From: OC GCP Questions
To: [redacted]
Subject: Query related to IRB"s approval
Date: Wednesday, September 02, 2015 9:26:57 AM

Good morning –

Please see my answers to your questions below.

In accordance with FDA regulations at 21 CFR 312.66, an investigator must ensure IRB oversight of the proposed clinical study and if the study is conducted with an FDA-regulated product (drug, biologic, or device) under an IND/IDE all FDA regulations must be followed. This includes IRB review and approval 21 CFR part 56 and informed consent 21 CFR 50.

Please see links to FDA guidance documents that also might assist you with understanding FDA regulations.

Search for FDA Guidance Documents > Institutional Review Boards Frequently Asked Questions - Information Sheet
Search for FDA Guidance Documents > A Guide to Informed Consent - Information Sheet

Clinical Trials and Human Subject Protection > Regulations

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Wednesday, September 02, 2015 6:00 AM
To: OC GCP Questions
Subject: Query related to IRB's approval

Dear FDA Representative,

Thank you in advance for acquiring your little time

This is [redacted], working as research associate in clinical research.

As per my understanding, FDA does not ever approved the clinical facilities to conduct investigation of the drug on human and FDA is solely depend upon the IRB review/approval to conduct the trials on human subjects. My apology if FDA has already posted in following matter.

If I am thinking correctly then my question is:

1. Should the clinical facility to be approved by the IRB to do human research? Yes
2. Does IRB provide time duration to carry out the research work at clinical facility? Yes
3. If I am conducting trial in US and IRB is located in Canada. Should it have any concern to get the approval to conduct investigation? Generally not. There are FDA-regulated clinical trials that have outside US sites.

Thanks

Best Regards,
[redacted]