From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, March 23, 2004 1:16 PM
To: **[Redacted]**
Subject: RE: **[Redacted]** IRB

Dear Mr. **[Redacted]**,

Your inquiry was referred to our office for reply. You can obtain information about any past inspection conducted by the FDA at Quorum by submitting an FOI request to our FOI office. That office will provide you with information that is publicly releasable about Quorum including the establishment inspection report (aka EIR) and any FDA-483s issued (should any have been issued).

We have a direct web link to the FOI office on our GCP home page (www.fda.gov/oc/gcp); you will see it at the bottom right hand side of this page.

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.

[Beers Block, Patricia] -----Original Message-----
From: **[Redacted]**
Sent: Thursday, March 18, 2004 12:38 PM
To: jmccorma@ora.fda.gov
Subject: **[Redacted]**

> **[Redacted]** is a community hospital in **[Redacted]**. We're thinking of participating in a clinical trial. The drug company wants us, mostly for efficiency reasons, to use a central IRB called **[Redacted]**. **[Redacted]**'s web site implies that they are in good standing with the FDA, by virtue of passing some audits conducted by the FDA.
>
> Before we delegate our own IRB's role to **[Redacted]** we'd like to confirm that they have a good track record with the FDA. Can confirm same?
> **[Redacted]**