From: OC GCP Questions
To: [redacted]
Subject: RE: FDA BIMO
Date: Thursday, September 18, 2014 10:03:00 AM

Dear [Redacted]-

Thank you for your question. I believe you are asking whether or not there is a more recent update to the slide presentation I gave to the VA IRB Chairs in August of 2012 (as you are probably already aware, VA made those slides available on their web site at http://www.research.va.gov/pride/conferences/irb.cfm – just click on the presentation called FDA Common Findings with my name, Janet Donnelly).

Unfortunately, I do not have a more recent copy of that presentation. However, the general information about IRB inspections in those slides hasn't really changed and if you want to look at more recent BIMO inspection metrics and findings (e.g., for fiscal years 2012 and 2013), including IRB inspections, you can access this information at the following web link on FDA's web page: http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/ucm261409.htm.

Also, if you want more information on IRB inspections, you may want to take a look at FDA's Compliance Program Guidance Manual (CPGM) on IRB inspections. You can find this document at http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/ucm133768.pdf. This CPGM provides uniform guidance and specific instructions to FDA's inspectors on conducting inspections of IRBs and it should give you a general idea of what transpires during the inspection of an IRB.

FDA also has other CPGMs for the other types of Bioresearch Monitoring (BIMO) inspections we conduct (e.g., clinical Investigators, sponsors, in-vivo bioequivalence facilities, and nonclinical laboratories). If you are interested in reviewing these other BIMO CPGMs, you can find them at http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/ucm255614.htm.

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, September 17, 2014 3:16 AM
To: OC GCP Questions
Subject: FDA BIMO

Hello,

I am writing to inquire if there is a more recent (2013 or 2014) PPT materials from **Janet Donnelly, CIP, RAC**, on the topic of ***FDA's BIMO Inspection Program, specifically, FDA inspections of IRBs.***

Thank you for your time and consideration,

[Redacted]