From: OC GCP Questions
To: [redacted]
Subject: IRB Registration
Date: Monday, November 02, 2015 10:53:24 AM

Good morning --

The OHRP registration database that is in operation functions to capture both FWA and IRB Registration information. It is the database for registration of IRBs that review only research that is FDA-regulated, only research that is OHRP-regulated, or research that is regulated by both OHRP and FDA. OHRP-regulated research means the study is federally funded and therefore requires an FWA. If an IRB only reviews FDA-regulated research, and none of that research is federally funded, only FDA IRB registration is required. As the FDA IRB Registration Rule states, only US IRBs/IECs that review FDA-regulated research are required to register. However, any IRB can voluntarily register. There is also an FDA guidance document found at www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM171256.pdf that you also might find useful. Please also see the registration web link below.
Electronic Submission System

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: Monday, November 02, 2015 8:53 AM
To: OC GCP Questions
Subject: IRB Registration

Good morning.
Our IRB has inquired as to whether or not we need to register with the federal government. It is my understanding that we do only if we conduct FDA-related research. I will appreciate your verification or your directing me to the process by which we need to register. [redacted]
does not conduct any FDA-related research.
Thank you ,
[redacted]