From: OC GCP Questions
To: [redacted]
Subject: redaction of patient names
Date: Wednesday, February 07, 2018 8:49:00 AM
Attachments: [redacted]

Good morning --

FDA's regulations relating to the confidentiality of clinical trial subjects includes the IRB regulations at 21 CFR 56.111, which outlines the criteria for IRB approval of research. One of those criteria [21 CFR 56.111(a)(7)] requires that, where appropriate, there are adequate provisions 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

In addition, the informed consent regulations at 21 CFR 50.25(a)(5) require that the informed consent include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA may inspect the records. The informed consent document signed by the subject usually includes a statement describing who will have access to the subjects' identifying records (e.g., the sponsor, CRO, and their representatives, the FDA, etc.).

ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance), section 2.11 states that the confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

According to the regulations, the sponsor/CRO's receipt of copies of documents with patient identifiers, while not prohibited, does require the sponsor/CRO 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/CRO 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 sponsor, CRO, institution, site, 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,

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U.S. FOOD & DRUG ADMINISTRATION

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: Friday, February 02, 2018 12:09 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: redaction of patient names

Hello –

Is it expected or required that all identifying information information (names, DOB, etc) be redacted from all documents such as visit notes, adverse event forms, source documents, etc., in a patients research chart?

Thank you,

[redacted]