

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Informed Consent
Date: Monday, October 06, 2014 2:56:28 PM

Good afternoon,

Your email was forwarded to our GCP queries box for a response. Our new draft informed consent guidance concerning physically challenged subjects states:

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf>

A person who is physically challenged (for example, physically unable to talk or write or has hearing or visual loss) can enroll in a clinical investigation if competent and able to signal consent when consistent with applicable State law. The records relating to the clinical investigation must include documentation of the informed consent process (21 CFR 50.27) unless excepted under 21 CFR 56.109(c). FDA recommends that the subject's case history include a description of the specific means by which the prospective subject communicated agreement to take part in the clinical investigation and how questions were answered.

Please also note that FDA's regulations only require a witness when a short form consent is used (see 21 CFR 50.27(b)(2)).

FDA does not think it is appropriate for the friend to sign the subject's name for him/her and that the lack of subject signature be explained in the case history.

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

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, September 30, 2014 2:52 PM
To: [redacted]
Subject: Informed Consent

Good afternoon Marsha,

I have a question about whether it is acceptable for a friend of a subject to sign the ICF on behalf of the subject if the subject verbally requests it. For example, subject's friend assisted subject on the original ICF with writing the date and therefore, subject friend also signed ICF as an impartial witness. Subject is alert and oriented and able to speak and make needs know. Subject has a hx of CVA and right hemiparesis. Later there was a revision to the ICF

which was read and explained to the subject. At that time subject had difficulty holding the pen and subject asked his friend to sign on his behalf. The subject's friend signed the subject's name and also signed their own name as an impartial witness. Is this acceptable or should the subject's signature have been left off the ICF and only the witness sign?

Thank you,
[redacted]