From: OC GCP Questions
To: [redacted]
Subject: Enquiry
Date: Tuesday, June 02, 2015 11:46:49 AM

Good morning –

All efforts should be made to recover lost documentation and the attempts should be documented in writing with a detailed "note to file" in case an FDA inspection should occur at your site. The subject should be re-consented. Detailed documentation of the situation is important.

You might also want to inform the sponsor of the study and the reviewing IRB/EC of this situation.

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

Kind regards,

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

From: [redacted]
Sent: Tuesday, June 02, 2015 8:37 AM
To: OC GCP Questions
Subject: Enquiry

Dear Sir/Madam,

I would appreciate your help if you can answer my question,

What actions are required to be done by the site staff and the monitor -according to GCP- if the signed informed consent was lost?

Regards,
[redacted]