From: OC GCP Questions
To: [redacted]
Subject: RE: FDA Question - Trial/Patient Confidentiality
Date: Wednesday, February 05, 2014 5:26:00 PM

Dear [Redacted]-

Thank you for your question. If I understand the information you provided correctly, you were performing a QA audit at a clinical investigator (CI) site for the purpose of reviewing your companies study records. The site staff hosted you in a room that also contained the study records for another sponsored study the site and CI are participating in. You are asking whether this is a HIPAA violation that requires reporting.

Unfortunately, I cannot advise you regarding matters concerning the Health Insurance Portability and Accountability Act (HIPAA) as HIPAA and its related statutes are under the jurisdiction of the Office for Civil Rights (OCR) and not FDA. For questions regarding issues pertaining to HIPAA, you may wish to contact OCR directly at OCRPrivacy@hhs.gov. I suggest you send your question to OCR to get their response. Here also is a link to OCR's general website for HIPAA http://www.hhs.gov/ocr/privacy/, and OCR also has HIPAA Frequently Asked Questions that can be accessed at http://www.hhs.gov/ocr/privacy/hipaa/faq/index.html. You may also wish to discuss your question with other in-house legal staff, including any Privacy Officer, within your sponsor organization.

I'm sorry that I couldn't be more helpful with your question. 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: Tuesday, February 04, 2014 1:31 PM
To: OC GCP Questions
Subject: FDA Question - Trial/Patient Confidentiality

To whom can answer this question:

I have a question regarding Trial/Patient confidentiality at an Investigator site.

I am auditor in the QA Department and during a recent PI site audit of our trial, I was also given private access (behind closed doors) to the charts/PI binder records to another sponsors on-going trial.

During the audit, I informed the PI that I shouldn't have private access to another sponsors records and although the PI indicated they have a space issue and no Monitor/Auditor complained before; the records were eventually removed by site personnel.

My question is this, should this be reported as a **MAJOR** breech to another sponsor and patient' confidential(HIPAA) records by this site or is this simply a **MINOR** observation where the site used bad judgment in giving me private access

Thank you

[Redacted]