From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, January 28, 2003 3:56 PM
To: [Redacted]
Subject: RE: legal ages

Dear [Redacted] ,

I apologize for the delay in getting back to you. It is State law that determines the legal age for consent to research. There is no "legal age" for assent; rather that is a determination that is left to the Institutional Review Board under FDA's regulations. See 21 CFR 50.55. I hope this information is helpful to you.

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

-----Original Message-----
From: [Redacted]
Sent: Friday, January 03, 2003 2:29 PM
To: gcpquestions@oc.fda.gov
Subject: legal ages

To Whom It May Concern:

I was wondering if the legal ages of consent and assent to participate in a clinical trial were state or federal regulated. If so, can you tell me what they are, or tell me where I can find that information. Thank you.

[Redacted]