From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, December 10, 2002 2:18 PM
To: [purged]
Subject: RE: informed consent question

Dear [purged], An IRB may establish any policy (which does not conflict with a federal or State regulation), even though that policy may not be required by regulation. Therefore, if your IRB requires something, you should probably ask your IRB why it has done so--there may be no regulatory basis. In fact, in this instance FDA regulations require informed consent from a human subject and the regulations define a "human subject [as]...an individual who is or becomes a participant in research, either as a recipient of the test article or as a control." See 21 CFR part 50.3(g). Thus, technically, if a potential subject were screened and found to be ineligible for a study, then that potential subject would not be a "human subject" under FDA's regulations. That being said, there are many instances were it may be appropriate to obtain a potential subject's consent either for screening interviews or for screening procedures (particularly where there are risks associated with those procedures). In those instances, it is reasonable to require informed consent from the potential subject, but to limit that consent to the screening portion of the study; consent for participation in the study would be sought only from those subjects who were eligible (through the screening mechanism) for entry into the study. Thus, while FDA regulations may not require informed consent for screening purposes, in some cases such consent may be required by State law, institutional policy, or by respect for those individuals who seek entry into a research study.

I apologize for the delay in getting back to you...unfortunately, I 've been ill. I do hope this information is helpful despite my delay.

Sincerely,

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

-----Original Message-----
From: [purgee]
Sent: Wednesday, October 30, 2002 2:11 PM
To: gcpquestions@oc.fda.gov
Subject: informed consent question

I work as a research coordinator in the Portland, OR area and have a question related to screening interviews on potential research subjects.

Our IRB recently revised a policy which now requires that informed consent be obtained before any pre-enrollment interviews take place. More specifically, if a patient is responding to a recruitment announcement, for example, my understanding is that before any medical-related eligibility or screening questions are asked, the potential subject must first be consented.

I was hoping for a brief explanation of this policy and a specific reference to a CFR.

Thanks.

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