From: OC GCP Questions
To: [redacted]
Subject: RE: ICF question for a [redacted] trial
Date: Monday, April 13, 2020 9:26:00 AM
Attachments: [redacted]

Dear [redacted],

FDA's regulations address the confidentiality of informed consent documents in 21 CFR 50.25(a)(5):

> A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

FDA's draft guidance, while not yet final, represents FDA's current thinking on this topic and states, in part:

> The consent process must describe the extent to which confidentiality of records identifying subjects will be maintained (21 CFR 50.25(a)(5)) and should identify all entities, for example, the study sponsor, who may gain access to the records relating to the clinical investigation. The consent process must also note the possibility that FDA may inspect records (21 CFR 50.25(a)(5)) and should not state or imply that FDA needs permission from the subject for access to the records…

In other words, the subject must consent ahead of time to the sharing of any information associated with the study with anyone.

As a general observation, and given the confidential nature of sponsor information, most sponsors do not permit sharing of any information about their study, including subject information, except with companies they have contracted with to participate in the study, e.g., CROs. Please discuss any potential sharing of information with your study sponsors. If they agree to do this, it will require modifying consent forms, getting approval from your IRB/IEC, and informing subjects of the reason for this change in the confidentiality statement. The laws/regulations of your country may also have specific requirements regarding privacy/confidentiality of identifiable information and data. Please check with your local authorities to clarify these issues.

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

Sheila Brown, RN, MS
Policy Analyst

Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration

Tel: 301-796-6563
sheila.brown@fda.hhs.gov

From: [redacted]
Sent: Thursday, April 09, 2020 9:10 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: ICF question for a [redacted] trial

Hello,

I would like to kindly request FDA opinion on an ICF question from an investigator site in [redacted] related to a clinical trial.
Is it acceptable for a site to share a subject signed ICF with other sponsors and CROs?
For example, can the site provide for review the subject signed ICF for a [redacted] study monitored by [redacted] and vice-versa if the subject signed ICFs for both studies?
I'm looking for regulatory guidance allowing this practice or preventing it.
Thank you in advance.
[redacted]