From: OC GCP Questions
To: [redacted]
Subject: ICF issue
Date: Monday, October 03, 2016 12:27:00 PM

Good afternoon --

Under FDA regulations, HIPPA is not part of the essential elements of informed consent (21 CFR 50.25).

Additionally, FDA does not have responsibility for the implementation of HIPAA. HIPPA is the responsibility of the Office of Civil Rights. You may wish to consult the Health Insurance Portability and Accountability Act (HIPPA) For questions regarding issues pertaining to HIPAA, you may contact OCR directly at OCRPrivacy@hhs.gov. Here also is a link to OCR's general website for HIPAA www.hhs.gov/ocr/privacy/, and OCR also has HIPAA Frequently Asked Questions that can be accessed at 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 and/or institution.

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

Kind regards,

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Senior Health Policy Analyst
Office of Good Clinical Practice
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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: Monday, October 03, 2016 9:43 AM
To: OC GCP Questions
Subject: ICF issue

Hello I was hoping someone could help me with an issue that was just raised on one of the studies I am working on.
It is a prevalence study and there is 100% remote monitoring by a CRO. For source document verification, documents are uploaded/attached into a database. Of course, documents such as lab reports and medical history are redacted. But the informed Consent Forms were uploaded non-redacted so that monitors could verify the patients actually signed consent.

The CRO is now stating that we are out of compliance according to HIPPA guidance. They cannot provide any language from the guidance proving this is the case. However they are refusing to review and verify data for patients that have a non-redacted ICF uploaded into the database.

Can you please provide your insight? Thank you so much in advance.

Have a nice day

[redacted]