From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, April 23, 2002 2:01 PM
To: **[Redacted]**
Subject: RE: Conflict of Interest in Clinical Trials
[Redacted],

FDA's Institutional Review Board (IRB) regulations state that "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide informatiion requested by the IRB." See 21 CFR 56.107(e).

Although not specifically addressing "conflict of interest", FDA has regulations that pertain to "Financial Disclosure by Clinical Investigators" at 21 CFR Part 54. This regulation is based on the concern that one source of bias in clinical studies is a financial interest of the investigator in the outcome of the study. You can view the whole regulation at: http://www.fda.gov/cder/about/smallbiz/financial_disclosure.htm

There is a draft interim Departmental guidance document, that was posted for comment last year. Although it is not an FDA document, it may be of interest to you. You can view this draft at: http://ohrp.osophs.dhhs.gov/nhrpac/mtg12-00/finguid.htm

If you have a particular interest that none of these documents address and you can be more specific, I may be able to help you further. I hope that this information is useful.

Sincerely,

Bonnie

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-----Original Message-----
From: **[Redacted]**
Sent: Tuesday, April 23, 2002 9:29 AM
To: 'gcpquestions@oc.fda.gov'
Subject: Conflict of Interest in Clinical Trials

Hello,

Are their any regulations, guidance documents, or FDA information sheets on the topic of conflict of interests in clinical trials?

Thanks in advance for your help.

[Redacted]