**From:** OC GCP Questions
**To:** [redacted]
**Subject:** HIPPA
**Date:** Friday, September 18, 2020 1:44:00 PM
**Attachments:** [redacted]

Good afternoon –

FDA recognizes that sponsors and monitors require access to subject records to ascertain the accuracy of the study data. That is why one of the essential elements of any informed consent document is a disclosure of the extent to which confidentiality of study records will be maintained (Title 21, Code of Federal Regulations - 21 CFR - 50.25(a)(5)). (This statement needs to specifically include the fact that FDA has the ability to access the information as well.) This informs potential subjects right up front of the fact that others besides study site personnel (who will automatically have access to their files) will have access to their files and therefore complete confidentiality cannot be fully assured.

FDA does not enforce the HIPAA regulations. This is the purview of the Office of Civil Rights. You can find information about HIPAA-related issues on their website at www.hhs.gov/ocr/privacy/. You should find contact information available there as well, should you not find the answers to your specific questions on the website.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration




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**From:** [redacted]
**Sent:** Friday, September 18, 2020 5:44 AM
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>
**Subject:** HIPPA

Hello,

My question is in regards to Source Documentation and HIPPA PHI.

A study provides source documentation worksheets from the coordinating center to sites and the worksheets contain licensed cognitive assessments that ask to collect certain PHI identified in HIPPA's 18 personal identifiers list (location smaller than state, partner first name, DOB, initials, sometimes a signature). Then these source worksheets are uploaded into the coordinating center Electronic Database for Monitor Review/source document verification.

Do these PHI elements need to be redacted/de-identified prior to being uploaded under the participant ID? The uploaded worksheets are not shared with anyone outside of the coordinating center.

Secondly, if they do not need to be redacted: would informed consent forms be allowed to be uploaded in the same venue? Associated with participant ID?

Thank you,

[redacted]