From: OC GCP Questions
To: [redacted]
Subject: Question about de-identification of study records
Date: Friday, February 20, 2015 2:44:36 PM

Good afternoon –

Marsha asked me to respond to your email. I contacted someone in FDA's field office (ORA) that conducts and coordinates FDA inspections. I have not heard back from him yet. Please see general information below regarding de-identifying records.

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: Monday, February 09, 2015 11:20 AM
To: Melvin, Marsha *
Cc: [redacted]
Subject: Question about de-identification of study records

Good Morning Ms. Melvin,
I am writing to inquire about guidance on the process of de-identifying study records.
We have been instructed by our IRB to de-identify the records that we maintain as our study source records. In order to do this we remove identifying information (HIPAA identifiers) using a black marker and then write the subject study number on the documents.

We had been instructed by an FDA auditor that this process should not be done and that it is actually not what the FDA wants to see.

In addition we noted that the de-identification of records was noted as a finding in a recent FDA warning letter.
(http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm429793.htm)

I am writing to see if you can perhaps shed light on what the expectations are from a regulatory perspective.

Thank you in advance for your time and assistance with this matter.

Kind regards,

[redacted]