From: OC GCP Questions
To: [redacted]
Subject: RE: Question concerning Inform Consent from parents and assent on minors
Date: Thursday, September 10, 2015 4:27:13 PM

Hi [redacted],

Thank you for your question. The regulatory requirements related to obtaining assent from children involved in FDA regulated clinical investigations can be found at 21 CFR 50 Subpart D. The relevant passage on assent is primarily discussed at Sec 50.55. FDA guidance on informed consent and assent can be found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm. Among other responsibilities, FDA regulations require the institutional review board (frequently called ethic review committees outside the United States) to determine when obtaining assent is appropriate. FDA would expect the institutional review board would consider requiring the clinical investigator obtain assent from children who possess the intellectual and emotional ability to comprehend the concepts involved with the proposed research. Assent is not mandatory by FDA regulations but when it is obtained it should include an age appropriate discussion about the research interventions and related procedures and be in a language understandable to the subject. Assent, if obtained, would be in addition to obtaining permission from the parent(s) or the child's legally authorized/legally acceptable representative. Generally, assent from children would be obtained after permission is obtained from the parent(s) or the legally authorized/legally acceptable representative.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Kevin
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From: [redacted]
Sent: Tuesday, September 08, 2015 3:12 PM
To: OC GCP Questions
Subject: Question concerning Inform Consent from parents and assent on minors

Dear Sirs,

I would like to know your input on this subject:

A clinical trial in minors with Schizophrenia, it means that it is vulnerable subject population, as a minors and as a Psychiatric study.

Considering that the subjects to be enrolled are minors (teen agers) , the Informed consent must be provided by their parents as legally acceptable representative. Then, as the first thing to do is to conduct the Informed Consent process with parents.
As it is stated in GCP , ICH, E6 Item 4.8.12. *When a clinical trial includes subjects who can only be enrolled in the trial with the consent of the subject´s legally acceptable representative (e.g. minors), the subject should be informed about the trial to the extent compatible with the subject´s understanding and, if capable, the subject should sign and personally date the written informed consent*. In this item are we talking about to have the assent from the subject, if he/she is capable and after having the Informed Consent of their parents?

Kind Regards,

[redacted]