From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, October 20, 2003 4:24 PM
To: [Redacted]
Cc: [Redacted]
Subject: RE: Questions regarding documentation of informed consent

Dear [Redacted],

Under FDA's regulations, an IRB has the authority to observe or have a third party observe the consent process and the research (see 21 CFR 56.109(f)) and is responsible for ensuring that informed consent is appropriately documented (see 21 CFR 56.111(a)(5)). FDA's informed consent regulations only require the use of a witness when a short form written consent document is used. See 21 CFR 50.27(b)(2). In that case, as explained in the preamble to the 1981 regulations, the purpose of the witness is to "...be present to attest to the adequacy of the consent process and to the voluntariness of the subject's consent." See 46 FR 8942 at 8949, comment 52. It is not clear from your email whether a witness would be required under federal regulations (cited above) or whether this is an additional requirement placed on the study by the IRB. If it is the latter, an IRB has the authority to require the use of a witness of the subject's signature if the IRB believes this would increase the protection provided to subjects. If the witness is solely functioning in the capacity of verify the signature of the subject, this should be indicated as the purpose of the witness's signature (in order to avoid confusion about what the witness is in fact witnessing). As to whether the witness needs to be impartial, I believe that you ought to ask the IRB that set forth this requirement what it expects. Because the requirement you have cited stems from the IRB and not from federal regulations, I do not know what the IRB may have expected. If, on the other hand, the IRB is requiring a witness because the consent process and documentation is consistent with use of a short form consent document, then you would be required to have a witness who could attest to the adequacy and voluntariness of the process. The veracity of that witness would be enhanced if the individual were impartial and independent from the research activity; however, as you note, this is not required in our regulations.

I hope that this information is helpful to you and your colleagues.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy, GCPP, FDA

-----Original Message-----
From: [Redacted]
Sent: Wednesday, October 15, 2003 2:11 PM
To: 'gcpquestions@oc.fda.gov'
Cc: [Redacted]
Subject: Questions regarding documentation of informed consent

To whom it may concern,

Could you please assist us by providing the Agency's view of the following.

An IRB for a investigational site of a clinical trial requires a witness

signature on the written informed consent document in addition to the subject and investigator's signature. The IRB defines the witness as a witness to the signature of the trial subject on the form and not a witness to the consent process. The IRB further denotes that the witness can be anyone since it is just a witness to the subject's signature.

Federal regulations only require a witness in the case of oral presentation (21 CFR 50.27). ICH-GCP addresses a witness in the event that the subject is unable to read (ICH-GCP 4.8.9). In this particular case, the IRB is requiring a witness for all subjects but only as witness to the subject's signature. ICH-GCP also defines a witness in the context of a subject as unable to read as an "impartial witness". The Federal Regulations do not define a witness. Finally, FDA Information Sheets, 1998, denote that consent is a process and not simply the signing of a form.

Is it acceptable practice for the IRB to require a witness to the subject's signature and not the consent process? In this context, does the witness need to be impartial?

Thanks,

[Redacted]