From: OC GCP Questions
To: [redacted]
Subject: surgical data question
Date: Wednesday, February 28, 2018 8:32:00 AM
Attachments: [redacted]

Good morning –

FDA's 1572 form is only used for FDA-regulated IND studies so I am unclear where you would list the SubI since it is not an FDA-regulated trial. I suggest you ask your reviewing IRB for advice.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
[mailto:Molly.Miller@franciscanalliance.org]
Sent: Tuesday, February 27, 2018 8:39 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: surgical data question

Hello,

We have a project that is not a FDA regulated trial but does have IRB approval. It involves collecting retrospective and prospective data on current treatments and surgery. The only procedure in the protocol is subject consent or waiver if approved. Would you require every surgeon to be listed as a SubI in order to collect a subject's data?

Please let me know if you need any additional information. I look forward to your thoughts.

Thank you,

[redacted]