From: [Redacted]
Sent: Monday, June 07, 2004 11:43 AM
To: OC GCP Questions
Subject: RE: What is the 'shelf life' of a signed Informed Consent?

Dear Bonnie,
Many thanks for your reply. I like the idea of a separate 'screening' consent, and have proposed it to my team.

[Redacted]

-----Original Message-----
From: OC GCP Questions [mailto:GCPQuestions@OC.FDA.GOV]
Sent: Monday, June 07, 2004 10:35 AM
To: [Redacted]
Subject: RE: What is the 'shelf life' of a signed Informed Consent?

Dear [Redacted], I apologize for the delay in responding to your question (below). FDA does not have a "30-day" rule. In fact, FDA regulations do not really address your question directly. We require IRB review of research (including the consent form) to occur according to the degree of risk, but at least annually. That does not mean that the consent form will change annually, or that subjects must provide consent on an annual basis. (Although, if the consent form were to change and that change was relevant to subjects enrolled in the study, then those subjects should be provided the new informed consent document.) However, because the IRB is responsible for reviewing the consent process, it would seem reasonable to ask the IRB if they have policies in this regard.

One way to avoid the problem you've described is to divide the consent process. That is, to have a separate consent form for the screening procedures and another one for the study. That way if the screening procedures are delayed, one would only need to remind the potential subject of the information in the screening consent form. As to whether the form would need to be re-signed, I think that's a judgment call based on the nature of the subject population (mental acuity), the research or the screening procedures (degree of risk, anticipated benefits), etc. I'm sorry that I can't be more specific. I hope this is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, 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: Wednesday, May 26, 2004 10:00 AM
To: gcpquestions@oc.fda.gov
Subject: What is the 'shelf life' of a signed Informed Consent?

Specifically, if a subject signs a consent to participate in a study and then for whatever reason does not have the screening visit procedures immediately performed, at what point does he have to be re-consented? We have always operated under a '30-day' rule, but we are being told that in fact a signed consent is valid for up to one year.

thanks,
[Redacted]