From: OC GCP Questions
To: [redacted]
Subject: Participation in more than one Trial
Date: Thursday, May 29, 2014 3:57:44 PM

Good afternoon–

I am not aware of any FDA regulation regarding enrollment of a subject in more than one clinical trial. However, FDA does strongly discourage this practice as enrollment in more than one clinical investigation could increase risks to the subject, particularly because the subject may be exposed to more than one investigational product for which the safety profile may not be well understood. In addition, the subject may find it difficult to understand all the risks and proposed benefits, much less meet the demands, of multiple protocols. There also may be potential drug or device interactions, and the simultaneous use of more than one investigational product may confound the results of the clinical investigations.

Sponsors generally include prohibitions related to the use of concomitant medications in the protocol or restrict (via exclusion criteria) inclusion of subjects who have participated in another clinical investigation within a specified period of time (for example, the washout period before a subject can enroll in a new clinical investigation). Implied in the prohibitions on concomitant medications is the idea that subjects should not participate in more than one clinical investigation at a time.

I hope this information is useful to you. If you need further information and/or have additional questions, please feel free to contact us at gcp.questions@fda.hhs.gov.

Kind regards,

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

From: [Redacted]
Sent: Wednesday, May 28, 2014 3:24 PM
To: OC GCP Questions
Subject: Participation in more than one Trial

Good afternoon,

We are currently conducting a trial which is only still active because the sponsor is looking for endpoints. The subjects are not on active drug I am trying to find some guidance on if we can enroll these subjects in other studies while they are still enrolled in this study. The sponsor changed the endpoint of the study and the patients nor we were aware it would go for this long initially.

Thank you,
[Redacted]