From: Toth-Allen, Jean
Sent: Thursday, November 30, 2006 2:52 PM
To: [purged]
Subject: RE: question

Dear [purged]:

Thank you for your inquiry regarding subjects participating in multiple clinical studies.

There are no FDA regulations that prohibit this. However, the sponsors of both studies need to be aware of what is occurring and properly evaluate and report the situation. If the subject is still being followed up for the first study, any intervention, whether approved or investigational, needs to be captured in the study records and evaluated with regard to the condition warranting the second intervention. For the second study the nature of both investigational products needs to be carefully considered, in particular the inclusion/exclusion criteria for the second study. If it was deemed appropriate to enter the individual in the second study, information concerning his/her involvement in the first study should be captured in study records for the second study.

Hope this information is useful. If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@*oc.fda.gov*, in lieu of responding to my personal e-mail address.
Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practice Program
OSHC, Office of the Commissioner, US 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: [purged]
Sent: Tuesday, November 28, 2006 7:02 AM
To: OC GCP Questions
Subject: question

Dear Sir/Madam,

I would like to ask a question which I could not find an answer for by
myself.
What are the regulations concerning patients involved in more than one
clinical trial?
I have come accross a patient who is in a trial for 2 years and was
admitted to hospital and given another investigational product (or
Placebo). Would this patient have to be discontinues from the first
ongoing trial?
Thank you in advance for your help.
Best regards

[purged]