From: OC GCP Questions
To: [redacted]
Subject: Protocol Amendment.
Date: Wednesday, May 10, 2017 7:40:00 AM
Attachments: [redacted]

Good morning –

You may want to consider documenting the situation with a Note to File. While FDA's regulations do not specifically mention Notes to File, some investigators may choose to utilize such items to document issues of noncompliance/corrective actions and/or to explain any unusual circumstances that may occur during the course of a clinical trial. It would be impossible for me to give you specific instances and any items that should be included, since they are not addressed in the regulations. However, FDA regulations do state that investigator records must be adequate and accurate. Clinical investigators may choose to utilize Notes to File as a tool in order to maintain their records according to FDA's regulatory requirements.

You may also want to inform the reviewing IRB.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, May 10, 2017 3:52 AM
To: OC GCP Questions
Subject: Protocol Amendment.

Hi,

We have an oncology clinical study ongoing under an IND. Recently (last month), we amended the clinical protocol with some minor changes, and it was approved by our IRB. Due to a miscommunication between the clinical and regulatory department, the protocol amendment was not submitted to the FDA. One patient was enrolled under the amended protocol, but before receiving the treatment the patient passed away due to disease progression. As soon as we learned about it, the protocol amendment was immediately submitted to the FDA.

Is there anything else we need to do? Since the patient did not receive any investigational treatment, the patient data will not be included in the data analysis.

Your advice will be highly appreciated.

Regards.

[redacted]