

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Question: Can a study subject act as an impartial witness?  
**Date:** Wednesday, August 13, 2014 11:29:05 AM  
**Importance:** High

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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. [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Additionally, FDA recently issued a new draft guidance on informed consent.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](mailto: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.

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**From:** FYXUM/XQ  
**Sent:** Wednesday, August 13, 2014 12:15 AM

**To:** OC GCP Questions

**Subject:** Question: Can a study subject act as an impartial witness?

**Importance:** High

Dear Sirs,

Referring to 1.26, ICH-GCP, E6, the definition of 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.

My concern is: if a subject who is participating in the study can act as an impartial witness in the Informed Consent Form process for other subject in the same study?

Can this subject already participating in the same study be considered as Impartial witness, this subject is independent of the trial? Can be considered independent of the trial if the subject is participating in the same study?

What is the interpretation of this ICH-GCP statement talking about "who is independent of the trial". What is the opinion of FDA about this? Could be considered an inspection finding if a study subject act as a witness in the ICF process for other subjects in the same study?

I would appreciate your help to clarify this questions

I look forward to hearing from you

Kind Regards,