From: OC GCP Questions
To: [redacted]
Subject: Expert witness
Date: Monday, June 18, 2018 8:44:00 AM
Attachments: [redacted]

Good morning –

Please see FDA's information sheets on IRBs and subject recruitment.

Search for FDA Guidance Documents > Institutional Review Boards Frequently Asked Questions - Information Sheet

Search for FDA Guidance Documents > Recruiting Study Subjects - Information Sheet

For device studies, you will need to contact the Center for Devices (CDRH) directly at DICE@fda.hhs.gov or by phone 1-800-638-2041 or 301-796-7100.

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

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From: [redacted]
Sent: Thursday, June 14, 2018 3:52 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Expert witness

Hello,

I need an expert witness on proper IRB protocols and patient recruitment for a study involving an ingestible device. Could you please contact me at your earliest convenience?

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]