From: OC GCP Questions
To: [redacted]
Subject: Informed Consent content - GCP - "timely manner"
Date: Wednesday, February 04, 2015 1:15:28 PM

Good afternoon –

The word timely is not required per FDA regulations. The expectation is as follows per the informed consent guidance –
Search for FDA Guidance Documents > A Guide to Informed Consent - Information Sheet

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

When it is anticipated that significant new findings that would be pertinent to the subject's continued participation are likely to occur during the subject's participation in the study, the IRB should determine that a system, or a reasonable plan, exists to make such notification to subjects.

The additional element at 21 CFR 50.25(b)(5) requires, when appropriate, that the ICF include a statement that significant new finding developed during the course of the research which may relate to the subject's willingness to continue to participation will be provided to the subject.

FDA has guidance titled, "Institutional Review Boards Frequently Asked Questions - Information Sheet" found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm. FAQ #45 states:

> **45. When should study subjects be informed of changes to the study?**
>
> Protocol amendments must receive IRB review and approval before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the subjects (21 CFR 56.108(a)(4)). Those subjects who are presently enrolled and actively participating in the study should be informed of the change if it might relate to the subjects' willingness to continue their participation in the study (21 CFR 50.25(b)(5)). FDA does not require reconsenting of subjects that have completed their active participation in the study, or of subjects who are still actively participating when the change will not affect their participation, for example when the change will be implemented only for subsequently enrolled subjects.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional information.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, 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.

From: [redacted]
Sent: Wednesday, February 04, 2015 11:10 AM
To: OC GCP Questions
Subject: Informed Consent content - GCP - "timely manner"

Hi,

I have a quick question concerning the required wording in an informed consent for a clinical trial.

We have an independent auditor who is insisting that the word “timely” must appear in the informed consent concerning informing study subjects of new information that may affect their willingness to continue participating in the study.

I don’t believe there’s a GCP requirement that the word “timely” appear in the consent.

Could you tell me the FDA’s position on this?

Thanks,
[redacted]