From: OC GCP Questions
To: [redacted]
Subject: question regarding ICH E11 2.6.1 Pediatric experts
Date: Wednesday, April 23, 2014 4:31:35 PM

Good afternoon –

Below is an answer to a similar question from our senior ethicist in our office.

Kind regards,

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

FDA does not have guidance that addresses this matter specifically. Generally, FDA relies upon the judgment of the institutional review boards and the independent ethics committees in making the determination that the IRB/IEC is appropriately comprised. As you may know, IRB/IEC membership should include individuals sufficiently qualified through experience and expertise.

The expertise needed on the IRB/IEC depends on many factors including, the protocol under review (protocol-specific), the disease under study, the study population, and what types of research is regularly reviewed by the IRB/IEC. An IRB/IEC that regularly reviews research that involves a vulnerable category of subjects, such as children, should include one or more individuals who are knowledgeable about and experienced in working with those subjects. If the IRB/IEC does not possess the professional competence necessary to review the specific research activities or to address the review of complex issues arising in the research, then it may invite individuals -on an ad hoc basis- to assist in the review.

FDA does not have guidance that addresses the "minimum requirement" for a pediatric expert nor does it have guidance that addresses what types of knowledge experts should cover. As can be seen from a review of FDA's regulatory provision on IRB membership, many factors must be considered by the IRB/IEC when reviewing research in order to protect the rights, safety and welfare of human subjects. (See 21 CFR 56.107) These would include, but not be limited to: scientific issues, ethical concerns, race, gender, cultural backgrounds, community attitudes, institutional commitments, applicable laws and regulations, standards of professional conduct and practice, additional protections of vulnerable subjects, etc.

I hope you find this response helpful.

From: [Redacted]
Sent: Wednesday, April 23, 2014 5:00 AM
To: OC GCP Questions
Subject: A question regarding ICH E11 2.6.1 Pediatric experts

Hi Sir,

Hope this email finds you well.
I would like to consult with you regarding the ICH E11, 2.6.1: When protocols involving the pediatric population are reviewed, there should be IRB/IEC members or experts consulted by the IRB/IEC who are knowledgeable in pediatric ethical, clinical, and psychosocial issues.
How can we define the "Pediatric expert"? Any requirement?
The IRB asked if there is an ethics expert specializes in minority care including children for many years. Can he or she be considered as a "Pediatric expert" and fulfil the ICH E11, 2. 6. 1.? Please advise.

Many thanks in advance.
[Redacted]