From: OC GCP Questions
To: [redacted]
Subject: FDA Form 1572 - Section 6 - Sub-Investigator Names
Date: Friday, August 14, 2015 10:08:37 AM

Good morning –

It is not a FDA requirement that all the names appear the same. It is assumed that the names are similar enough so that the documents can be traced back to the appropriate (same) person.

Kind regards,

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

From: [redacted]
Sent: Thursday, August 13, 2015 3:09 PM
To: OC GCP Questions
Subject: FDA Form 1572 - Section 6 - Sub-Investigator Names

Hi,

I'm trying to find guidance on investigator (both sub and PI) names on the Form 1572.

When collecting regulatory documents for study sites, it's not uncommon to have investigators' names appear differently on different documents. For instance, their medical licensure is likely to have their full name, for example Johnathan David Doe, but their CV would have their name as they are commonly addressed, John D. Doe. And when they fill out their financial disclosure form they may write John Doe.

I have some people insisting that the names be an exact match across all documents. I was under the impression that the name would need to be consistent across the documentation. The consistency of the names are subject to a reasonable person standard than be required to be exact.

Could you tell me the FDA's position on this?

Thanks for your help,

[redacted]