From: OC GCP Questions
To: [redacted]
Subject: Question regarding original signed consent forms
Date: Tuesday, March 24, 2015 3:27:12 PM
Attachments: [redacted]

Good afternoon [redacted] –

Joanne is out of the office for the next two days. She forwarded your email to me for a response. Please see the two past queries one from 2014 and one last week (that includes 2 new draft guidances on IC) that addresses your questions.

Additionally, FDA regulations do not specifically address the documentation of destroyed ICDs. However when the regulations are silent it might be best to have a standard operating procedure that all study staff can follow when destroying informed consent documents.

Please let me know if you have additional questions.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, March 24, 2015 01:32 PM
To: Less, Joanne
Cc: [redacted]
Subject: Question regarding original signed consent forms

Dear Joanne,

I direct the [redacted] at [redacted]. My work involves auditing and educating clinical investigators, as well as advising them on best practices for conducting research. I work closely with [redacted]

who suggested I contact you with a question regarding the storage of the *signed informed consent form*: Does FDA take a stance on whether or not the HARD copies must be kept on file? Or, can the signed ICF be scanned and then destroyed? If FDA is agreeable to ICFs being scanned and destroyed, does FDA have any expectations regarding documentation of the scanning/destruction process?

Thanks very much,
[redacted]