From: Hommel, Carolyn - OC
Sent: Thursday, June 10, 2004 11:29 AM
To: [Redacted]
Subject: Link

Hi, [Redacted],

The item in FDA's information sheets related to re-consenting of study subjects is question #45.

45. When should study subjects be informed of changes in 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've pasted it into this e-mail for your convenience, but you can also access the Information Sheets in their entirety by visiting the GCP website at http://www.fda.gov/oc/gcp . Once there, click on "Guidances and Information Sheets"; it's the first item in the list; scroll down to frequently asked question #45.

Here's a quick link to the actual FAQs page:

http://www.fda.gov/oc/ohrt/irbs/faqs.html#Informed%20Consent%20Document%20Content

Hope this is what you were looking for.

Carolyn

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

Phone: 301/827-3340
Fax: 301/827-1169

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