

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: FDA advise requested on Impartial Witness
Date: Wednesday, May 21, 2014 9:11:34 AM

Good morning,

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. 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.

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](#)

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

Kind regards,

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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: Wednesday, May 21, 2014 1:04 AM
To: OC GCP Questions
Subject: FDA advise requested on Impartial Witness

Dear GCP FDA advisory team,

I would like to obtain your feedback on FDA's position on Impartial witness. Generally I would like to know if FDA accepts family members of a subject as an acceptable impartial witness for an Informed consent process? There have been different opinions throughout the industry on this issue and a clear clarification from FDA office would be really useful for us to advise the site staff and train them on FDA's expectations.

Awaiting your early response,

Thanks in advance and best regards,
[Redacted]