From: OC GCP Questions
To: [redacted]
Subject: RE: Regarding Principal Investigator Heading the Bioanalytical Laboratory
Date: Monday, January 05, 2015 11:02:00 AM
Attachments: [redacted]

Dear [Redacted]-

Thank you for your question. I consulted some of my colleagues in the FDA Center for Drug Evaluation and Research (CDER), Division of Bioequivalence and Good Laboratory Practice Compliance with your question. I have copied here their response to your question:

> The regulations at 21 CFR Part 320 do not define the roles of principal investigator for clinical portions of a bioavailability or bioequivalence study, or discuss whether the head of the bioanalytical laboratory can also be the principal investigator. Please note that 21 CFR Part 58 (Good Laboratory Practice for Nonclinical Laboratory Studies) does not apply to bioavailability or bioequivalence studies. The separation of functions for facility management, study director, contributing scientists, and quality assurance unit required by Part 58 has no counterpart in Part 320. As long as the person 1) is qualified to perform the roles of principal investigator for clinical portion and head of the bioanalytical laboratory, and 2) performing both roles does not cause a conflict between the roles, the FDA regulations (21 CFR Parts 312, 314, and 320) and guidances do not discourage the same person from performing both roles. However, please note that only the clinical site (CRO or rarely part of a sponsor-owned facility) or an independent third party may hold reserve samples from a BA-BE study.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [Redacted]
Sent: Wednesday, December 31, 2014 2:13 AM
To: OC GCP Questions
Subject: Regarding Principal Investigator Heading the Bioanalytical Laboratory

Dear Sir / Madam:

Greetings !!

We would like to have a clarification regarding the following general query;

Whether the Principal Investigator [MBBS, MD], for the BA/BE studies, Can also perform the role of Head - Bioanalytical Laboratory which conducts the analysis of the samples for the bio studies within the organization.

Thanks and Regards

[Redacted]