

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: RE: Pediatrician required for subjects of 16- 17 Yrs age?
Date: Tuesday, February 24, 2015 1:48:16 PM

Hi [REDACTED]

Thank you for your question. The regulations that govern FDA research does not specifically require that a pediatrician be present in the EC quorum while approving the study protocol. Specifically, 21 CFR 56.107(c) states that the IRB must review proposed non-exempt research at "convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas." So the only specific type of individual that needs to be present for the quorum is the nonscientist. However, if the IRB regularly reviews research that involves children, consideration should be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with children (see 21 CFR 56.107). <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=56>

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.

Thanks

Kevin

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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.

From: [REDACTED]
Sent: Tuesday, February 24, 2015 1:14 AM
To: OC GCP Questions
Subject: Pediatrician required for subjects of 16- 17 Yrs age?

Hi,

There is a study which enrolls adult subjects (>18yrs age) and also subjects who are 16 & 17 yrs of age. ICH E11 defines Adolescents (12 to 16-18 years (dependent on region)) as

sub group of Pediatric population. Hence, For such studies, does the Ethics Committee require a Pediatrician present in the EC quorum while approving the study protocol?
Please opine.

Thanks

Regards

