From: OC GCP Questions
To: [redacted]
Subject: RE: Question Regarding the Collection of Medical Records for Study Inclusion
Date: Tuesday, September 29, 2015 3:48:00 PM

Dear [redacted],

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 privacy and confidentiality of medical records, 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 - 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 want to discuss your question with your institution's Privacy Officer.

Based on the limited information provided, we are not able to provide an opinion outside of the FDA inspectional process because many other considerations go into making an assessment of the scenario you describe.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [redacted]
Sent: Wednesday, September 23, 2015 1:30 PM
To: OC GCP Questions
Subject: Question Regarding the Collection of Medical Records for Study Inclusion

Good Afternoon,

An issue has come up with a study we are conducting that has our site concerned. The sponsor has contracted a central recruitment agency that is using a 3rd party vendor to obtain the potential subject's medical records prior to their first visit with us.

Basically, they pre-screen the potential subject over the phone (the phone screener has been IRB approved) and if they meet the initial criteria then they are offered a service that will send the subject an authorization to release medical records for the subject to sign and send

back, then the 3rd party company will attempt to obtain records to be sent directly to the research site selected to screen them. Please note that the subject has not signed a informed consent form prior to any of this occurring.

It has always been my understanding that if you are obtaining medical records solely for the purpose of trial inclusion or for study participation that it is considered a study procedure and must be done only after the informed consent process has taken place. We usually have a pre-screening visit with the subject and review the trial with them and after they sign consent, we have them sign a records release authorization and then try and obtain records. When I brought up my concerns to the study team and the IRB, I was told that

> "HIPAA is signed to “pre-screen” subjects medical records and release them because the doctors office is a covered entity and the records will be removed from the covered entity to the 3rd party. This is simply a standard pre-screening recruitment process with the insertion of a 3rd party to facilitate the movement of those records following the subjects authorization to release. HIPAA preparatory to research waiver is not applicable, so a HIPAA is signed. This does not constitute as a study procedure."

I really don't agree with their stance and was wondering how this would be viewed during an FDA audit. Can you share your opinion on the matter?

Thank you in advance for your time.

Best Regards,

[redacted]