From: OC GCP Questions
To: [redacted]
Subject: Question regarding ICH E11 2.6.1 Pediatric experts
Date: Monday, April 14, 2014 3:39:11 PM

Good afternoon –

The guidance document below on IRB indirectly answers your question.

Guidances > Institutional Review Boards Frequently Asked Questions - Information Sheet

17. Which IRB members should be considered to be scientists and non-scientists?

21 CFR 56.107(c) requires at least one member of the IRB to have primary concerns in the scientific area and at least one to have primary concerns in the non-scientific area. Most IRBs include physicians and Ph.D. level physical or biological scientists. Such members satisfy the requirement for at least one scientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as provided by 21 CFR 56.107(f).

FDA believes the intent of the requirement for diversity of disciplines was to include members who had little or no scientific or medical training or experience. Therefore, nurses, pharmacists and other biomedical health professionals should not be regarded to have "primary concerns in the non-scientific area." In the past, lawyers, clergy and ethicists have been cited as examples of persons whose primary concerns would be in non-scientific areas.

Some members have training in both scientific and non-scientific disciplines, such as a J.D., R.N. While such members are of great value to an IRB, other members who are unambiguously non-scientific should be appointed to satisfy the non-scientist requirement.

It would be difficult to specifically answer your question. However if the pediatric RN has the expertise and experience with pediatric clinical trials and/or practice, she/he may be appropriate as a scientific member of the IRB that reviews pediatric studies.

FDA's IRB Compliance Program states –

http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133768.pdf

If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration should be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects. In addition to possessing the professional competency necessary to review the specific research activities, the IRB should be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and practice.

Additionally, I can point you to a few documents to review. Please see ICH E-11 Clinical Investigation of Medicinal Products in the Pediatric Population. Specially, please see section 2.1

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002926.pdf

FDA issued a final rule on Additional Safeguards for Children in Clinical Investigations of Food and Drug Administration-Regulated Products. Please see the link below.

http://www.gpo.gov/fdsys/pkg/FR-2013-02-26/pdf/2013-04387.pdf

Additionally there is a FDA website that specifically discusses pediatric research.

Pediatrics

An additional reference which you may find helpful is An additional reference which you may find helpful is Appendix B (State Regulation of Medical Research with children and Adolescents: An Overview and Analysis by Amy T. Campbell) found in the Institute of Medicine Report on Ethical Conduct of Clinical Research Involving Children, The National Academies Press, Washington, DC. found in the Institute of Medicine Report on Ethical Conduct of Clinical Research Involving Children, The National Academies Press, Washington, DC..

The Ethical Conduct of Clinical Research Involving Children

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

Kind regards,

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Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

-----Original Message-----
From: [redacted]
Sent: Monday, April 14, 2014 12:17 AM
To: OC GCP Questions
Subject: 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 a nurse who works in pediatric department for many years. Can she be considered as a "Pediatric expert"? Please advise.

Many thanks in advance.

[Redacted]