

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Good Clinical Practices
Date: Tuesday, January 20, 2015 11:13:25 AM

Good morning –

I've asked a few colleagues and we think that the mother-in-law may be considered a family member. However we are unclear if this is an official FDA position. Again it is best to ask and obtain guidance from the sponsor.

Kind regards,

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From: [REDACTED]
Sent: Saturday, January 17, 2015 9:40 PM
To: OC GCP Questions
Subject: RE: Good Clinical Practices

Thank you, Doreen The Code of Federal Regulations Title 21, sec 50.1 Scope (m) and a Family Member reads; Spouse; Parents; Children, (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association to the subject is the equivalent of a family relationship. Can you please clarify "related by blood or affinity whose close association to the subject is the equivalent of a family relationship"? I believe that a mother-in-law would fall under the first or second degree meaning of affinity. Is this correct? I sincerely appreciate your assistance.

[REDACTED]