From: OC GCP Questions
To: [redacted]
Subject: Study of an exempt device
Date: Monday, March 09, 2015 4:12:46 PM

Good afternoon –

It is best to ask the Center for Devices (CDRH). Please email them at DICE@fda.hhs.gov

Kind regards,

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

From: [redacted]
Sent: Monday, March 09, 2015 3:39 PM
To: OC GCP Questions
Subject: Study of an exempt device

Dear FDA,
When an investigator conducts research on a device that is determined to be exempt from 21 CFR 812 requirements for an IDE, is the investigator required to follow the abbreviated requirements under 21 CFR 812.2b?

Sincerely,
[redacted]