From: OC GCP Questions
To: [redacted]
Subject: RE: White Out to Redact PHI Inquiry
Date: Wednesday, November 14, 2018 8:44:00 AM
Attachments: [redacted]

Dear [redacted],

It isn't clear from your email whether you are asking about de-identifying or redacting information for HIPAA or for research. 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(R2) in section 4.9.3 on changes or corrections https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm464506.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 https://www.hhs.gov/sites/default/files/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 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 .

There may also be state or facility requirements regarding de-identification/redaction of PHI. You may wish to contact your facility's management for assistance.

Best regards,

Sheila

Sheila Brown, RN, MS
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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, November 13, 2018 1:40 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: White Out to Redact PHI Inquiry

Hello,

Can you please confirm if the use of white out to redact PHI is acceptable? I am assuming no, but just want to confirm.

Thank you!
[redacted]

[redacted]

[redacted]

[redacted]