From: OC GCP Questions
To: [redacted]
Subject: Question on lost patient laboratory samples
Date: Tuesday, April 04, 2017 1:19:00 PM
Attachments: [redacted]

Good afternoon –

From the limited information is your email, it appears that the site should document the lost samples in the research records. Documentation is important as well as sample accountability whether the samples are de- identified or not. If you have specific questions related to a particular study, CI and sponsors may directly contact the FDA review division that is overseeing the study. If the information for this one subject cannot be found, this may compromise the study data. I would highly recommend that you and/or the sponsor of the study contact the assigned reviewing division(s) for further advisement.

Kind regards,

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

From: [redacted]
Sent: Monday, April 03, 2017 3:13 PM
To: OC GCP Questions
Subject: Question on lost patient laboratory samples

Good day,

I have a questions regarding lost patient lab samples that are de-identified. I want to know if lost patient lab samples by a central labs or a sponsor representative is to be reported and documented at the site level (IRB and patient)? Because the samples are de-identified, this would not be a breach to patient confidentiality but would be a deviation at the sponsor level with regards to sample accountability. Would the site require to note this as a deviation?

Thank you very much for your assistance

Regards,

[redacted]