From: OC GCP Questions
To: [redacted]
Subject: Do NIH funded studies observe FDA regulations and should they follow ICH-GCP Guidelines?
Date: Thursday, February 19, 2015 12:18:09 PM

Good afternoon –

Not all clinical studies are FDA-regulated. If the studies are under an IND (Investigational New Drug) or IDE (Investigational Device Exemption), the studies must be in compliance with FDA regulations. 21 CFR Parts 50, 56, 312 and 812. Please see the link to the regulations below.

Clinical Trials and Human Subject Protection > Regulations

For research not conducted with FDA-regulated products, then the Common Rule provisions would most likely apply. Please see OHRP (Office of Human Research Protections) website below.

Office for Human Research Protections (OHRP) | HHS.gov

FDA also has a guidance regarding foreign clinical studies not conducted under and IND. See link below.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294729.pdf

Adherence to the principles of good clinical practices (GCPs), including adequate human subject protection (HSP) is universally recognized as a critical requirement to the conduct of research involving human subjects. Many countries have adopted GCP principles as laws and/or regulations. The Food and Drug Administration's (FDA's) regulations for the conduct of clinical trials, which have been in effect since the 1970s, address both GCP and HSP.

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: Saturday, February 14, 2015 8:07 AM
To: OC GCP Questions
Subject: Do NIH funded studies observe FDA regulations and should they follow ICH-GCP Guidelines?

Hello FDA Staff,

I am a Clinical Research Associate (CRA) and I have monitored FDA regulated studies for the past 18

years. I am now working on my first NIH Study. It appears to me that NIH funded studies do not necessarily adhere to FDA regulations and follow ICH-GCP Guidelines, but I may be misunderstanding this.

Question: Are NIH funded studies required to observe FDA regulations and should they follow ICH-GCP Guidelines? If not, where are the regulations and guidelines that they do use? It is very important to me that I find a resource for this information.

Thank you in advance for your advice,
[redacted]