From: OC GCP Questions
To: [redacted]
Subject: RE: FDA Inspections
Date: Friday, May 29, 2015 10:35:00 AM

Dear [redacted]

Thank you for your question. I hope you enjoyed the SoCRA conference as much as I did!

I consulted my colleague, Hugh McClure, who is FDA's National BIMO expert with your question. You may remember Hugh, as he also presented at the SoCRA conference.

Hugh confirmed that yes, the FDA does allow the use of recording devices during the close-out meeting/discussion with management per IOM 5.3.5; however, the FDA investigator will also record the discussion to ensure the accuracy of FDA's records. FDA will not depend on the firm/PI to provide FDA a copy of the recording and will make our own recording using our own device.

The IOM referred to above is FDA's Investigations Operations Manual. This manual is available to the public at the following web link http://www.fda.gov/iceci/inspections/iom/default.htm. The specific section that Hugh mentions (section 5.3.5) can be accessed at http://www.fda.gov/iceci/inspections/iom/ucm122531.htm#5.3.5.

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: Thursday, May 28, 2015 11:23 AM
To: OC GCP Questions
Subject: FDA Inspections

Good morning. I recently attended a SoCRA conference in Cincinnati, OH where Janet Donnelly spoke. A question regarding audio recording the FDA inspection meetings was recently asked of me. Do you know if PIs are allowed to audio record the final FDA inspection meetings?

Thank you,

[redacted]