From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, June 17, 2005 1:12 PM
To: [Redacted]
Cc: Chhabra, Renu
Subject: RE: independent vs local IRBs

Dear Ms. [Redacted],

I apologize for the delay in responding to your email below. A sponsor is required to select clinical investigators who through their training and experience are qualified to conduct the clinical investigation. Those investigators may be affiliated with an institution that has an IRB or may not have such an affiliation and may use an independent IRB. FDA's regulations allow investigators to use an IRB that meets the requirements of FDA's IRB regulations--they may be local or independent. The regulations also permit for multi-institutional studies to use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort. If the research is conducted within an institution (either with or without an IRB) typically there is some agreement, if the IRB review is to be conducted elsewhere) between the institution and the other IRB. That agreement may delegate the responsibility for the IRB review, or a portion of it. Typically, we encourage independent IRBs to be sure that the local IRB or institution (if one exists) has agreed to delegate its review to the independent IRB and that the independent IRB has accepted that review responsibility. If, by "IRB shopping" you mean looking for a favorable decision from an IRB, we have not really seen good documentation that that occurs (at least at a frequency that would cause concern). I hope this information is helpful to you.

Sincerely,

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: Chhabra, Renu
Sent: Friday, May 13, 2005 11:42 AM
To: OC GCP Questions
Subject: FW: independent vs local IRBs

Would you please answer and cc me?

Thanks

Renu Chhabra
LCDR, USPHS

Division of Drug Information/CDER/OTCOM/FDA
301-827-0505

-----Original Message-----
From: [Redacted]
Sent: Friday, May 13, 2005 11:09 AM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: Dear Sir/ Madam
I am a Research Scholar in Pharmaceutical Medicine.
Lately, I have read a lot about "IRB Shopping" by Sponsors. From what i have read so far, it appears to me that a sponsor can choose an IRB to suit its needs. Does this imply that a sponsor has the option to choose between an independent and local IRB for a single-site study to review the study? does not the local IRB have complete jurisdiction over all studies done in the institution to which it is attached? Or can independent IRBs also approve such studies? Is such a choice allowed by regulatory standards? I understand that when multi-centric trials are to be conducted, independent IRBs can be approached; but can u do the same when its only a single-centre trial? Any reference or guidance on this issue will be appreciated. Thank you Ms. [Redacted]