From: OC GCP Questions
To: [redacted]
Subject: new medical device protocol
Date: Thursday, September 21, 2017 7:38:00 AM
Attachments: [redacted]

Good morning –

The IRB review and IDE submission can be done in any order or even simultaneously. The critical thing is that the investigator may not begin the study (e.g., screen or recruit subjects, secure informed consent) until the IDE is in effect.

It is recommended that the IRB approval letter indicate that the study requires submission of an IDE to FDA prior to initiation of the study. The IRB may also choose to approve the study "with conditions", with the condition being that the IDE is submitted to FDA and active before beginning the study.

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

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Wednesday, September 20, 2017 2:50 PM
To: OC GCP Questions
Subject: new medical device protocol

To whom it may concern;

I was wondering if you can submit a medical device application to the FDA while simultaneously submitting the protocol for IRB approval.

Thanks
[redacted]

[redacted]