From: OC GCP Questions
To: [redacted]
Subject: Clinical Study
Date: Wednesday, January 28, 2015 11:48:09 AM

Good morning –

In order to determine whether you need an IND (drug) or IDE (device) you will need to contact the Centers directly. Please see their contact information below.

Center for Devices (CDRH) DICE@fda.hhs.gov
Center for Drugs (CDER) druginfo@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: Wednesday, January 28, 2015 10:53 AM
To: OC GCP Questions
Subject: Clinical Study

Dear [redacted]

I am in the process of submitting a protocol to IRB for an investigator initiated study. For one of the imaging I want to use modified sequencing protocol for brain MRI to measure volume. I don't have any commercial interest in new sequencing. Do I need FDA approval prior to using modified MRI protocol? or IRB approval is good enough.

If the answer is yes do I have to ask the vendor to get the approval?

Thank you,
[redacted]