From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, October 08, 2004 2:52 PM
To: [Redacted]
Subject: RE: surrogate consent

Dear [Redacted],

A legally authorized representative (LAR) may give informed consent when a potential subject is not competent to do so. State law determines who may serve as a LAR—that is, the relationship between an LAR and subject. The need to obtain consent from an LAR may vary depending on the complexity of the research; for example, a simple blood draw may be basic enough that the subject could understand what it entails and give consent; a complex study may not. If the subject regains the capacity to consent during the research, the subject cannot consent to what has already been done (since it has been done), but they can indicate whether they are willing to continue in the study and should be provided with the opportunity to withdraw from the research where doing so would not endanger the safety of the subject. Based on State law, the IRB can establish standards for documenting the LAR's knowledge of the subject; the hierarchy for decision-making, and the other standards as you described in your email. For more information on this topic, see the National Bioethics Advisory Commission's report entitled Research Involving Persons with Mental Disorders that may affect Decisionmaking Capacity, available online at http://www.georgetown.edu/research/nrcbl/nbac/capacity/TOC.htm.

I hope this helps.

Bonnie

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

-----Original Message-----
From: [Redacted]
Sent: Monday, September 27, 2004 10:52 AM
To: GCPQuestions@OC.FDA.GOV
Subject: surrogate consent

I'm writing for some guidance on surrogate informed consent. Is there a national standard that describes the following issues?

How to document the subject's decision making capacity to give informed consent, and the surrogate's competence?

Under what circumstances surrogate consent for research participation may be permitted?

If surrogates are asked to give consent, means of documenting their relationship to the subject and their willingness to serve as surrogate decision-makers?

What to do in the event the subject regains the capacity to provide informed consent while participating in the research?

Standards for documenting the surrogate's knowledge of the subject, the order of priority the proxy holds in the surrogate tree, and whether possible surrogate decision makers in higher categories in the proxy tree disagree on enrolling the subject or the continued participation fo the subject in the research.

[Redacted]