From: Lee, Bonnie on behalf of OC-GCP Questions
Sent: Tuesday, November 19, 2002 9:52 AM
To: [people@fda.gov]
Subject: RE: Named person

Dear [people],

I apologize for the delay in responding to your e-mail. FDA's informed consent regulations require the research subject to be provided with information about whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. See 21 CFR 50.25(a)(7). While the clinical investigator may be the appropriate individual to contact for information about the research and possibly in the event of a research-related injury, it may be more appropriate to list a different contact individual for questions about the research subjects' rights. In your e-mail, you asked who might serve as this contact person. In our regulations, we do not specify the types of individuals who might serve this role. However, if you have a research subject advocate within the hospital, that might be an appropriate individual, as could staff to your Ethics Advisory Board, a patient advocate, or other individual separated from the specific research project but with an interest in patient/subject rights. I think that it is important that you seek an individual who can both "listen" to the concerns as well as ensure that appropriate "action" is taken. I'm sorry that I can't be more specific, but I think that there is variability within institutional structures, and the "appropriate person" in one institution may not necessarily be the appropriate individual in another.

Hope this information is helpful to you. And, again, I apologize for the delay in getting back to you.

Sincerely,

Bonnie

Bonnie M. Lee
American Division for Human Subjects Protection
Good Clinical Practice Program, FDA

---- Original Message ----
From: [people]
Sent: Tuesday, October 22, 2002 4:58 AM
To: [people@ora.fda.gov]
Subject: Named person

Lists the contracts managers in the R&D office of the [people] negotiating clinical trials contracts with commercial sponsors.

FDA rules state that there should be a named independent person who can act
as a contact/advocate for patients in clinical trials. I wonder if you
could provide us with a recommendation as to who this person should be
and whether we will be in violation if we do. If, for any, we wonder that there
should be such a person and the patient would generally go to the principal
investigator with any such problems. We are trying to identify who
within the hospital would be the best point of call.

Thanks for your help.

Sincerely,

[people]