From: OC GCP Questions
To: [redacted]
Subject: RE: ICF Process
Date: Friday, February 07, 2020 9:10:00 AM
Attachments: [redacted]

Dear [redacted]
Please check with your IRB and sponsor regarding how they want the informed consent process and subsequent documentation handled. There are many ways to meet the requirements of the informed consent regulations, as indicated by the examples you provided.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcpquestions@fda.hhs.gov .

Best regards,

Sheila

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From: [redacted]
Sent: Thursday, February 06, 2020 3:23 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Fwd: ICF Process

Dear Food and Drug Administration,

Do you have any recommendations or preferences between the two different ways to document the informed consent process attached? There is one SOP from [redacted] that includes a dictated note on

the informed consent process and the other process is in the form of a checklist. Are there any checklists that you recommend that includes all important details or is one process (dictated note vs. checklist) preferred over the other one?

Thank you!

Kind Regards,

[redacted]