

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Enquiry
Date: Thursday, January 16, 2014 11:35:55 AM

Good morning –

Your request is very broad. You can go to our GCP website and search around. There are many resources for you. Please look at the panel on the left entitled “Science and Research Special Topics.” There are links to topics such as clinical trials and human subject protections, FDA regulations and FDA guidance documents and information sheets and much more. This should help you get started on your research.

[Clinical Trials and Human Subject Protection](#)

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, 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.

From: [Redacted]
Sent: Thursday, January 16, 2014 9:47 AM
To: OC GCP Questions
Subject: Enquiry

Hello
My name is [redacted].
We have an existing Internal med practice in [redacted].
We are interested in starting a research lab in it.
Can we get some guidelines in Starting with it.
We would appreciate the help
THanking you
[redacted]