From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, November 02, 2004 3:02 PM
To: [Redacted]
Subject: RE: question?

Dear Dr. [Redacted],

Perhaps the best way to explain what we mean by IEC is to look at the recently published proposed rule for 21 CFR 312.120 entitled "Foreign Clinical Studies Not Conducted under an Investigational New Drug Application" (see www.fda.gov/oc/gcp/draft.html). In this proposed rule, we propose to define an independent ethics committees (IEC) as a "review panel that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation and is adequately constituted to provide assurance of that protection". An adequately constituted IEC includes a reasonable number of members with the qualifications and experience to perform the IEC's function (see e.g., section 3.2.1 of the Good Clinical Practice ICH E6 guidance). This proposed definition of independent ethics committee also specifies that an IRB, as defined in 21 CFR 56.102(g) and subject to the requirements of part 56, would be one type of IEC.

I hope this information is helpful to you.

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: Tuesday, November 02, 2004 6:52 AM
To: gcpquestions@oc.fda.gov
Subject: question?

Respected Sir,
Is there any difference between IRB and IEC?

Thanks,

[Redacted]