From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, October 08, 2004 2:44 PM
To: **[Redacted]**
Subject: RE: question
Dear **[Redacted]**,

If two principle investigators want to open the same protocol, both can be listed as investigators on that same protocol so that the IRB does not have to review the material twice. If one investigator already has a trial open, the qualifications of the second investigator should be reviewed by the IRB and, if found acceptable, added to the original protocol.

I hope this helps.

Sincerely,
Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
-----Original Message-----
From: **[Redacted]**
Sent: Wednesday, September 29, 2004 10:24 AM
To: gcpquestions@oc.fda.gov
Subject: question
I am the chair of **[Redacted]** IRB.
We have two medical oncologists who are Principal Investigators.
If both want to open the same protocol, how does this work as far as what goes through the IRB?
If one of the PI's already have a trial open, what does the second one have to do to open the same trial?
It seems redundant for both to put everything through the IRB

[Redacted]