From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, November 14, 2003 2:24 PM
To: [Redacted]
Subject: RE: Informed Consents

Dear [Redacted],

Normally, when an IRB approves a revised consent form, it will indicate that the revised form supersedes all previously approved versions. Even if the IRB has not specified that this is the case, I think that it is fair to assume that is what the IRB intended. (Granted, one can always go back to the IRB and ask what their intentions were.) In the case you have described below, it would seem reasonable to only expect the new subject to sign the 6/15/03 version of the consent form because that is the latest approved version of the consent document. I hope this is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy, GCPP

-----Original Message-----
From: [Redacted]
Sent: Friday, November 07, 2003 12:58 PM
To: gcpquestions@oc.fda.gov
Subject: Informed Consents

Good afternoon-

I would appreciate your input on the following issue:

If an IRB approves a revised ICF on 6/12/03, and then another ICF on 6/15/03 and the subject comes in for a visit on 7/12/03 (the previous visit was 5/12/03) and all information in the 6/12/03 version is also in the 6/15/03 version, is the subject required to sign both ICFs or just the 6/15/03 version?

Thank you.
[Redacted]