From: OC GCP Questions
To: [redacted]
Subject: RE: GCP_Informed Consent_Copy Of ICF to Impartial Witness
Date: Tuesday, December 27, 2016 10:40:00 AM
Attachments: [redacted]

It is not clear whether or not you are talking about a witnessed short form. 21 CFR 50.27(b) describes the two methods of documenting informed consent:

(b) Except as provided in 56.109(c), the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by 50.25. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

(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.

Witnesses usually only sign a consent form; in general, only the subject/LAR receive a copy of the document. Whether or not a witness receives a copy of the informed consent document is not addressed in FDA's regulations, although there may be local laws or regulations, institutional policy, or policy by the ethics committee that reviewed your study as to who has access to this document. Please check with your IRB and sponsor to see if witnesses may be permitted to have a copy of the informed consent document.

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

Best regards,

Sheila

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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.

From: [redacted]
Sent: Sunday, December 25, 2016 11:22 PM
To: OC GCP Questions
Subject: GCP_Informed Consent_Copy Of ICF to Impartial Witness

HI,

Can a site can provide a copy of fully executed consent from to Impartial witness, were its not the requirement/request of site SOP or ICE SOP.

my view is impartial witness are witnessing the consenting process but not taking any decision on behalf of subject, sometimes or most of the cases Impartial witness are from out of the hospital/institute. giving a copy of consent with subject personal details entered on ICF could compromise the confidentiality of the subject. if we provide a copy of consent to impartial witness they will carry this out of the institute or Hospital, where a sponsor or CRO or Site have control to when it goes out.

any documentation suggestions that need to be in place where CRO/Sponsor requested the site to follow this type of process.

Regards,
[redacted]