From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, February 11, 2004 2:01 PM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Mr. [Redacted]:

FDA's regulations do not specifically address the situation you describe.

However, 21 CFR 50.20 requires an investigator to obtain "the legally effective informed consent of the subject or the subject's legally authorized representative." Once a child-subject reaches the age of majority (which may vary according to state law), the parent's permission for the child to participate in the trial would no longer constitute "legally effective informed consent," because the subject, who is now an adult, can make decisions for him/herself and, in fact, should be offered the opportunity to do so. Thus, the site would need to obtain "legally effective informed consent" from the now-adult subject regarding his/her continuation in the study.

With respect to your suggestion to use "another type of form for reaffirming consent," I would have to say that FDA's regulations are fairly specific as to what constitutes legally effective informed consent and what must be included in the form (see 21 CFR 50.27). In short, FDA would expect sites in this situation to reconsent these subjects regarding their participation in the study.

I hope this is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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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: CDER DRUGINFO
Sent: Friday, January 30, 2004 9:47 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [Redacted]
Sent: Friday, January 30, 2004 2:56 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: I have been trying to address the issue of what to do when a pediatric study subject who has assented (and has had parental informed consent/authorization) reaches the age of majority (becomes an adult) during study participation. Does the study subject need to reconsented as an adult using the informed consdent form that the parent used? Can another type of form be used for "reaffirming" consent (an attaching a copy of the original consent form), rather than going through the entire informed consent process? I know that this is of concern for long-term studies when active treatment with the investigational agent may be over and patients are in follow-up observation. Any advice you can give me?