From: OC GCP Questions
To:

Subject: ICF in EMR

Date: Tuesday, March 10, 2015 9:27:34 AM

Good morning -

It is not an FDA requirement to have the ICD in the subject's medical record.

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.

From:

Sent: Friday, March 06, 2015 4:46 PM

To: OC GCP Questions **Subject:** ICF in EMR

Happy Friday

I am looking for a regulation or a guidance as to whether or not it is mandatory from the FDA's perspective to place a copy of the signed ICF in the subject's medical chart or not.

Please advise.