From: OC GCP Questions
To: [redacted]
Subject: ICF question
Date: Monday, March 31, 2014 12:25:28 PM

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. 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

Lastly, FDA cannot comment on what should be included in an informed consent based on Virginia law/regulations.

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: Thursday, March 27, 2014 3:11 PM
To: OC GCP Questions
Subject: ICF question

Greetings,
I am writing to ask for a reference point to a debate I had with a friend of mine in clinical research. We were discussing the difference between witness and impartial witness as it pertains to the informed consent process. In some cases it is require to have a witness signature and in some cases an impartial witness line is provided in the ICF just in case. So I guess I have a three part questions

1. In ICH E6/GCP it explains an impartial witness. When the definition is broken down the part we were curious about is as follows “Who is independent of the trial:” This could be a person who is a family member. It would not be a member of the site staff involved with the study." does this mean it CAN be a staff member of the site as long as they have no part in the study?

2. In some states like Virginia a witness is required to be present during the consent process and then they must sign the informed consent. Can the terms witness and impartial witness be used interchangeably on issued informed consents to satisfy this requirement. I have attached the section of the code for your reference.

Current Commonwealth of Virginia Code
Commonwealth of Virginia Legislative Code Chapter 5.1 Human Research, section 32.1-162.18. Informed consent, paragraph A. it reads *“A. IN ORDER TO CONDUCT HUMAN RESEARCH IN THIS COMMONWEALTH, INFORMED CONSENT MUST BE OBTAINED IF THE PERSON WHO IS TO BE THE HUMAN SUBJECT IS AS FOLLOWS: (I) CAPABLE OF MAKING AN INFORMED DECISION, THEN IT SHALL BE SUBSCRIBED TO IN WRITING BY THE PERSON AND WITNESSED.”*

In Commonwealth of Virginia Legislative Code Chapter 5.1 Human Research, section 54.1-2982. definitions. A “witness” is described as follows “''WITNESS'' MEANS ANY PERSON OVER THE AGE OF 18, INCLUDING A SPOUSE OR BLOOD RELATIVE OF THE DECLARANT. EMPLOYEES OF HEALTH CARE FACILITIES AND PHYSICIAN'S OFFICES, WHO ACT IN GOOD FAITH, SHALL BE PERMITTED TO SERVE AS WITNESSES FOR PURPOSES OF THIS ARTICLE.”

3. If a witness line is to be requested to satisfy the above listed commonwealth code. would a basic witness line be sufficient or would the line need to reference the code that requires the signature?

Thank you so much for taking time to answer these questions :)

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Cheers,
[Redacted]