

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

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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,

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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.

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

Hello Sir,

I was having a question

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

Thanks and Regards

[REDACTED]