

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

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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,

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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.

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**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,

