From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, May 13, 2005 2:58 PM
To: REDACTED
Subject: RE: study involving minors?

Dear REDACTED:

It would seem that there are a couple of things that you should consider.

You didn't mention whether the study is federally funded or if it is being conducted at an institution that has (1) a Federal "assurance" or (2) decided to apply 45 CFR 46 to all research conducted at the institution. If any of these is true, then 45 CFR 46 Subpart B (Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research) would apply. Your IRB would need to find this out so that the research could be reviewed under the appropriate regulations.

Once the children are born, the research is subject to 21 CFR 50, subpart D (Additional Safeguards for Children in Clinical Investigations), so the IRB would need to review the research under these regulations also. (Assessment of the children, if "only" for REDACTED, would still constitute research in the children.)

I hope this is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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Rockville, MD 20857

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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.

-----Original Message-----
From: REDACTED
Sent: Thursday, May 12, 2005 5:26 PM
To: gcpquestions@oc.fda.gov
Subject: study involving minors?

Good Afternoon,
REDACTED IRB is in the process of reviewing a protocol: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-center Study to Assess the Efficacy, Safety, and Tolerability of REDACTED

REDACTED is FDA-approved but not for the current indication (REDACTED). My question is this: Post delivery, the baby will be assessed REDACTED to make sure that the administration of the drug during mother's pregnancy had no effect on the child. These are REDACTED the PI will be able to access information from the charts. No procedures or research will be done on these babies. This being said, is this study technically involving 'minors'?? The babies will be part of the assessment post-drug, but only for REDACTED. When we review this protocol, I need to know if we should assume that it is involving minors as well as pregnant women, or just pregnant women.

I would appreciate your opinion on this.
Thank you,
REDACTED