

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,

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Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 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: 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]