

From: OC GCP Questions
To: [REDACTED]
Subject: legal name vs nickname
Date: Wednesday, August 09, 2017 6:17:00 AM
Attachments: [REDACTED]

Good morning –

Please review FDA's 1572 guidance
<https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf> It states -

19. How should an investigator's name appear on the 1572?

Section #1 should contain the investigator's full legal name (e.g., name on the investigator's birth certificate or marriage certificate). Titles, degrees, and/or professional qualifications may follow the investigator's legal name, if desired.

This would be expected for all study trial documents.

Kind regards,

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From: [REDACTED]
Sent: Tuesday, August 08, 2017 10:38 AM
To: OC GCP Questions
Subject: legal name vs nickname

Good Morning,

Can you please offer me guidance on whether it is appropriate to use nicknames/shortened names on 1572's, financial disclosures and other clinical trial documents? If it is appropriate, should a memo to file be added to the regulatory binders stating that the nickname is the same person as the legal name?

Thank you for your assistance.

[REDACTED]