From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, April 02, 2003 3:08 PM
To: [Redacted]
Subject: RE: Informed Consent Forms

Dear [Redacted],

I apologize for the delay in responding to your email (below). I am not sure whether "BMI" refers to a basal metabolic index or something else. Assuming however that it is not relevant to the subjects who have already entered into the study, then you are correct that those subjects do not need to be provided the information or reconsented because the information is not relevant to the subjects or their decision-making. I hope this information is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee

Associate Director for Human Subject Protection Policy

Good Clinical Practice Program, HF-34, FDA

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, March 13, 2003 7:56 PM
To: 'gcpquestions@oc.fda.gov'
Subject: Informed Consent Forms

To whom it may concern,

We have recently had discussions within our department regarding the ICF procedure and paragraph 4.8.2. The paragraph states that the subjects should be informed about any new information that may be relevant to the subject's consent. Thereby making them resign a new consent form.

In one of our trials, the age limit and BMI limit was increased - would this be necessary to obtain all subjects consent once again? Bearing in mind that these changes do not affect their safety and are not relevant to the women, as they are all below the age limit and BMI. We are of the opinion that the participants that are already in the trial do not need to resign, however, of course all new participants should and will sign the new consent form.

We would be very grateful for your feedback on this important issue.
Thank you in advance for your prompt reply.

Kind regards
[Redacted]