

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Clinical Study  
**Date:** Wednesday, January 28, 2015 11:48:09 AM

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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](mailto:DICE@fda.hhs.gov)  
Center for Drugs (CDER) [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)

Kind regards,

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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

**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]