From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, December 29, 2004 12:24 PM
To: [Redacted]
Cc: Daciek, Barbara J
Subject: Who Can Consent a Person in a Clinical Trial

Dear [Redacted], I apologize for the delay in responding to your email below. There is no regulatory policy as to the experience needed to provide consent information to a subject in a clinical trial. Clearly, the individual needs to be knowledgeable about the trial so that he/she can describe it, respond to questions, etc. In some instances, there may be a team of individuals who provide and reinforce information provided to the subject both in writing and verbally. However, we stop short in describing specific criteria for the person(s) obtaining informed consent. It is possible, and likely in some circumstances, that the IRB may specify who may obtain consent; and when it does, we would expect the IRB's determinations to be followed. I hope this information is helpful to you. Happy new year.

Bonnie

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

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

-----Original Message-----
From: [Redacted]
Sent: Tuesday, November 16, 2004 7:00 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site (GCP)

Name: [Redacted]

E-Mail: [Redacted]

Comments: Is there Regulatory Policy regarding who may consent a subject to participate in a clinical trial? For example, a person with 10 years regulatory and human protection experience, who is not a nurse or physician?

Please advise.

Many thanks.