From: OC GCP Questions
To: [redacted]
Subject: clarity
Date: Monday, July 21, 2014 12:52:04 PM

Good afternoon –

Unfortunately, I cannot advise you regarding matters concerning the Health Insurance Portability and Accountability Act (HIPAA) as you state 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 don't know if there is a generic HIPPA form for clinical trials. FDA expects that investigators, sub-investigators and study staff will be knowledgeable about good clinical practice, including human subject protection, data integrity and confidentiality, and recordkeeping.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, July 18, 2014 1:00 PM
To: OC GCP Questions
Subject: clarity

I would like to inquire about the following even though I know that the office of civil rights overseas HIPPA. As a Clinical site Center we have our staff working in *study manager* and wonder if they should sign some kind of HIPPA statement even though we understand we are always responsible for the privacy of all our subjects. Perhaps you could comment. Should we have everyone sign a HIPPA statement and would you know if there is a generic one for clinical trials available?

Kind Regards
[redacted]