From: OC GCP Questions
To: [redacted]
Subject: Question regarding accidentally destroyed clinical trial records
Date: Wednesday, February 21, 2018 8:31:00 AM

Good morning -

FDA might consider the situation that you describe as serious or continuing non-compliance and may need to be reported as unanticipated problem if subject safety is at risk. The CI, sponsor, and IRB can determine this. All efforts should be made to recover documentation and the attempts should be documented in writing in case an FDA inspection should occur at your site.

If you have specific questions related to a particular study, CI and sponsors may directly contact the FDA review division that is overseeing the study. If the information cannot be found, this may compromise the study data. Sometimes under unusual circumstances trial data is lost (such as through fire, flood or other natural disaster). I would highly recommend that you and/or the sponsor of the study contact the assigned reviewing division(s) for further advisement.

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 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.

-----Original Message-----
From: [redacted]
Sent: Tuesday, February 20, 2018 11:13 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Question regarding accidentally destroyed clinical trial records

Good morning.

I'm trying to determine how to proceed and what consequences to expect for a medical provider participating in clinical trials that discovered it accidentally destroyed certain clinical trials records. The records include, in particular, patient consent forms. While we do not believe the volume of participants was significant, we are uncertain at this time whether we can recreate the destroyed records.

Please contact me at your earliest convenience.

Thank you.

[redacted]