From: OC GCP Questions
To: [redacted]
Subject: US Restrictions on DOB & Subject Initials
Date: Tuesday, September 04, 2018 11:24:00 AM

Good morning --

FDA regulations do not prohibit sponsors and or CROs to have subject names and identifiers. I can offer you the following information (below).

FDA regulations do not dictate how subject files are maintained as far as identifiers are concerned. FDA does expect that the clinical sites and study sponsors take appropriate measures to ensure the confidentiality of subject records. While it is not forbidden for sponsors to maintain files with subject names, most sponsors prefer to have initials at the most or even numbers or other identifiers so that major procedures are not required to maintain that confidentiality. However, study sponsors/CROs, and sites usually follow their own Standard Operating Procedures (SOPs) that direct document handling and maintaining confidentiality

With regard to citations related to ways to identify study subjects, the ICH E6 (R2) document referred to above does contain a definition for a "subject identification code" (1.58) - "A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial-related data." While this document has been adopted as official guidance by FDA, it is just guidance. There is no definition relevant to such identifiers found in FDA regulations regarding the conduct of investigational studies with pharmaceuticals or devices. However, study sponsors/CROs, and sites usually follow their own Standard Operating Procedures (SOPs) that direct document handling and maintaining confidentiality

Please see a link to the guidance below.

https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf

Kind regards,

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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.

-----Original Message-----
From: [redacted]
Sent: Friday, August 31, 2018 7:19 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: US Restrictions on DOB & Subject Initials

Do you know of any restrictions in the US that would limit DOB and subject initials from being provided to the sponsor? If so, can you provide citations?

[redacted]