From: OC GCP Questions
To: [redacted]
Subject: Witness to Consent Question
Date: Tuesday, August 18, 2020 11:05:00 AM

Good morning-

Thank you for your inquiry. A witness is not required by FDA's regulations unless a "short form" consent document is used.

A witness should be a neutral and impartial third party. When required, a witness should be an impartial adult such as, for example, an adult who is not a member of the study team and who is not a family member of the participant. A signature of the witness means the requirements for informed consent have been satisfied and consent is voluntary and freely given by the participant, guardian, or legally-authorized representative. For reference, see Guidance for Industry - E6 Good Clinical Practice: Consolidated Guidance, at page 4, paragraph 1.26; “Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.” https://www.fda.gov/media/93884/download

Here are the regulations for documenting informed consent:

"21 CFR 50.27 Documentation of Informed Consent

(a) Except as provided in 56.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form. (b) Except as provided in 56.109(c), the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by 50.25. This form may be read to the subject or the subject's legally authorized representative, but , in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed. (2) 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."

FDA's "Information Sheets" provide additional guidance about documenting informed consent including use of the "short form," and the requirement that a witness be present when the short form is used:

"The informed consent documentation requirements [21 CFR 50.27] permit the use of either a written consent document that embodies the elements of informed consent or a "short form" stating that the elements of informed consent have been presented orally to the subject. Whichever document is used, a copy must be given to the person signing the document.

"When a short form consent document is to be used [21 CFR 50.27(b)(2)], the IRB should review and approve the written summary of the full information to be presented orally to the subjects. A witness is required to attest to the adequacy of the consent process and to the subject's voluntary consent. Therefore, the witness must be present during the entire consent interview, not just for signing the documents. The subject or the subject's legally authorized representative must sign and date the short form. The witness must sign both the short form and a copy of the summary, and the person actually obtaining the consent must sign a copy of the summary. The subject or the representative must be given a copy of the summary as well as a copy of the short form. While the regulations do

not prohibit the use of multiple consent documents, FDA suggests that they be used with caution. Multiple consent documents may be confusing to a research subject and if, inadvertently, one document is not presented, critical information may not be relayed to the research subject. For some studies, however, the use of multiple documents may improve subject understanding by "staging" information in the consent process. This process may be useful for studies with separate and distinct, but linked, phases through which the subject may proceed. If this technique is used, the initial document should explain that subjects will be asked to participate in the additional phases. It should be clear whether the phases are steps in one study or separate but interrelated studies. For certain types of studies, the Agency encourages the process of renewing the consent of subjects."

Here is a direct link to the information sheets: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guide-informed-consent

https://www.fda.gov/patients/clinical-trials-what-patients-need-know/informed-consent-clinical-trials

Again, The witness to the consent process witnesses the delivery of information given to the subject or the subject's legally authorized representative as well as the signature on the consent form. The purpose of the witness is generally to ensure that the information was accurately conveyed, questions were answered, and the subject voluntarily consented through signing the form. In some cases the witness may help to clarify information when a subject has difficulty understanding something being said. The 1981 preamble to the informed consent regulations state that "...a witness must be present to attest to the adequacy of the consent process and to the voluntariness of the subject's consent. See 46 FR 8949, comment 52. January 27, 1981. Thus, we expect the witness to be present during the entire consent interview, not just for signing the documents. The FDA regulations are silent as to who can serve as the witness. There is consensus I believe that the witness needs to be impartial and knowledgeable in order to perform these tasks.

Kind regards,

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-----Original Message-----
From: [redacted]
Sent: Monday, August 17, 2020 5:02 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Witness to Consent Question

If a subject is literate (can read and write), speaks and understand English, and is mentally competent, is a witness required when the subjects signs the consent? If so, must it be an impartial witness?

[redacted]