From: OC GCP Questions
To: [redacted]
Subject: RE: Question to FDA on GCP
Date: Wednesday, November 14, 2018 8:52:00 AM
Attachments: [redacted]

Dear [redacted],
It isn't clear whether this is a study regulated by FDA. If the study is being conducted in the United States, you will need to determine which agency has jurisdiction over the study in order to determine which regulations must be followed. Please note that individual states and sometimes local jurisdictions may also have regulations regarding studies involving deceased patients.

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

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst

Office of Special Medical Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration
Tel: 301-796-6563
sheila.brown@fda.hhs.gov

This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 21 CFR 10.85(k), which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Thursday, November 08, 2018 7:18 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question to FDA on GCP

Dear Sir,

I'm working in CRO in charge of clinical operation.

We are preparing an observational study, and wee need to collect data from [redacted].
Would you please let me know which guideline I have to refer?

Best Regards,
[redacted]