From: OC GCP Questions
To: [redacted]
Subject: RE: Sponsor Investigators
Date: Monday, December 14, 2015 2:43:00 PM

Dear [redacted] -

Thank you for your question. As you know, FDA defines Sponsor-Investigator at 21 CFR 312.3(b) as:

> *Sponsor-Investigator* means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.

As the name suggests, and is as stated in the definition above, a sponsor-investigator assumes the responsibilities of, and must comply with, FDA regulations applicable to both a sponsor and an investigator (refer to 21 CFR 312 subpart D).

The regulations at 21 CFR 312.50 and 312.53 say that sponsors are responsible for ensuring proper monitoring of investigations and for selecting monitors, qualified by training and experience to monitor the progress of the investigation, so in the case of a sponsor-investigator study, the sponsor-investigator must fulfill these sponsor responsibilities.

FDA has draft guidance titled, "*Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators*" that can be found at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm446695.pdf. Section VII B addresses sponsor-investigator responsibilities with regard to monitoring ongoing investigations. The guidance says that sponsor-investigators are responsible for ensuring proper monitoring of the investigation.

FDA conducts BIMO inspections using our Compliance Program Guidance Manuals (CPGMs) which can be found at http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/ucm255614.htm. The CPGMS were developed to provide uniform guidance and specific instructions for inspections of Clinical Investigators and Sponsor-Investigators (CP 7348.811), Sponsors, Contract Research Organizations and Monitors (CP 7348.810), In-Vivo Bioequivalence facilities (CP 7348.001), Institutional Review Boards (CP 7348.809), and Nonclinical Laboratories (CP 7348.808). You can take a look at the CPGMs to get an idea of what FDA looks at during inspections.

None of the resources noted above specifically say **WHO** is permitted to monitor a study, nor do they specifically address your questions. When the regulations are silent, sponsors, investigators and institutions are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

I was able to reach out to some of my BIMO program colleagues in ORA who are not aware of the statement you shared that; *"… the FDA BIMO inspector or chief stated that sponsor-investigators cannot monitor themselves."* There is nothing specific in the regulations to say a sponsor-investigator is not permitted to monitor their own study. However, with that said, there are certain considerations a sponsor-investigator and an institution should think through when determining **WHO** is responsible for monitoring such studies at your institution. Monitoring is generally considered a means of checks and balances and is typically a function carried out by qualified persons independent from the actual conduct of the study. We are aware that some sponsor-investigators may contract with independent CROs to conduct the monitoring responsibilities, or some may work with qualified individuals/groups within their institution to carry out monitoring responsibilities. We recommend that you discuss your approach for ensuring proper monitoring of investigations and for selecting qualified monitors for sponsor-investigator studies with the appropriate institutional officials at your institution. You may consider creating an institutional policy and procedure or an SOP for your institution so that expectations are clear to sponsor-investigators.

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

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Office of Special Medical Programs, Food and 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 09, 2015 3:13 PM
To: OC GCP Questions
Subject: Sponsor Investigators

Dear FDA,

We are learning that the FDA BIMO inspector or chief stated that sponsor-investigators cannot monitor themselves.
We of course want our sponsor-investigators to be successful and typically we require a monitoring visit from our compliance review team however, we don't have this written as part of the research plan that is submitted to the IRB. So my questions are two:

Is it true that sponsor-investigators cannot monitor themselves?
Is it appropriate for institutional monitors (who are well versed in FDA regulatory compliance issues) to serve as official monitors for these local SIs?

Sincerely,

[redacted]