From: OC GCP Questions
To: [redacted]
Subject: Ref- Steering review committee
Date: Thursday, January 05, 2017 6:22:00 AM
Attachments: [redacted]

Good morning –

Qualifications of steering committee members are not specifically mentioned in FDA regulations. However, the expectation is that investigators, sub-investigators, study staff, and all members involved with research will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc. As noted, the sponsors have discretion in determining what qualifications will be needed to conduct a study and may identify in the protocol a required frequency of GCP training, in which case the investigator and sub investigators would be expected to meet that frequency of training in order to comply with the sponsors requirements. Every effort should be made to train the investigational sites. This is the sponsor's responsibility.

Kind regards,

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

From: [redacted]
Sent: Wednesday, January 04, 2017 3:01 PM
To: OC GCP Questions
Subject: Ref- Steering review committe

Hello Sir,

I was having a question

What are the education and qualification requirement for steering review committee member

Thanks and Regards
[redacted]