From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, December 20, 2005 1:27 PM
To: [purged]
Subject: RE: Clinical Research (Principal investigator)

Dear Mr. [purged],

Dr. Lepay asked me to respond to your email below. FDA does not pre-certify individuals to conduct research. Rather, FDA regulations require a sponsor to select only investigators qualified by training and experience as appropriate experts to investigate the drug. See 21 CFR 312.53(a). Clearly, the necessary expertise will depend upon a number of factors including the nature of the clinical investigation. It is the responsibility of the sponsor to determine the adequacy of the qualifications of an individual to become an investigator. I'm sorry that I can't be more helpful.

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: [purged]
Sent: Wednesday, December 14, 2005 9:25 AM
To: gcpquestions@oc.fda.gov
Subject: Clinical Research (Principal investigator)

To
Dr. David A. Lepay, M.D., Ph.D.,
Senior Advisor for Clinical Science and Director
Food and Drug Administration
Rockville, MD 20857

SUB: Reg- clinical research (Principal investigator)

Respected Sir;
Greetings from India. I am very much interested to do Clinical Research in Critical Care and Emergency Medicine. I had fulfilled the Training and Education Standard issued by the NIH-USA for conducting clinical research(Principal investigator) and scored 76% in the exams. I had won several Young Scientist awards for best clinical research .I am one of the investigator for ongoing four clinical trials and twenty five descriptive studies in Critical Care and Emergency Medicine. I would like to know whether I am eligible for (US- FDA) approved Principal investigator. I had attached my NIH Certificate & Resume for your consideration.
Thankingyou

Yours sincerely
[purged]
Critical Care Medicine
[purged]
Attached : (1) NIH Certificate
(2) CURRICULUM VITAE

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