

Good Clinical Practice Q&A: Focus on Informed Consent

Under GCP requirements, must the clinical investigator personally be involved in obtaining informed consent from study subjects? Can the principal investigator delegate the administration of informed consent to study staff, such as a nurse?

21 CFR Section 312.60-General responsibilities of investigators states that, "an investigator shall... obtain the informed consent of each human subject to whom the drug is administered." The ICH GCP guideline states that, "in obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s)."

Although the wording of the GCP regulations and ICH GCP guideline seems to imply an investigator's direct involvement in the informed consent process, it is not required. In fact, the ICH GCP guideline makes clear in several other provisions that the person conducting the informed consent discussion can be "a person designated by the investigator." In its Information Sheets, the FDA notes that "FDA does not specify who this individual should be. Some sponsors and some IRBs require the clinical investigator to personally conduct the consent interview."

Some experts maintain that, particularly for studies that raise issues that are clinically complex, a study physician should be directly involved in the consent process and should participate in a face-to-face discussion with a potential subject.

In some cases, medical assistants who are marginally trained and inexperienced are delegated the responsibility of relating complex clinical issues and study requirements in the consent process without any direct input from a physician. Under these circumstances many industry professionals would conclude that valid informed consent cannot be obtained.

Regardless of who leads the consent process for a site, it is the principal investigator who is ultimately responsible for the administration of informed consent. As noted, although the investigator may delegate the task to appropriately qualified study staff, such as a registered nurse, there are caveats, most importantly that the individual assuming this responsibility must have the requisite clinical background to provide a thorough description of the study and answer the study candidate's questions. Some studies are so complex that only a physician should administer the consent. In many cases, the administration of the consent is a collaborative effort undertaken by both the principal investigator and the study nurse.¹

What qualifies a person to be a "witness" under the FDA GCP provisions or an "impartial witness" under the ICH GCP guideline for the informed consent process? Can a study coordinator or other site staff be considered impartial?

A. The ICH GCP guideline defines impartial witness as "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."

FDA regulations/guidelines make no references regarding what qualifies a person to be a witness.

A study coordinator who is being paid to conduct the study in question would not be considered "impartial." Site staff who are not participating in a particular study might be considered "impartial," so long as they could not be unduly influenced by study staff.

A source document or the informed consent form should document exactly why a witness was necessary. For example, a notation in the source document might state that, "Patient BXY is legally blind."

In many cases, informed consent forms have a witness line, but sponsors and IRBs provide no guidance as to whether a signature on this line is mandatory or optional (and if optional, under what conditions it should be used). Generally, the witness line should be used only if the subject has serious vision or comprehension problems or if the consent process is perceived by the primary consentor to be open to future challenge.

It is important to note, however, that some IRBs require a witness signature irrespective of a subject's ability to read the consent. In such cases, obviously, a witness line would be necessary. If the IRB or sponsor places a witness line on the informed consent form, then the IRB or sponsor should provide written guidance to site staff as to when this line should be signed and by whom.²

References

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2006, pgs. 83-84
2. Ibid, pg. 111

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2005," is available for \$39.95 at <http://www.barnettinternational.com/>