From: OC GCP Questions
To: [redacted]
Subject: ICF Question
Date: Wednesday, November 05, 2014 11:54:37 AM

Good morning,

The regulations are silent on how to handle the issue you describe. There are a number of factors to consider when determining what actions to take in these circumstances. You may wish to consider contacting the sponsor of the study to obtain their input on how to handle the situation. This discussion might include whether the subject had all the information necessary prior to entering the study, whether the institution's IRB should be made aware of the situation, and/or how best to contact the subject should you wish to re-consent the subject. It may be advisable to document any discussions and their outcomes related to the situation and keeping such documentation in appropriate study files.

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

-----Original Message-----
From: [redacted]
Sent: Tuesday, November 04, 2014 2:44 PM
To: OC GCP Questions
Subject: ICF Question

What is the agency view on a missing IFC page? The page missing is the optional information page.