From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, August 30, 2004 12:24 PM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear [Redacted],

It's really up to the IRB to determine the process it will require for obtaining informed consent, as long as that process is consistent with the regulations. As you know 21 CFR §50.27(b)(2) requires the person getting the consent to sign the form; it does not require the signature of the investigator (assuming consent is obtained by someone else). If, however, there is a space on the consent form for the investigator to sign, then we assume the IRB requires that signature and we may note that as a violation of the regulations if the signature is missing. As I've said, there is no requirement, however, on our part, for the investigator to sign the form.

I am confused about your question regarding just one person signing the consent form; I'm assuming the subject will also sign it—if I'm wrong, and you're talking about the waiver of documentation contained in 56.109(c)(1), then in that case, because consent is not documented, there is no signature by anyone. To meet the criteria of that rule, generally the research needs to involve minimal risk (defined in the regulations) and no procedures for which consent is required outside the research context. For the latter, that is generally determined in large part by State law and the IRB. If I have not been responsive to your question, please let me know and try to provide further information. I hope this has been helpful, however.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: CDER DRUGINFO
Sent: Tuesday, August 17, 2004 1:32 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [Redacted]
Sent: Wednesday, July 21, 2004 8:35 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: I am working with our institutuion to develop a policy & procedure that meets the regulations & guidance documents, but am having difficulty with one area regarding Informed Consent (IC).

We have a small percentage of investigators that conduct only blood draw studies (e.g., registry studies). The IRB currently requires the investigator signature in addition to 'the person who conducts consent'. Since the investigator may delegate consent to a study coordinator (not necessarily a sub-investigator), does the investigator need to sign the informed consent if the regulations are followed?

I realize that if the IRB requests a signature, we must comply, but is there a regulation or guidance document that states the investigator must sign the IC? If our IRB and institution determine we may allow only the person conducting consent sign the IC, do you have any guidance on the parameters we might consider when setting the policy, e.g., low risk or blood draw or is it up to the investigator and IRB discretion?

Feel free to contact me at [Redacted] if you have any questions or if I should direct this question to someone else. I will also be contacting OHRP for their guidance.

Thanks for any help you can offer. - [Redacted]