From: OC GCP Questions
To: [redacted]
Subject: Confirmation of CRF requirements Date of Birth - urgent query please!
Date: Thursday, June 25, 2015 10:09:26 AM

Dear [redacted] –

FDA regulations do not specifically address how a date of birth should be entered on the electronic CRFs. When the regulations are silent, sponsors, sites and institutions are free to develop their own standard operating procedure (SOP) for handling a specific situation. SOPs assure consistency from all study staff when entering data in a clinical trial.

You might find this guidance helpful. – Electronic Source Data in Clinical Investigations

http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Thursday, June 25, 2015 5:51 AM
To: OC GCP Questions
Subject: Confirmation of CRF requirements Date of Birth - urgent query please!

Dear Sir/Madam,

In a clinical trial in the US is it acceptable to collect the full Date of Birth in an electronic CRF, or only the month/year, or possibly only the year?

Many thanks in advance,

Kind regards,
[redacted]