From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, September 09, 2004 4:55 PM
To: [Redacted]
Subject: RE: Question
Dear [Redacted],

FDA has always and continues to defer to state law on issues relating to age of consent, including emancipated minor status. Your understanding is correct.

I hope this is helpful.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy, GCPP, FDA

> -----Original Message-----
> **From:** [Redacted]
> **Sent:** Wednesday, September 08, 2004 9:47 AM
> **To:** 'gcpquestions@oc.fda.gov'
> **Subject:** Question
>
> Thank you in advance for considering this question.
>
> It has always been my understanding that FDA deferred to state law when it comes to legal age of consent/assent/etc. But the following posting on [Redacted] qualifies this by saying that FDA and HHS defer only to a point--that is, the agencies defer to state law ONLY with regard to the LEGAL AGE of consent and that, under Subpart D, the agencies DO NOT allow for state-by-state exceptions to this legal age (e.g., for emancipated minors, etc.). In case I have not captured this issue sufficiently, I have attached the referenced posting below.
>
> Does the passage below accurately capture the FDA's current position--that is, that the agency will not make exceptions based on state laws for emancipated minors and other minors who would otherwise be able to consent to treatment under state laws? If so, will the FDA, as a practical matter, enforce this?
>
> Thanks and best regards,
>
> [Redacted]
>
> Message: 4
> From: [Redacted]
> Date: 2004-09-07 07:58:00
> Subject: Re: What is a child?
>
> >45 CFR 46.402(a) defines "children" as "persons who have not attained
> the legal age for consent to treatments or procedures involved in the
> research, under the applicable law of the jurisdiction in which the
> research will be conducted.

A literal reading of the HHS regulation makes it clear that OHRP is not deferring to state law on who may consent for themselves. The rule explicitly states the person shall attain the LEGAL AGE for consent. The wording provides no exception for emancipated minors or others.
Unfortunately, FDA adopted this same definition in its Subpart D of 21 CFR 50. Prior to subpart D becoming effective, FDA did defer to state law on which children could consent for themselves.

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[Redacted]