From: OC GCP Questions
To: [redacted]
Subject: Guidelines for proper ICF notations
Date: Wednesday, June 24, 2020 12:34:42 PM
Attachments: [redacted]

Good afternoon -

Thank you for your inquiry. A sponsor or an IRB could require that the investigator obtain the subject's initials and date on each page of the consent form. The investigator is required to comply with the sponsor's investigational plan and the IRB's conditions of approval for the study (see 21 CFR § 312.60 for drug and biologics studies and 21 CFR § 812.110(b) for device studies). If the sponsor or IRB had such a requirement, FDA could cite an investigator for failure to comply with the investigational plan or the conditions of approval for the study if the investigator failed to have the subject initial and date each page. However, again this is not an FDA regulatory requirement.

How the initials are noted on the ICF is an internal issue that should be made by the IRB or the sponsor. IRBs often times have internal written procedures in place to handle a certain situation. Please see FDA's guidance on IRB Written Procedures.
https://www.fda.gov/media/99271/download

Kind regards,

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From: [redacted]
Sent: Tuesday, June 23, 2020 2:16 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Guidelines for proper ICF notations

What are the guidelines for the initials on an ICF when the patient has multiple last names.

Do the initials for all of their last names get listed? And what if they do not have a middle initial? Is it left blank or does one of

their last names get listed? Please let me know, thank you.

Warmest Regards,