From: OC GCP Questions
To: [redacted].
Subject: Good Documentation Practices - Late Entry (LE)
Date: Monday, January 23, 2017 8:47:00 AM
Attachments: [redacted]

Good afternoon –

Late Entry is not specifically defined in FDA regulations. It is usually associated with adding additional information to study trial documents. Because the term in not addressed in FDA regulations, we cannot legitimately endorse the Acronym LE.

Kind regards,

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

From: [redacted]
Sent: Thursday, January 19, 2017 2:31 PM
To: OC GCP Questions
Subject: Good Documentation Practices - Late Entry (LE)

Good afternoon,

Is using the Acronym LE for Late Entry a universally accepted abbreviation in Clinical Research? Is this something that is accepted by the regulatory agency?

Regards,
[redacted]