From: OC GCP Questions
To: [redacted]
Subject: Copy of the ICF
Date: Tuesday, August 25, 2020 1:34:02 PM
Attachments: [redacted]

Good afternoon –

Thank you for your inquiry. FDA regulations do not require that the informed consent document provided to the subject be signed, just that it be the same ICF as the one that is signed and maintained in the study records. The scenarios you describe appears to not conflict with FDA regulations. However, internal SOPs should be developed to ensure consistency.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration

From: [redacted]
Sent: Monday, August 24, 2020 6:16 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Copy of the ICF

Hello,

According to GCP, it is written that the patient should receive a copy of the ICF. In this case, 2 copies could be 2 signed originals (one for the patient and one for the investigational site), 1 original signed ICF for the investigational site and 1 photocopy of the original signed ICF given to the patient or 1

original signed ICF for the investigational site and 1 photocopy with no signatures of the ICF for the patient. Correct?

Warm regards,