From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, August 10, 2004 1:20 PM
To: [Redacted]
Subject: RE: GCP Question

Dear Dr. [Redacted] --

I'm responding to your question on the necessity of reconsenting a study subject who reaches the age of majority during a study. I apologize for the delay in responding to you.

FDA's regulations do not specifically address the situation you describe.
The answer to your question, however, is yes--FDA would expect sites in this situation to reconsent these subjects regarding their participation in the study. I base this on the following:

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.

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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Rockville, MD 20857

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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: [Redacted]
Sent: Tuesday, January 27, 2004 3:37 PM

To: swoollen@oc.fda.gov
Subject: GCP Question

Dear Stan,

Can you answer this one:
Assume that a 17-year-old provides his/her assent for participation and this his/her parent/LAR provides consent to be in a research study and, during the study, the subject reaches the age of majority in his/her state. Must the subject then be consented/reconsented as an adult?

Best wishes,
[Redacted]