From: OC GCP Questions
To: [redacted]
Subject: Diference between IRB and IEC
Date: Thursday, October 30, 2014 12:59:26 PM

Good afternoon –

There is no difference between IRB and IEC. The IRB term in used in the US, generally IEC is used in the EU, and REB (Research Ethics Board) is used in Canada. There is no difference in their function to protect the rights, welfare, and safety of research subjects. Please see a few guidance links below that might be helpful to you.

Guidance documents included under the umbrella title of FDA Information Sheets represent the agency's current thinking on protection of human subjects in research.

IRBs –Frequently Asked Questions – Information Sheet.

Guidances > Institutional Review Boards Frequently Asked Questions - Information Sheet

ICH-E-6 Guidance on Good Clinical Practice –
Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve human subjects. Compliance with GCP assures that the rights, safety, and well-being of trial subjects are protected and that the clinical trial data are credible. This International Conference on Harmonization (ICH) guidance provides a unified standard for the European Union, Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in those jurisdictions.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

This is the document in Spanish.
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073128.pdf

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

Kind regards,

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

From: [redacted]
Sent: Wednesday, October 29, 2014 12:33 PM
To: OC GCP Questions
Subject: Diference between IRB and IEC

Dear FDA:

I am preparing a training directed to CRAs in [redacted] , and I have some doubts:

Reviewing the GCP definitions, I can´t note a difference between IRB and IEC
I do not understand why at Code of Federal regulations they only mention the IRB and no mention IEC.
I also do not understand the definition of IRB: " Independent body….., the term independent refers "to the Institution" or refers "That it is independent from the PI and Sponsor"
Thank you very much in advance.

Best Regards
[redacted]