistance is appreciated.

Warm regards,
[Redacted]