From: OC GCP Questions
To: [redacted]
Subject: Dual Enrollment
Date: Thursday, December 13, 2018 8:52:03 AM
Attachments: [redacted]

Good morning –

FDA does not have regulations that address this specific issue. There are multiple scenarios in which subjects could potentially enroll in more than one clinical trial. Some trials may only follow the progress of a subject's illness and do not involve interventional treatment, whereas others may potentially involve multiple treatments. The concern with subjects participating in more than one clinical investigation that involves multiple drugs and/or devices lies with the unknown side effects and safety profiles for the investigational products that are administered. Because of the unknowns, it is difficult to understand all the risks and proposed benefits for the products being studies. Moreover, there may be potential drug or device interactions, and the simultaneous use of more than one investigational product may confound the results of the clinical investigation. This being said, the ultimate decision is left to the sponsors, clinical investigators and, perhaps, the IRBs associated with the trials to determine whether or not concurrent participation would interfere with their research results and/or be harmful to the subjects in question. Therefore, it is recommended that all parties involved be notified.

FDA does strongly discourages dual enrollment 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. Although you do state the second trial is observational. 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.

Please consult the sponsors, CI, and your reviewing IRBs.

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

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, December 12, 2018 3:02 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Dual Enrollment

Hi,

I am wondering if a clinical research subject can be enrolled in two studies at the same time if the second study is purely observational and there are no interventions being performed. Thank you!

Best Regards,

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]