From: Lepay, David on behalf of OC GCP Questions
Sent: Wednesday, February 18, 2004 9:13 AM
To: [Redacted]
Subject: RE: certification of clinical trials center

Dear Ms. [Redacted]:
Again there is no FDA certification or accreditation process for investigators, IRB's, or institutions (including hospitals).

There are voluntary, non-FDA, non-governmental programs that do provide accreditation services. But these are not FDA-run accreditation or certification programs. FDA can not comment on or provide endorsement for any of these programs.

Sincerely,
David A. Lepay, MD PhD

-----Original Message-----
From: [Redacted]
Sent: Wednesday, February 18, 2004 8:15 AM
To: OC GCP Questions
Subject: RE: certification of clinical trials center

Dear Dr Lepay,
thank you very much for that information. I would like to ask another question: If there is no accreditation for study centrals by the FDA than maybe for a hospital as a whole, including IRB?
Thanks in advance,
[Redacted]

>-----Original Message-----
>From: [Redacted]
>Sent: Tuesday, February 17, 2004 4:42 AM
>To: gcpquestions@oc.fda.gov
>Subject: certification of clinical trials center
>
>
>Dear sirs,
>I learned that the FDA certifies clinical trials centers conducting trials
>due to GCP.
>Is it possible to apply for such a certification and how?
>And what are the requirements to obtain the certification?
>I look forward to your reply.
>Best regards,
[Redacted]