From: Kezer, Doreen M
To: [redacted]
Subject: Question about de-identification of study records
Date: Saturday, March 07, 2015 10:48:52 AM

Good morning –

Please see the response from FDA's field office (ORA) below.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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.

Here is my response:

Although sometimes challenging, ideally FDA would like to see and get copies of, original unchanged records. If not possible, the de-identification of records should be done as to not obliterate the required info necessary to identify the subject and the evidence of his/her participation in the study. Usually a **combination** of subject initials and subject number on study records will suffice this requirement.

The Privacy Rule also indicates the following: "…the Privacy Rule provides that, unless the use or disclosure is otherwise permitted or required by the rule, the use or disclosure of the protected health information of an individual, such as a research subject, is permitted only if the individual signs an authorization for the use or disclosure (45 CFR 164.508)."

One of the required elements of an Informed Consent Form is a statement describing the extent to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA may inspect the records. By signing the ICF the study subject is, in part, authorizing the disclosure of study info to FDA.

Hope this helps,

Héctor J. Colón Torres, MPH
LCDR, US Public Health Service
CSO, BIMO Program Expert
FDA/ORA/Office of Operations
Office of Medical Products and Tobacco Operations

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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]