From: OC GCP Questions
To: [redacted]
Subject: CT
Date: Friday, May 18, 2018 11:35:00 AM

Good morning --

You email was forwarded to my office for a response. Yes, the subject (patient) can ask the PI, study center, or the sponsor of the study the reason why the patient was not enrolled. It could be that the patient did not meet eligibility criteria. Often, when a patient is not enrolled in a study, the reason is generally conveyed to the patient.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
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: Thursday, May 17, 2018 7:08 PM
To: [redacted]
Subject: CT

Hello,

If a patient is not accommodated in a clinical trial, and when no reason was given from the study center or PI, it is reasonable to ask for it from the behalf of the patient, especially if this information may help the patient to save time and effort by avoiding similar trials for medical, administrative or other exclusion reasons that were not mentioned in the trial description?

Thank you for your opinion.

Best regards,
[redacted]