

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 is not addressed in FDA regulations, we cannot legitimately endorse the Acronym LE.

Kind regards,

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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.

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]