From: OC GCP Questions
To: [redacted]
Subject: Component Analysis
Date: Friday, January 23, 2015 10:55:15 AM

Good morning –

Your question was forwarded to my office for a response. I can direct you to our Pediatrics Ethics web site (first link) and a presentation on component analysis from our pediatric ethicist Dr. Robert (Skip) Nelson (second link). If the side presentation does not answer your question, Skip's email address is on the side. You can email him directly.

Pediatrics > Pediatric Ethics

http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/UCM331657.pdf

I hope this information is helpful.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

-----Original Message-----
From: druginfo@fda.hhs.gov [mailto:druginfo@fda.hhs.gov]
Sent: Thursday, January 22, 2015 12:16 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [redacted]

E-Mail: [redacted]

Comments: I am the [redacted]. I am trying to identify the best practice for conducting and documenting a component analysis during an IRB review of a pediatric clinical trial. However, I am having difficulty finding specific guidance. For example, are there specific things that should be documented at the convened meeting to ensure that a proper component analysis was done? Are there specific questions that an investigator should answer, or justifications they need to

provide? Is it sufficient to document and determine an overall risk level to the study, or do we need to make a risk level determination for each study arm? Thanks for any assistance you can provide.