From: OC GCP Questions
To: [redacted]
Subject: RE: Impartial Witness Signature
Date: Thursday, August 20, 2020 7:23:00 AM
Attachments: [redacted]

[redacted]

It is not clear from your query whether this study is under FDA's regulations, HHS regulations (i.e., a federally funded study), or both (i.e., a federally funded study of a medical product regulated by FDA).

FDA's only requirement for a witness to sign an informed consent document is when a 'short form' consent is used, per 21 CFR 50.27(b) (2):

> A *short form* written consent document stating that the elements of informed consent required by §50.25 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.

As noted in FDA's 2014 draft *Informed Consent Information Sheet* guidance, an *impartial* witness is *recommended* when using a short form consent, but this is not a regulatory requirement for FDA regulated studies:

> Use of the short form requires that a witness be present to the oral presentation of information to the subject or the subject's legally authorized representative. (21 CFR 50.27(b)(2).) FDA recommends that an impartial third party, not otherwise connected with the clinical investigation (for example, clinical staff not involved in the research or a patient advocate), serve as the witness. FDA recommends that the witness be present (physically or by some other means, for example by phone or video conference) during the entire consent process, not just the signing of the consent form. The purpose of the witness is generally to attest to the voluntariness of the subject's consent and the adequacy of the consent process by ensuring that the information was accurately conveyed and that the subject's questions were answered.

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's or Agency's) current thinking on this topic. It can be found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent

Under FDA's regulations, failure to have an impartial witness sign all informed consent forms would not generally be considered to be a protocol deviation, unless perhaps the signature of an impartial witness was specifically required by the protocol. However, the study sponsor's requirements for informed consent documentation, your institution's policies, or the IRB's requirements may require that an impartial witness sign all informed consent forms. You should consult your IRB and institution to clarify any such requirements. You may also wish

to discuss this request with the CRO who is instructing you in this matter. If your study is federally funded, you may wish to check with the Office of Human Research Protections (OHRP) at OHRP@HHS.gov regarding their informed consent regulations at 45 CFR 46.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcpquestions@fda.hhs.gov .

Best regards,

Sheila

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[redacted]

Subject: Impartial Witness Signature

Good morning,

It has come to our attention that we did not have an "impartial" witness sign on our consent forms. This was noted by a CRO audit of one of our studies. The auditor noted that we should mark this as a protocol deviation and follow our normal procedure for reporting to our IRB if necessary.

Is this truly a protocol deviation or is it something else, and how would we address it?

Thanks.

[redacted]