From: OC GCP Questions
To: [redacted]
Subject: competent subject capable of granting consent but physically unable to sign or make a mark?
Date: Friday, June 13, 2014 10:18:32 AM

Good morning –

I've consulted with my colleagues here in OGCP and this is what we have discussed.

We is not aware of any guidance on this issue and FDA has no specific expectations that an investigator or an IRB plan ahead for obtaining consent from subjects physically unable to sign written consent unless the nature of the research was likely to include such populations. However if during the conduct of a trial you come across an individual you want to enroll who is unable to sign written consent in the traditional manner then you may want to consider options such as signing it electronically or using a witness and having the subject make a mark through some mechanism. Often paraplegics are equipped with tools to permit interactions with computers to facilitate communication and mobility so I think the use of electronic signature might be the way to go.

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. FDA recommends that investigators accommodate the specific needs of the study population.

I am aware that you are inquiring as an IRB specialist, however, If an investigator comes across a potential participant who is a paraplegic and not able to make a mark, much less sign and date the consent form, FDA recommends that the CI discuss this with his/her IRB who should be informed and can likely help them determine an adequate mechanism to present the consent information and document it. The site might also consult their legal counsel for assistance with applicable state law.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have addiitnal questions.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, June 11, 2014 4:19 PM
To: OC GCP Questions
Subject: competent subject capable of granting consent but physically unable to sign or make a mark?

Hello,
I've looked through the regs, the information sheet on Informed Consent, and your archive of replies to GCP inquiries, and have found guidance regarding planning ahead for obtaining consent from subjects physically unable to sign written consent.

However, could you please clarify what is expected of a study team that isn't planning to specifically recruit subjects from a target population unable to write (and therefore witness signature lines were not previously included on the IRB-approved consent form) who come across a potential participant who is paraplegic and not able to make a mark, much less sign and date the consent form?

If the consent process, observed by a witness, was documented in the study record, who should've signed what? Study staff were hesitant to make any alteration to the approved consent form, but leaving the subject name, date, and signature lines empty didn't seem like a good option either.

Thank you,
[redacted]