From: OC GCP Questions
To: [redacted]
Subject: informed consent - patients under 18
Date: Wednesday, October 14, 2015 11:56:42 AM

Good morning –

It appears from the limited information in your email that the subject at age 17 would be ineligible as the subject did not meet inclusion criteria according to his/her age. Additionally in most states, at age 17, the individual is still considered a minor and would need someone to sign for the subject (assent or LAR).

In title 21, Code of Federal Regulations (CFR), § 50.3(l), "Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research." In 21 CFR 50.3(l), the federal regulations defer to "applicable law". Therefore, who may serve as a legally authorized representative (LAR) is determined by the applicable State or local law.

In 21 CFR 50.3(s), "Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research. For purposes of subpart D of this part [21 CFR part 50], a guardian also means an individual who is authorized to consent on behalf of a child to participate in research." In 21 CFR 50.3(s), the federal regulations defer to "applicable State or local law". Please note, in 21 CFR 50.55(f), that permission by parents or guardians must be documented in accordance with and to the extent required by 21 CFR 50.27 – Documentation of informed consent. For the applicable federal regulations, please see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50.

You did not indicate whether the 17 year old subject received investigational product. I strongly suggest you discuss this situation with your reviewing IRB and the sponsor of the study. Any corrections that are made should be documented in the study records.

You might find helpful FDA's guidance document on frequently asked questions. Please see "Institutional Review Boards Frequently Asked Questions - Information Sheet", at www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, 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.

From: [redacted]

Sent: Tuesday, October 13, 2015 5:06 PM
To: OC GCP Questions
Subject: informed consent - patients under 18

If a protocol requires a patient to be 18 yrs or older to participate in the study and the patient signs consent 1 week prior to his/her 18th birthday should this patient be considered ineligible since he/she is technically 17 when signing consent? What if the patient signs consent at age 17 and turns 18 one week later and is registered in the database when he/she is 18?

Thank you.

[redacted]