From: OC GCP Questions
To: [redacted]
Subject: Regulations related to qualifications necessary to read ECGs
Date: Tuesday, March 18, 2014 10:29:02 AM

Good morning –

You are correct, the regulations are very broad. The regulations require that sponsors choose investigators qualified by training and experience (see 21 CFR 312.53(a)). The regulations also require that investigators commit themselves to personally conduct or supervise the investigation (see 21 CFR 312.53(c)(1)(vi)(c)).

It might be helpful for you to review FDA's guidance on Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf)

FDA would expect physicians to follow state and local laws regarding medical licensure and medical practice requirements in addition to sponsor requirements.

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: Monday, March 17, 2014 3:06 PM
To: OC GCP Questions
Subject: Regulations related to qualifications necessary to read ECGs

Hello,
Are there any references in regulations to who is qualified to read an ECG. What I have been able to find is relatively broad, stating that an investigator must be qualified by education, experience and training to perform trial duties.
Specifically I am seeking guidance on whether a licensed MD other than a cardiologist is qualified to read and interpret ECG's as they relate to ICH Guidance E14: Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs and generally to cardiovascular screening and monitoring.
Is this up to the sponsor to determine, or is there any precedent in federal regulation or previous FDA experience?
Thanks, [redacted]