From: OC GCP Questions
To: [redacted]
Subject: Compassionate Devise Use
Date: Monday, October 05, 2015 5:45:21 AM

God morning –

It is best to send your email directly to the Center for Devices (CDRH) at DICE@fda.hhs.gov. This Center oversees compassionate device use.

Kind regards,

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

From: [redacted]
Sent: Friday, October 02, 2015 3:05 PM
To: OC GCP Questions
Subject: FW: Compassionate Devise Use

Good afternoon,

My question is regarding Expanded/Compassionate Use of a Device. I research this topic and there seems information regarding IRB concurrence. However, it does not provide details what that entails. The FDA Guidance on Expanded Access (attached) requires IRB approval. What is the current guidance on expanded access regarding IRB approval?

Thank you,

[redacted]