From: OC GCP Questions
To: [redacted].
Subject: FDA advise requested on Impartial Witness- when is an IW needed
Date: Wednesday, March 16, 2016 11:39:18 AM
Attachments: [redacted]

Good morning –

Since you are located in [redacted] you should check with your local authorities also.

FDA's regulations on informed consent do not use or define the terms "impartial witness" or "independent witness". The regulations require a witness when a "short form" written consent document is used, see 21 CFR 50.27(b)(2), which states:

A short form written consent document stating that the elements of informed consent required by 50.25 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.

In FDA's "A Guide to Informed Consent - Information Sheet Guidance for Institutional Review Boards and Clinical Investigators", available at www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm, however, the term "impartial witness" is used in the section on "Illiterate English-Speaking Subjects"; however, no definition of "impartial witness" is provided:

A person who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" on the consent document, when consistent with applicable state law.

A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means. If (1) the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent) and (2) is able to indicate approval or disapproval to study entry, they may be entered into the study. The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document.

A witness is only required with the two scenarios stated above. It is generally assumed that as long as the person is not a member of the study team and not under the direct supervision of the investigator or other members of the study team, it seems reasonable to believe that person could be an impartial witness.

Please see our draft guidance document on informed consent. Witness is explained throughout the document
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf

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:
To: OC GCP Questions
Subject: FDA advise requested on Impartial Witness- when is an IW needed

Dear GCP FDA advisory team,

As per ICH GCP E6 section 4.8.9
4.8.9 If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion.
Per this statement my understanding is that an impartial witness is only needed if the subject or LAR is unable to read the ICF, however I have an ethics person pushing back to the site saying that Impartial witness is needed for all patients even if they are able to read and understand the consent form. Keeping in mind that this trial is not recruiting any vulnerable or special cases subjects of any sort, I would argue that, IMPARTIAL WITNESS is only needed when the patient cannot read/ understand the Informed consent.

Could you please advise the FDA's stand on this. Does FDA require an impartial witness for all patients, even if they are able to read and understand the consent form well?

Thanks and best regards,

[redacted]