From: OC GCP Questions
To: [redacted]
Subject: EKG
Date: Tuesday, October 28, 2014 1:19:09 PM

Good afternoon --

A subject signing the informed consent form indicates that the subject is entering research and may be referred to as "enrolled." In many studies, the selection criteria necessitates procedures be performed that are done solely for the purpose of determining eligibility for the study. **Such procedures may only be performed after the subject has consented to participate in research. [Emphasis added]** When such procedures are performed, the subject's participation in research has begun although whether the subject actually meets the selection criteria for the study has not been determined.

If the EKG was done solely for screening purposes for entry into a clinical study, then yes a note to file is needed as study related procedures were performed before the informed consent was signed. Additionally you might suggest that study staff be retained and document the training to demonstrate that the site is in compliance with the regulations.

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

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: Tuesday, October 28, 2014 12:49 PM
To: OC GCP Questions
Subject: EKG

I would like to know how would the agency view a screening EKG done at 12:12:05pm and initial Informed consent was signed at 12:12pm. Should a note to file be written?

[redacted]