From: OC GCP Questions
To: [redacted]
Subject: FW: 21 CFR 56.109(c)
Date: Wednesday, August 19, 2015 6:29:43 AM

Hi [redacted]–

It is probably best to contact the Center for Devices (CDRH) directly as registry studies are handled differently in each Center.

For devices -- DICE@fda.hhs.gov Phone: 1-800-638-2041

Kind regards,

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

From: [redacted]
Sent: Tuesday, August 18, 2015 5:05 PM
To: OC GCP Questions
Subject: Re: 21 CFR 56.109(c)

Hi Doreen,

I am wondering about registry studies that are required as a result of a expedited access application for a device. In particular, are registry studies that do not require IDEs as per April 2015 Balancing Premarket And Postmarket Data Collection for devices subject to Premarket Approval, page 12, second paragraph, There are no 21 CFR 812 investigational device exemption (IDE) requirements for the post approval confirmatory study, as long as the device is studied in accordance with its approved labeling, including indications for use. Does this

Does this mean that 21 CFR 56 and 21 CFR 50 do not apply to these studies either since they apply to studies that require IDEs?

Thanks,
[redacted]