From: Lee, Bonnie on behalf of OC CCP Questions
Sent: Tuesday, December 10, 2002 5:38 PM
To: [people]
Subject: RE: Informed Consent Amendments Via telephone and Follow-up in Mail

Hi!

Dear [people], I apologize for the delay in responding to your question (below). There is no question that the ideal situation is to comment on a subject, chat in, hold consent discussions, in person. It facilitates one's ability to read a subject's body language, better determine if they truly understand the information presented, provides a far better "opening" for the subject to ask questions, etc. However, where that is not possible, it MAY be acceptable (if the IRB agrees) to hold follow-up conversations over the phone (only assuming that the subject has the written information in hand), and as long as that telephone conversation allows for a mutually-beneficial exchange of information (that is, allows for the subject to ask questions and receive answers to them). I think that there is a difference between what is acceptable and what one ought to strive for...in this instance, unless there is a good and compelling reason for not doing the consent discussion in person, there is seldom a reason to do it in person, that is ought to be done that way. I think that we all have experience with participating in meetings conducted on telephones...they are far less effective than meeting in person. We do those meetings sometimes for very good reasons, but they are not the ideal and should not be done unless those reasons exist.

I hope this is helpful to you. Again, my apologies for the delay in getting back to you.

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

-----Original Message-----
From: [people]
Sent: Monday, October 21, 2002 2:40 PM
To: [people@fda.gov]
Subject: Informed Consent Amendments Via telephone and Follow-up in Mail
Importance: High

Good afternoon,
It has always been my understanding that consent discussions with subjects and/or their legal guardians are to occur in person. I have been challenged on this assumption by a colleague. Is it acceptable to hold informed consent/consent amendment, re-discuss these changes in the protocol, with the subjects/guardians over the phone, mail them a revised consent form for review and signature, and then consider the signed consent via mail. Is this acceptable in your view?
Your response, as usual, is greatly appreciated.

[people]

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