From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, March 31, 2004 8:04 AM
To: **[Redacted]**
Subject: RE: question regarding informed consent

Dear Ms. **[Redacted]**,

You are correct that under FDA's IRB regulations the IRB has the authority to place conditions on a study that it believes are necessary to protect the rights and welfare of research subjects. In this case, the IRB has indicated that it wants documentation of a parent's consent to either permit their child to receive PK testing or to refuse such testing. While the monitor is correct that declining to participate in the PK testing is not informed "consent", it is informed "refusal" and documents for the record that the child is not taking part in the PK testing part of the study. There is nothing in FDA's regulations that precludes documentation of refusal to participate in a study. Since the IRB has requested this documentation, you would need to document this activity to be in compliance with the conditions the IRB has placed on this study.

I would like to mention that the wording in the consent page may be somewhat problematic. While it is fine to use the phrase "I have read", it is not a good practice to say "and understand" because the parent may not truly understand the study. For that reason, most consent forms don't contain the phrase "and understand".

I hope this information is helpful. Please feel free to let us know if you need any further assistance.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340

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: Friday, March 26, 2004 9:22 AM
To: gcpquestions@oc.fda.gov
Subject: question regarding informed consent

We are participating in a pediatric clinical trial which has a PK sub study with a separate informed consent. We are associated with a central IRB for this study and in their informed consent has a page as follows:

CONSENT

I have read and understand this informed consent document for the Pharmacokinetic sub-study. I have received an explanation of the nature, purpose, duration, and

foreseeable effects and risks of this additional testing with regard to my child and what we will be expected to do. My questions have been answered satisfactorily.

_____ I agree to permit my child to take part in the additional PK testing.

_____ I do not agree to permit my child to take part in the additional PK testing.

What we have been doing at our site is explaining this procedure, giving the parent the consent and having them read, check one of the above boxes and sign the final page. Our monitor however says we should not be having them sign this consent form at all if they do not agree to have their child participate. I want to be doing what is right in regards to FDA, however everything I can determine from 21CFR is the IRB has the authority to require certain things in regards to approval of research.

If we have parents signing this form and checking "no" to agreeing to participate, is this considered fraud and is it against the federal regulations.

Thank you for your help,
[Redacted]