From: Goldkind, Sara
To: [redacted]
Cc: OC GCP Questions
Subject: RE: ICH E11 question about pediatric experts
Date: Wednesday, April 23, 2014 12:41:58 PM

Ms. [redacted]:

Thank you for inquiring about what constitutes (or defines) pediatric expertise and what that expert should be knowledgeable about (for example, ethical clinical and/or psychosocial issues).

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.

Sincerely,

Sara F. Goldkind, MD, MA
Senior Bioethicist, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration
Tel: 301-796-8342; Fax: 301-847-8640
Email: Sara.Goldkind@fda.hhs.gov

From: [redacted]
Sent: Monday, April 21, 2014 11:48 AM

To: OC GCP Questions
Subject: ICH E11 question about pediatric experts

Dear Sir,

Hope this mail finds you well.

I'd like to ask your advise regarding to the ICH E11 which has stated there should be pediatric experts consulted by IRB when performing pediatric study.

1. How is pediatric experts were defined?

2. And I'd like to clarify the minimum requirement is that there should be pediatric expert knowledgeable in one or two aspects: ethical /clinical /psychosocial issues be consulted or It is mandatory for IRB to consult experts which covered those three aspects ?

1. Institutional Review Board/Independent Ethics Committee (IRB/IEC) (2.6.1)

The roles and responsibilities of IRBs and IECs, as detailed in ICH E6, are critical to the protection of study participants. 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.

Thank you for your kindly reply.

BRs,

[redacted]