From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, April 04, 2003 2:39 PM
To: [Redacted]
Subject: RE: informed consent

Dear [Redacted], While it is really up to your IRB or IEC to determine the adequacy of the informed consent information and process, I do not see a problem with including some statement that subjects will be more closely monitored in a clinical trial if your IEC believes that is true. I believe that there have been studies that have shown that subjects may improve in part due to the increased attention and monitoring they receive in a clinical study. The information should not be over-emphasized as a benefit; but if balanced information is provided, I think that it may be appropriate to mention it as a possible benefit. Again, however, because it depends on the particular study, it is important for the IEC to consider whether the information ought to be included in a particular study's consent form. 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: Friday, April 04, 2003 10:20 AM
To: 'gcpquestions@oc.fda.gov'
Subject: informed consent

Dear Sir/Madam,

I have a question about getting informed consent from the study participants. It is stated in section 4.8.10 of the GCP guidelines that the "reasonably expected benefits" should be explained in the informed consent. Can it be considered part of the benefits that the patient will be closely monitored and will receive more attention from clinicians for his/her health condition during the course of the clinical trial. Or this kind of statements are considered coercive and should not be stated in the informed consent?

Thank you for your time.
[Redacted]