From: Lee, Bonnie
Sent: Wednesday, April 30, 2003 9:15 AM
To: [Redacted]
Subject: RE: Patient Consent Form

Sorry, this sent itself prematurely....here's the rest of the answer. (Below)

-----Original Message-----
From: Lee, Bonnie On Behalf Of OC GCP Questions
Sent: Wednesday, April 30, 2003 9:12 AM
To: [Redacted]
Subject: RE: Patient Consent Form

Dear [Redacted],

FDA does not maintain information about State laws. FDA relies on the Institutional Review Board to ascertain the acceptability of proposed research in terms of applicable law (see 21 CFR 56.104) and it is State law that determines the age at which one can legally consent to a research procedure. I hope this is helpful to you.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, HF-34, FDA

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: Wednesday, April 30, 2003 1:46 AM
To: gcpquestions@oc.fda.gov
Subject: Patient Consent Form

Hi,

Could you please let me know at what age a person is legally able to sign a "patient consent form" for a clinical trial that is conducted in [Redacted]?

thank you.

Regards,
[Redacted]