From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, May 05, 2004 10:27 AM
To: [Redacted]
Subject: RE: Informed Consent and Expiration

Hi, You are correct that many IRBs require a date on the consent form in order to ensure that when consent is obtained, it is obtained using the consent form most recently reviewed and approved by the IRB. You are also correct that there is only a need to obtain informed consent again if there are changes in the information or new information that need to be conveyed to the subject in a revised consent form. Hope this helps.

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

-----Original Message-----
From: [Redacted]
Sent: Tuesday, May 04, 2004 11:43 AM
To: OC GCP Questions
Subject: Informed Consent and Expiration

Hi. I am in [Redacted]. Someone involved in a study is questioning whether there is and expiration date for informed consent agreements forcing them to obtain them repeatedly. There form has an expiration date on it and they repeat them every year. I was under the impression that we only require it to be repeated when there are changes in the trial that need to be revealed to the patient or new precautions, etc. The dates on these forms are something the IRB or investigators devise to keep track of the forms. Is this correct? Thank you for any help!

[Redacted]