From: OC GCP Questions
To: [redacted]
Subject: Question regarding witness in the ICF process
Date: Monday, October 20, 2014 2:16:58 PM
Importance: High

Good afternoon,

In general, 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 states 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 (link: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm113818.htm). Thus, FDA expects the witness to be present during the entire consent interview, not just for signing the documents.

FDA's regulations are silent as to who can serve as a witness to the informed consent process, but FDA recommends that **an impartial third party, not otherwise connected with the clinical investigation, serve as the witness. [Emphasis added**] Generally, in order to be impartial, the witness should not have a relationship with the subject as well as being unconnected with the clinical investigation. In order to fulfill the role of a witness (such as ensuring that information was accurately conveyed), the person acting as the impartial witness would need to understand the medical and design aspects of the study in order to attest that the information discussed was an adequate description of the study. It is expected that the subject read the consent form unless otherwise not able to do so.

See link below to A Guide to Informed Consent. The witness role is also mentioned in this guidance.
Guidances > A Guide to Informed Consent - Information Sheet

Additionally, FDA recently issued a new draft guidance on informed consent. Please see the link below.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hh.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

From: [redacted]
Sent: Friday, October 17, 2014 5:09 PM

To: OC GCP Questions
Subject: Question regarding witness in the ICF process
Importance: High

Hope are you fine!!

I want to ask you who do not can be a witness during ICF process?
I know that is a question with several answers but if you can give several examples is great?
Also, I want to know if a randomized subject can be witness of other possible subject for the same study?

Thanks in advance for your prompt response

Best regards
[redacted]