From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, December 18, 2002 11:23 AM
To: [purged]
Subject: RE: Informed Consent Form questions

[purged], The expiration dates on most informed consent forms are meant to convey the date by which, IF THE FORM HAS NOT BEEN SIGNED, the form would expire. In other words, if a consent form was taken off the shelf after the expiration date and then handed to a potential subject, the expiration date would alert that subject that the form had expired and that there ought to be a new IRB-approved form. If, however, the form is signed by a subject before the expiration date, then that form ought to be "good" until or unless the IRB specifies that new information needs to be provided to all subjects and that subjects need to reconsent to continue their participation in the research. That being said, I would note that it is generally State law that dictates what is "legally effective" in that State. I do think, however, that you are putting more emphasis on the "expiration date" than anyone ever intended... I hope this helps.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program

-----Original Message-----
From: [purged]
Sent: Tuesday, December 17, 2002 11:08 AM
To: 'OC GCP Questions'
Subject: RE: Informed Consent Form questions

Hi Bonnie,

Thanks for your responses. They are very helpful.

One more thing...
For my last scenario, Continuing review and IRB approval. Most of the ICFs have expiry
dates, usually a year after the initial approval. There is nothing to
change in the ICF since its last revision and approval. So the ICF is
approved and has a new expiry date. Do the subjects need to re-sign/date
this ICF even it is the same ICF they signed previously? no,unless the IRB
required it for some
other reason...

In 21 Part CFR 50.20, it states, "...no investigator may involve a human
being as a subject in research covered by these regulations unless the
investigator has obtained the legally effective informed consent of the
subject or the subject's legally authorized representative."

The key words here are "legally effective IC." The subject signs an IC. It
expires. So technically it is not 'legally effective' by the IRB(?). The
study and IC has been reapproval by the IRB, the IC has no changes and has a
new expiry date, which will now be the legally effective IC.

Maybe I am interpreting the regulation incorrectly?

Please advise.

[purged]

-----Original Message-----
From: OC GCP Questions [mailto:GCPQuestions@OC.FDA.GOV]
Sent: Monday, December 16, 2002 10:00 AM
To: [purged]
Subject: RE: Informed Consent Form questions

Dear [purged],

I assume that your questions relate to when a subject (who has already given
informed consent to be in a study) should be asked to again consent to be in
that study due to changes in the study that have occurred since the original
consent. Generally, one asks a subject to provide consent in this situation
when changes in the study could impact on the subject's decisionmaking.
I've given some guidance below--I don't know whether it will help--because I
think you are too focused on changes in the form, rather changes to the
study and, in the end, it is up to the local IRB to determine when the
revised consent form needs to be provided to all subjects, regardless of
whether some have previously consented. Please see below.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: [purged]
Sent: Thursday, December 12, 2002 1:27 PM
To: 'OC GCP Questions'
Subject: Informed Consent Form questions

Hi,

We are having a number of discussions on this subject and were wondering
what your thoughts were.

For the below scenarios when should the site obtain subject signature/date
for IC. I know some of them the answer is YES and some of them are, well,
a little gray. I hope answers from you would put a halt to these
discussions...

* If the IC was revise due to administrive changes (i.e., change "the"
to "a" or "our" to "I") - no
* If the IC was revise due to study stuff changes - deperds; if the
contacts on the consent form are changing, subjects currently enrolled need
that information; if the study staff are now becoming less experienced and
it impacts on the risk/benefit ratio, then subjects should know.
* If the IC was revise due to changes to the "basic" elements - more
than likely, yes
* If the IC was revise due to changes to the "additional" elements,
more than likely, yes
* What if the only change to the IC was the approximate number of
subjects (i.e., subject number goes from 36 enrolled to 44 enrolled)? it
depends--what if the original number given was 300 and it's now been changed
to 400? Depends on how this change could impact on a subject's
decision to enroll or continue in the research study.
* Continuing review and IRB approval. Most of the ICFs have expiry
dates, usually a year after the initial approval. There is nothing to
change in the ICF since its last revision and approval. So the ICF is
approved and has a new expiry date. Do the subjects need to re-sign/date
this ICF even it is the same ICF they signed previously? The only thing
that changed is the expiry date. no,unless the IRB required it for some
other reason...

Please let me know if you need further explanation on these scenarios.

Happy holidays and thanks for the quick reply!

Best regards,

[purged]