From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, March 09, 2004 1:04 PM
To: **[Redacted]**
Subject: RE:

Dear Dr. **[Redacted]**,

Thank you for your inquiry. What's required by the regulations is that a Clinical Investigator obtain approval of a study (both for the initial and continuing reviews) from the IRB of record (i.e., the IRB identified in the Form FDA 1572). There is no regulatory prohibition that prevent other IRBs from providing secondary reviews, and in some cases institutional policy and procedure may require secondary review and approval before a protocol may proceed at the study site. (In such a case, FDA would expect the existence of SOPs describing this procedure, and that the SOPs be followed).

When more than one IRB has reviewed any study, and disapproved a study, the IRB that disapproves it must provide a written statement of the reasons for its decision to the investigator and the institution [21 CFR 56.109(e)]. If the study is submitted to a second IRB, a copy of this written statement should be included with the study documentation so that it can make an informed decision about the study. 21 CFR 56.109(a) requires an IRB to "... review ... all research activities [emphasis added] ...." The FDA regulations do not prohibit submission of a study to another IRB following disapproval. However, all pertinent information about the study should be provided to the second IRB (You can find this information in the FDA Information Sheets located at http://www.fda.gov/oc/gcp/guidance.html).

I hope this information is helpful.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340

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: Monday, March 01, 2004 2:30 PM
To: gcpquestions@oc.fda.gov
Subject:

I need to know, can more than one IRB for one site be overseeing one study protocol. My understanding is that a site cannot have more than one IRB approval for particular study protocol.
Please send me e-mail with the answer.
Thanks
[Redacted]