From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, April 05, 2005 2:01 PM
To: [Redacted]
Subject: RE: Health - Conflict of Interest
Dear [Redacted] ,

[Redacted]

You are right that the amounts you cite really apply to investigators, not IRBs. If you go to the final guidance at: http://www.hhs.gov/ohrp/humansubjects/finreltn/finalguid.pdf , the PHS and FDA (Part 54) regulations are cited. Because both related to investigators, I don't think that either are particularly helpful in establish conflict of interest amounts for IRB members (unless you want to do that--but they weren't established for that purpose). IRB Operations (and conflicts related to IRB members) are discussed in the third column on page 26396. I think that we'd be comfortable with whatever you decided to do....as to what your IRB members would think, that may be something else. I'd suggest discussing the whole issue with your IRB. They may believe that no amount should be named; a different amount; or they could believe that zero-tolerance is appropriate. In the preamble to the 1981 rule, we said that it was really up to the IRB to determine what constitutes a conflicting interest.

I hope this helps.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, 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.
-----Original Message-----
From: [Redacted]
Sent: Thursday, March 31, 2005 9:23 AM
To: blee@oc.fda.gov
Subject: Health - Conflict of Interest
Hi Bonnie:
[Redacted]

Our Board is updating SOPs and wants to make sure they are following all applicable guidelines regarding conflict of interest as it relates to ownership of stock, etc. I copied the Final Guidance Document (last page dated May 5, 2004) from HHS, an item giving actual monetary figures in the footnote on page 1. It says "The PHS [Public Health Service] threshold for significant financial interest is $10,000 per year income or equity interests over $10,000 and 5 percent ownership in a company (45 CFR 94.3 - just pulled this up and basic same wording)." These appear to relate to investigators; do they also translate to IRB members? And is the FDA comfortable with the use of that language?

Hope to hear from you soon.
[Redacted]
PLEASE NOTE NEW EMAIL ADDRESS.