

From: Brown, Sheila (OGCP)
To: [REDACTED]
Subject: RE: Best Practice for De-identifying data
Date: Monday, July 20, 2015 3:42:00 PM

Dear [REDACTED],

It isn't clear from your email whether you are asking about de-identifying or redacting information for HIPAA, or for research, or asking about corrections. FDA does not require redaction or de-identification of data for regulated studies. FDA's regulations do not have specific information about corrections, but there is some information in ICH E6 in section 4.9.3 on changes or corrections <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073122.pdf> that may be helpful.

HIPAA is regulated by the Office for Civil Rights (OCR), not FDA. There is a document on their website entitled "Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule", which may be helpful. It can be found at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/hhs_deid_guidance.pdf. There is also a section devoted to research topics on the OCR/HIPAA website at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/index.html>. If you have any questions regarding de-identification or redaction of data to meet HIPAA requirements, please contact the Office of Civil Rights at OCRPrivacy@hhs.gov.

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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Office of Special Medical Programs, Food and Drug Administration

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: Monday, July 13, 2015 1:00 PM
To: OC GCP Questions
Subject: Best Practice for De-identifying data

Good Afternoon,

I was a clinical research nurse prior to when all the HIPAA was in effect (over 15 years ago). Back then we were taught never to use white out for corrections. I never use white out for corrections of course, but is there a written policy anywhere for correct ways to de-identify data? I worked at one place that only de-identified data by using a black magic marker. I also worked at another place that de-identified data using the white-out correction tape. Is there a right or wrong way to de-identify data for research purposes?

Thanks & Kind Regards,

[REDACTED]