From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, March 27, 2002 1:13 PM
To: [purged]
Subject: RE:

[purged],

FDA does have regulations that speak to the informed consent process, but not to the degree that you might hope. FDA's regulations at 21 CFR 50.20 state:

"Except as provided in Sect. 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence."

In order to provide the subject with "sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence" it is reasonable, following a discussion of the study (with an opportunity to have questions answered), to give the subject the consent form to take home and consider the information further. This also allows the subject to discuss with family members the study information and whether the subject should consent to participate. If the consent form is a "long" form (as described in 21 CFR 50.27(b)(1)), then there is no reason why the subject could not sign it at home or outside of the clinic. If, however, the consent form is a "short" form (as described in 21 CFR 50.27(b)(2)), then there must be a witness, and in that case, the witness must be present both for the oral presentation as well as for the signature.

Although I believe the International Conference on Harmonisation guidelines suggest that the investigator should also sign the consent form, there is no requirement in FDA's regulations that this be done. If, as noted above, the consent form is a "short" form, it must be signed by both the subject (or the subject's legally authorized representative) and the witness before the subject can participate in any aspect of the study (including a questionnaire).

I hope that this information is helpful to you.

Bonnie

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-----Original Message-----
From: [purged]
Sent: Tuesday, March 26, 2002 2:56 PM
To: gcpquestions@oc.fda.gov
Subject:

Hello,
I have a few questions regarding good clinical practice with the consent form process. Does the FDA have any regulations that speak to the process? Specifically, can a patient sign the consent form at their home, outside of the clinic where they will be treated? Can a patient complete a questionnaire required by the study after they have signed the consent form but prior to the investigator signing the consent form? Thank you for your help.

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