From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, December 13, 2004 4:47 PM
To: [Redacted]
Subject: RE: parental permission and possible waiver for use of [Redacted]

Dear Ms. [Redacted]:

I apologize for the delay in responding to your e-mail.

In the situation you've outlined, the testing involves an investigational product under FDA's jurisdiction, and is therefore research within the meaning of the Food, Drug, and Cosmetic Act and FDA regulations.

You are correct that FDA regulations do not allow for waiver of informed consent except under very limited circumstances. This is in contrast to HHS' regulations which do contain a provision for IRB waiver of the parental permission requirement. Based on your e-mail, because the study involves an FDA regulated product, FDA's regulations would need to be followed.

The answer to your other question about the age of consent is that it depends on the law of the particular state in which the research takes place [21 CFR 50.3(o)]. State law can vary widely from jurisdiction to jurisdiction, and such variations in different states' laws allow individuals to execute informed consent at different ages for different things. For example, even though a 17-year old is able to consent for themselves to donate blood in a particular state, the same state may require an individual to be 18 in order to give consent to participate in research (such as [Redacted]). Perhaps your institution's legal department can provide you with an opinion on the activities for which a "mature minor" can give consent in your state.

Unless your state's law also states that a 17-year old is able to provide informed consent to participate in research, then FDA's regulations for research involving pediatric subjects (21 CFR 50, Subpart D) apply and parental permission/assent would need to be obtained in accordance with procedures that the IRB has reviewed and approved for the study.

I hope this is helpful.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
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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: Monday, October 18, 2004 7:10 PM
To: gcpquestions@oc.fda.gov
Subject: parental permission and possible waiver for use of [Redacted]

Dear FDA,

We are an IRB that has reviewed a protocol for an investigational test kit to test [Redacted]. The "study" is set up such that they want all persons donating blood to have the test, so the option is donate blood and participate in the research, or not donate blood because the persons in charge of the blood distribution ([Redacted]) will not accept blood that has not been tested. We are in the state of Illinois, which has a legal age of consent at 18. We at the IRB have indicated that children age 17 cannot be enrolled in the research, which effectively eliminates them as blood donors, without parental permission, because the FDA regulations do not allow a waiver of parental permission.

However, [Redacted] and the PI have indicated that the state law does allow a 17 year old to donate blood without parental permission. We are taking the stance that this is not limited to donating blood, but also involves research participation, and therefore the federal regulations apply and the 17 year olds cannot participate without parental permission. The PI has indicated that every other site all over the country including in Illinois is enrolling minors (age 17) because of the same or similar state law that 17 year olds can provide consent for a blood draw. [Redacted] has informed the sites that the state law supercedes the federal regulations. We insist that this cannot be the case and have offered two options:

1) they send parental permission documents home and only those 17 year olds who return them on the day of the blood draw can donate their blood.

2) they need some documentation from the FDA that the parental permission requirement for this"study" has been waived by the FDA to agree with the state law for donor consent, not necessarily research consent.

I was hoping we could get some ruling on the parental permission issue and whether the FDA has or would grant such a waiver. I was looking at the FDA information sheets and it indicated that although portions of IRB review could be waived, consent could not. So, I am not sure that such a waiver is really possible. I simply do not understand how all other sites in the US, including in Illinois are enrolling 17 year olds without parental permission. Would this data be allowed by the FDA in support of the NDA application, if the consent was not legally effective consent for research?

[Redacted]