From: OC GCP Questions
To: [redacted]
[redacted]
Subject: sponsor responsibilities for minimal risk studies
Date: Thursday, August 30, 2018 8:10:00 AM
Attachments: [redacted]

Good morning –

You email was forwarded to my office for a response. It is best to send your question directly to the Center for Devices (CDRH) at DICE@fda.hhs.gov However please see a few guidance documents that might be helpful to you.

https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126418.pdf

https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm127067.pdf

Investigational Device Exemption (IDE) > IDE Approval Process

And device regulations 21 CFR 812 –
eCFR — Code of Federal Regulations

Kind regards,

The OGCP Group

From: [redacted]
Sent: Tuesday, August 28, 2018 9:40 AM
To: [redacted]
Subject: sponsor responsibilities for minimal risk studies

Good morning,

I am looking for guidance on Sponsor responsibilities for a minimal risk study. Can you help me understand which regulations/guidances apply for such a study? I am specifically interested in which device regulations are applicable for a minimal risk device study.

Thank you,

[redacted]