From: OC GCP Questions
To: [redacted]
Subject: ICH R2 section 8.2.2 and signed sample case report forms
Date: Monday, August 27, 2018 9:39:00 AM
Attachments: [redacted]

Good morning –

It is not a FDA requirement to have the investigator sign a sample CRF and the regulations require very few signatures. However, the sponsor may require or ask the CI to sign sample CRFs. The ICH E-6(R2) is a guidance document. What is written in guidance are recommendations and not required by the regulations.

The regulations state in 312.62(b) "Case histories. An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study."

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Friday, August 24, 2018 11:40 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: ICH R2 section 8.2.2 and signed sample case report forms

Hello-

ICH R2 section 8.2.2 calls for an investigator to sign SAMPLE case report forms with a purpose of To document investigator and sponsor agreement to the ...CRF.

Industry wide, I have not seen an investigator signature on sample case report forms. I have only seen investigator signatures on completed CRFs and sample CRFs filed in the regulatory binder

Please advise on how this should be implemented.

Thanks

[redacted]