From: Lepay, David
Sent: Tuesday, August 09, 2005 2:33 PM
To: [Redacted]
Subject: RE: Interpretation of 56.114

Dear Dr. [Redacted]:

I was wondering whether you have seen FDA's recent draft guidance on "Using a Centralized Institutional Review Board Process in Multicenter Clinical Trials". This can be accessed from our GCP website (www.fda.gov/oc/gcp through the link to "Proposed Reulgations and Draft Guidance" and hence to the 3/25/05 entry for the draft guidance --- or alternatively through the direct link http://www.fda.gov/OHRMS/DOCKETS/98fr/05d-0103-gdl0001.doc). This may answer your questions. If not, please feel free to contact our office again through our queries mailbox at gcpquestions@oc.fda.gov.

Sincerely,

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, GCP Programs,
OSHC, Office of the Commissioner, US 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: Tuesday, August 09, 2005 12:05 PM
To: gcpquestions@oc.fda.gov
Subject: Interpretation of 56.114

Dear Dr. Lepay, or other FDA official:

Can you assist me in interpretation of your regulations at Title 21, subpart 56.114. Specifically, if our institution were to have an application for IRB approval of a multi-institutional study, what would we need to have in place in order to rely upon the review of another qualified IRB? OHRP has on its website an IRB Authorization Agreement, which satisfies this requirement for HHS-funded research. Would FDA expect that same or a similar document to be executed in order for our IRB to rely on another qualified IRB? Is FDA less specific or more specific in what it requires for this reliance to occur?

Your thoughts are appreciated.

Regards,
[Redacted]

§ 56.114 Cooperative research.

In complying with these regulations, institutions involved in multi- institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

[Redacted]