

From: [Brown, Sheila \(OGCP\)](#)
To: [REDACTED]
Subject: RE: HIPAA question
Date: Tuesday, September 13, 2016 7:57:00 AM

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.

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

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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: Tuesday, September 13, 2016 7:25 AM
To: OC GCP Questions
Subject: RE: HIPAA question

Good Morning-

A few questions regarding HIPAA came up recently and I would like to know what the FDA's ruling is as far as the CRA (Clinical Research Associate) coverage. Here are the questions:

1. When a CRA is at a site with multiple trials ongoing, and the site staff is conversing either with the covering CRA or another staff member, is the CRA covered under a HIPAA rule?
2. If a CRA is within "earshot" of a staff member, and the staff member is in conversation with a subject either in person or by telephone, is that CRA covered?
3. I understand HIPAA is in place to protect the patient and it is a federal ruling, so can the contract between the site and the sponsor overrule any HIPAA regulation?

I thank you in advance for your time and for the information. Have a nice day.